EUROIMMUN Medizinische Labordiagnostika AG

Instructions for use

EUROIMMUN Analyzer I-2P

CE

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The product

The EUROIMMUN Analyzer I-2P is used for the fully automated processing of infectious, autoimmune and allergic diseases by means of ELISA tests provided, developed and validated by EUROIMMUN.

It is a fully automated analyser for microplates that performs the complete sample processing (sample pre-dilution, sample and reagent dispensing, incubation, washing procedures, plate transport) as well as photometric measurement and evaluation. The system was developed for use in diagnostic facilities.

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Revision

The descriptions and other information, the images and drawings are constantly revised and adjusted. In some details, the images may slightly differ from the product (e.g. from the actual design). However, these differences have no influence on the safe use of the product.

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1 Introduction

This document is intended for the user and describes how to use the product EUROIMMUN Analyzer I-2P safely and correctly.

This document describes how to use, maintain and service the product. The product may only be installed and commissioned by EUROIMMUN Technical Service or by a service technician authorised by EUROIMMUN. Abbreviations and special terms are explained in the glossary. If this document refers to EUROIMMUN or to the Technical Service of EUROIMMUN, this can alternatively also be the authorised representative in the relevant country.

Read this document and keep it for the entire lifetime of the product.

1.1 Further documents on this product

The following documents are additionally available for this product:

- Adjustment of the EUROIMMUN Analyzer I/I-2P for the use of barcoded reagents in 2ml Sarstedt (YG_1410_V_UK_Axx)
- Care and Maintenance of the EUROIMMUN Analyzer I-2P (YG_1401_F_UK_Axx)
- Entry of lot-specific variables for tests from other manufacturers (YG_0210_F_UK_Axx)
- EUROIMMUN Analyzer I/I-2P Combination of EUROIMMUN ELISAs on microplates (YG 0014_A_UK_Uxx)
- EUROIMMUN Analyzer I-2P, Quick Start (YG_0015_A_UK_Vxx)
- Instruction for use SETUP CLEAN (ZG_0009_A_UK_Bxx)
- Quick Reference User guide to Start a Worklist with the EUROIMMUN Analyzer I-2P (YG_0015_A_UK_Zxx)
- Short instruction - EUROIMMUN Analyzer I/I-2P Processing of the Plasma Renin Activity (PRA) ELISA (YG_0014_A_UK_Wxx)
- Short instruction - EUROIMMUN Analyzer I/I-2P Automated processing of interferon-gamma release assays (IGRA) unsing EUROLab Quan-T-Cell (YG_6841_A_UK_Zxx)
- Short instruction – Use of QA feature (YG_0211_F_UK_Axx)
- Start-up Information for the EUROIMMUN Analyzer I-2P (YG_1402_F_UK_Axx)

1.2 Changes

The following changes to the previous version (YG_0015_A_UK_C05) have been made:

	Chapter
New	
Changed	► *Fig. 1: Type label (example), p. 20* ► *Fig. 2: Label on the packaging (example), p. 21*
Deleted	

Tab. 1: Document changes

1.3 Typographic conventions

Some term categories are highlighted in these instructions for use so that they can be better recognised.

Instruction	1) Numbered instruction step → Intermediate result ✓ Result
Interface elements Button Control element, Window, tab	 Edit, ✓, Close DASHBOARD
The command to press several control elements one after the other (command cascade)	☰ > SETTINGS > DEVICE
File name, Folder reference, program code	`Result.txt` `C:\program daten\EUROIMMUN`
Parameter name	Volume
Parameter value and unit	*5 µl*
Cross reference	► *Chapter 1.1 Further documents on this product, p. 17* ► *step 1)*
Reference to a documentation	Document number/Document name

1.4 Symbols

There are various symbols on the product, on the packaging and in this document.

Warning signs

Warning signs refer to potential hazards. Please observe the associated warning and safety information.

Symbol	Description
	General warning sign

Symbol	Description
	Warning; Electricity
	Warning; Biological hazard
	Warning; Laser beam
	Warning; Crushing of hands
	Warning; Hot surface
	Warning; Automatic start-up

Tab. 2: Warning signs

Mandatory action signs

Follow the mandatory action signs to avoid accidents.

Symbol	Description
	Disconnect mains plug from electrical outlet
	Wear protective gown
	Wear protective gloves
	Wear eye protection

Tab. 3: Mandatory action signs

Prohibition signs

Refrain from the actions displayed on the prohibition signs.

Symbol	Description
	Do not look into the beam

Tab. 4: Prohibition signs

Further symbols

Symbol	Description
	Observe the instructions for use
	Note in these instructions for use
	Recommendation in these instructions for use
	Attention property damage

Tab. 5: Further symbols

1.5 Type label

The type label is on the back of the instrument.

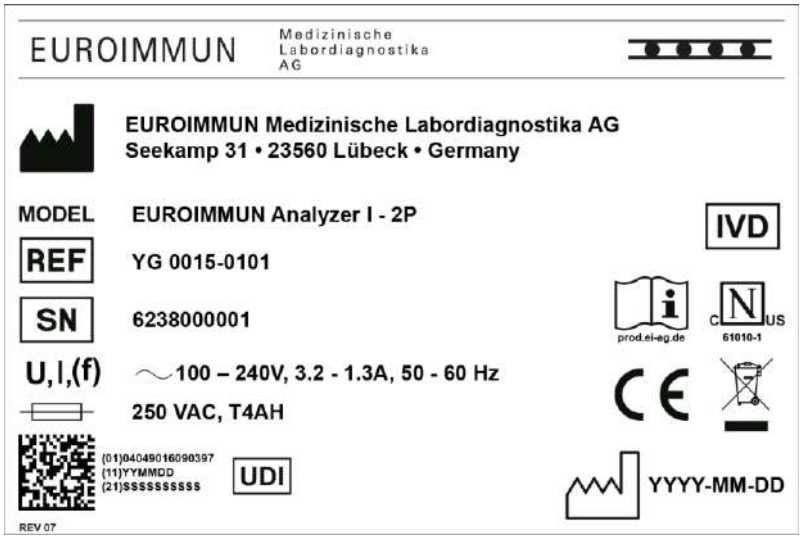


Fig. 1: Type label (example)

Symbol	Description
	Manufacturer
	Manufacturing date
REF	Catalogue number
SN	Serial number
U	Power supply voltage
I	Power consumption
(f)	Mains frequency

Symbol	Description
	Main fuse
IVD	In vitro diagnostic medical device
UDI	**U**nique **D**evice **I**dentifier
CE	The product complies with the applicable European directives (declaration of conformity)
	Marking pursuant to European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)
prod.ei-ag.de	Instructions for use available electronically
c N US	The product complies with the applicable directives for Canada and the USA (Declaration of Conformity)

1.6 Labelling on the packaging

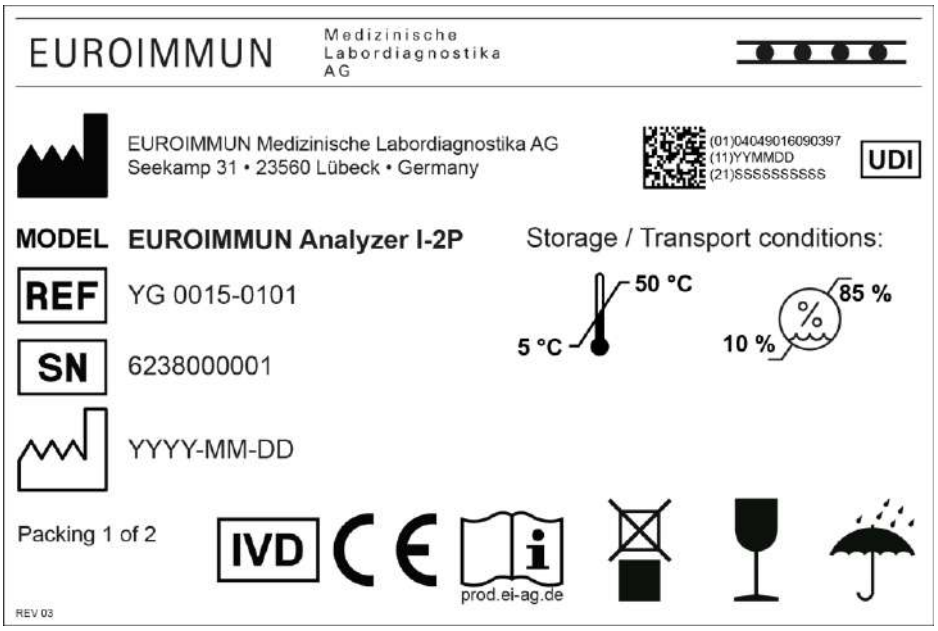


Fig. 2: Label on the packaging (example)

Symbol	Description
	Temperature limit
	Humidity limitation

Symbol	Description
	Keep away from rain
	Fragile; handle with care
	Do not stack

1.7 Warranty

Applicable regulations. Unless agreed otherwise, contractual relations with EUROIMMUN shall be governed by German law and the regulations of EUROIMMUN General Terms and Conditions of Delivery. In case they differ from the aforementioned regulations, subsequent regulations have priority.

Software defect. A software defect or software error shall only be considered as such if the software differs from the software description.

1.8 Limitation of liability

Proper use. The EUROIMMUN Analyzer I-2P including original accessories, must only be used for its intended purpose ► *Chapter 2.1 Intended purpose, p. 25*). For any other use, EUROIMMUN assumes no liability.

General. EUROIMMUN is generally liable for breaches of contractual obligations of its legal representatives or vicarious agents and for tort only for intentional or grossly negligent actions, and otherwise only in the event of a breach of an essential contractual obligation. This limitation of liability does not apply to damages arising from death, physical injury or damage to health, if a defect is fraudulently concealed, if a guarantee of quality is not observed, or to liability according to the Product Liability Act.

Amount of liability. EUROIMMUN's liability is limited to the contractually typical damage.

Exemption for the use of third-party tests/reagents. Liability is only assumed if a validated combination of the product and a EUROIMMUN test has been used with EUROIMMUN reagents and in compliance with the respective current instructions for use. In the case of the use of third-party tests and/or reagents, EUROIMMUN assumes no liability for the functionality of the third-party tests/reagents, in particular not for work results obtained with them.

Exemption due to malpractice. EUROIMMUN assumes no liability for damages resulting from malpractice by the customer, in particular

- failure to comply with the instructions for use and with the instructions for the respective reagents,
- use other than the intended use,
- natural wear and tear,

- maintenance or use by unqualified and/or untrained personnel,
- use of information or data from the use of products without verifying their plausibility or completeness,
- independent interventions such as conversions or technical modifications by the user,
- deactivation of safety equipment without permission,
- non-cooperation by the customer during the solution of safety problems on the part of the customer,
- use of reagents of other manufacturers in instruments that have been purchased by EUROIMMUN or provided in another manner,
- use of parts or accessories from other manufacturers,
- use of hardware or software configurations of other manufacturers, i.e. lack of compatibility of the EUROIMMUN software with third-party configurations.

Exemption due to export restrictions. EUROIMMUN assumes no liability for damages resulting from delivery delays or de-livery failures due to legal or official export restrictions or from third-party behaviour based on such legal or official export restrictions.

Software. Suitable measures for failure safety (e.g. data backups) and updates are the responsibility of the customer. The customer has to ensure that the system safety of the provided Windows system or systems is kept up to date by regular updates. The customer is solely responsible for the safety of their data. The installation and updating of protection systems, i.e. antivirus and firewall programs, is strongly recommended by EUROIMMUN, but is the sole responsibility of the customer. The interaction between the protection system and the EUROIMMUN software may cause malfunctions, e.g. instrument or software failure, due to the configuration of the protection system. EUROIMMUN assumes no liability for resulting damage. EUROIMMUN will support the customer in correcting the malfunction. The customer is obliged to assist in the best possible manner in solving the problem with their own resources.

Limitation period. Claims against EUROIMMUN from or in connection with deliveries or services are subject to a limitation period of one year after the delivery of the product or initial commissioning, if the installation of the instrument was performed by EUROIMMUN. The limitation period does not apply to damages resulting from injury to life, limb or health.

1.9 Information on IT security

The operator is obligated to implement IT security measures corresponding to the state of the art. It is recommended to apply ISO/TR 80001-2-7 for this purpose. For the integration of the product into the operational environment, the following is emphasised:

- The IT infrastructure must be implemented according to the state of the art. This includes in particular
  - the implementation of appropriate physical access control measures in the laboratory environment

  - the implementation of appropriate control measures for access to the IT infrastructure of the laboratory
  - the implementation of appropriate network access control measures, e.g., segmentation of the network
  - regular updates and checkups of the IT infrastructure of the laboratory, notably of the operating systems (security updates), virus scanners and firewalls as well as their configuration
- Only removable storage devices (e.g. USB stick, memory card) that have been checked in advance by means of a virus scanner, preferably in another network segment, may be used.
- Appropriate measures for data backup and recovery must be implemented and checked regularly. At least 1 backup copy must be saved offline.
- If a PC is supplied with the product, the following must be observed:
  - Security updates of the operating system must be independently installed by the operator.
  - Other updates of the operating system or applications on the PC may only be performed after consultation of the technical service of EUROIMMUN.

Furthermore, EUROIMMUN Medizinische Labordiagnostika AG points out the following in accordance with IEC 82304:

- The use of the product in an IT network could lead to as yet unknown risks for patients, users and third parties.
- The operator of the system is advised to identify, analyse, assess and manage these risks.
- The following changes to the IT network could lead to new risks and therefore require additional analyses:
  - changes to the IT network configuration
  - addition of components (hardware and/or software platforms or software applications) to the IT network
  - removal of components from the IT network
  - updates of hardware and/or software platforms or software requirements in the IT network
  - upgrades of hardware and/or software platforms or software requirements in the IT network

1.10 Technical Service

In case of problems, please contact your local distribution partners.

2 Safety

The product was developed and manufactured according to the state of the art in compliance with the requirements of Regulation 2017/746 on in vitro diagnostic medical devices. The instrument complies with the prescribed safety regulations. However, improper use may result in damage to property and personal injury.

Meaning of the signal words in warning notes

Warning notes are highlighted and categorised by signal words:

⚠ DANGER signals the direct risk of fatal or serious injury.

⚠ WARNING signals the potential risk of serious (irreversible) injury.

⚠ CAUTION signals the potential risk of non-serious (reversible) injury.

ATTENTION signals the risk of material damage.

2.1 Intended purpose

The EUROIMMUN Analyzer I-2P is an IVD instrument for the fully automated performance of ELISA in vitro tests with the following human sample material: serum, plasma, cerebrospinal fluid, saliva, stool and dried blood spot extract. The processes of the EUROIMMUN Analyzer I-2P include sample dilution, transfer of primary sample material or sample dilutions and secondary reagents to ELISA microplates, incubation at different temperatures, washing processes, measurement of optical density and evaluation of the measurement results.

The EUROIMMUN Analyzer I-2P has been validated exclusively with test systems from EUROIMMUN for which compatibility has been declared by EUROIMMUN in the instructions for use for the ELISA tests.

When using tests that have not been declared compatible, the customer has the regulatory and legal responsibility to demonstrate compatibility.

The EUROIMMUN Analyzer I-2P may only be operated in diagnostic laboratories and away from the patient by trained specialist personnel. The determined test results must always be checked for correctness and plausibility by qualified medical personnel. For a diagnosis and therapy decision, the patient's clinic and medical history as well as any other examination findings must always be taken into account in addition to the examination results. The EUROIMMUN Analyzer I-2P is compatible with the following other systems: ASTM standard for LIMS.

The EUROIMMUN Analyzer I-2P can be used for time-critical emergency examinations, but the operator must then have at least one alternative examination method available in case the instrument fails.

2.2 General safety information

- Follow all the safety instructions, warning instructions and precautionary measures on the product and in this document

- Pay attention to all warning signs on the product and the accessories.
- Only use the product as specified in the intended purpose.
- Only use the specified accessories.
- Do not manipulate any safety devices.
- Do not place objects in the instrument.

2.3 Instrument-specific safety instructions

Electrical safety

The instrument is powered by electric current. There is an electric voltage hazard.

- Only connect the instrument to a mains power supply that corresponds to the voltage and frequency defined on the type label.
- Only connect the instrument to a correctly installed power socket with protective earth contact.
- Only use the cables included in the scope of delivery.
- Disconnect the instrument from the mains if the housing or cables are defective. The instrument can no longer be operated.
- Immediately disconnect the instrument from the mains if liquid penetrates into the inside of the instrument.
- Only use spare fuses of the stipulated specification (rated voltage, rated current, type).

Mechanical safety

The instrument has automatically moving components. There is an impact and crushing hazard.

- Do not touch the moving components while the instrument is in operation.
- Do not reach into the instrument while the instrument is in operation.
- Do not bend into the instrument while the instrument is in operation.

Laser safety

The instrument uses a laser. There is an optical radiation hazard.

- Do not look directly into the laser beam.
- Do not hold reflective items into the laser beam (e.g. jewellery, mirror).

LED safety

The instrument uses an LED. Looking into the LED light for a longer period of time can cause eye injuries.

- Do not look directly into the light source.

Biological safety

The instrument uses biological substances. There is a risk of infections.

- Follow the instructions for use of the used test kits.
- Wear personal protective equipment (protective gown, protective gloves and eye protection).
- Avoid skin and mucous membrane contact with the biological substances.
- Immediately clean and disinfect any contaminated areas in the instrument with a validated method.

Chemical safety

The instrument uses chemical substances. There is a risk of eye injuries and skin irritation.

- Follow the instructions for use of the used test kits.
- Wear personal protective equipment (protective gown, protective gloves and eye protection).
- Avoid skin and mucous membrane contact with the biological substances.
- Immediately clean and disinfect any contaminated areas in the instrument with a validated method.

2.4 Prerequisites for safe use

The user must be trained to deal with biological material and have technical knowledge of dealing with laboratory equipment. Typical qualification levels for this are biology lab technician or medical lab technician.

The user has been instructed in operating the product by EUROIMMUN.

2.5 Safety labels on the product

Observe the safety labels on the product. Replace damaged or missing safety labels.

2.6 Safety devices

A plastic cover protects the visible working area. The closed position of this cover is monitored by a contact switch. The EUROIMMUN Analyzer I-2P cannot be operated without this cover to protect the operator from coming into contact with the working area during a run.

NOTE

If a cover lock is not installed, the software can be configured to automatically stop the system if the unit cover is opened during a run.

2.7 In the event of danger

Disconnecting the instrument from the power supply

In the event of danger, disconnect the instrument from the power supply.

To do this, pull the mains plug out of the socket.

Dangerous situations can include e.g.:

- liquid gets inside the instrument
- liquid leaks from the instrument
- instrument components collide

2.8 Conduct in case of incidents

Regulatory information for customers in the European Union: Please observe the obligation to report any serious incidents occurring in connection with this product to the competent authorities and to EUROIMMUN.

2.9 Foreseeable incorrect use

- Only process liquids that may be used with this instrument.
- Do not use the instrument to mix liquids intended for other purposes.
- The disposable tips of the pipetting unit must not be used to pierce open sealed (e.g. blistered or similarly sealed) labware. Disposable items (e.g. disposable tips) must not be reused.
- The containers must not be used for intermediate storage of foreign liquids.

2.10 Environmentally hazardous substances and materials

The instrument uses biological and chemical substances. Dispose of the residual liquids and used consumables in accordance with the legal regulations.

2.11 Additional safety information

EUDAMED

Further information on the product can be found in the European database for medical devices (EUDAMED).

3 Instructions for reliable operation

Follow the following instructions to maintain the computing power, compatibility and stability of the system.

Software

- Only install software on the computer that has been released by EUROIMMUN.
- Avoid the automatic updates of third-party software and the automatic operation of a virus scanner.
- Reboot the computer at least once a week to install safety updates of the operating system and to free storage resources.

Hardware

- Only use the computer included in the scope of delivery.
- Only use peripheral devices with the computer that have been approved by EUROIMMUN.
- Do not cover ventilation slits to avoid overheating.
- Do not expose the barcode scanners and the barcoded materials to direct sunlight or directed light sources in order to ensure reliable scanning.
- Do not operate the instrument in proximity of devices which emit stray radiation (e.g. electron microscope, vacuum interrupter).
- Avoid vibrations that may disrupt the operation of the instrument.
- Pay attention to the prescribed environmental conditions

►► *Chapter 13.3 Environmental conditions, p. 237*

This instrument is not intended to be used in residential areas and cannot ensure adequate protection of radio reception in such environments.

This equipment has been designed and tested in accordance with CISPR 11 Class A. It may cause radio interference in a domestic environment. In this case, you may be required to take measures to eliminate the interference.

4 Scope of delivery and equipment features

The actual scope of delivery can differ from the standard described in the following in the case of special models, additional ordering options, or due to the latest technical changes.

4.1 Scope of delivery

Number	Description
1 x	Instructions for use EUROIMMUN Analyzer I-2P
1 x	EUROIMMUN Analyzer I-2P (YG 0015-0101)
5 x	Sample racks (16 positions each)
3 x	Standard/control racks (15 positions each)
2 x	Combi racks (2 positions for sample buffer and 6 positions for conjugate, substrate, stop solution and sample buffer bottles).
1 x	Lid rack
1 x	Set of stickers for sample racks
1 x	Starter-Set: 1 Conductive tips, 1100 µl (10 x 96 tips) 1 Conductive tips, 300 µl (10 x 96 tips) 5 Deepwell plate (sample dilution) 3 Adjustment solution, 50ml 3 Microplate (Nunc MaxiSorp-Lockwell) 3 Filter Minisart SRP25 1 Clip with thumbscrews for VP9101 2 Stickers for buffer bottle (EU Wash Buffer) 2 Buffer bottle stickers (Adjustment Solution) 2 Stickers for buffer bottle (Distilled Water) 1 Sticker for reagent racks (A B C D E) 5 Bottle for reagents (brown), 15ml 5 Bottle for reagents (brown), 5ml 2 Stop solution bottle, (white, with lid), 24ml 2 Substrate bottle (black, with lid), 24ml 1 Sample buffer bottle (with lid), 100ml 10 Sarstedt tubes (with lid), 2ml
1 x	External 2D barcode scanner
1 x	EUROIMMUN PC
1 x	Monitor
1 x	Loudspeaker
1 x	USV TX1000D
1 x	Printer
1 x	Commissioning protocol

Number	Description
1 x	EAI-2P Checklist for device briefing
1 x	Instruction protocol
1 x	Quick start guide for a worklist
1 x	EAI-2P Consumables and Accessories List
1 x	EAI-2P Maintenance and Care Guide
1 x	Barcode scanner Quick Setup Guide
1 x	EAI 2P Quick Start Guide
1 x	Document for diluter clip with knurled screw
1 x	EAI-2P – Start-up instructions
1 x	EAI-2P – Installation Checklist
1 x	Information Flyer Connector
1 x	Declaration of Conformity

Tab. 6: Scope of delivery

4.2 Accessories

Order no.	Description
ZG 025y-0101-048	Wash buffer bottle, PVC, 2 litres, with lid
ZG 025y-0101-047	Wash buffer bottle, PP, 1 litre, with lid
ZG 025y-0101-030	Sample rack-2P
ZG 025y-0101-029	Replacement label for the definition of sample racks-2P
ZG 025y-0101-028	Standard/ Control rack
ZG 025y-0101-188	Q-Rack
ZG 025y-0101-200	Q-Rack with adapter for 2ml Sarstedt tubes
ZG 025y-0101-026	Combi rack-2P
ZG 025y-0101-032	Lid rack
ZG 025y-0101-031	Sample rack holder
ZG 025y-0101-176	Waste bags (10 pieces)

Tab. 7: Accessories

4.3 Spare parts

Order no.	Description
ZG 025y-0101-108	ASSY., DISPOSABLE TIP ADAPTER V3
ZG 025y-0101-109	ASSY., PIPETTOR TUBE NON APM
ZG 025y-0101-037	ASSY., MANIFOLD, WASH (ASP.+DISP.)
ZG 025y-0101-129	BCL8 SCANNER, FLEX CABLE
ZG 025y-0101-128	BCL8 SCANNER W/ HOUSING
ZG 025y-0101-054	LAMP, 13.8V, 30W
ZG 025y-0101-181	PUMP, DILUTER, VP9101
ZG 025y-0101-135	PUMP, DISPENSE, BUFFER, EMS10
ZG 025y-0101-136	PUMP, WASTE, ETS 15
ZG 025y-0101-169	SENSOR, LEVEL, SYSTEM LIQUID
ZG 025y-0101-046	SENSOR, LEVEL, WASH BUFFER
ZG 025y-0101-167	SENSOR, LEVEL, WASTE
ZG 025y-0101-035	SENSOR, VACUUM, 2.5-40MBAR, 0.5A/250V
ZG 025y-0101-142	SET, CLEANING, WASHER
ZG 025y-0101-101	TOOTHED Z-BAR

Tab. 8: Spare parts

4.4 Consumables

Order no.	Description
ZG 0201-0118	Conductive tips, 300 µl (18 folding boxes = 17,280 tips)
ZG 0202-0110	Conductive tips, 1100 µl (10 folding boxes = 9,600 tips)
ZG 9923-0150	Deepwell plates (sample dilution), 2 ml (50 pieces)
ZG 0130-0101	Sarstedt tubes 2 ml (500 pieces)
ZG 0103-0105	Brown bottles 5 ml (calibrator) (292 pieces)
ZG 0105-115	Brown bottles 15 ml (conjugate) (115 pieces)
ZG 0106-0130-1	Substrate bottles (TSH-R), 24 ml, with lid new (20 pieces)
ZG 0106-0130-2	Substrate bottles (TSH-R fast), 24 ml, with lid new (20 pieces)
ZG 0106-0130	Substrate bottles, black, 24 ml, with lid new (20 pieces)
ZG 0120-0120	Stop solution bottles, white, 24 ml with lid new (20 pieces)
ZG 0110-0100	Square bottles, white 100 ml (sample buffer) (100 pieces)

Order no.	Description
ZG 0132-0101	Lids for Sarstedt tubes 2ml (500 pieces)
ZG 0115-010	Lids for 5 ml bottles (calibrator) (300 pieces)
ZG 0104-0101	Lids for 15 ml bottles (conjugate) (120 pieces)
ZG 0107-0101	Lids for 100 ml bottles (sample buffer) (100 pieces)
ZE 1120-1850-7	Adjustment solution, 50 ml (18 bottles)
ZG 1100-0100-L	CSF sample buffer 100ml (1 bottle)
ZG 0009-0505	Setup Clean, 500 ml (1 piece)

Tab. 9: Consumables

5 The Product

5.1 Overview

5.1.1 Windows 7 System Overview

Fig. 3: System Windows 7

Number	Description
①	All-in-one-PC with touch screen
②	Rack system for samples and reagents
③	Tip ejection station with waste bag or waste tunnel system for disposable tips
④	Wash buffer bottles and waste bottles for the wash unit

Windows 10 System Overview

Fig. 4: System Windows 10

Number	Description
①	External PC with monitor
②	Rack system for samples and reagents
③	Tip ejection station with waste bag or waste tunnel system for disposable tips
④	Wash buffer bottles and waste bottles for the wash unit

5.2 Components

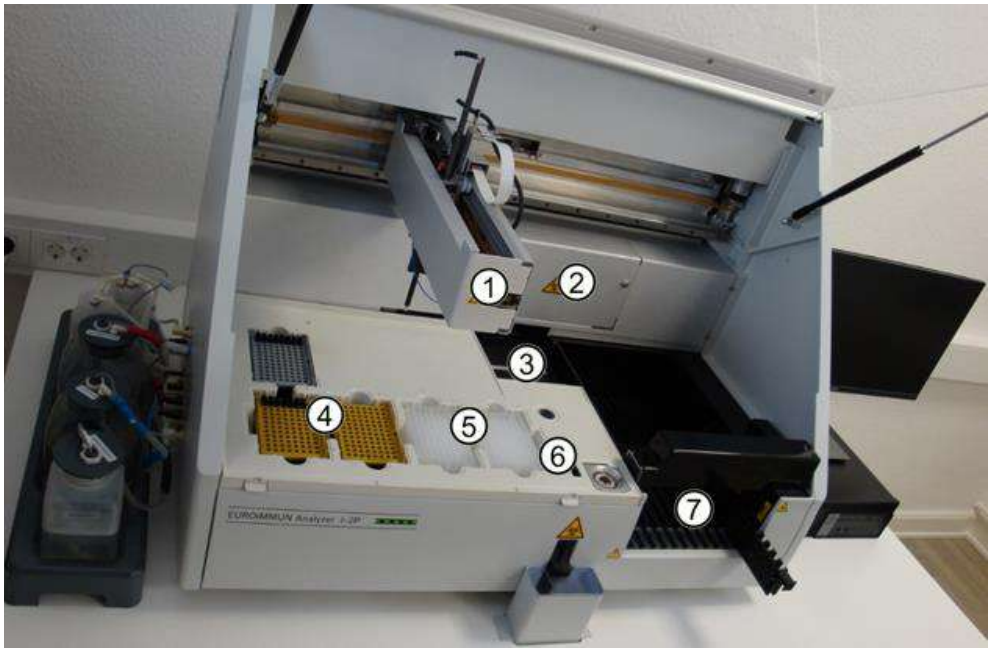


Fig. 5: Components

Number	Description
①	Pipettor
②	Service cover of washer
③	Plate transport unit
④	3 positions for disposable tip racks
⑤	Positions for dilution plates
⑥	Pipettor washing station, tip ejector station and cover locking mechanism
⑦	Rack system barcode scanner

5.2.1 Microplates in the plate transport unit

The plate transport unit moves microplates between the modules of the EUROIMMUN Analyzer I-2P system.

The plate transport unit can also shake a microplate in order to mix the well contents. The microplate is moved linearly at a given frequency and amplitude. The shaking time is controlled through the assay protocol.

NOTE

Only insert the microplates into the plate transport unit if you are requested to do so by the EUROIMMUN Analyzer I-2P software.

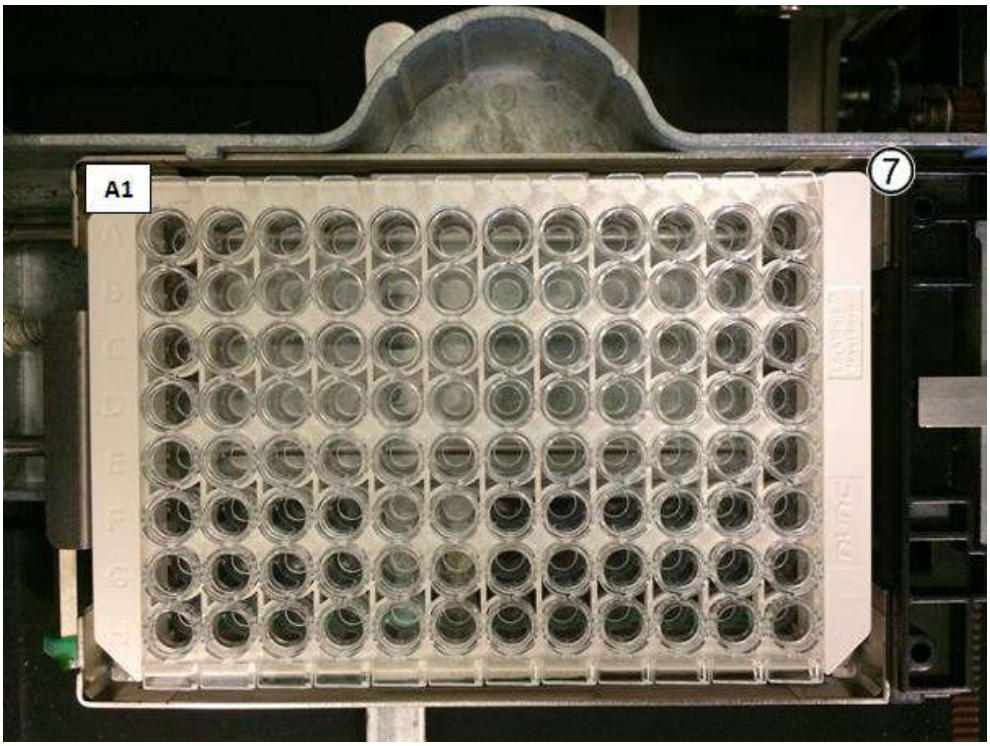


Fig. 6: Microplate in the plate transport unit

Load the microplate into the plate frame of the plate transport unit (7) at the request of the EUROIMMUN Analyzer I-2P software. Position A1 should be at the rear right. Push the microplate firmly down so that it sits on the floor completely and evenly.

5.2.2 Disposable Tip Racks

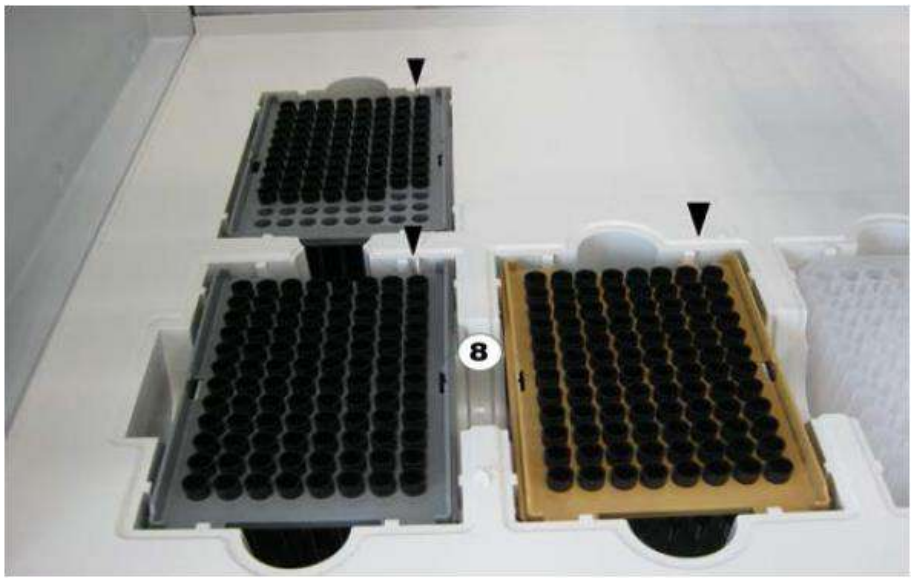


Fig. 7: Disposable tip racks

NOTE

Please carefully check the tip rack allocation, following the specific colour code and type in the software. The instrument does not recognise misplaced tips, which may cause mechanical damage.

Insert the disposable tip racks into the corresponding rack positions (8) at the request of the EUROIMMUN Analyzer I-2P software. The rack marker should be at the rear right (see triangular markers). Push the disposable tip rack(s) firmly down so that they sit on the floor completely and evenly.

5.2.3 Dilution Plates

NOTE

To be able to use dilution plates, a metal base plate is required. The metal base plate allows the correct detection of the liquid surface as well as the usage of the complete liquid volume in the dilution plate (less the specified remaining volume).

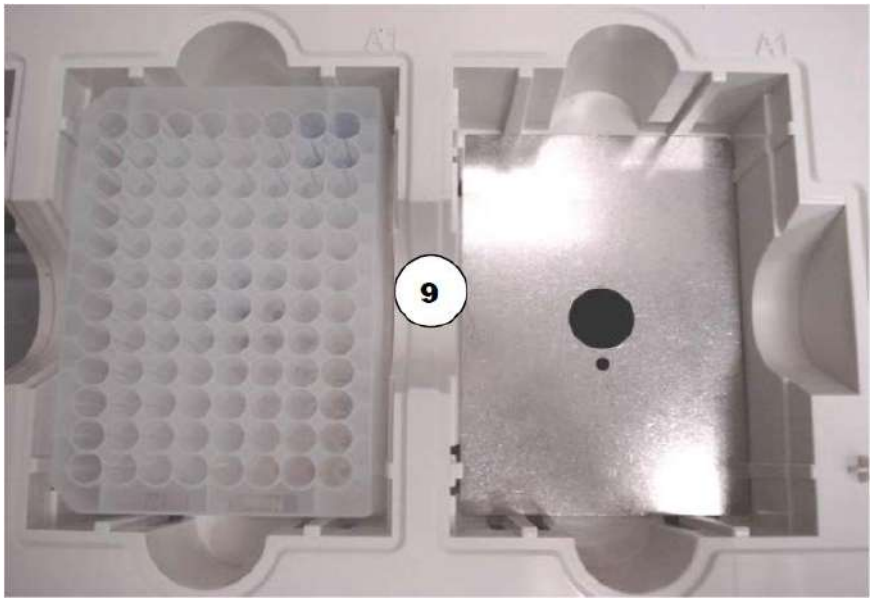


Fig. 8: Metal base plate in the right position

Place the metal base plate on the corresponding position (9) at the request of the EUROIMMUN Analyzer I-2P software. Push the metal base plate firmly down so that it sits on the floor completely and evenly.

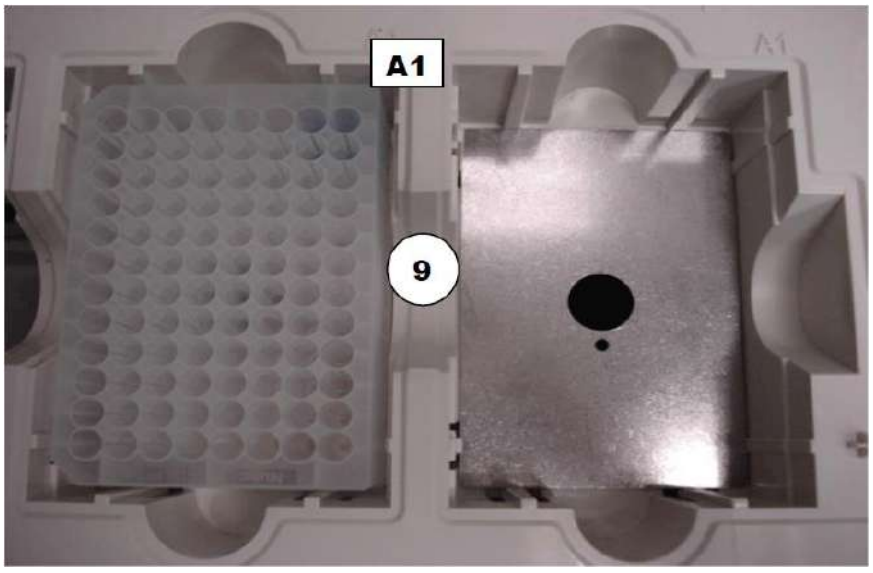


Fig. 9: Dilution plate in the right position

Place the dilution plate on the metal base plate. Position A1 should be at the rear right. Push the dilution plate firmly down so that it sits on the floor completely and evenly.

5.2.4 Rack System for samples and reagents

Patient samples and reagents are loaded into the EUROIMMUN Analyzer I-2P system using so-called racks. By means of the pipettor, the patient samples and the reagents can then be distributed in the course of a test run.

To avoid patient samples or reagents being mixed up, the rack system is provided with a barcode scanner (on the right-hand side). By means of this scanner, the barcodes, which are attached to the corresponding reagent bottles, can be read and processed in the EUROIMMUN Analyzer I-2P software later.

The rack system is provided with 12 tracks for insertion of up to 12 racks, depending on their width. The track to be used is marked by lamp (LED).

⚠ WARNING

Pointed components in the pipetting unit

Risk of stabbing

> Do not reach into the rack system with your hand when the unit is in operation.
> Do not reach into the pipetting unit with your hand while loading samples or reagents.

NOTE

Always use the handle to push in or pull out the racks.

NOTE

Never load more than one rack at the same time! For proper barcode identification the racks must be loaded one after the other, as indicated by the LEDs.

Fig. 10: Rack system with racks

5.2.5 Racks

Racks are used for loading patient samples and reagents in reagent tubes or bottles into the rack system in a controlled way. There are different racks depending on the intended purpose.

NOTE

Within one rack, only tubes of the same type may be used to avoid problems during the aspiration of liquids. The tube type must be approved for the relevant rack.

Each rack includes a contact pin; on racks occupying one track, this pin is located at the top centre, and on the broader racks at the top right.

The software specifies which track is to be used for the respective rack. This is indicated by a LED. A reagent rack occupying 3 tracks must be inserted such that the contact tappet is in contact with the lit-up LED. Each rack has to be inserted up to the stop.

Reloading of patient and reagent racks is possible when the instrument is in the incubation mode.

The following racks are supplied:

Type	Description
T:	Sample rack for 16 patient samples (occupies one track).
8:	Calibrator and control rack for 15 bottles (occupies one track).
5:	Combi rack for 6 round bottles and 2 square bottles for reagents (occupies two tracks).

Tab. 10: Supplied racks

5.2.6 Washer and Wash Buffers

To be able to wash microplates in the course of a test, the EUROIMMUN Analyzer I-2P system is provided with a washer. By means of the washer, the microplates can be cleaned strip by strip using different wash buffers.

The wash head of the washer aspirates liquid from the microplate wells as well as dispenses wash buffer into them. The wash head comprises eight dispense nozzles and eight slightly longer aspiration nozzles. The wash head is lowered into the microplate wells for each aspiration or dispensing step.

The washer is located behind a cover (6).

A maximum of 3 bottles (1 x 1 litre, 2 x 2 litres) (15) can be used for various wash buffers to clean the microplates and cleaning fluid (e.g. distilled water) to clean the washer head.

The connection fitting (13) consists of 3 colour-coded connection pairs: one tubing and one level sensor each per bottle.

Two waste bottles (14) are available for the wash unit. One waste bottle contains the liquid waste which is pumped to the waste container positioned below the instrument. The second bottle serves as overflow protection.

5.2.7 Incubator and Room-temperature incubator

Next to the washer there are two independent heatable incubator chambers; the microplates are automatically transported into these incubators and out again according to the assay protocol.

The heatable incubator chambers can also shake a microplate in order to mix the well contents. The microplate is moved linearly at a given frequency and amplitude. The shaking time is controlled through the assay protocol.

The instrument is also equipped with three light-protected storage chambers (room-temperature incubator) accommodating microplates for room temperature incubation. It is located below the incubator.

5.2.8 Photometer

The photometer uses photodiodes located above the microplate to measure the amount of light passing through the microplate wells from the light source below the microplate. The optical system includes optical interference filters (up to 8 filters), mounted in a filter wheel, to obtain monochromatic light of the desired wavelength and optical lenses to obtain an optimal light beam passing through the microplate wells.

The photometer measures the absorbance in eight wells simultaneously as the microplate moves through the photometer. Comparing the measurement values to the zero value with air in between (equivalent to 100 % light source output), the absorbance is calculated using the Lambert-Beer law. A reference channel continuously compensates for any instability of the light source or any dirt or stains on the microplate.

The photometer (400 - 700 nm) is installed in the lower left part of the instrument.

5.2.9 Pipettor and Dispense Pump

The EUROIMMUN Analyzer I-2P system is provided with a fully automatic pipetting system.

The microprocessor-controlled dispense pump (12) installed on the left side of the system allows a very precise aspiration and dispensing of the liquids to be pipetted. The tube system of the pipetting system is filled with system liquid.

The pipettor uses disposable tips to avoid cross-contamination. Different sizes of disposable tips (300 µl or 1100 µl) can be attached to the tip adapter of the pipettor automatically. After pipetting the disposable tips can be emptied in the wash station (10) or dropped into the tip eject station (10).

5.2.10 Dispense Pump

The dispense pump is used for transferring liquids (samples, controls, standards, reagents or sample buffer).

The disposable tip is moved into the source position (e.g. sample, reagent) by the pipettor to aspirate liquid. The downward motion of the pump's syringe plunger causes the system liquid to aspirate fluid into the disposable tip.

After the liquid is aspirated, the tip is moved to the intended destination (e.g. microplate, dilution plate). The upward motion of the syringe plunger causes the system liquid to dispense fluid through the disposable tip into the intended destination. By the motion of the syringe plunger and the system liquid, fluid is drawn into the disposable tip and dispensed.

The system liquid container (16) is located beside, behind or under the instrument and connected through tubing. The system liquid container is fitted with an electric level sensor.

The system liquid can be filled as soon as the instrument is properly installed.

5.2.11 Liquid Level Detection (LLD)

Each disposable tip has independent liquid level detection (LLD) capabilities. LLD detects liquid based on a change in capacitance. As the tip enters the sample or reagent well the LLD circuitry baselines. The tip is lowered a change of capacitance is detected. Once liquid is detected, the tip submerges up to a programmed depth. As the system aspirates/dispenses liquid, the tip is lowered/raised with the decrease/increase of the liquid level. The tip is moved based on the liquid level calculated using well geometry. This mechanism ensures that sample or reagent will be aspirated/dispensed without unnecessary external contamination of the tip.

Disposable tips with LLD capability are impregnated with carbon and are black in colour. These are called 'conductive tips’. Tips not impregnated with carbon, normally clear in colour, have no LLD capability and can only be used if a fixed height for aspirating or dispensing is used.

5.2.12 Tip Ejection Station and Pipettor Wash Station

Tip ejection station and waste bag or tunnel system (10):

The opening serves as an ejection station for disposable tips. The ejected tip is transported via a slide-through, which is attached to the front side of the instrument then into the waste bucket. Alternatively, a waste bag can be installed instead of the waste tunnel system.

⚠ WARNING

Biological substances and reagents (in tip disposal station, waste chute system, waste bags)

Potential risk of infection/skin irritation

> Avoid skin/mucous membrane contact with the biological substances and reagents used and equipment parts that come into contact with biological substances and reagents.
> Handle the above-mentioned parts like potentially infectious material.
> Wear suitable protective clothing (protective gown, protective gloves and, if necessary, protective goggles).
> Observe the appropriate safety precautions.

Pipettor wash station (10)

The pipettor wash station is located behind the tip ejection station.

5.2.13 Touch Screen (only Windows 7)

With the integrated touch screen it is very easy to use the system. All input is made with a stylus (tip capacitive) or a finger directly on the touch screen. An external keyboard or mouse is not needed.

Use:

- Keyboard (alphanumeric input, e.g. A - Z, 0 - 9, etc): The EUROIMMUN Analyzer I-2P software provides special input dialogs to enter letters (► *Chapter 7.6 Edit Text and Selection window, p. 63*) or numbers. Additionally, there is a callable screen keyboard to enter letters or numbers on the Windows systems (see Windows Start button).
- Mouse:
  Mouse pointer: Touch the screen with your finger. Now the mouse pointer will follow your moving finger.
- Single mouse click:
  Touch the screen with your finger once.
- Double mouse click (double click):
  Touch the screen with your finger twice. Do not wait between the first and the second touch.

Handling and cleaning the touch screen

- Use a stylus (for capacitive surfaces) or tap the screen with your finger without applying increased pressure.
- The use of sharp-edged or hard objects is not permitted.
- It is absolutely forbidden to draw lines along the edge of the case, as the extreme force will damage the PET/foil and cause the touch screen to fail.
- Keep the surface clean.
- Clean the touch screen with a soft cloth and neutral cleaner or ethanol.
- Do not use chemical solvents or acidic or alkaline solutions.
- Prevent liquid from entering the junction between the film and the glass, as this may cause the film to peel off or malfunction.

5.3 Principles of Methods

5.3.1 Absorbance Photometry

The measurement principle of absorbance photometry plays the most important role in clinical chemistry. With this method, the intensity of a monochromatic light beam of a suitable wavelength is compared before and after passing through a sample. The degree of attenuation of intensity of the light beam provides a measure of the concentration of the substance under investigation. The photometer consists of a polychromatic light source. In the case of the EUROIMMUN Analyzer I-2P, this is a halogen lamp which emits a light spectrum.

The desired wavelength is filtered out using a wavelength selector (i.e. a filter). The light with this wavelength passes through the sample with the substance to be measured in an optically clear solution. A part of the light is absorbed in the sample. The intensity of the light coming out of the sample is measured with a measuring cell (detector). The light striking the detector is converted into an electrical signal and stored as the measurement signal.

5.3.2 Bichromatic Measurement

In the case of the bichromatic measurement principle, measurements are performed at two wavelengths, the measuring and the reference wavelength. The measuring wavelength is close to the absorbance maximum of the chromogen. The absorbance is mainly dependent on the amount of chromogenic substance in the sample. The reference wavelength lies outside the absorbance range of the chromogen and indicates the blank value of the sample.

The absorbance value of the reference wavelength is substracted from the absorbance value of the measuring wavelength. In this manner, external influences such as scratches on the microtiter plate, dust, turbidity of the solution and the drift of the electronic measuring instrument can be compensated.

5.4 Connections

5.4.1 Liquid Connections

Fig. 11: Left side - liquid connections

Number	Description
①	Dispense pump
②	Liquid connections
③	2 washer waste bottles (vacuum extraction)
④	3 wash buffer bottles
⑤	System liquid container
⑥	Waste liquid container

NOTE

The waste liquid container should always be positioned under the analysis system.

NOTE

Waste bottle 1 and 2 for the liquid waste from the washer must be lined up, so that they cannot accidentally fall over during operation!

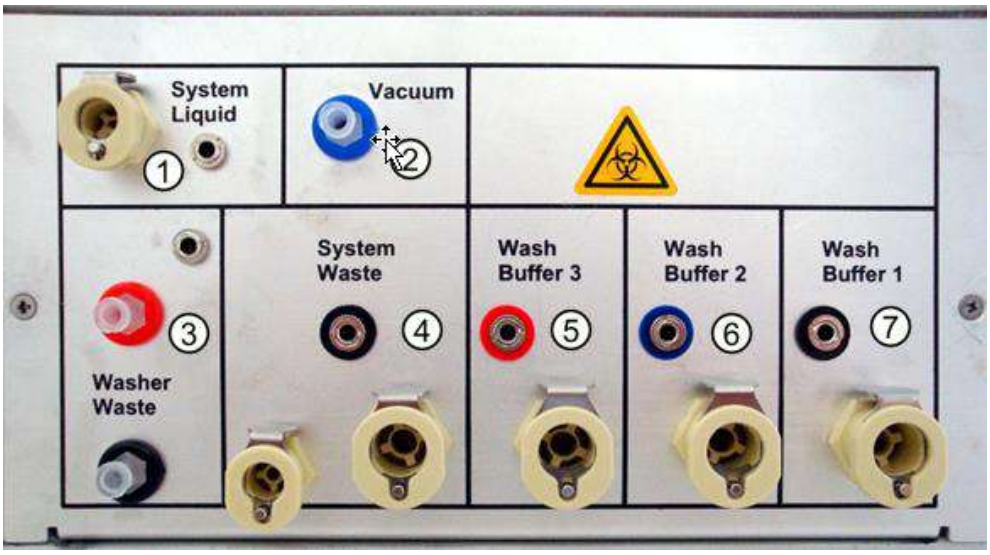


Fig. 12: Liquid connections

Number	Description
①	System liquid container
②	Waste bottle no. 2 overflow bottle and vacuum connection of washer
③	Waste bottle no. 1 for washer liquid (collection bottle)
④	Waste liquid container
⑤	Wash buffer bottle - red channel
⑥	Wash buffer bottle - blue channel
⑦	Wash buffer bottle - black channel

5.4.2 Electrical Connections (Windows 7)

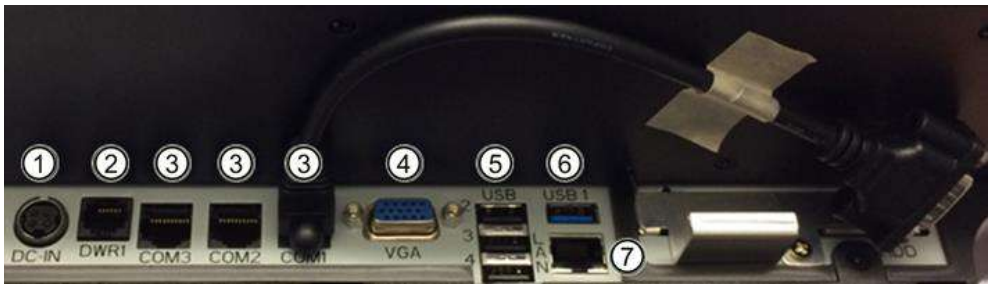


Fig. 13: Back - Electrical connections (Windows 7)

Number	Description
①	DC-power input
②	RJ 11-interface
③	Serial interface (RS 232) 3 pieces
④	VGA-port for external monitor
⑤	3 USB-ports 2.0
⑥	USB-port 3.0
⑦	Network connection (LAN)

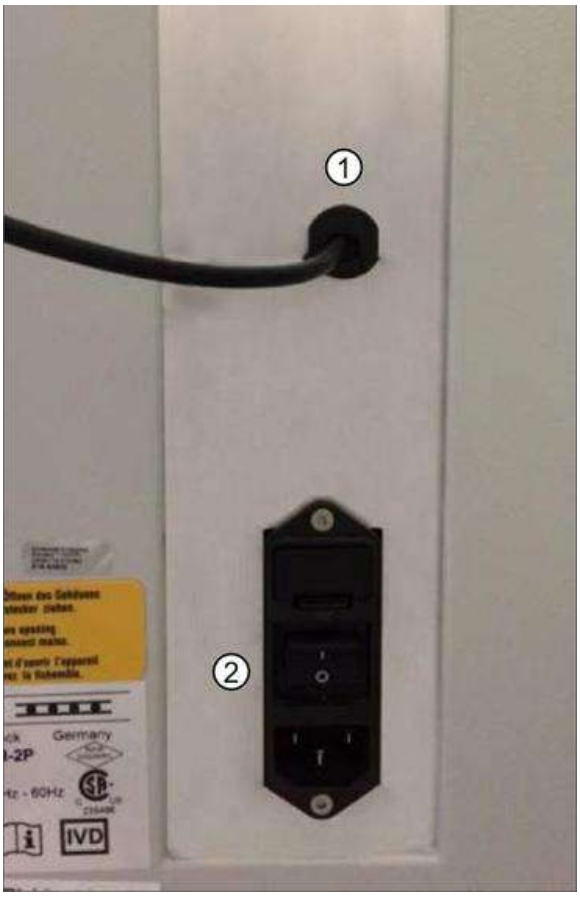


Fig. 14: Right side electrical connections

Number	Description
①	USB cable PC USB 2.0 port
②	Main power connection with power switch and main fuse

5.4.3 Electrical connections (Windows 10)

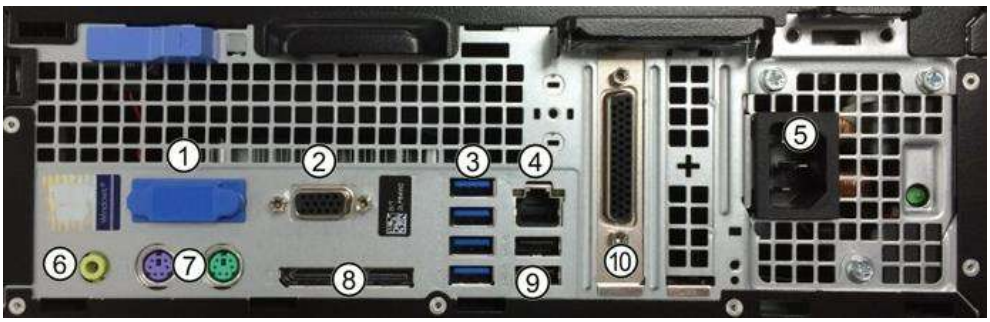


Fig. 15: Back of the PC - Windows 10 system

Number	Description
①	COM 1 (disabled)
②	VGA port
③	4 USB 3.0 ports
④	Network connection (LAN)
⑤	Power connector
⑥	Speaker connector
⑦	PS2 connector keyboard/mouse
⑧	2 Displayport ports
⑨	2 USB 2.0 ports
⑩	SUNIX serial interface card for Y-cable

Fig. 16: Y-cable for serial card

5.5 Function description

See ► *Chapter 8 Operation, p. 66*.

6 Installation and commissioning

The system may only be installed and commissioned by EUROIMMUN Technical Service or by a service technician authorised by EUROIMMUN.

The following sections show you how to connect the system components.

7 Operating software structure

This chapter describes the basic functions of the EUROIMMUN Analyzer I-2P software. A brief overview of all software menus and symbols is also included in this chapter.

NOTE Required access rights: Start worklist ► *Chapter 8.7 Start Worklist, p. 87.*

7.1 Menus and symbols

The following tables, sorted alphabetically, describe various menu items. Some menu items are only active if you can use them.

7.1.1 General options

Category	Option	Symbol	Description
Editor	OK		The input/change is applied and the corresponding dialog is closed.
Editor	Cancel		The entry/change is not applied and the corresponding dialog is closed.
Editor	Restore		This option allows you to restore the previously changed data.
Editor	Reverse		This option allows you to undo the changes you made previously.
Help	Help		Opens the online help.
Keyboard	Ctrl		Simulates the Ctrl key on your keyboard. When this option is selected, you can select several non-consecutive items from a list.
Keyboard r	Shift		Simulates the shift key on your keyboard. When this option is selected, you can select several consecutive items from a list.
Search	Scroll buttons (active with multi-page documents)		Jumps to the previous/next line.
Search	Scroll buttons (active with multi-page documents)		Jumps to the previous/next page.
Search	Scroll buttons (active with multi-page documents)		Jumps to the first/last page.
Selection	Select all		This option selects all the displayed items in a list.

Category	Option	Symbol	Description
Selection			This symbol indicates that the corresponding option has not been selected.
Selection			This symbol indicates that the corresponding option has been selected.

Tab. 11: General options

7.1.2 Options of the file menu and selection window

Shows a selection window (► *Chapter 7.6.3 Make a Selection window, p. 65*) for the following options. These are the same options as in the FILE menu.

Option	Symbol	Description	Chapter
Close		Closes the active document	–
Exit		Exits the program	–
New		Shows a selection window for creating a new document (e.g. tests, work lists or findings)	►► *Chapter 7.2 Options of the selection window NEW, p. 57*
Open		Shows a selection window for opening a document	► *Chapter 7.3.1 Options of the Open selection window, p. 58*
Print		Prints the active document (e.g. work list, findings).	► *Chapter 7.5.1 Print, p. 61*
Side view		Shows the active document as a print preview.	► *Chapter 7.5.3 Print Preview, p. 63*
Printer Setup		Sets printer and print options	► *Chapter 7.5.2 Printer setting, p. 62*
Save		Saves the active document (e.g. work list, findings)	► *Chapter 7.4 Save, p. 60*
Save as		Saves the active document (e.g. work-list, findings) under a new name	► *Chapter 7.4 Save, p. 60*
Latest protocols		Displays the 4 most recently opened and already saved test log files for selection	–
Last results		Displays the 4 most recently opened and already saved result files for selection.	► *Chapter 8.9.3 Save/Open the Result Report, p. 116*
Latest work lists		Displays the last opened and already saved work lists for selection.	–

Tab. 12: Menu and File selection window

7.1.3 Options of the Edit Menu

Option	Symbol	Description	Chapter
Export Archive…		Exports archiving information as a file. Not used.	–
Load Additional Ressources…		Allows reloading of disposable tips and dilution plates.	► *Chapter 8.7.6 Load Tip Racks, p. 99*
Lot Specific Values…		Opens the LOT SPECIFIC VALUES FOR: dialog box to view or edit the required reagent data.	► *Chapter 8.5 Lot-specific Values, p. 75*
Optimise		Optimises the proposed schedule of the defined worklist, if necessary.	► *Chapter 9.5.1 Optimise the Schedule, p. 148*
Panel Definition…		Opens the SET-UP PANEL dialog box for editing the current work list. This option is also called EDIT PANEL.	► *Chapter 8.4 Create a worklist, p. 74*
Panel Options…		Opens the WORKLIST OPTIONS dialog box to change the work list options. This option is also called EDIT OPTIONS.	► *Chapter 9.4 Worklist Options, p. 142*
Start		Opens the LOAD dialog box for assigning the required resources. A run is then started with the current work list.	► *Chapter 8.7 Start Worklist, p. 87*
Stop		Interrupts the current run. One or more plates can be removed and the run can then be continued. Or the entire run can be aborted completely.	► *Chapter 8.8.5 System Paused Dialog, p. 110*
EUROIMMUN Allercoat		Starts the EUROIMMUN Allercoat-Software.	–
Unloading Finished Plates…		Allows unloading of fully processed plates before the end of the run.	► *Chapter 8.10 Unloading, p. 118*

Tab. 13: Options of the Edit Menu

7.1.4 Options of the Utilities menu and selection window

Option	Symbol	Description	Chapter
Export results		The results of the individual tests or the entire plate, when displayed on the screen, can be exported to the laboratory software with this option.	► *Chapter 16.1.4 Export of Test Results, p. 250*
Log-Off / Log-On		Allows the operator to change. If the system was started by one operator and another operator wants to take over, the second operator must log in under his or her user name.	–

Option	Symbol	Description	Chapter
Options		Definition of software parameters (e.g. user access rights, lab details, preferences, directories, file queries, ASTM).	► *Chapter 10.1 System Options, p. 168*
Patient Details…		Opens the full PATIENT EDITOR dialog box to view or edit patient data.	► *Chapter 9.2 Complete Patient Editor, p. 125*
Present Carriers		With this function, all plate holders are moved one after the other to the loading and unloading station.	► *Chapter 9.5.3 Test Plate Removal, p. 153*
Scanner		Allows you to manually select a track for the next rack. Click on the desired track in the SELECT A TRACK dialog box. **NOTE** Two-track racks can only be inserted into every second track. Otherwise, the software rejects the rack. See warnings below.	–
Select Language…		Allows you to change the software language. Only visible when no window is open.	► *Chapter 9.9 Software Language, p. 166*
Selftest		Carry out a self-test (initialisation).	► *Chapter 9.1 Initialisation and Self-test, p. 123*
System Setup		Unit settings can be changed.	► *Chapter 10.2 System Set-up, p. 177*
System properties		Manual control of the system. Not recommended for normal use.	► *Chapter 9.5.3 Test Plate Removal, p. 153*
Turn Scanner Off		Turns off the barcode scanner in the rack loading area. **NOTE** The barcode scanner in the rack loading area returns to its rest position. See warnings below.	–
Turn Scanner On		Turns on the barcode scanner in the rack loading area. See warnings below.	–
Verify Colorimeter		Checks the photometer using a verification plate.	► *Chapter 10.2.3 Colorimeter tab, p. 181*

Tab. 14: Menu Extras

ATTENTION

MOVEMENT OF THE BARCODE SCANNER

Damage to the barcode scanner.

> Do not use the rack loading area as a storage area.

⚠ WARNING

MOVEMENT OF THE BARCODE-SCANNERS

Risk of impact, crushing, stabbing

> > Only load or unload in the specified lane.
> > Wait until you are prompted to load/unload.
> > Wait until the barcode scanner stops.

⚠ WARNING

BACKWARD MOVEMENT OF THE BARCODE SCANNER

Risk of impact, crushing, stabbing

> Never reach into the rack loading area to the right of the barcode scanner.

7.1.5 Options of the menu and selection window

Option	Symbol	Description	Chapter
Arrange Icons		Arranges all minimised windows from the bottom left to the top right of the workspace.	–
Cascade		Arranges all windows from top left to bottom right of the workspace.	–
New Window		Displays the active document in a new window. The new window only shows a new view of the document, it is not a new document.	–
Tile		Arranges all windows and aligns them in rows.	–

Tab. 15: Menu and selection window

7.1.6 Options of the Menu and Selection Window Help

Option	Symbol	Description	Chapter
About EUROIMMUN Analyzer I-2P		Displays the version number of the EUROIMMUN Analyzer I-2P software.	–
Contextual help		Displays the online help for the selected option (if available).	–
Support topics		Displays the online help (if available).	–

Tab. 16: Menu and selection window Help

7.2 Options of the selection window NEW

Option	Symbol	Description	Chapter
Assay		Opens the dialog window SELECT ASSAY PROTOCOL TYPE to create a new assay.	See Assay Programming Manual (available from your EUROIMMUN Service Engineer).
Job List		Shows a list of patient IDs with the tests to be performed for each individual patient, i.e. patient data and test orders that have already been saved in the system but not yet processed. This corresponds to the data currently available in the PATIENT EDITOR dialog box. This option is useful as you will quickly know if there is a backlog or if there is still a lot of work to be done. This JOB LIST can be printed out. This JOB LIST is different from the work list displayed in the SET-UP PANEL window.	–
Patients Results Report		Opens the PATIENT RESULTS dialog box for creating a patient report.	► *Chapter 9.7 Patient result report, p. 161*
QA Analysis Report		Opens the Q.A. ANALYSIS to create a QC analysis report.	► *Chapter 9.8 Quality Control Analysis Report (Levey Jennings Plot), p. 165*
Spectral Response		After selecting SPECTRAL RESPONSE, the system prompts you to load a test plate. The photometer then measures the 96 wells of the micro-titre plate with all filters installed. From these readings, the system creates a spectral response curve. Recommended test and reference filters are displayed on the screen. After double-clicking on a specific cavity, the curve recorded for this cavity is displayed. After another double-click, the overview is displayed again.	–
Worklist		Opens the SET-UP PANEL dialog box to create and start a new work list.	► *Chapter 8.4 Create a worklist, p. 74*

Tab. 17: Selection window New

7.3 Loading (Open)

With the Open option, findings, work lists, event logs, etc. saved on the PC can be reloaded and displayed. In the first step the file type is selected, in the second step the file itself.

7.3.1 Options of the Open selection window

Option	Symbol	Description	Chapter
ASCII Patient Information (*.txt)		Displays the OPEN dialog box for opening ASCII files with patient data.	► *Chapter 16.1.3 Defining Import Parameters, p. 245*
Assay Protocol Files (*.asy)		Displays the OPEN dialog box for opening test log files.	see Assay Programming Manual (ask your EUROIMMUN service engineer)
Event Log Files (*.log)		Displays the OPEN dialog box for opening event log files.	► *Chapter 8.6.6 Active Event Log, p. 84*
Reagent Layout Files (*.rea)		Displays the OPEN dialog box for opening reagent layout files.	–
Result Files (*.res)		Displays the OPEN dialog window for opening result files.	► *Chapter 8.9.3 Save/Open the Result Report, p. 116*
Selftest Reports (*.tst)		Displays the OPEN dialog box for opening self-test report files.	► *Chapter 9.1 Initialisation and Self-test, p. 123*
Spectrum Files (*.spe)		Displays the OPEN dialog window for opening spectrum files.	–
Verification Reports (*.ver)		Displays the OPEN dialog box for opening test report files.	–
Worklist Files (*.wor)		Displays the OPEN dialog box for opening worklist files.	► *Chapter 9.3.4 Save or Open a Worklist, p. 141*

Tab. 18: Open selection window

7.3.2 Opening a file

With the option Open results, work lists etc. saved on the PC can be reloaded and displayed. For this purpose, the dialog window OPEN is selected. In this dialog window, the storage address (folder) and the file can be selected.

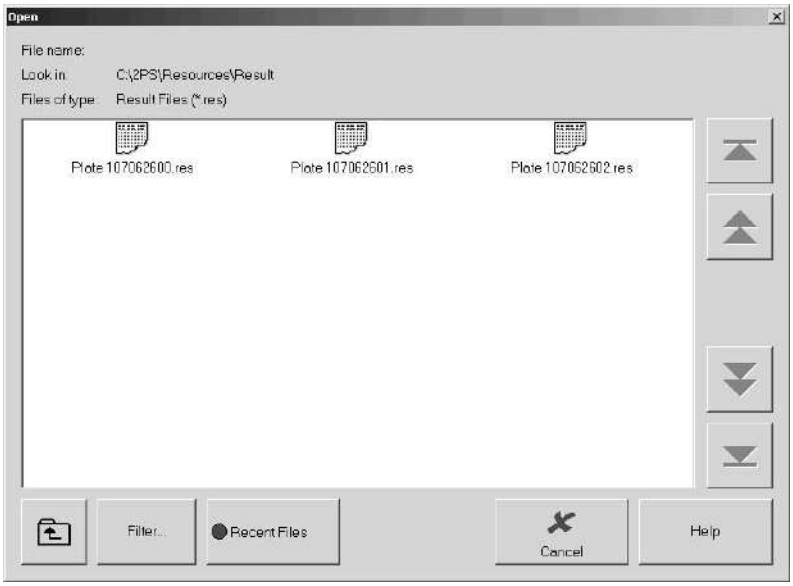


Fig. 17: Open dialog window

Option	Description
File name	
Files of type	Displays the type of file
Filter...	This option can be used to limit the number of files displayed. After selecting this option, the dialog window Text input is displayed. (► *Chapter 7.6.1 Edit Text Dialog, p. 63*) is opened. After the input, only the files containing the entered text are displayed. The filter ignores capitalisation. Example: Filter input: *0706* Displayed files:*Plate07062001, Plate07062701*
(One folder level up)	With this button you can switch to the parent folder. Example: `C:\ProgramData\Euroimmun Analyzer I - 2P\System` => `C:\ProgramData\Euroimmun Analyzer I - 2P`
Recent Files	After selecting this option, only files that have already been opened recently are displayed. After clicking this option again, all files are displayed again. This option has priority over the option Filter.

7.4 Save

Save Option

With the option Save results, work lists etc. can be saved on the PC. If no file name has been given yet, the option Save as opens automatically.

Option Save as

With the option Save as results, work lists etc. can be saved on the PC. For this purpose, the dialog window SAVE AS is opened. Here the storage location (folder) and the file name can be defined. If a file with the entered name already exists, the EUROIMMUN Analyzer I-2P-software asks whether the
existing file should be overwritten.

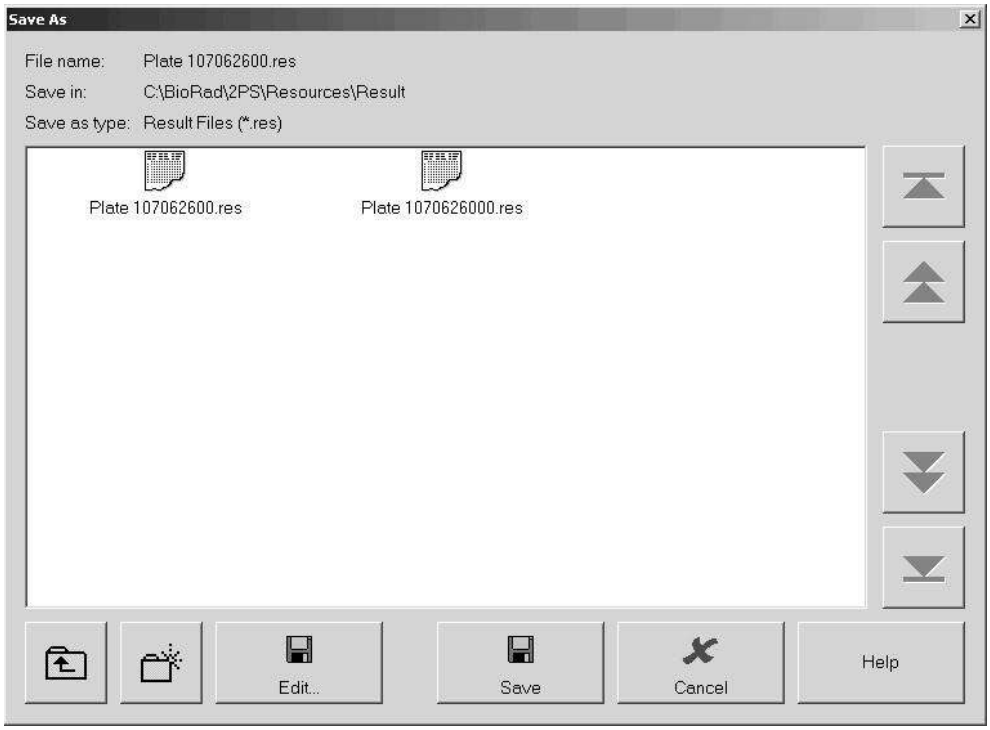


Fig. 18: Save As dialog box

Option	Description
Edit...	After selecting this option, the EDIT TEXT dialog window (► *Chapter 7.6.1 Edit Text Dialog, p. 63*) opens. A new file name can be entered here.
File name	Shows the existing or automatically generated file name.
(One folder level up)	With this button you can switch to the parent folder. Example: `C:\ProgramData\Euroimmun Analyzer I - 2P\System` => `C:\ProgramData\Euroimmun Analyzer I - 2P`

Option	Description
(New folder)	A new folder can be created via this button. The name is entered in the EDIT TEXT dialog window (► *Chapter 7.6.1 Edit Text Dialog, p. 63*).
Save	After clicking on this button, the file is saved under the name entered.
Save as type	Displays the file type (► *Chapter 10.1.8 File types and locations, p. 176)*.
Save in	Displays the selected or defined folder (► *Chapter 10.1.7 Directories tab, p. 175*) in which the file is to be saved.

7.5 Printing on the printer

With the option Print results, work lists, etc. can be printed on the printer. Before printing, it is possible to select the printer, adjust the printer settings and display a print preview on the screen.

7.5.1 Print

With the option Print results, work lists, etc. can be printed directly.

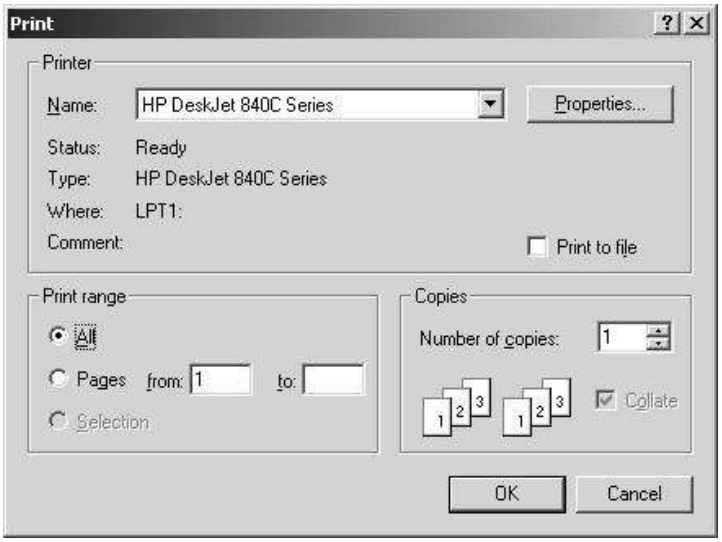


Fig. 19: Print dialog

Number	Description
Name	The default printer is displayed. Another printer can be selected from the list.
Print to file	After selecting this option, a file is created instead of a printout. The file is a print-only file and cannot be opened with the EUROIMMUN Analyzer I-2P software.
Properties	Displays the properties of the selected printer. For de-tailed information on the settings, refer to the printer manual.
Status/Type/Where	Printer information

Number	Description
All	Prints the complete document (results, test, etc.)
Pages	Prints the specified pages of the document
Selection	Prints the marked part of the document
Collate	If several printouts are to be created, you can specify here whether the printouts are to be sorted
Number of copies	This option allows the number of copies to be specified

7.5.2 Printer setting

With the option printer setting the printer to be used can be selected and pre-configured. The settings apply to all subsequent printouts.

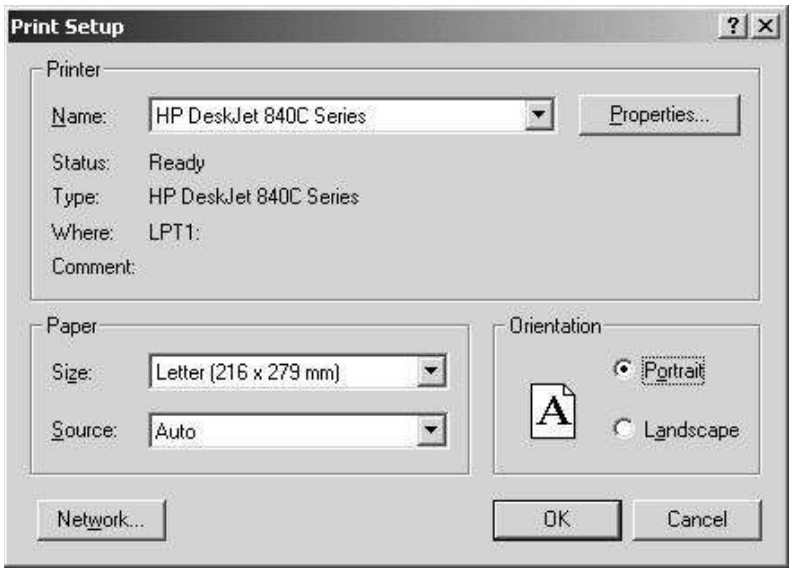


Fig. 20: Printer settings

Number	Description
Name	The default printer is displayed. Another printer can be selected from the list
Properties...	Displays the properties of the selected printer. For de-tailed information on the settings, refer to the printer manual
Status/Type/Where	Information about the printer
Size	Allows selection of the paper size to be used
Source	Allows you to select the printer tray with the selected paper
Landscape	The selected paper is used in landscape format
Portrait	The selected paper is used in portrait format

7.5.3 Print Preview

This option displays a preview of the printout on the screen. In this way, the printer presettings can be checked.

Option	Description
Close	Closes the print preview
Next page	Displays the next page
Previous page	Displays the previous page
Print...	Prints the preview (► *Chapter 7.5.1 Print, p. 61*).
Two pages	Displays two pages on the screen
Zoom in	Enlarges the displayed page
Zoom out	Reduces the displayed page

Tab. 19: Options of the Page View dialog box

7.6 Edit Text and Selection window

7.6.1 Edit Text Dialog

The EDIT TEXT dialog window allows the practical input of text on a touch screen. For this purpose, a "keyboard" for text input is displayed on the screen.

The input itself is displayed in a separate text area. Next to this text area, the respective purpose is shown (e.g. password).

Fig. 21: Dialog window Edit Text (example: password input)

Option	Description
Cancel	The input is not imported and the EDIT TEXT dialog box is closed
Delete	Deletes the character or digit to the left of the cursor
Left	Moves the cursor one character to the left
OK	The entry is accepted and the EDIT TEXT dialog window is closed
Right	Moves the cursor one character to the right
Shift	Shift switches to upper case for the next character to be entered
Shift Lock	Shift Lock switches between upper- and lower-case letters or between numbers and special characters. ▪ Not activated: Numbers or special characters indicated in the lower part of the respective key as well as lower case letters can be used. ▪ Activated: Special characters that are indicated in the upper part of the respective key as well as upper case letters can be used.

7.6.2 Enter a Number Dialog Window

The ENTER A NUMBER dialog window allows practical entry of numbers on a touch screen. For this purpose, a "numeric keypad" for entering numbers is displayed on the screen.

The input itself is displayed in a separate text area.

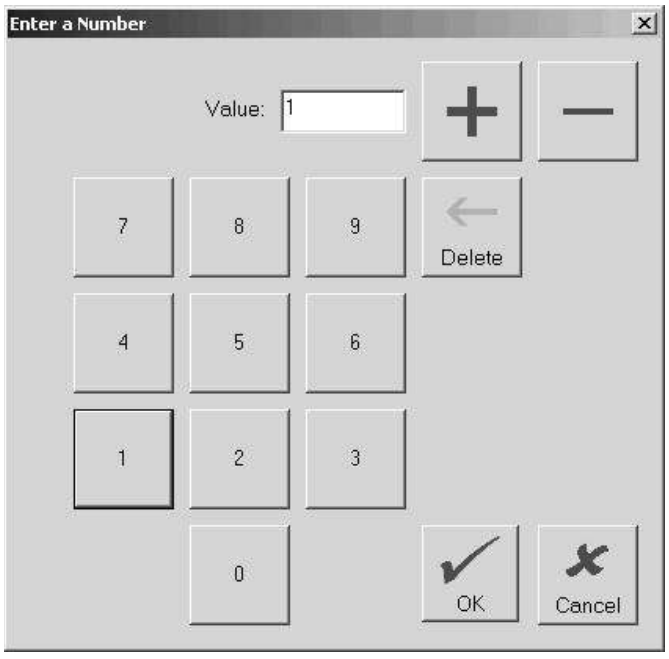


Fig. 22: Enter a Number dialog box

Number	Description
Cancel	The entry is not accepted and the ENTER A NUMBER dialog box closes
Delete	Deletes the digit to the left of the cursor

Number	Description
Minus	The displayed value is reduced by one
OK	The entry is accepted and the ENTER A NUMBER dialog window is closed
Plus	The displayed value is increased by one

7.6.3 Make a Selection window

You can select special options in MAKE A SELECTION window. Using the MAKE A SELECTION is very simple: Search for the desired option. If necessary, use the arrow keys. Then click on the desired option.

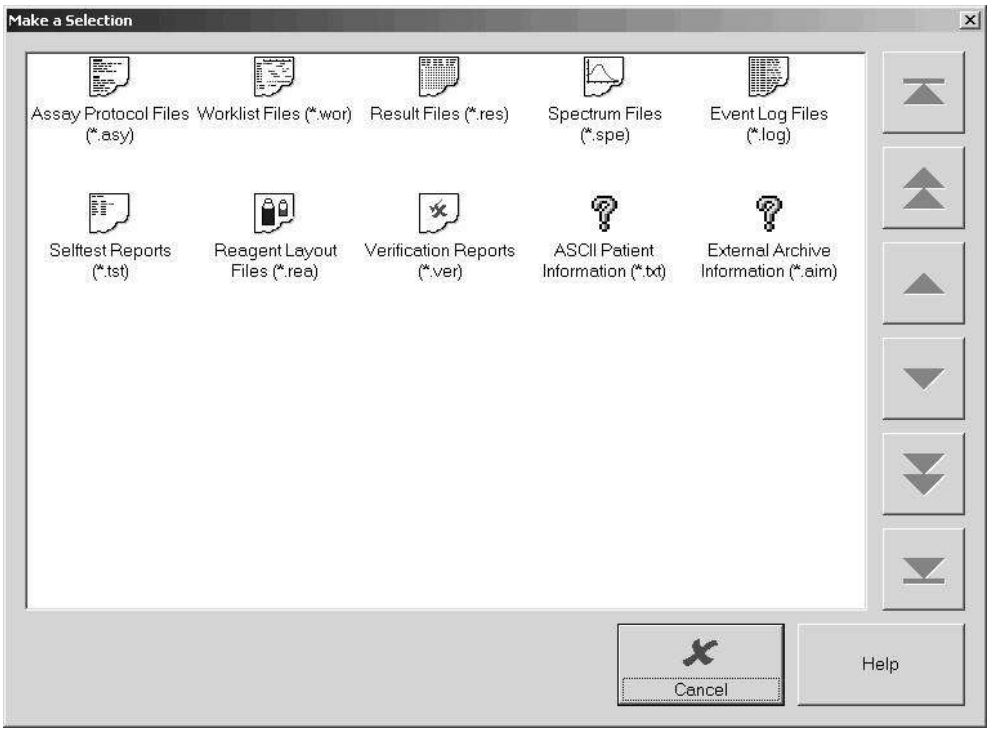


Fig. 23: Make a Selection box (e.g. Test Files)

8 Operation

This chapter describes all the steps of a test case from switching on to switching off the system for a "normal" user with the authorisation to start a worklist.

In ► *Chapter 10.1.1 Access Control tab, p. 168* the access rights are described.

In ► *Chapter 7 Operating software structure, p. 52* the basic functions of the EUROIMMUN Analyzer I-2P software are described.

Further functions for "normal" users and for users with additional rights are explained in ► *Chapter 9.5 Advanced Options, p. 148*.

8.1 Short schedule

Option	Description	Chapter
Start-Up	• Switch on • Start EUROIMMUN Analyzer I-2P software • Carry out the "Washer Check-2P" test	► *Chapter 8.2 Start-Up, p. 67*
Load patient samples and assign tests	• Load patient samples • Assign tests	► *Chapter 8.3 Loading patient samples and assigning tests, p. 68*
Create worklist	• Check microplates • Check assays • Check patient samples	► *Chapter 8.4 Create a worklist, p. 74*
Lot specific values	• Scan the 2D barcode of the respective quality control certificate	► *Chapter 8.5 Lot-specific Values, p. 75*
The worklist window	• Check worklist	► *Chapter 8.6 The Worklist Window, p. 77*
Start worklist	• Load patient samples • Load reagents • Load unstable reagents • Load dilution plates • Load tip racks • Fill up wash buffer and rinse solution • Fill up system fluid • Load test plates	► *Chapter 8.7 Start Worklist, p. 87*
Process run	• Tests before the run • Steps of a typical test run • What you can do • System/pipetting error • System pause	► *Chapter 8.8 Processing the Run, p. 104*
End run / findings window	• Structure • Interpretation of findings • Edit/recalculate results • Save/open findings • Print findings • Export results	► *Chapter 8.9 End of Run/Result Report Window, p. 112*

Unloading	• Unload test racks • Unload sample racks • Unload reagent racks • Unload tip racks and dilution plates • Unload other resources • Dispose of waste	► *Chapter 8.10 Unloading, p. 118*
Shutdown	• Maintenance • Exit EUROIMMUN Analyzer I-2P software • Shut down operating system • Switch off	► *Chapter 8.11 Shutdown / End of Day Maintenance, p. 121*

Tab. 20: Short schedule

8.2 Start-Up

Maintenance

1) Check the level of the system fluid in the system fluid reservoir. Top up with liquid when the level is low.

2) Check the level of the waste liquid in the waste liquid container. If the container is full or almost full, empty and decontaminate it.

Dispose of waste liquid according to the legal regulations for biohazardous substances.

3) Check the pipetting system tubing and syringe for air bubbles or leaks as these can cause pipetting errors.

📖 *Quick start guide Start-up instructions EUROIMMUN Analyzer I-2P*

Switch on

Depending on the version of the device, the PC is also booted up when the device is switched on. In this case, step 3) is not applicable.

1) Close the cover.

2) Switch on the instrument.

3) Boot up the PC.

✓ The system is initialised, and the integrated PC starts the Windows operating system.

Starting the EUROIMMUN Analyzer I-2P-software and logging in

1) Double-click on the programme icon to start the EUROIMMUN Analyzer I-2P-software.

→ The EUROIMMUN Analyzer I-2P-software displays the login window:

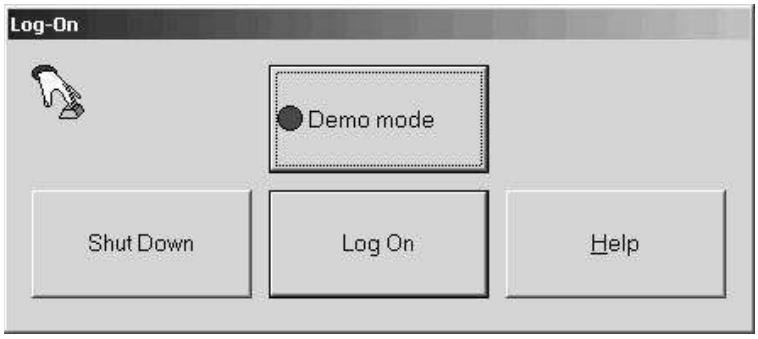


Fig. 24: Log-On dialog

Option	Description
Log On	Displays a dialog box for entering the user name
Demo mode	Starts the EUROIMMUN Analyzer I-2P software without connection to the instrument. Tests or processes can be checked in demo mode.► *Chapter 9.10 Simulation mode/demo mode, p. 166*
Shut Down	Exits the program
Help	Calls up the online help

2) Click on the Log On button.

→ Die EUROIMMUN Analyzer I-2P-software displays the EDIT TEXT dialog where you can enter your user name (► *Chapter 7.6.1 Edit Text Dialog, p. 63*). The User Name entered during registration automatically appears in the User field in the self-test report and also in the header of the results files and findings. This ensures better traceability of the tests performed.

3) Click on ✓ OK.

→ The EUROIMMUN Analyzer I-2P-software displays the EDIT TEXT dialog again for entering the password

4) Enter the password (if necessary) or leave the field blank.

NOTE Users with password could have different permissions than users without password (► *Chapter 10.1.1 Access Control tab, p. 168*).

5) Click on ✓ OK.

→ The EUROIMMUN Analyzer I-2P carries out a self-test.

6) Before the first run, start the "Washer Check-2P" test to check the washing performance. *short instructions Maintenance and Care EUROIMMUN Analyzer I-2P*

8.3 Loading patient samples and assigning tests

This section describes how to load patient samples into the system with or without barcodes and then assign them to one or more tests.

Information for test used

Before working through a test (especially if you are using it for the first time), you should look at the various processing steps, their sequence, incubation times, reagents used, etc.

To do this, open the test file and print it according to the description in ► *Chapter 7.3 Loading (Open), p. 57* und ► *Chapter 7.5.1 Print, p. 61* . Details on the tests can be found in the Assay Programming Manual (ask your EUROIMMUN service technician).

8.3.1 Loading patient samples

ATTENTION

Movement of the barcode-scanner

Damage to the barcode-scanner.

> Do not use the rack loading area as a storage area.

WARNING

Movement of the barcode-scanner

Risk of impact, crushing, stabbing

> Only load or unload in the specified lane.
> Wait until you are prompted to load/unload.
> Wait until the barcode scanner stops.

WARNING

Reverse movement of the barcode scanner

Risk of impact, crushing, stabbing

> Never reach into the rack loading area to the right of the barcode scanner.

NOTE

Never load more than one rack at a time! For correct barcode recognition, the racks must be loaded one after the other, as indicated by the LEDs.

NOTE

Only tubes of the same type may be used in a single rack to avoid problems when aspirating liquids. The type of tube must be approved for the particular rack.

NOTE

To avoid clots, the patient samples must have been treated appropriately (e.g. centrifuged) before use in the EUROIMMUN Analyzer I-2P.

1) Place the 12 sample tubes in the sample racks.

- Patient samples with barcode:

  Make sure that the barcode labels on each patient sample face to the right so that they can be scanned by the barcode reader when the rack is inserted.
- Patient samples without barcode:

  If you are using sample tubes without barcodes and you want to assign the samples using the Auto Assign Samples option, you must place the samples in the racks in the order that the system will use to assign the samples. (► *Chapter 8.3.1 Loading patient samples, p. 69*).

2) Click on the button Utilities. ► *Chapter 7.1.4 Options of the Utilities menu and selection window, p. 54*

3) Click on the button Turn Scanner On.

4) Insert the first sample rack into the track indicated by the lit LED.

Place the rack in front of the track and then push it in evenly as far as it will go (with the nose engaging the contact hole on the back wall).

→ The barcodes of the rack and the individual samples are read. If the rack has been correctly pushed all the way in, the LED for this position goes out and the LED for the next loading position starts to light up.

5) For patient samples without barcode, enter an ID and assign tests to all loaded patient samples (► *Chapter 8.3.2 Assign assays to patient samples (Tabular patient editor), p. 70*).

6) Insert the other sample racks in the same way.

Troubleshooting ► *Chapter 12 Troubleshooting, p. 217*

8.3.2 Assign assays to patient samples (Tabular patient editor)

Pre-Defined Assays

In this chapter, it is assumed that the tests are performed using pre-defined assays supplied by EUROIMMUN.

However, the EUROIMMUN Analyzer I-2P system also allows users to create and use their own assays (see *EUROIMMUN Analyzer I-2P – Assay Programming Manual* (contact your EUROIMMUN service technician)).

Processing Several Assays

The EUROIMMUN Analyzer I-2P instrument and software allow the user to process different assays in the same test run. In most cases, a different test plate will be used for each assay. This is described in this section

However, the EUROIMMUN Analyzer I-2P system is flexible and also allows the user to combine several compatible assays on the same test plate (► *Chapter 9.3.3 Processing Several Assays per microplate, p. 137*).

Procedure

Each time you load a sample rack as described ► *Chapter 8.3.1 Loading patient samples, p. 69* the following tabular PATIENT EDITOR dialog is automatically displayed:

Fig. 25: Tabular Patient Editor dialog (with patient IDs and assigned assays)

NOTE

The system displays one dialog per inserted rack (if you insert three racks, the system will display this dialog three times).

NOTE

This dialog is not displayed if you use the EUROIMMUN Analyzer I-2P software in demo mode. In this case, please refer to the manual procedure with the complete Patient Editor dialog (► *Chapter 9.2 Complete Patient Editor, p. 125*).

Barcoded samples

If you are working with barcoded patient samples, column 1 shows the Patient IDs as read on the barcodes.

Barcoded and non-barcoded samples:

If you have both barcoded and non-barcoded samples on the same rack, the barcoded positions in column 1 will be filled while the non-barcoded positions will be blank. You have to enter the (non-barcoded) Patient IDs manually in column 1:

1) Select the empty Patient ID field.

NOTE Do not remove or exchange any of the barcoded samples (the system compares successive readings).

2) Enter the correct patient ID.

NOTE The entered patient ID must be unique! If non-unique patient IDs are used (e.g. same ID for different persons on different worklists), the patient database is incorrect. In this case, features like patient history or patient result report must not be used.

NOTE

Double-check the entered patient ID and the patient ID of the sample.

A blank position can also indicate that a position is actually empty (no test tube was inserted) or that the system has not been able to read the sample barcode correctly (► *Chapter 12.2.2 Troubleshooting while Loading Reagents, p. 233*).

Non-barcoded samples

If you are working with non-barcoded samples, you have to enter the Patient IDs manually in column 1 (see above). If you have a lot of non-barcoded samples to process, you may prefer to close this dialog box (click OK button) and do the assay assignments using the manual procedure described in ► *Chapter 9.2 Complete Patient Editor, p. 125*.

Assign one or more assays to each patient

1) Click on the button over the first free column.

NOTE The left side of the dialog shows an enlarged view of the red marked area on the right side.

2) Select the assays to be processed in this test run in the selection dialog (► *Chapter 7.6.3 Make a Selection window, p. 65).* If you want to assign more assays, additional columns will be automatically displayed.

3) Select the cell in the assay columns for the patients who are to be tested with the assay you selected in the corresponding drop-down list. Use the green arrow buttons to scroll the screen.

4) Click on the Close button OK to close the tabular PATIENT EDITOR dialog.

NOTE Never use the x button in the top right-hand corner of the dialog to close it - entered data would not be retained.

NOTE If you inserted more than one rack, the system displays the dialog for the next rack (it may take a little while to show on the screen). Repeat the procedure for each rack.

Import Patient Data and Linked Assays via the Host Connection

If the EUROIMMUN Analyzer I-2P system is connected to a host computer, patient data can be downloaded to the system via this connection. These downloads can be requested by the user or performed automatically

as described in chapters ► *Chapter 16.1.2 Importing patient data and work-list files (types of* import *files), p. 243* and ► *Chapter 16.1.8 Communication, p. 255*. The downloaded data can include the patient personal details (ID Code, Name, Birth date, Sex) and the tests/assays required for each patient if these have already been assigned (at the host computer level).

Procedure

If the racks you inserted correspond to a test order that has already been imported into the EUROIMMUN Analyzer I-2P, the tabular PATIENT EDITOR dialog will be automatically displayed with all the appropriate fields already filled in.

1) Check that everything is correct and click on the OK.

NOTE Never use the X button in the top right-hand corner of the dialog to close it - entered data would not be retained.

2) If you have inserted more than one rack, the tabular PATIENT EDITOR dialog corresponding to the next rack will be displayed. Check it and close it.

3) Repeat the steps for each inserted rack.

If you have inserted the rack(s) before importing the data and are using ASCII file imports

1) The tabular PATIENT EDITOR dialog is blank when it is displayed. Click on the button OK to close it. Repeat this step, if you have inserted more than one rack, to close all tabular PATIENT EDITORS.

2) Import the desired file as described in ► *Chapter 16.1.3 Defining Import Parameters, p. 245*.

3) When you have obtained a message indicating that the file has been successfully imported, click on OK.

4) Pull out your sample racks and load them again.

5) Wait until the tabular Patient Editor dialog is displayed again with the appropriate data already entered. This may take some time.

6) Check that everything is correct and click on OK.

7) If you have inserted more than one rack, the tabular PATIENT EDITOR Patient Editor dialog corresponding to the next rack will be displayed. Check it and close it. Repeat this for each inserted rack.

See ► *Chapter 16.1.3 Defining Import Parameters, p. 245* for information on importing multiple test order requests for the same patient.

If you have inserted the rack(s) before importing the data and are using an ASTM connection.

1) If you had checked the Query Host For Test Orders item in the ASTM dialog (► *Chapter 10.1.5 ASTM Tab, p. 173*) the software will automatically check the host for test orders related to the patient samples you have just loaded.

2) If you had not previously checked this item, you can check it now and then reload your samples.

8.4 Create a worklist

A worklist is a work instruction for the EUROIMMUN Analyzer I-2P system. In the worklist, the sequence and the plates to be processed with the assigned assays are defined.

The following instruction describes how to generate and check a worklist which was automatically suggested by the EUROIMMUN Analyzer I-2P system. The EUROIMMUN Analyzer I-2P system suggests a worklist whenever you load patient samples as described in the previous chapters.

If the assays included in the worklist belong to the same combination group and if the assay parameters (incubation time, shaking parameters...) are compatible, the system will automatically try to combine several assays on the same plate (provided the number of samples allows this). For more information on processing several assays on one plate ► *Chapter 9.3.3.*

If you want to edit a suggested worklist or generate a worklist yourself, please refer to ► *Chapter 9.3 Create your own worklist, p. 131.*

8.4.1 Create a Worklist

1) Click on the menu item File > New > Worklist or the New Worklist button.

→ The EUROIMMUN Analyzer I-2P software shows the SET-UP PANEL dialog ► *Chapter 9.3.1 Set-up Panel Dialog, p. 134* .

2) Click on the ⊞ sign of the first plate to open the complete plate/assays tree.

3) Check the assays.

4) If something is not correct, make the required changes:

   a) Click on the ⊞ sign of the first assay to open the complete assay/patients tree.

   b) Check the assigned patients!

   c) If something is not correct, make the required changes.

   d) Repeat the steps for all other assays on the selected plate.

5) Repeat the steps for all other plates.

6) If everything is correct, click on the ✓ OK button. The EUROIMMUN Analyzer I-2P software shows the LOT SPECIFIC VALUES FOR: dialog ► *Chapter 8.5 Lot-specific Values, p. 75*).

✓ Once the worklist is defined, the system checks all parameters and signals any error. Errors must be corrected before you start a run.

8.5 Lot-specific Values

After an internal check of the worklist, of the assay protocols and of the required resources, the EUROIMMUN Analyzer I-2P software requests the required reagents (sample buffer, calibrators, controls, conjugate, substrate, stop solution, wash buffer and adjustment solution) in the LOT-SPECIFIC VALUES FOR: dialog. The LOT SPECIFIC VALUES FOR: dialog also allows you to enter additional information for specific kit types.

If a lot is changed or if a new kit is used, the 2D barcode from the quality control certificate must be scanned in this window using the 2D barcode manual scanner.

The barcodes for the reagents, the target values, the tolerance values for the standards and controls, the expiry date and the lot number will be automatically entered and saved.

For every used plate, an individual LOT-SPECIFIC VALUES FOR: dialog is displayed. In this dialog, the Lot-specific values for all assays are listed, which are used on the relevant plate. The name of the plate is displayed in the title of the dialog (top left).

Before scanning the 2D barcodes the line Kit must be selected and highlighted in blue, as shown in ► *Fig. 26: Dialog Lot Specific Values For: (e.g. 'Plate 1' with two assays), p. 75.* Then scan the 2D barcode using the manual scanner. After the first test has been scanned in, select the next test by clicking on the corresponding tab and repeat the procedure.

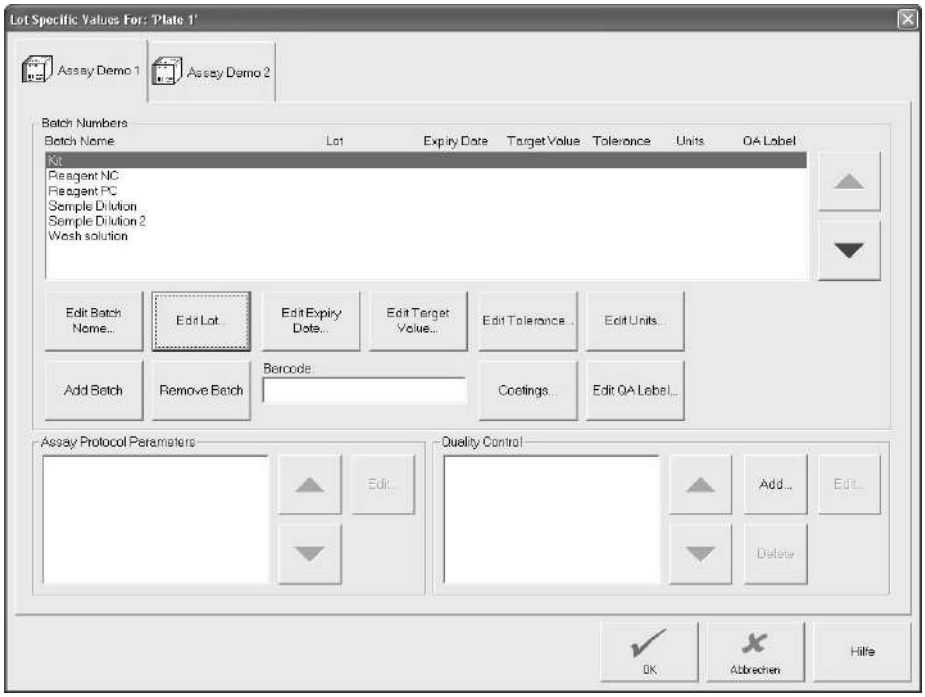


Fig. 26: Dialog Lot Specific Values For: (e.g. 'Plate 1' with two assays)

Special case „Manual entry of quality control data”

The dialog LOT SPECIFIC VALUES FOR: is subdivided into two areas:

- Lot Numbers:
  Lot-specific data can be scanned and edited.
- Assay Protocol Parameters
  If the assay includes standards for which the concentration is lot-dependent or if control value ranges are lot-dependent, these items are listed here with their respective lot-specific values/data (otherwise the list is blank).
- Quality Control
  In order to specify validation criteria for standards and controls, the valid range can be defined.

1) Click on the Add button.
2) Enter the label, tolerance range (see quality control certificate), and the unit.
3) Click on the OK button.
4) Repeat these steps for all standards and controls.

Functions

The following functions always refer to the highlighted line in one of the two lists:

Function	Symbol	Description
Assay registers		Via the assay registers, you reach the Lot-specific values belonging to the relevant assay.
Add Batch		This function is not supported by the EUROIMMUN Analyzer I-2P software
Barcode		This function is not supported by the EUROIMMUN Analyzer I-2P software.
Coatings		Click this button to enter coating criteria.
Edit Batch Name...		With this function, you can edit the Batch Name. However, this is not necessary because it is defined in the reagent database and in the assay definition.
Edit Expiry Date...		With this function, you can enter the expiry date for the selected lot.
Edit Lot...		Click this button to enter the barcode of the selected reagent.
Edit QA Label...		Entering QA labels (e.g. NC, NC1, PC2, etc.) or controls allows you to follow the results obtained with a particular control over a period of time by compiling a QA Analysis Report (► *Chapter 9.8 Quality Control Analysis Report (Levey Jennings Plot), p. 165*).

Function	Symbol	Description
Edit Target Value...		Click this button to enter the target value for the selected lot.
Edit Tolerance...		With this function you can enter a tolerance range for the selected lot.
Edit Units...		With this function you can enter the unit of the tolerance range for the selected lot.
Remove Batch		Removes the highlighted reagent from the list. **NOTE** This function deletes the reagent only from the list

Tab. 21: Functions of the LOT-SPECIFIC VALUES FOR: dialog

The overview of the bug fixes can be found in ► *Chapter 12 Troubleshooting, p. 217*

8.6 The Worklist Window

The Worklist windows show all data of the generated worklist and the current process status during the start later on. With the buttons on the left side, the individual data can be displayed. Additionally, the menu Edit is activated (► *Chapter 7.1.3 Options of the Edit Menu, p. 54*).

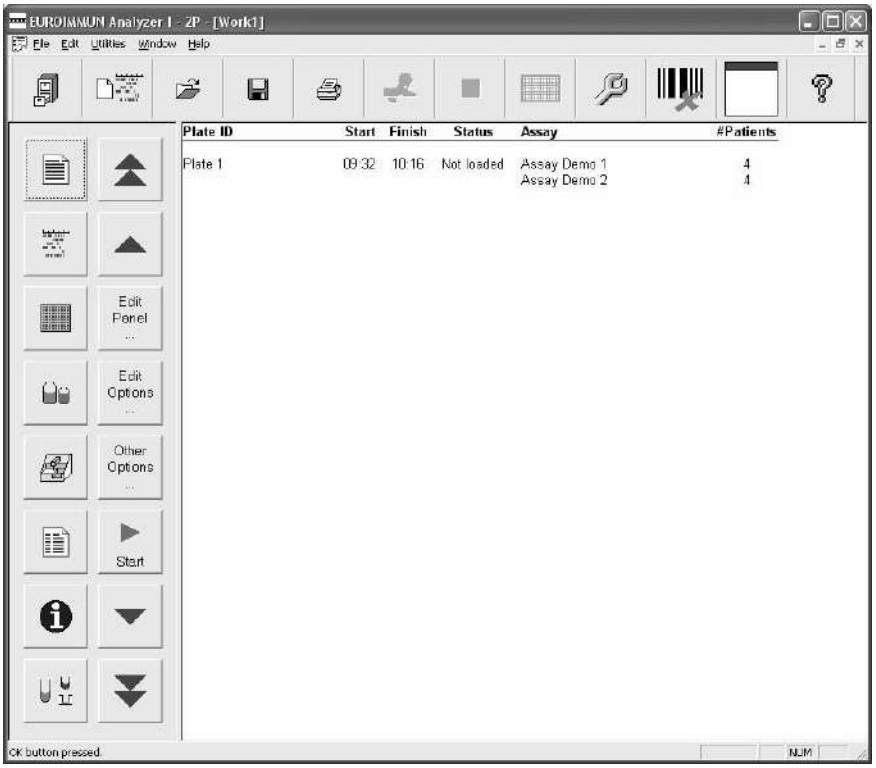


Fig. 27: Worklist window - worklist parameters information

Function	Symbol	Description	
Worklist parameters		Shows worklist details (e.g. plate ID, start and finish time, load status, assays and amount of patients).	► *Chapter 8.6.1 Worklist Parameters, p. 78*
Schedule		The schedule displays graphically the actions being performed (e.g. pipetting, washing, incubation etc.).	► *Chapter 8.6.2 Schedule, p. 79*
Plate layouts		Shows the plate layout (e.g. assays, controls, patients) of all plates.	► *Chapter 8.6.3 Plate Layouts, p. 81*
Reagent requirements		Shows the required volume of all reagents that are necessary for the run.	► *Chapter 8.6.4 Reagent Requirements, p. 81*
System Status		Shows the status of the system components (e.g. incubators, rack system etc.).	► *Chapter 8.6.5 System Status, p. 83*
Active event log		Shows a list of all steps performed in the run. The screen is blank when viewed before the start of the run.	► *Chapter 8.6.6 Active Event Log, p. 84*
Job list		Shows all patients with the assigned assays.	► *Chapter 8.6.7 Job List, p. 87*
Patient Archiving Information		Shows information about the sample archiving.	► *Chapter 8.6.8 Patient Archiving Information, p. 87*
Edit Panel		Opens the SET-UP PANEL dialog with editing options of the current worklist. This function is also called Panel Definition.	► *Chapter 9.3.1 Set-up Panel Dialog, p. 134*
Edit Options		Opens the WORKLIST OPTIONS dialog to change worklist processing options. This function is also called Panel Options.	► *Chapter 9.4 Worklist Options, p. 142*
Other Options		Opens a MAKE A SELECTION dialog to select further options (e.g. Lot Specific Values or Optimise etc.).	► *Chapter 8.5 Lot-specific Values, p. 75*
Start		Opens the LOAD dialog to allocate the required resources. After that, a run using the current worklist will be started.	► *Chapter 8.7 Start Worklist, p. 87*

Tab. 22: Functions of the Worklist window

1) View and/or change the worklist settings.

2) To start the worklist see ► *Chapter 8.7 Start Worklist, p. 87*.

8.6.1 Worklist Parameters

This window shows the parameters of the worklist (► *Chapter 8.6 The Worklist Window, p. 77*):in the following columns:

Column	Description
Plate ID	List of defined plates and indication of the plate names.
Start	Start time of run. This is the time at which you quit the SET-UP PANEL dialog by clicking OK and the worklist was displayed.
Finish	Time at the end of the run, calculated using the work steps and their duration. **NOTE** The actual finish time depends on when the run is actually started. The time displayed here allows you to calculate how long the run will take.
Status	Shows the status of each plate. If **Error** is displayed, see ► *Chapter 12.3.1 Error detection when creating a worklist, p. 234*. Otherwise, you see **Not loaded** as long as the test plates have not yet been loaded. The status then changes to **Processing** and finally to **Finished** (or **Aborted** if the processing of that plate has been stopped and not resumed).
Assay	Shows the name of the respective assay file. If there is more than one assay on a given plate, all the names are listed one below the other.
#Patients	Shows the number of patient samples per plate (and per assay if there is more than one on the same plate) as defined in the worklist.

Tab. 23: Columns of the Worklist parameters window

8.6.2 Schedule

The SCHEDULE shows how the test will actually be performed. This allows the user to get an accurate view of the duration of each step and the sequence in which they will be conducted, as well as how the system will combine the processing of all the plates that are to be processed in the same run (interlacing). It is therefore a good idea to check the Schedule before starting the run (the Schedule is also useful afterwards, when the run is being processed, to follow how the test run is executed and which step is currently being performed on which plate).

The schedule is displayed in two ways:

Module Schedule (bottom)

Each strip or segment shows at which time each instrument module (pipettor, washer, colorimeter, incubator, plate transport unit) will be used for each plate. Each plate is depicted in a different colour. The run time scale is on a horizontal line above the strips. When the test run is started, the vertical line on the left will move forward (towards the right), allowing the user to check at any given time what part of the run is currently being processed.

Plate Schedule (top)

Each plate is shown as a horizontal strip. The various steps of the process (pipetting, incubation, reading, washing) are shown as segments on this strip (each step marked by a different colour). As in the MODULE SCHEDULE VIEW, the time scale is at the top and the vertical line on the left will move forward once the run is started.

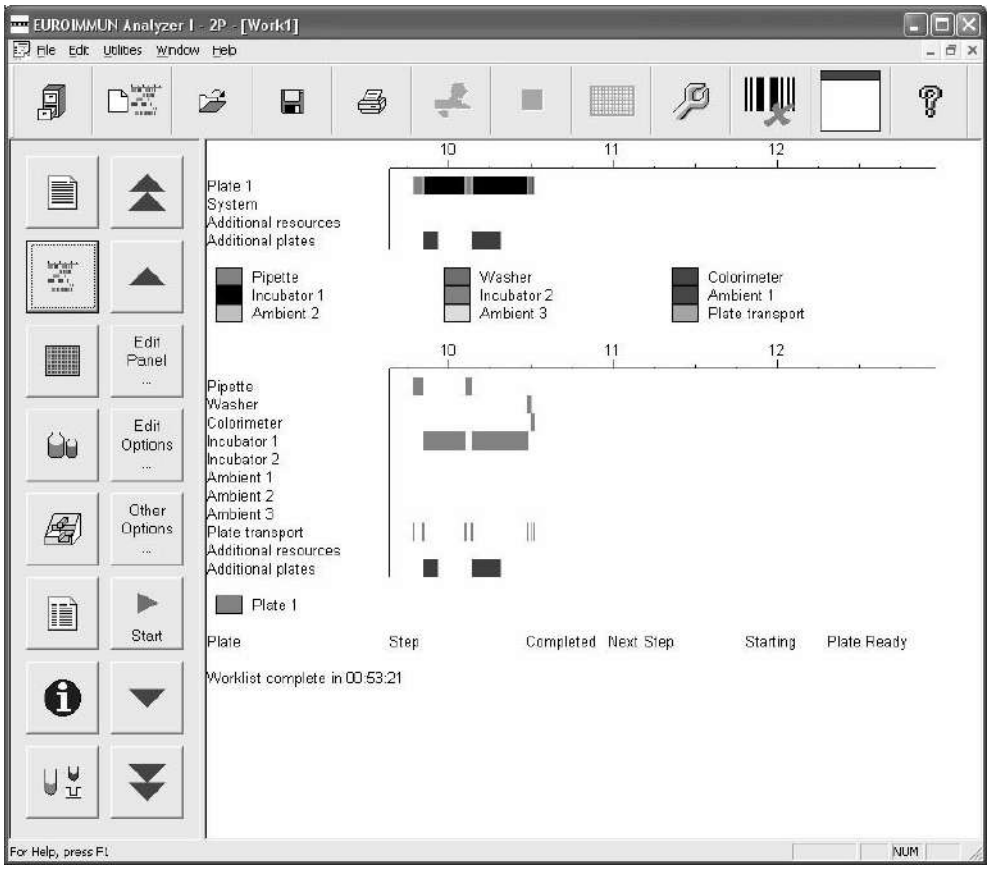


Fig. 28: Worklist window - schedule

Below the strips, additional information is displayed:

	Description
System	Shows when the sample archiving operations will be performed.
Additional resources	Shows when additional resources such as tips or reagents are to be loaded. If such reloading is necessary, a line saying "Operator intervention required in X minutes" will also be displayed.
Additional plates	Shows the time periods when it is possible to reload test plates (corresponds to periods when all the loaded microplates are incubating).

Tab. 24: Additional information

When you click on a segment of the schedule view, a screen with detailed information about the respective assay step will be displayed. Clicking again on this screen will display again the complete schedule.

NOTE

When processing a run in Demo Mode (► *Chapter 9.10 Simulation mode/demo mode, p. 166*) the run time displayed in the Schedule window will be accelerated, i.e. 1 second in the Schedule window = 1 minute in a real run.

8.6.3 Plate Layouts

Selecting Plate Layouts will show the exact plate layouts. All plate layouts defined in the current worklist are displayed one below the other.

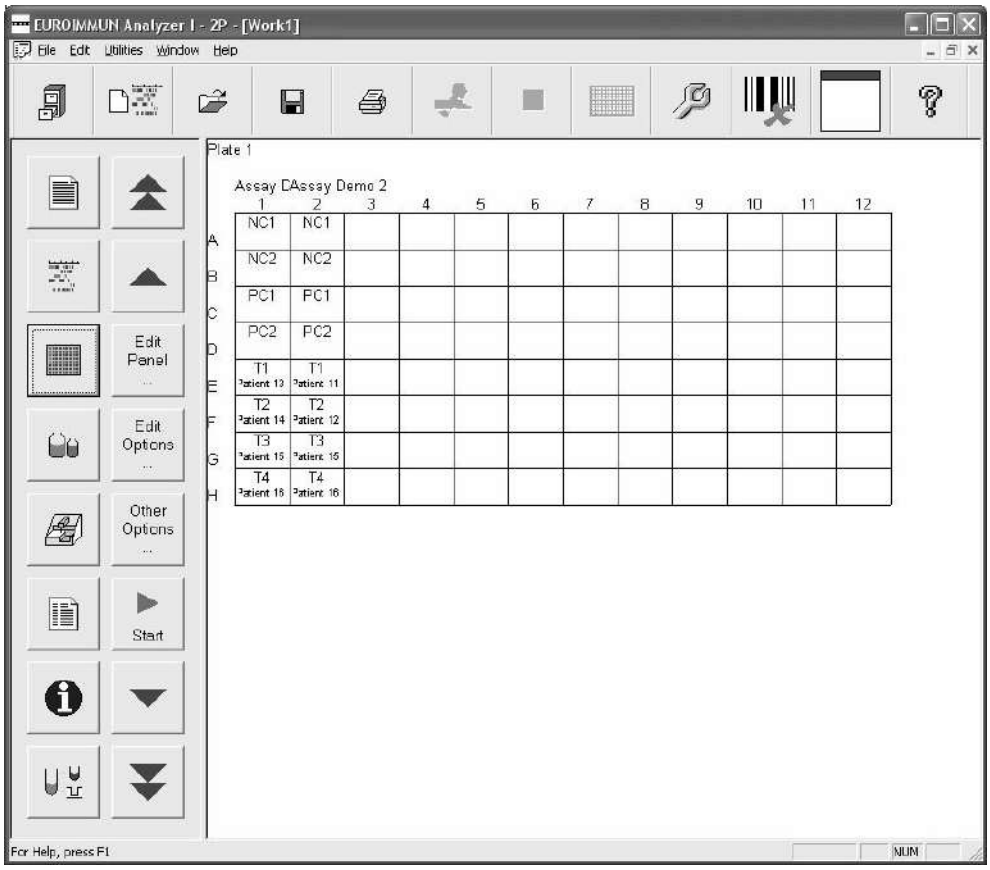


Fig. 29: Worklist window - plate layouts

8.6.4 Reagent Requirements

Selecting Reagent requirements shows the list of all reagents required for the tests.

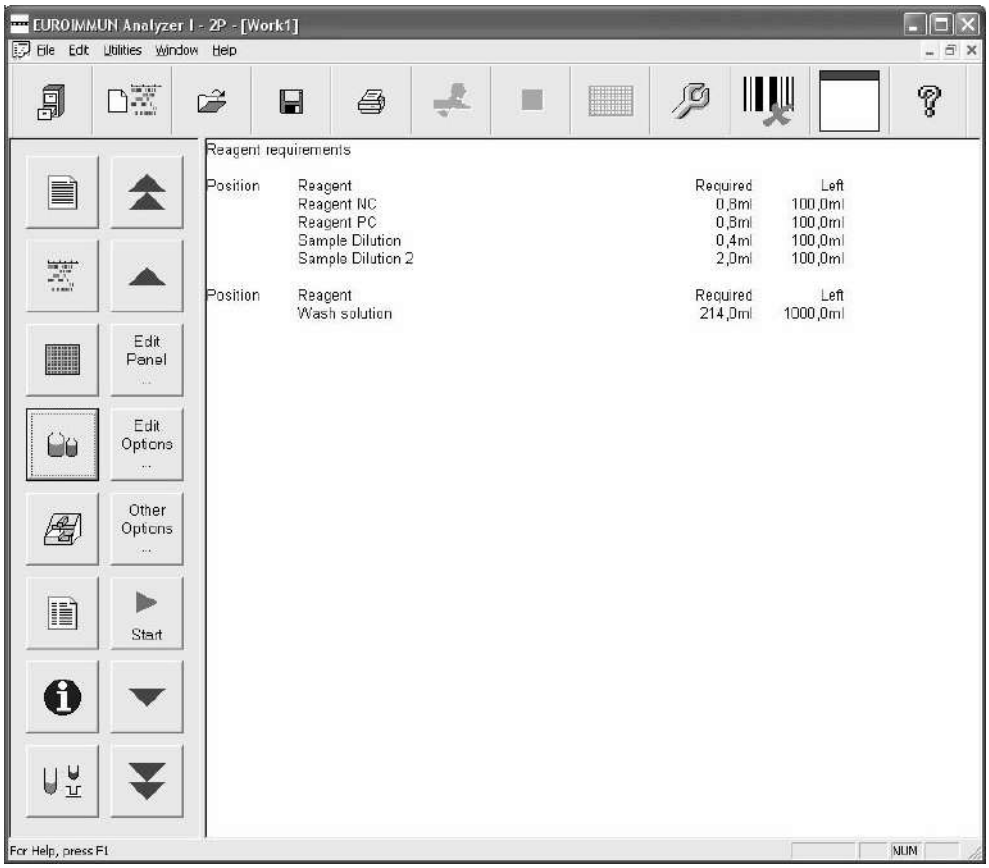


Fig. 30: Worklist window - reagent requirements

This window shows the reagent information in the following columns:

Column	Description
Position	Indicates where each reagent has been loaded on the instrument. This column remains empty until all reagents are loaded and allocated (► *Chapter 8.7.3 Load Reagents, p. 93*).
Reagent	List of all the required reagents. The order of the list follows the order of the assays to be processed. Cleaning fluid and wash buffers are listed separately at the bottom.
Required	Volume of each reagent required for the run.
Left	Volume available. This entry will decrease as the run is being performed. By default, the volume displayed before the start of the worklist that will be used to calculate the available volume while the run is being performed is the volume of one full reagent bottle. If you want the system to determine the exact volume that is actually available in the bottles, you have to enable the Check reagent levels before a run option in the Worklist Options dialog (► ► *Chapter 8.6.4 Reagent Requirements, p. 81*). This will then be used as the starting basis.

Tab. 25: Additional information

NOTE

It is possible to print this list and use it as a checklist when preparing the various reagent and control bottles before loading them onto the reagent racks.

8.6.5 System Status

The button System status displays a graphical presentation of the work area.

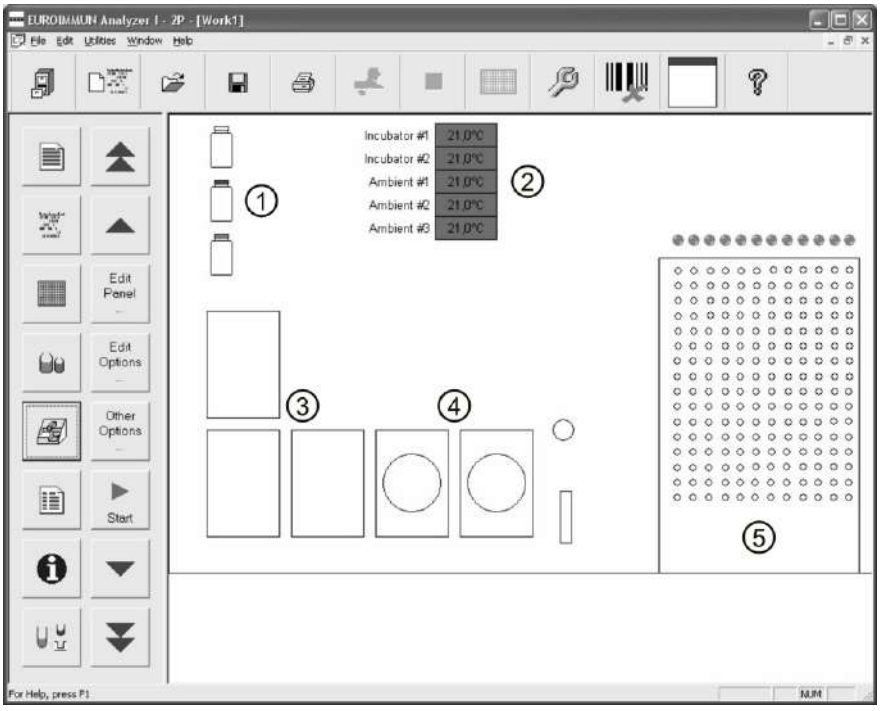


Fig. 31: Worklist window - system status

Number	Description
①	Cleaning fluid and wash buffers
②	2 incubator and 3 ambient positions
③	3 tip rack positions
④	2 dilution plate positions
⑤	Rack system

This display is useful to check the status of the incubators. If they are functioning correctly, they appear in green; if any problem is detected or before they have reached the correct temperature during preheating, they appear in red. The temperature of each incubator is displayed, as well as the room temperature (below the incubators).

8.6.6 Active Event Log

The Active Event Log lists in real time the steps of the run as they are performed. The screen is blank when viewed before the start of the run. Entries always appear at the top of the list, i.e. the step currently being performed is always at the top of the list while already completed steps are further down.

Contents

The wording used in the log file is generally simple and descriptive, making it easy to follow even for operators who have little experience using the EUROIMMUN Analyzer I-2P system. The only exception are the Dive In/ Dive Out values. These values are included in the log file to allow detailed monitoring of the pipetting/liquid detection system.

This monitoring is intended for EUROIMMUN Analyzer I-2P specialised technicians only. General users can safely rely on existing flags to detect and signal pipetting errors (Clot, NoLiq, InsLiq, see ► *Flags, p. 116*).

If you require assistance in understanding a particular log file, you can easily save it (see below) and mail it to your EUROIMMUN service engineer.

Colours

Different colours are used in the log

Colour	Description
Black	Indicates steps that have been correctly performed.
Red	Signals any problem occurring during the run (e.g. incorrect dispense, system paused, errors...)
Green	Signals actions taken by the operator to enable the system to resume or continue the run.

Tab. 26: Colours

Example:

```
14:56:36 <System>: Starting worklist.
14:57:21 <System>: 'Pos Ctrl Mono PLUS, 0,6ml' manually assigned to posn.
14:57:21 <System>:  10.2
14:57:21 <System>: 'Neg Ctrl Mono PLUS, 2,3ml' manually assigned to posn. 12.5
14:57:21 <System>: 'Neutr. Mono PLUS, 2,2ml' manually assigned to posn. 12.6
14:57:21 <System>: 'Diluent WB#1 N30 R2, 4,4ml' manually assigned to posn. 12.2
14:57:21 <System>: 'R7a Conj. conc. Mono PLUS, 0,6ml' manually assigned to
14:57:21 <System>:  posn. 12.7
14:57:21 <System>: 'Substrate N60 (1:11) R8+R9, 17,0ml' manually assigned to posn. 10.1
14:57:21 <System>: 'Stop Sol. N30 H2SO4 1N R10, 15,0ml' manually assigned to posn. 12.3
14:57:21 <System>: 'R3 Neg Ctrl Mono Ultra, 0,9ml' manually assigned to posn. 10.3
14:57:21 <System>: 'R4 Pos Ctrl Mono Ultra, 0,6ml' manually assigned to posn. 12.8
14:57:21 <System>: 'R7 W1 Spl. Dil. MB, 15,1ml' manually assigned to posn. 12.1
14:57:21 <System>: 'Conj. Mono Ultra, 7,2ml' manually assigned to posn.
14:57:21 <System>:  12.4
14:57:45 <System>: System cover opened.
14:57:54 <System>: System cover closed.
15:01:55 Plate 1: Putting into Ambient 1 at Ambient (26,0°C).
15:02:07 Plate 2: Starting to pipette 'Dispense Positive Control :'.
15:05:39 Plate 2: Finished pipetting 'Dispense Positive Control :'.
15:05:39 Plate 2: Starting to pipette 'Dispense Negative Control :'.
15:06:17 Plate 2: Finished pipetting 'Dispense Negative Control :'.
15:06:21 Plate 2: Reading at 492nm/*.
15:07:50 Plate 2: Dispensing 50ul of Neutr. Mono PLUS.
15:08:05 Plate 2: Shaking at 20Hz/0.5mm for 59 seconds.
15:09:09 Plate 2: Reading at 492nm/*.
15:09:57 Plate 2: Putting into Incubator 2 at 40,0°C (39,9°C).
15:12:33 Plate 3: Starting to pipette 'Dispense Negative Control :'.
15:13:38 Plate 3: Finished pipetting 'Dispense Negative Control :'.
15:13:38 Plate 3: Starting to pipette 'Dispense Positive Control :'.
15:13:52 Plate 3: Finished pipetting 'Dispense Positive Control :'.
15:13:52 Plate 3: Starting to pipette 'Dispense Samples :'.
...
```

Fig. 32: Example of an active event log

NOTE

Line-wraps: Generally, each operation or user intervention starts in a new line. When the line is too long, it wraps automatically. Note, however, that when the log file is "active" (during the actual run), the scripting is done from bottom to top, so that the end of a line will be above the beginning of the line instead of below. In a saved log fil, on the other hand, the correct line-wrap order (with the end of the line below) is restored.

Use

The active event log is an important document. It can:

- Be followed while the run is being processed so that the operator can act rapidly to correct any malfunction of the system.
- Be used after the run is over to check whether all steps have been properly performed. If, for example, some results are flagged, the active event log enables the user to understand why this is the case.
- Be printed
- Be used at a later date to check how the run was processed

Open a formerly saved Event log File

Event log files are automatically saved by the system. By default, they are saved in the `C:\Programme\EUROIMMUN\EUROIMMUN_Analyzer_I\Logfile` directory. They have a (*.log) extension and the file

name corresponds to the date on which the run(s) was (were) performed: e.g. "20070315.log" (YYYYMMDD)

NOTE

The logs of all the test runs performed on the same day are aggregated in the same log file. Access to the event log file of the current day is restricted. It can only be viewed from the Worklist window. It cannot be opened via the File > Open menu item as indicated below.

1) Click on Open.
2) Click on the button Event Lof Files (*.log) (► *Chapter 7.3.1 Options , p. 58*).
3) Click on the relevant log file (► *Chapter 7.3 Loading (Open), p. 57*).

✓ When the log file is created, the scripting is done in a way that the current step is always at the top while earlier steps are further down. But when you open a formerly saved event log, the daily chronological order is rearranged from start-up to shutdown.

Event Log Filter

The purpose of the event log filter is to allow the user to find in the log file all the lines related to one specific worklist, one specific plate or even one specific patient.

The event log filter is available only if you open a formerly saved event log. It is not available from the worklist window or when the run is being processed.

To open the EVENT LOG FILTER dialog:

1) Open an event log file as described above.
2) Click on View > Filter... or the Filter... button

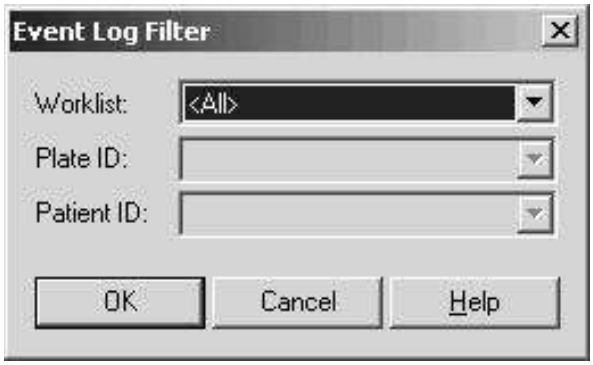


Fig. 33: Event Log Filter dialog

3) Select a WORKLIST.
4) Select a PLATE ID (if desired).
5) Select a PATIENT ID (if desired).
6) Click on the button OK.

8.6.7 Job List

Selecting Job List shows a reminder of which test(s) are to be performed for which Patient IDs.

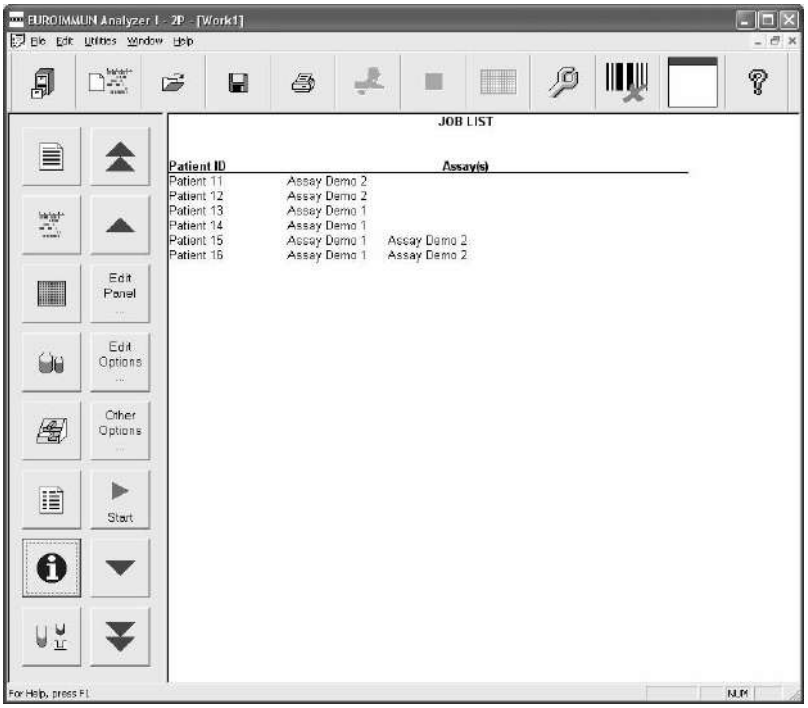


Fig. 34: Worklist window - job list

8.6.8 Patient Archiving Information

Not used.

8.7 Start Worklist

If the loaded worklist is error-free, the ▶ Start button in the worklist window is enabled (appears in green instead of grey). If you click this button, the system prompts you to load the instrument with the required resources (reagents, dilution plates, tip racks, wash buffer, cleaning fluid, etc.) and opens the Load dialog box. Test plates are loaded at a later stage.

The loading process on the EUROIMMUN Analyzer I-2P system includes three stages:

- The actual (physical) loading of reagents, racks and accessories in the instrument.
- The allocation of these resources in the software.
- The loading of the test plates.

The purpose of the allocation process is to enable the software to track whether each sample, each reagent and each of the other required resources has been loaded, and where it has been placed in the instrument.

The purpose of the allocation process is to enable the software to track whether each sample, each reagent and each of the other required resources has been loaded, and where it has been placed in the instrument.

When using barcoded components, part of the allocation process is done automatically since the system can then identify each component and monitor its location through the barcode.

For items that are not barcoded, the allocation process is done on the screen in the Load dialog (for samples, reagents, dilution plates, and tip racks).

For those elements that have a set location on the instrument (wash buffer, system liquid) the system is able to monitor directly through other devices (e.g. sensors) which quantity is available on the instrument and if more is required for the current worklist, this is displayed in the Load dialog. For those elements, no allocation process as such is necessary but they should be loaded on the instrument in strict accordance with what is displayed in the Load dialog.

Procedures

1) Click on the Reagent requirements button to note the required quantity of reagents, wash buffer and cleaning fluid (► *Chapter 8.6.4 Reagent Requirements, p. 81*). If necessary, fill the wash buffer and cleaning fluid bottles.

2) Click on the ▶ Start button in the worklist window to start the worklist (► *Chapter 8.6 The Worklist Window, p. 77*).

→ The EUROIMMUN Analyzer I-2P software shows the Load dialog (► *Chapter 8.7.1 Load Dialog, p. 89*).

- Usually, all patient samples must be loaded and assigned at this point of time. If, however, you made supplements during the generation of the worklist, those patient samples must still be assigned (► *Chapter 8.3.2 Assign assays to patient samples (Tabular patient editor), p. 70*).
- Load all required reagents (► *Chapter 8.7.3 Load Reagents, p. 93*). Please observe the hints about unstable reagents (► *Chapter 8.7.5 Load Dilution Plate, p. 98*).
- Load all required dilution plates (► *Chapter 8.7.6 Load Tip Racks, p. 99*)
- Load all required disposable tips (► *Chapter 8.7.9 Load Test Plates, p. 102*)
- Fill wash buffer and cleaning fluid bottles (► *Chapter 8.7.7 Fill Wash Buffer and Cleaning fluid, p. 101)*
- Fill system liquid container, if necessary (► *Chapter 8.7.8 Fill System Liquid, p. 102*)

3) Click on the OK button to confirm the LOAD dialog.

4) Load all required microplates (► *Chapter 8.7.9 Load Test Plates, p. 102*).

✓ After the last plate, the worklist will be started automatically (► *Chapter 8.8 Processing the Run, p. 104*).

8.7.1 Load Dialog

The LOAD dialog illustrates the top level of the instrument (work area):

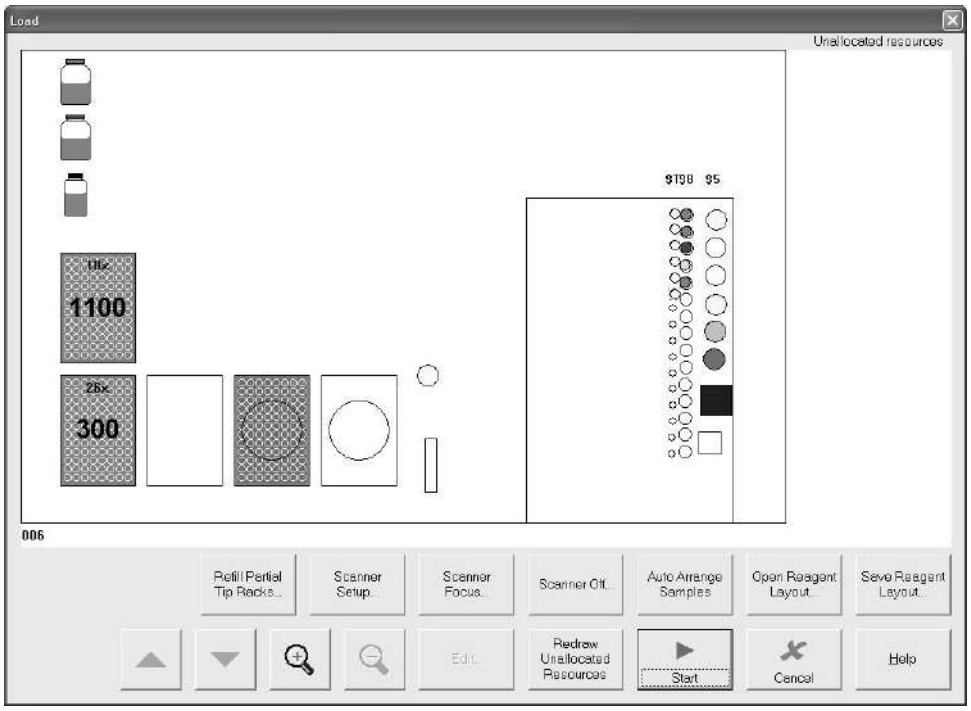
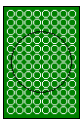
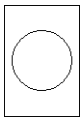
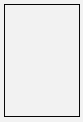
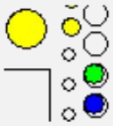
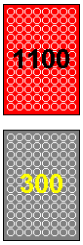


Fig. 35: Load dialog

Function	Symbol	Description
Auto Arrange Samples		Click this button to allocate all patient samples in the Unallocated resources column in ascending order on the sample racks (from right to left) (on when to use this button).
Cleaning fluid and wash buffers		The cleaning fluid and wash buffer symbols indicate which type of cleaning fluid and wash buffer is required in which bottle (colour-coded lids). By clicking on the corresponding symbol, the type and required volume of the cleaning fluid and wash buffer is displayed.
Dilution plate		The dilution plate symbol indicates which type and how many dilution plates you need. If required, you can arrange the dilution plates in another way than suggested.

Function	Symbol	Description
Edit		Allows you to use already used reagents. After clicking on a reagent and then on the Edit button the Reagent Properties dialog is opened. Enter the remaining liquid in percent.
Free position		Free position for dilution plates.
Free position		Free position for tip racks.
Open Reagent Layout...		With this function, you can load the positions for reagents saved earlier. This makes the manual assignment obsolete. After clicking on the function, the Open dialog is opened. **Warning:** The system won't check opened reagent layouts. Make sure that positions are correct!
Reagents and samples in racks		In the sector rack system, all racks are displayed which have already been loaded. The individual reagents or samples can be assigned to these rack positions. Click on the relevant symbol to get more information on it or rearrange it.
Redraw Unallocated Resources		If reagents or samples are pushed into the sector Unallocated Resources again, it can happen that they are laid on top of each other. With the function Redraw Unallocated Resources, you can have the sector Unallocated Resources rearranged.
Refill Partial Tip Racks		Allows you to refill 300 µl or 1100 µl disposable tip racks.
Use New Dilution Plate		If the dilution plate should not be used again, click on the Use New Dilution Plate button to start a new one.
Save Reagent Layout...		With this function, you can save the selected positions for the reagents and reuse them later for a similar test. After clicking on the function, the Save dialog is opened.

Function	Symbol	Description
Scanner Focus…		Allows the track where the system will accept the next rack to be chosen. Click on the desired track in the Select a Track dialog. **Note:** Double lane racks can only be inserted in every 2nd track (the software will reject rack otherwise). See warnings below.
Scanner Off…		Switches the barcode scanner off. See warnings below.
Scanner Setup…		Opens the Scanner Configuration dialog and you can view and edit the scanner parameters or the rack types and positions.
Start		Closes the dialog when all required resources (samples, reagents, dilution plates, tip racks, wash buffer/cleaning fluid and system liquid) are properly loaded and allocated and starts the test plate loading procedure.
Tip rack		The tip rack symbols indicate which tip size and how many tips are required. If required, the tip racks can be arranged in another way than suggested. Note: If more tips are required than can be loaded, the missing tips must be reloaded at a later time. The EUROIMMUN Analyzer I-2P software indicates the relevant point of time.
Unallocated Resources: Reagents and samples		In the area Unallocated Resources, all reagents and samples that are required for the test run but have not yet been assigned or loaded are displayed. By clicking on the relevant symbol, you receive more information on it or its assignment.
Zoom In		With this function, you can enlarge the sector rack system and Unallocated Resources. With this enlarged presentation, the assignment of samples and reagents is facilitated.
Zoom Out		After clicking on this function, the complete Load dialog is presented.

8.7.2 Functions of the Load

At this stage, the patient sample racks should already have been loaded in the instrument as described in chapter ► *Chapter 8.3 Loading patient samples and assigning tests, p. 68* (it is usually the first thing to do when starting a test run). However, if it has not been done, you can refer to that section and load them now.

Allocate Barcoded Racks and Individual Samples

If the racks and the individual samples were barcoded, they should now appear in the central section of the Load dialog as rows of small dots. Moving the mouse pointer over a dot will show the Patient ID of each sample. The colour of each dot indicates the status of each sample

Colour	Description
Coloured	Indicates samples that have been correctly loaded by the operator and correctly identified by the system through their barcodes. No further allocation is needed. The actual colour used depends on what has been specified in the Pipette tab of the System Set-Up dialog (► *Chapter 10.2.4 Pipette tab, p. 183)*
Blank	Signals either an empty position (i.e. partially full racks) or a sample tube without barcode (or a barcode the system cannot read). Allocate manually if necessary (► *Chapter 8.3 Loading patient samples and assigning tests, p. 68*).
Black	Indicates a sample that has been loaded but which is not required for the run, i.e. no assay is assigned to that sample. Either remove the sample from the rack or go back to the Set-Up Panel dialog to check why this is the case and correct the assay assignment for this patient.

Tab. 27: Colour of Patient-ID

For more details on barcode settings ► *Chapter 10.2.5 Sample Rack Tab, p. 188.*

Allocate Barcoded Racks and Non-barcoded Individual Samples

If the racks were barcoded but not the individual samples, the racks are depicted as empty (rows of blank dots) in the central section of the Load dialog while the samples are depicted as Unallocated resources. You now need to allocate them either manually or automatically.

To allocate patient samples manually

1) Click on the first sample (coloured dot) in the UNALLOCATED RESOURCES area you want to allocate. This will show its code name/ID.
2) Click on the rack position where the patient sample is located in the instrument. The patient sample is moved in the LOAD dialog.
3) Repeat for each sample.

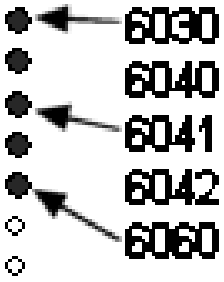
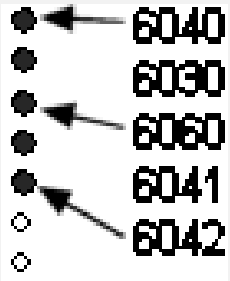
NOTE

Make sure that the position to which you allocate a sample on the screen corresponds exactly to the real position of the corresponding patient tube in the rack! This is very important as wrong allocation is equivalent to mixing up samples.

Automatic allocation of samples

1) Click on the Auto Arrange Samples button in the LOAD dialog.

→ The unallocated samples are then allocated to the available sample racks, from the top down and starting with the first rack on the right. The order in which samples are allocated to the consecutive rack positions (position 1, position 2, etc.) follows the order selected in the PATIENT EDITOR dialog (Ascending, Descending or None – ► *Chapter 9.2 Complete Patient Editor, p. 125*).

Order	Patient Editor	Sample rack
Ascending	6030 6040 6041 6042 6060	
None	6040 6030 6060 6041 6042	

Tab. 28: Rack positions - order

NOTE

Automatic allocation is a timesaving option if you have a lot of non-barcoded samples to allocate. It implies that the person who actually places the sample tubes in the racks and the racks in the instrument does it in strict compliance with the order resulting from the automatic allocation.

8.7.3 Load Reagents

To incubate certain EUROIMMUN test kits, additional reagents may be required for automatic processing with the EUROIMMUN Analyzer I-2P. These are not included in the ELISA test kit and must be ordered separately.

These additional reagents are requested by the system during the loading process when starting a work list.

The additional reagents include:

- Orange sample buffer ZE1100-0100-L (needed to incubate CSF assays)
- Adjustment solution ZE 1120-1850-7 (needed to compensate the pipetting times during the wash step)

Placing the Reagents on the Racks

On the EUROIMMUN Analyzer I-2P system, there is no need to transfer the kit reagents into any particular container before loading them on the instrument. The EUROIMMUN Analyzer I-2P reagent racks have been specially designed to be compatible with all EUROIMMUN kit bottles as well as most types of kit bottles, vials or tubes available on the market. The reagents can therefore generally be placed directly in the racks. This is not possible only in a small number of cases: unstable reagents which have to be prepared separately, kit bottles that are too large (e.g. 125 ml bottles) or too small for the racks, controls which have to be decanted in haemolysis tubes. These cases are dealt with in ► *Chapter 8.7.3 Load Reagents, p. 93* and ► *Chapter 8.7.4 Load Unstable Reagents, p. 97* .

For more information on EUROIMMUN rack types, ► *Chapter 5.2.4 Rack System for samples and reagents, p. 40.*

NOTE

Do not refrigerate reagent racks! Because they are made of metal, excessive cooling of the racks could influence the temperature of the reagents and of the work area inside the instrument.

Using the reagent requirements checklist (► *Chapter 8.6.4 Reagent Requirements, p. 81*), check that you have fitted all the required reagents on the racks. If you need a reminder of where you placed each reagent/control, you can copy and fill in the rack layout forms.

When opening the reagent bottles, be careful not to mix the bottle caps as these may be needed again after the run and should not be exchanged from one bottle to another

Loading the Racks on the Instrument

ATTENTION

Movement of the barcode scanner

Damage to the barcode scanner

> Do not use the rack loading area as a storage surface.

⚠ WARNING

Movement of the barcode scanner

Risk of impact, crushing, stabbing

> Only load or unload on the indicated lane.
> Wait for a load/unload message!
> Wait until the barcode scanner stands idle.

⚠ WARNING

Reverse movement of the barcode scanner

Risk of impact, crushing, stabbing

> Never reach into the loading bay on the right side of the barcode scanner!

i NOTE

Never load several racks at the same time!

1) Once you have fitted all the required reagents on the racks:

   a) Insert the first rack on the lane that is marked by a LED.

   b) Place the rack in front of the lane and then push evenly up to the limit stop (with the tappet in the contact opening on the rear panel).

i NOTE A reagent rack occupying 2 tracks must be inserted so that the contact tappet touches the lit-up LED. The barcode labels (if any) must face right towards the barcode reader.

   → The LED goes off and moves to the next position that can be loaded. A graphical representation of the correctly inserted rack appears in the Load dialog on the screen.

2) Insert the next reagent rack (if available) as described.

Allocate Barcoded Racks and Barcoded Reagent Containers

If both the racks and the individual reagent containers, vials or bottles were barcoded and were correctly inserted, the racks and the reagent containers should now be displayed on the screen in the rack system area of the Load dialog:

- The reagents that are required for the run and have been correctly loaded and identified (from their barcodes) are automatically allocated and appear in the racks as larger or smaller coloured dots (a different colour is used for each reagent) with a cross
- Loaded reagents that are on the instrument and have already been identified through their barcodes (or otherwise allocated) but are not needed for the current worklist are presented in black.
- For more details on barcode settings, ► *Chapter 9.3 Create your own worklist, p. 131 .*

Allocate Non-barcoded individual Reagent Containers

Unlike patient samples, reagent bottles usually have barcodes. Reagent barcode stickers can also be ordered separately from EUROIMMUN.

However, it can happen that a barcode is missing, damaged or illegible. When a container with a missing or damaged barcode is loaded and the system is not able to identify the reagent, the corresponding rack position is displayed as empty (larger blank dot) and the required reagent remains depicted in the Unallocated resources area of the Load dialog. It has to be manually allocated.

Manual allocation of reagents

1) In the UNALLOCATED RESOURCES area, identify the reagent you want to allocate by clicking on it. This shows its name and barcode number.
2) Click on that reagent and then click on the desired location (corresponding blank position in the reagent racks in the system rack area of the LOAD dialog).
3) Repeat for each unallocated reagent.

NOTE

The user has to make sure that the manually allocated positions correspond to the actual placement on the reagent rack. Manually allocated reagents are not crossed. In the log file, manually allocated reagents can be tracked as such.

The Auto Arrange function (automatic allocation of non-barcoded resources) is not available for reagents (only for samples, ► *Allocate Barcoded Racks and Non-barcoded Individual Samples, p. 92*. For reagents, a similar function is provided by the Save Reagent Layout... / Open Reagent Layout... buttons (► *Chapter 9.5.2 Advanced Load Options, p. 148*).

Allocate Non-Barcoded Reagent Racks

If the reagent racks do not have barcodes, you can identify them manually as described for non-barcoded patient sample racks (► *Allocate Barcoded Racks and Non-barcoded Individual Samples, p. 92*).

Replacement barcode labels for reagent racks can be ordered from EUROIMMUN.

Identical Reagent in Two Separate Bottles

In some cases, two separate bottles of the same reagent are required for the same assay. If this has been taken into account in the assay definition and when entering the reagent in the reagent database (see "Assay Programming Manual" (ask your EUROIMMUN service engineer) - "Allow changing of bottles during a dispense"), the pipettor will automatically switch from one bottle to the other during the run avoiding having to pause the run, exchange bottles, etc.

To make sure this switch is correctly performed:

- Make sure to fill each bottle with the appropriate volume (as specified in the Reagent Requirements list, ► *Chapter 8.6.4 Reagent Requirements, p. 81*). At any rate, the total volume should equal the total volume specified in the list.
- Load both bottles on the rack before the start of the run. When barcoded reagent bottles are used, the system requires the first scanned bottle to be full. Therefore, first insert the full bottle into the rack and then the half-full bottle.
- If the bottles are non-barcoded, allocate them manually in the Load dialog to the respective rack locations (if the bottles are barcoded, they should already be allocated when the Load dialog is displayed).

8.7.4 Load Unstable Reagents

Some unstable reagents have to be prepared separately and loaded on the instrument only after the test run has begun.

Preparing the Reagent

The preparation procedure depends on the reagent required. Please refer to the appropriate documentation.

However, the following recommendations apply to all separately prepared reagents:

- Do not fill the bottle above the shoulder level.
- If a bottle for this preparation is not included in the kit but a specific bottle type is recommended, always use the recommended type.

Strictly follow the manufacturer's recommendations on reusing the bottles. Even if it is allowed to reuse a bottle, never use the same bottle for different reagents and strictly follow the recommended maintenance procedure.

Loading the Reagent

If an unstable reagent is required for a test, it will be listed in the REAGENT REQUIREMENTS LIST (► *Chapter 8.6.4 Reagent Requirements, p. 81*).

When the LOAD dialog opens for the first time, load all required reagents **except** the unstable reagent. Allocate the unstable reagent manually, click on it in the **Unallocated resources** area and then click on the rack position where you will later load it.

NOTE

Because the properties of this reagent have been included in the reagent database (see "Assay Programming Manual" (ask your EUROIMMUN service engineer), the system knows that this reagent requires a preparation time.

1) When the indicated time span is over, the LOAD dialog is displayed.
2) Remove the reagent rack in which you initially allocated the unstable reagent.
3) Place the reagent bottle in the position indicated in the LOAD dialog.

4) Then click on the OK button.

The time span available to actually load the reagent has been defined in the Worklist Options dialog (► *Chapter 9.4 Worklist Options, p. 142*). Recommended time is 180 seconds (3 minutes). If the reagent has not been loaded within that time, the system will either

- abort the plate for which this reagent is required if this option has been checked in the Worklist Options dialog, or
- pause the system until an operator loads the required reagent.

NOTE

Note that in the latter case, the resulting pause can lead to wrong incubation times and - if a washing step is affected - dehydration of wells. In case an unstable reagent is not loaded in time, carefully check the results and the event log. Excessive incubation times will be flagged automatically, but in doubt discard the results produced when a long pause of the worklist is reported.

NOTE

Never click on the OK button before loading the reagent! Even if you could do it, the system would not take it into account and would not dispense the reagent.

For troubleshooting see ► *Chapter 12.2 Troubleshooting while Loading, p. 230 .*

8.7.5 Load Dilution Plate

Type of dilution plate:

The Nunc 2ml deep well dilution plate has to be used on the EUROIMMUN Analyzer I-2P system: The specification of this plate type is stored in a coordinate file. Plate coordinate files have a (*.mpc) extension. They cannot be opened directly.

The default dilution plate type is selected at system level in the tab PIPETTE of the SYSTEM SET-UP dialog (Dilution Plates field, ► *Chapter 10.2.4 Pipette tab, p. 183*).

Load Dilution Plate

1) Make sure that the metal base plate(s) is/are in place.
2) Insert the dilution plate(s) into the correct positions as shown in the Load dialog. Push the dilution plate(s) firmly down so that it sits on the metal base plate(s) completely and evenly. Position A1 should be at the rear right.

8.7.6 Load Tip Racks

Tip types

The pipettor on the EUROIMMUN Analyzer I-2P system operates with disposable tips. Two different types of tips can be loaded on the instrument:

- 1100-µl-tips (long tips)
- 300-µl-tips (small tips)

NOTE

Because the pipettor on the EUROIMMUN Analyzer I-2P system is also used for liquid level detection, clot detection, etc., the tips have to be conductive tips. Therefore do not replace the EUROIMMUN tips with other tips with different conductivity properties.

Ordering information for EUROIMMUN tips is available in ► *Chapter 4.4* .

Tip Rack in the Load dialog

The LOAD dialog shows the number of tips of each size required to perform the current worklist.

The colours in which the tip racks are displayed vary not only according to the required tip size but also according to whether racks are already available on the instrument.

Colour	Tip size	Description
Grey Black	1100 µl	Load a full new tip rack with 1100 µl tips.
Red	1100 µl	An incomplete tip rack is already loaded. The number of tips that are still available is taken into account by the software.
Grey Yellow	300 µl	Load a full new tip rack with 300 µl tips.
Red	300 µl	An incomplete tip rack is already loaded. The number of tips that are still available is taken into account by the software.

Tab. 29: Tip Rack in the Load dialog

Load Tip Racks

1) Insert the tip rack(s) into the correct position(s) as shown in the Load dialog. Push the dilution plate(s) firmly down so that it sits on the floor completely and evenly. Place the tip rack into the holding device of the instrument, so that the pin sits in the groove of the tip rack (right rear).

NOTE

Always observe the position of the tip racks defined in the Load dialog! Using a short tip instead of a long one may cause splashing and contamination. Using a long tip instead of a short one may cause damage to the pipettor. Note that the EUROIMMUN Analyzer I-2P system can be configured to perform an automatic tip size check (► *Tip Size Check, p. 107*).

Tip Management Options

The EUROIMMUN Analyzer I-2P system offers several tip management options depending on whether you want to be able to reuse partial tip racks and whether you are prepared to reload tips during a run or want the system to operate unattended as much as possible.

Use only full Tip Racks

If you prefer starting a run with only full tip racks:

- Deselect in the WORKLIST OPTIONS the Re-use partial disposable tip racks (► *Chapter 9 Advanced functions, p. 123* / ► *Chapter 9.5 Advanced Options, p. 148*).

Worklist options settings are retained until they are edited again. This means that you do not have to do this before each run (the option continues to apply to all later runs unless you decide to change it).

When you actually load the tip racks on the instrument, make sure to unload all partially used tip racks and load only full tip racks (in the LOAD dialog, only grey and green tip racks should be displayed).

Reuse partially used Tip Racks

If you prefer starting a run with partially used tip racks (i.e. the tips left over from the previous runs):

- Select the checkbox Re-use partial disposable tip racks in the WORKLIST OPTIONS (► *Chapter 9.5 Advanced Options, p. 148*).

This is possible because the system monitors the number of tips used during operation. At the end of a run, it knows how many tips of each size are still available. If the Re-use partial disposable tip racks option is selected, when the system calculates the number of tips required to perform the next worklist, it takes into account the number of tips still available on the instrument. In the LOAD dialog, partially used tips racks are displayed in red.

Reload Tip Racks during a run

If you want to try and avoid having to reload tips during the run, it is recommended to work only with full tip racks (i.e. to deselect the Re-use partial disposable tip racks checkbox (► *Chapter 9.5 Advanced Options, p. 148*). However, even if you started the run with only full tip racks, it may still be necessary to reload tips during the run if you are processing "heavy" worklists (e.g. with several tests, many patient samples, a predilution and/or a sample archiving step).

If tip reloading is going to be required in the course of a run:

- At the bottom of the Schedule display (see chapter ► *Chapter 8.6.2 Schedule, p. 79*), the system displays the following indication: "Operator intervention required in X minutes".
- A message on the screen and an acoustic signal warns you when it is time to get ready to reload.
- The Load Additional Tips button is enabled.
- Click on the Load Additional Tips button and reload the tips as described in ► *Chapter 8.7.6 Load Tip Racks, p. 99.*

In most cases, if you initially loaded the tips as required in the Load dialog, the need for reloading will arise only for the last plate of a worklist. The system then prompts you to reload and pauses the pipetting until new tips have been reloaded, with the risk of blocking the whole run for a long time if no operator is there to load the new tips.

8.7.7 Fill Wash Buffer and Cleaning fluid

Instrument

The wash buffer and cleaning fluid bottles are located on the left side of the instrument.

- Two 2-litre bottles can be used for various buffers.
- Another position (1 litre bottle) is reserved for the cleaning fluid used to clean the washer head.

The connection fitting consists of 3 colour-coded lines (cap, tubing, filter) allowing a better identification of each one as well as the level sensor per bottle.

Load Dialog

In the Load dialog, when you have loaded a correct worklist and clicked on the Start button, the required wash buffer(s) and cleaning fluid are displayed in the respective containers (► *Chapter 8.7.1 Load Dialog, p. 89*). The containers are identified through coloured push-on caps.

Under default settings, the cleaning fluid bottle is the first bottle on the left. For wash buffers, the system determines which buffer should be put in each bottle. Click on each bottle to see the name of its corresponding buffer.

If, for some reason, you do not wish to fill a buffer in the bottle specified by the system (e.g. if the blue-capped bottle is damaged) you can click on the desired buffer and allocate it to the desired bottle. If you want to always use the same bottle for the same type of wash buffer (e.g. blue-capped bottle for wash buffer), you can do so by changing the washer default settings (► *Chapter 10.2.6 Washer tab, p. 191*).

In any case, make sure that when you actually fill the bottles, you do it in strict compliance with what is set in the Load dialog.

To fill in wash buffer/cleaning fluid

1) Remove the cap of the respective wash buffer bottle. Refill it or replace it with another full wash buffer bottle.

2) Carefully put the cap back onto the bottle and ensure that the level sensor and connections sit correctly.

Type of Wash buffer/Cleaning fluid

The type of wash buffer to be used for a test is specified during assay definition (see "Assay Programming Manual" (ask your EUROIMMUN service engineer)). The properties of each wash buffer are stored in the reagent database and can (in some cases) be edited.

Deionised water is used as cleaning fluid.

Quantity of wash buffer/cleaning fluid

The REAGENT REQUIREMENTS list (► *Chapter 8.6.4 Reagent Requirements, p. 81)* lets you know the quantity of wash buffer and cleaning fluid required for the respective worklist. If you have filled in the correct quantities, then no refill should be needed during the run.

The system automatically monitors the quantity of wash buffer left and warns the operator before each run or before each wash cycle, if the quantity still available is not sufficient (► *Chapter 8.8.1 Pre-Run Checks, p. 105*).

8.7.8 Fill System Liquid

Normally, system liquid can be filled in as soon as the instrument is installed, as described in ► *Chapter 5.4.1 Liquid Connections, p. 46* and in ► *Chapter 5.2.11 Liquid Level Detection (LLD), p. 43*. Checking the level of system liquid (and refilling the container if necessary) is also prescribed as part of the daily start-up maintenance routine (► *Chapter 11 Maintenance and Cleaning, p. 201*). If this has been done as prescribed, no additional refilling should be required before each run.

8.7.9 Load Test Plates

When all the required resources (samples, reagents, dilution plates, tip racks, wash buffer/cleaning fluid and system liquid) are properly loaded and allocated, close the Load dialog by clicking on the Start button.

The system automatically moves a plate carrier to the loading position. The Load Plate dialog is displayed. The software uses this dialog box to request the microplates that are needed to perform the current worklist.

NOTE

Microplates can only be loaded when this is requested by the software!

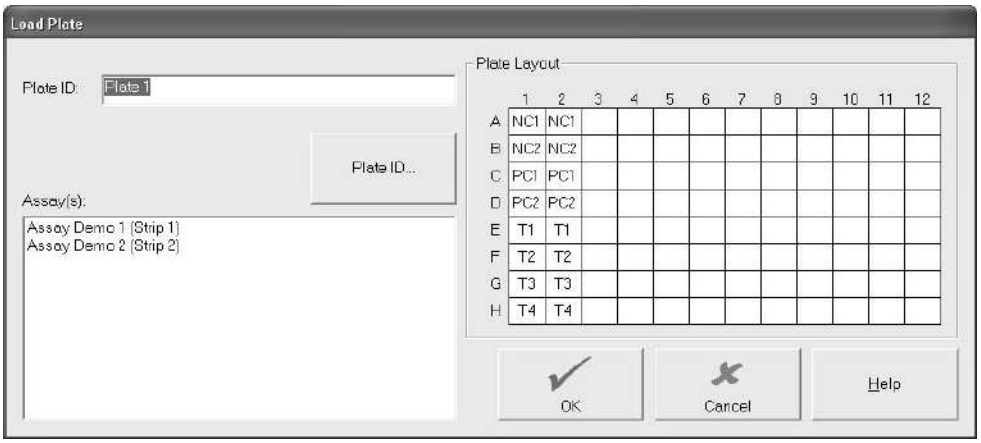


Fig. 36: Load Plate dialog

Function	Description
Plate ID	Shows the name of the requested plate as defined in the SET-UP PANEL dialog. If you have not yet defined a plate ID, click on the Plate ID button and enter a plate ID of up to 12 characters. It is advantageously to add an 8-character "YYMMDDNN" identifier (with YY = year, MM = month, DD = day and NN = "00" for the first plate of the day, "01" for the second plate, etc.) at the end of the plate IDs. Depending on the system configuration provided by the manufacturer this will be automatically done by the software.
Assay(s)	Shows the assay(s) used on the displayed plate.
Plate Layout	Shows the number of wells required for the individual tests.

Test plates used on the EUROIMMUN Analyzer I-2P system are 96-well microplates (8 rows each with 12 wells) with or without removable strips. The precise type of plate used for a test is specified during assay definition (see "Assay Programming Manual" (ask your EUROIMMUN service engineer).

NOTE

Check that you are using the correct plate corresponding to the assay.

NOTE

If you are using more than one assay per plate check that the strips correspond with the plate layout!

To load the test plates

1) In the LOAD PLATE dialog, the first plate (of the current worklist) is requested for loading. Check the PLATE LAYOUT displayed in the right-hand side of the dialog.
2) Place the requested test plate correctly onto the plate transport unit before the test plates can be loaded into the instrument. To do so, fit

the plate into the frame so that the A1 corner of the plate matches the A1 inscription on the frame (rear right), then push it in, overcoming a slight resistance. Make sure that you do not move the plate carrier. It must remain firmly held by the catch spring of the plate transport unit.

3) As soon as you have inserted the plate, enter the plate name and then click on the OK button. The test plate is pulled in. In order to save time in case ✓ OK is accidentally clicked before the plate is actually loaded, the software will not close the LOAD PLATE dialog if no opening and closing of the cover for loading a plate has been detected.
4) The test plate is then moved first into the photometer to check that the correct number of strips is present. The plate is then moved into the stacker. Meanwhile the Load Plate dialog is closed.
5) The plate transport unit moves the next plate carrier to the load position and the LOAD PLATE dialog prompts you to insert the second plate.
6) Repeat the procedure for each requested plate. After the last plate, the worklist will be started automatically (► *Chapter 8.8 Processing the Run, p. 104*).

8.8 Processing the Run

Once all the prerequisite steps (load patient samples, assign assays to patients, define worklist, load required resources, load test plates) have been completed and you have clicked OK in the LOAD PLATE dialog, the software downloads all the processing information to the instrument and the test run starts.

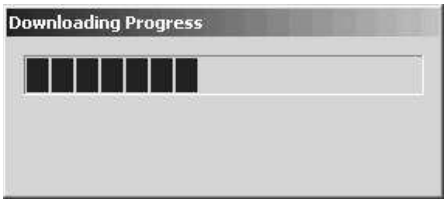


Fig. 37: Acknowledging Progress dialog

The EUROIMMUN Analyzer I-2P is locked during a run.

The cover is automatically locked before the processing can start. If the cover is not completely closed the system cannot be locked and the processing cannot start, and the software will ask you to close the cover first.

If the system has been configured so that a self-test is performed before each run (► *Chapter 9.1 Initialisation and Self-test, p. 123*) the cover is locked during this pre-run self-test.

It is possible to disable the automatic cover lock (in the System Set-up, ► *Chapter 10 System configuration, p. 168* /► *Chapter 10.2.1 System tab, p. 177)*. This, however, is not recommended and may be done only by supervisors or users who are authorised to change the System Set-up. Even if the cover may be opened, opening it will automatically stop the processing (pause the worklist).

- The cover will automatically unlock if an error occurs or if the Stop button is clicked (► *Chapter 8.8.5 System Paused Dialog, p. 110*). It will be locked again when the error is cleared or when the Resume button has been clicked.

8.8.1 Pre-Run Checks

Before actually processing the assays, the system will perform pre-run checks. The wash buffer / cleaning fluid volume check is performed automatically. The three other pre-run checks (reagent volume check, sample volume check and tip size check) are optional. They are performed only if the user has requested them by checking the corresponding items in the Worklist Options dialog. (► *Chapter 8.8.5 System Paused Dialog, p. 110)*.

Wash Buffer/Cleaning fluid Volume

The level of liquid in the wash buffer/cleaning fluid bottles is monitored through level sensors. If the level detected in a bottle is not sufficient for the current worklist, the following message is displayed:

"Insufficient volume of ‘reagent’, position ‘colour’, for the worklist."

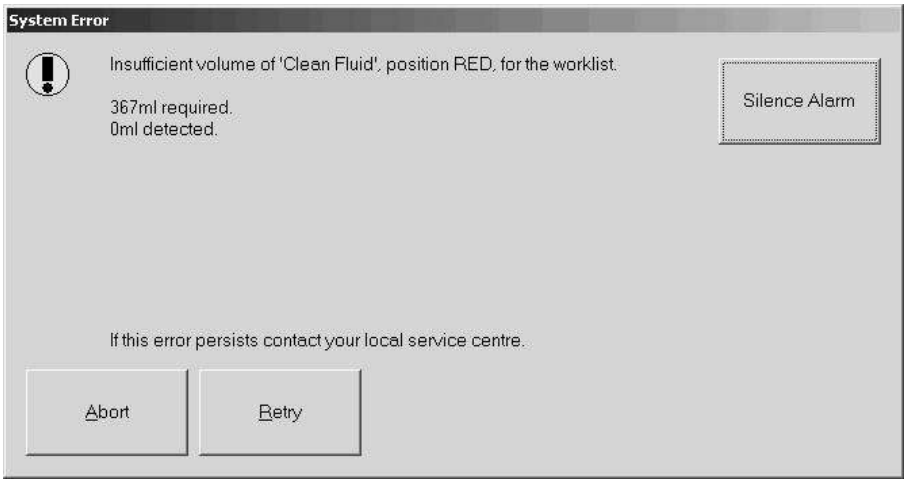


Fig. 38: Insufficient volume dialog

The message tells you which buffer is required in which bottle (colour indication).

Refill

1) Refill the liquid bottle (► *Chapter 8.7.7 Fill Wash Buffer and Cleaning fluid, p. 101*).
2) Click on the Retry button. The system rechecks the volume and, if satisfactory, goes on to check the volume of the next wash buffer.

NOTE

This is only applicable if wash buffer bottles with advanced level sensors are installed. With standard bottles, the system will only raise an error message if the remaining volume is below the minimum volume (dead volume).

Reagent Volume Check

The systems checks that all the reagents needed for the current worklist have been loaded in sufficient quantity. To do this, the pipettor actually checks every reagent bottle until the tip touches the surface of the reagent and the system calculates the volume that is available.

If the system finds that the volume of a reagent is lower than what is required for the current worklist, an error message (► *Chapter 8.8.1 Pre-Run Checks, p. 105*) is displayed.

The message shows the name and the location of the reagent to be restocked.

To refill the respective reagent or to replace it by a new bottle:

1) Click on the Refill Bottle button.
2) Pull out the respective reagent rack.

→ The LOAD DIALOG shows you where it should be placed.

3) Refill the respective reagent bottle or replace the bottle.
4) Insert the rack again. If the reagent was allocated manually, the position in the rack has to be allocated again.
5) Click Sie auf OK.

→ The software will check that all of the barcoded reagents in that rack are still in their correct positions. If not, an error message will be displayed and you will be given the opportunity to reload the rack or to continue anyway. If you choose to continue anyway then this will be logged in the event log and all wells that will subsequently use one of the incorrect reagents will be flagged with the **RgtRem** flag.

✓ When all of the barcodes have been verified the rack LED will be turned off. The system will check the volume of the next reagent.

If the reagent cannot be supplied:

- Click on the Abort Worklist button. This will abort any further volume check but it will also abort the whole test run.
- Click on the Continue button. This skips the volume check for this specific reagent only and continues with the reagent check for the next one. The insufficient volume is logged. With this option, you may decide to start the run and load the missing reagent at a later stage. If you do not refill the corresponding reagent, then some wells will not have reagent dispensed.

NOTE

The reagent volume check is a good option if you intend to use the EUROIMMUN Analyzer I-2P as a "walk away" system (e.g. at night). However, it takes time and uses several tips (one per reagent bottle or control vial).

Delayed volume check for unstable reagents

Unstable reagents have to be prepared and loaded just before use, i.e. while the run is already being processed (► *Chapter 8.7.4 Load Unstable Reagents, p. 97*). As a consequence, they cannot be included in the pre-run reagent volume check. If the reagent volume check option has been selected for a run including unstable reagents, the system will perform the pre-run check for all other reagents but will also perform a volume check on the unstable reagents later, once these have been loaded.

If the volume detected is not sufficient, the available options are:

- Continue to continue the worklist and flag the corresponding results.
- Refill Bottle to load additional reagent and allow the system to continue the worklist without flagging the results.
- Abort Plate(s) to abort all plates that require this particular unstable reagent.

Sample Volume Check

The sample volume check is very similar to the reagent volume check.

However, (depending on the number of patient samples you intend to test), it is likely to take even longer than the reagent volume check and use even more tips (one per sample tube). It is therefore recommended only as a response to specific sample volume problems.

Tip Size Check

If the Verify disposable tip racks option in the WORKLIST OPTIONS DIALOG (► *Chapter 9.4 Worklist Options, p. 142*) has been checked, the system automatically checks the size of the first tip of each rack to make sure the racks have been loaded in the correct locations.

The consequence of this verification depends on whether the tip checked corresponded (or not) to the type of tip the software expected to find on that rack (as displayed in the LOAD dialog).

Expected tip size	Detected tip size	Description
300 µl	300 µl	The pipettor uses this tip for the pipetting step.

Expected tip size	Detected tip size	Description
300 µl	1100 µl	The pipettor ejects the tip. The system displays an error message telling the user to go back to the Load dialog, check in which order the tip racks should be loaded and change them accordingly in the instrument. When the user closes the Load dialog, the system checks the tip size once more.
1100 µl	1100 µl	The pipettor ejects the tip. It will use the next tip in the same rack to perform the next pipetting step.
1100 µl	300 µl	The pipettor ejects the tip. The system displays an error message telling the user to go back to the Load dialog, check in which order the tip racks should be loaded and change them accordingly in the instrument. When the user closes the Load dialog, the system checks the tip size once more.

Tab. 30: Tip Size Check

Change incorrectly loaded tips:

1) Remove the tip rack with the wrong-size tips and replace it with a correct tip rack.

8.8.2 Steps of a Typical Test Run

The different steps (also their duration and sequence) that will be performed by the instrument during a run depend on which assays are to be tested in the run.

In a typical test run:

- The test plate will be transported to the pipetting position.
- The pipettor will aspirate the samples from the tubes (in the order defined in the complete Patient Editor,► *Chapter 9.2 Complete Patient Editor, p. 125*) and the controls from their respective bottles. It will then dispense them into the microplate.
- The plate will go through an incubation period.
- The plate will be transported to the wash unit for washing.
- The pipettor will dispense the conjugate.
- The plate will go through a second incubation period and a second wash.
- The pipettor will dispense the substrate.
- The plate will go through a third incubation period.
- The pipettor will dispense the stop solution.
- The microplate will be transported back to the photometer for the final read.

In some cases (depending on the assay):

- A pre-dilution step will be performed at the beginning. This pre-dilution can take place either directly in the test plates or in dilution plates.
- Shaking steps will also be included. The test plates can be shaken either when they are in the heated incubators or on the plate transport unit.

When several assays are combined in the same worklist, the system does not process one plate after the other but optimises the process so as to shorten the total processing time (► *Chapter 9.6.2 Preparing and Loading the New Patient Samples, p. 159*).

For partial processing i.e. processing only some steps of an assay, see "Assay Programming Manual" (ask your EUROIMMUN service engineer).

8.8.3 Operator intervention during a run

The EUROIMMUN Analyzer I-2P system has been designed as a "walk-away" system, which means that if everything has been correctly planned it can operate unattended.

Three exceptions, however, require the intervention of an operator during the run:

- When tips need to be reloaded.
- When an unstable reagent needs to be loaded.

  When a system error or a pipetting error occurs.

If you wish to monitor the run process:

1) Click on the SCHEDULE BUTTON in the Worklist window to follow the run on the Schedule screen (► *Chapter 8.6.2 Schedule, p. 79*).
2) Click on the Active event log button to check the Active event log (► *Chapter 8.6.6 Active Event Log, p. 84*) to see if the different steps are correctly executed.

NOTE

DO NOT interfere with the run during the run unless requested to do so by the software.

Information on emergency shutdown can be found in ► *Chapter 8.8.7 Emergency Stop/Cancelling a Run, p. 112*

For information on removing sample or reagent racks before the end of a run, see the ► *Chapter 8.10.2 Unload Sample Racks, p. 119* and ► *Chapter 8.10.3 Unload Reagent Racks, p. 120.*

For reloading patient samples or microplates, refer ► *Chapter 9.6 Continuous Loading, p. 158*.

If it is necessary to reload peaks during the processing of a work list, note the following ► *Tip Management Options, p. 100*.

If a specific reagent needs to be prepared after the start of a run, the software will inform you in advance and instruct you to prepare it as described in ► *Chapter 8.7.4 Load Unstable Reagents, p. 97*.

8.8.4 System-/Pipetting Errors

The system automatically pauses the run when system errors are detected. Check the error message list in ► *Chapter 12.1 Error messages, p. 217*.

Depending on the kind of error detected the system will either display a specific error message, describing the problem, or open the SYSTEM PAUSED dialog (► *Chapter 8.8.5 System Paused Dialog, p. 110*) and describe the problem detected in the status bar.

When specific pipetting errors occur, the system can also pause the run and request the intervention of an operator.

8.8.5 System Paused Dialog

This dialog is displayed either when a system error occurs (► *Chapter 8.8.4 System-/Pipetting Errors, p. 110*) or if you click on the Stop button in the toolbar.

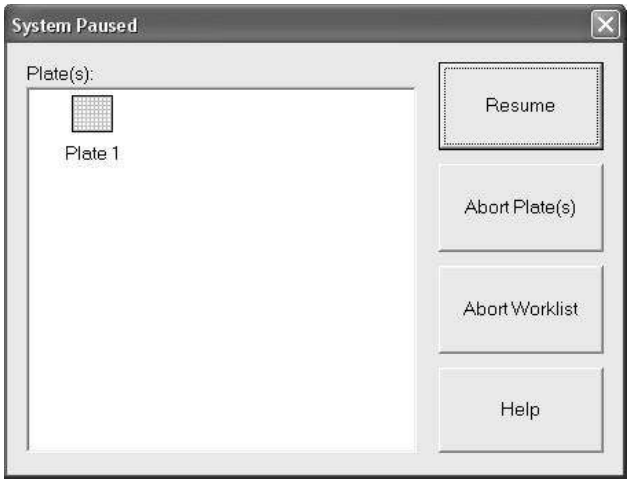


Fig. 39: System Paused dialog

Function	Description
Plate(s)	Shows the plates that have yet to be processed. Plates that have not yet been completely processed are displayed as well.
Resume	Continue the run.
Abort Plate(s)	In the plates list, select the plate(s) that you do not want to process any more. Then click on this button to delete it from the worklist. You can then continue the run with the remaining plates only.
Abort Worklist	The run is over. None of the plates listed in the Plates list will be processed any more.

NOTE

When you click on the Abort Plate(s) or the Abort Worklist button, the system will take some time to respond because it has to communicate with the instrument to alter all the processing information that has been downloaded to the instrument at the start of the run.

Consequences of a System Pause

If the system is paused but you resume the run without removing any racks, the processing continues normally (for all non-aborted plates). The pause duration is mentioned in the **Title Block** section of the **Result Report**. These results should be closely examined by a user who will validate them or not, depending on why the system was paused and for how long, and on whether the samples may have been tampered with.

The EVENT LOG lets you know at which stage of the process a pause occurred. Taking into account the results obtained for the control wells and/or for the standards and referring to the kit insert may also be helpful in assessing the potential impact of the pause on the analysis.

8.8.6 Pipetting Errors/Manual Pipetting

Depending on what has been defined in the assay (see "Assay Programming Manual" (ask your EUROIMMUN service engineer)), when pipetting errors (insufficient liquid, clot, pipettor hardware error...) occur, the system will either:

- **Raise alarm and stop:** In this case, a specific error message is displayed on the screen explaining the problem and what the operator can do (e.g. Abort, Retry, Ignore...).
- **Log and continue**: In this case, the error is documented (log and flag) but the run continues without any operator intervention.
- Request the operator to **manually pipette** at the end of the step (see below).

Whatever the case, the pipetting error is entered in the EVENT LOG and the affected samples / controls are flagged in the COMBINED REPORT (► *Chapter 8.9.2 Result Interpretation, p. 115*).

Manual Pipetting

When manual pipetting is required, the system displays a message indicating precisely what to pipette and where.

If the manual pipetting needs to be done into a microplate, the appropriate plate is automatically moved to its load / unload position.

The instrument is unlocked and you can access other resources (dilution plates, sample racks...) as required to perform the manual pipetting.

NOTE

If you need to pull out racks, please make sure to put them back exactly in the same position! Make sure everything is reloaded before clicking on the OK button in the above message.

8.8.7 Emergency Stop/Cancelling a Run

If you need to stop the processing immediately, what you can do is:

- In the software, click on the Stop button in the toolbar. This will open the SYSTEM PAUSED dialog (► *Chapter 8.8.5 System Paused Dialog, p. 110*) and unlock the instrument so that you can open the cover flap and access the work area (in case of liquid overflow (► *Chapter 11.6.2 Visually Check Syringe and Three-Way-Valve, p. 210*).
- If the problem can be corrected, you can choose to continue the processing by clicking the Resume button of the System Paused dialog.
- If the problem cannot be corrected rapidly, you can choose to abort the processing of one plate (highlight the plate and click the Abort Plate(s) button) or to cancel the run altogether by clicking Abort All Plates.

8.9 End of Run/Result Report Window

On the EUROIMMUN Analyzer I-2P system, it is not necessary to wait for the entire processing to be finished to view the results. As soon as the processing of one microplate is finished, the system generates the result file for this plate.

NOTE

To prevent incorrect results it is essential to check the result report carefully for flags, entries in the event list or other irregularities.

NOTE

The system generates one result file per plate (not per worklist or per assay). When several assays have been processed on the same plate, (► *Chapter 9.3.3 Processing Several Assays per microplate, p. 137)*.

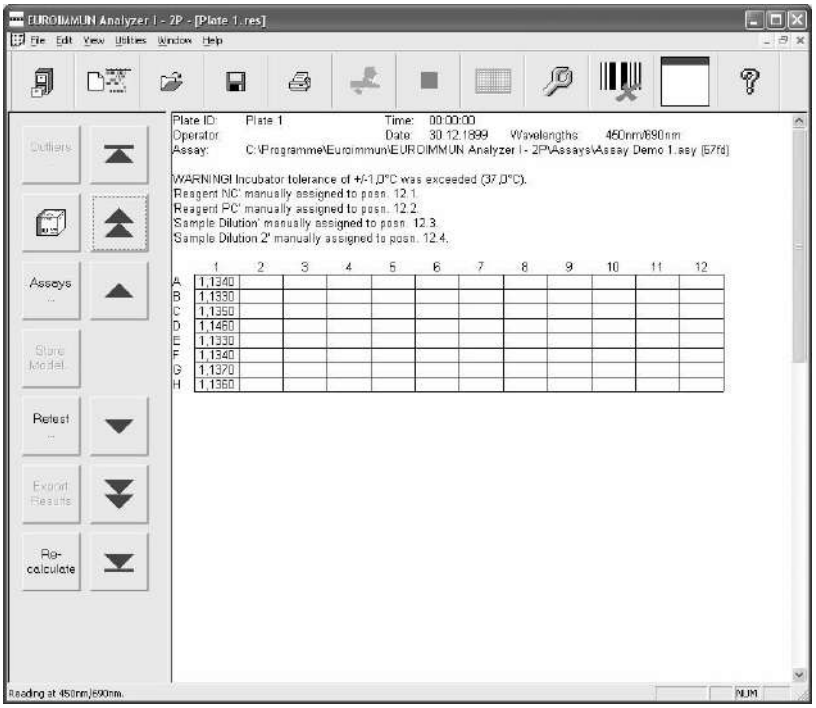


Fig. 40: Result window

Function	Symbol	Description	Chapter
Assays...		This function allows you to recalculate the results with another assay protocol while retaining the original OD values of your plate.	► *Chapter 9.5.4 Editing/Recalculating the Results, p. 154*
Export Results		This function allows you to export test results to a host computer either through an ASTM link or as a (*.txt) file.	► *Chapter 8.9.5 Export the Results, p. 117*
Lot Specific Values		Opens the **Lot-specific Values** dialog box to show or edit the required reagent information.	► *Chapter 8.5 Lot-specific* Values*, p. 75* und ► *Chapter 9.5.4 Editing/Recalculating the Results, p. 154*
Outliers...		The **Outliers** function allows you to manually remove from the results some OD values which you think are not consistent with the test.	► *Chapter 9.5.4 Editing/Recalculating the Results,/Editing Outliers, p. 154*
Recalculate		This function allows you to recalculate the results.	► *Recalculation with another Assay, p. 156*
Store Model		This function allows you to save the statistic model used for the calculation of the quantitative results so that they can be used in a new assay.	See Assay Programming Manual (ask your EUROIMMUN service engineer)

Tab. 31: Option Result window

8.9.1 Structure of the Result Reports

The exact structure of the Result Report (and printout) depends on what has been specified for that particular assay when it was defined (see "Assay Programming Manual" (► *Chapter 1.10 Technical Service, p. 24*).

Title Block

The Title Block section identifies the test that has been performed. It provides information on:

- The Plate ID
- The person responsible for running the test.
- The assay used.
- The date and time of the test performance.
- Certain default settings such as the upper cut-off and the wavelength as well as the reference wavelength of the photometric measurement.

NOTE

Important error messages that come up in the course of processing the worklist are also displayed here.

Laboratory Details

This section provides information on the laboratory where the test has been performed.

The information displayed (e.g. name, address) reflects the data that has been entered in the Laboratory tab of the Options dialog (► *Chapter 10.1.6 Laboratory Tab, p. 174*).

Incubation Results

This section shows the incubation parameters. If incubation problems occurred during the run, this is shown directly on the result report.

Photometer

This section shows the OD values read by the photometer.

Validation Criteria

The data displayed in this section indicate if the calibrators and controls are within the valid range. If the values of the calibrators and controls are within the limits specified by the formula in this field, the test is considered valid and can therefore be evaluated.

If one of the criteria failed, the test will not be evaluated. In this case, the word "FAILED" is displayed next to each criteria.

Quantitative Results

This section shows the graph which is created with the standards defined in the assay see "Assay Programming Manual" (► *Chapter 1.10 Technical Service, p. 24*).

Qualitative Results

This section provides information regarding the cut-off value of the test. The parameters and terms used are set during assay definition (for details, see "Assay Programming Manual" (► *Chapter 1.10 Technical Service, p. 24*).

Spreadsheet Results

This section contains the results calculated by means of a spreadsheet. The OD values measured by the photometer or the calculated concentrations are calculated further using the defined formulas (see Assay Programming Manual (ask your EUROIMMUN service engineer)).

The data reduction of an assay can use up to four spreadsheets. Each individual result of the four spreadsheets can be included in the RESULT REPORT.

Events

This section displays error messages as well as messages about user interaction taken from the ACTIVE EVENT LOG (► *Chapter 8.6.6 Active Event Log, p. 84*).

Combined Report

The COMBINED REPORT is an important part of the Result Report because it gives a view of the results per patient sample (Patient ID) (► *Chapter 8.9.2 Result Interpretation, p. 115*). The data shown on the combined report can be specified in the test definition.

8.9.2 Result Interpretation

Accurate result interpretation depends on the assay that was processed in the test run. Only a general outline is given here.

Per Plate

The first part of the Result Report (all sections except the COMBINED REPORT) gives you a global view of the test run per plate. You can trace who the operator was, what reagents and lots were used, you can check if the incubation steps were correctly carried out, you can detect any discrepancy in the OD values (e.g. according to the locations of the wells on the plate), you can check if controls met the validation criteria, if some wells were removed due to bad pipetting, etc.

Make sure to pay attention to any WARNING! line(s) in the Title Block section. If your RESULT REPORT includes an EVENTS SECTION, check the red lines to see if any critical event occurred during the run.

Per Patient

The Combined Report, on the other hand, gives you the results per Patient ID. The precise data fields included in the Combined Report depend on what has been specified for each assay (see "Assay Programming Manual" (ask your EUROIMMUN service engineer)). The order in which patient samples are listed in the Combined Report depends on the option selected in the complete Patient Editor dialog (► *Chapter 9.2 Complete Patient Editor, p. 125*).

Flags

Flagged results are not necessarily wrong results. A flag indicates that something happened during the run that may have affected the result for this patient sample.

The software uses different flags to give an indication of the type of problem encountered:

Flag	Description
Clot	Clot detected. Results for flagged samples are not calculated.

Tab. 32: Flags

When results are flagged but calculated, it is the user's responsibility to check the Result Report and the Active event log, to find out precisely why a particular result was flagged. Only then will it be possible to determine whether the result can be accepted as valid or if the patient sample must be re-tested.

When results are flagged and not calculated, it is possible, in some cases, to force the system to calculate the results in spite of the problem that occurred. This is done via the Outliers function (► *Chapter 9.5.4 Editing/Recalculating the Results, p. 154*).

8.9.3 Save/Open the Result Report

The Result report is automatically saved to a result file. By default, this result file is saved in the C:\Programme\EUROIMMUN\EUROIMMUN Analyzer I-2P\Results directory. By default, the name of the result file is the name of the Plate ID, plus a (*.res) extension.

Save the report

To save the result file under a specific name:

1) Click on the File > Save Result as menu item.
2) The Save As dialog is shown (► *Chapter 7.4 Save, p. 60)*. Enter an appropriate file name and save the reagent report. (Reagent layout files have a (*.res) extension.)

File name in case of recalculated/changed results

If the results are changed for any reason and the file is saved, the software creates a backup of the original results file before saving the changes. The backup will have the same basic filename but with a revision index appended. The revision index will start at "0" and will automatically increment whenever a new file is saved.

For example, if "Plate_07030601.res" is changed and saved again, the original result file will be backed up as "Plate_070306010.res".

Open

1) Click on the button Open.
2) In the OPEN dialog (► *Chapter 7.3 Loading (Open), p. 57*) which is displayed, select the entry Result Files (*.res).
3) Select the desired (*.res) file and open it. The file is loaded and the calculation is performed again before it is displayed.

8.9.4 Print the Result Report

To print the complete Result report:

1) Click on the button Print (► *Chapter 7.5 Printing on the printer, p. 61*)

NOTE

If you have checked the Automatically print result item in the Worklist Options dialog (► *Chapter 9.4 Worklist Options, p. 142*), the Result report will be automatically printed each time it is generated.

8.9.5 Export the Results

NOTE

Required access rights: Send Results to LIMS

The EUROIMMUN Analyzer I-2P system can export test results to a host computer either through an ASTM link or as a (*.txt) file.

The export of test results can be ordered individually by the operator once a result report is displayed on the screen, or the EUROIMMUN Analyzer I-2P software can be configured to systematically export the results. The choice between these two possibilities will generally depend on whether the user wants to examine and validate the results before exporting them or whether the validation will be done at host computer level.

For more information on result exports, ► *Chapter 16.1.4 Export of Test Results, p. 250*. For the format, structure and contents of (*.txt) export files, (see "Assay Programming Manual" (ask your EUROIMMUN service engineer)). For ASTM export of test results ► *EUROIMMUN Analyzer I-2P to Host (Test Results), p. 259.*

8.10 Unloading

NOTE

Inspect instrument deck, plates, racks, etc. for spillages. If spills occurred, check the instrument for leaks (► *Chapter 11 Maintenance and Cleaning, p. 201*).

8.10.1 Unloading of Test plates

NOTE

Inspect test plates after unloading for unexpected or irregular fill heights.

At the End of the Run - Basic Procedure

By default, fully processed plates ("finished plates") are stored on the instrument in the room-temperature incubators.

Then, once the processing of the complete worklist is finished, the system prompts you to start unloading the plates by displaying the following message:

Fig. 41: Remove plate message

1) Open the cover of the instrument.
2) Remove the plate.
3) Close the cover of the instrument.
4) Click on the OK button to confirm removal in the software.

Before the End of the Run – Unload fully processed Plates

If some plates are already fully processed and you want to unload them before waiting for the end of the run:

1) Select Edit > Unload Finished Plates....

→ This opens the UNLOAD PLATES dialog.

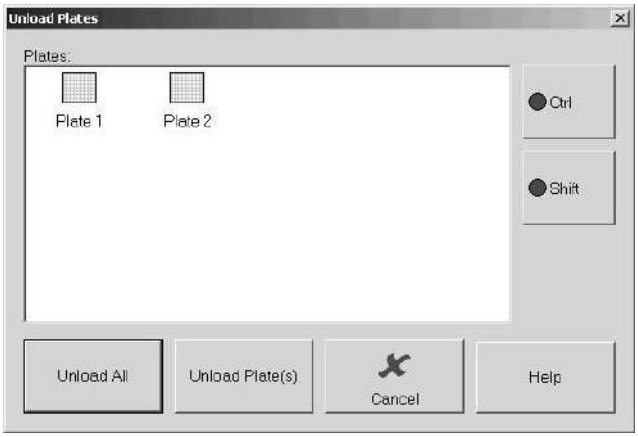


Fig. 42: Unload Plates

2) In the list, select the plate or plates that you want to unload and click Unload Plate(s) or simply click Unload All if you want to unload all the plates listed. Only fully processed plates are shown in the list.

3) Remove the plate(s) (► *Chapter 8.10.1 Unloading of Test plates, p. 118).*

NOTE Only fully processed plates are shown in the list.

Choosing to unload finished plates before the end of the run can be useful for example if you want to visualize a plate in which some wells have been incorrectly pipetted or if you want to further process a plate manually or on another instrument. You do not need to use this procedure if you intend to reload additional samples and plates using the Continuous Loading feature. In this case, the system automatically lets you remove fully processed plates before allowing you to reload new plates (► *Chapter 9.6.5 Reloading Test Plates and Further Processing of the Worklist, p. 161*).

Before the End of the Run – unfinished plates

The only way to remove plates that are not fully processed is by using the pause and test plate removal procedure (► *Chapter 8.8.5 System Paused Dialog, p. 110*).

8.10.2 Unload Sample Racks

At the End of the Run

To remove/unload a rack at the end of a run:

1) Pull out the rack(s) designated by a flashing LED.

Before the End of the Run

Technically, it is possible to remove a rack from the instrument even while the run is still being processed.

Two cases have to be considered: either the rack which you want to remove is fully processed or it is not.

A rack is fully processed when all the pipetting operations out of that rack have been completed (i.e. that rack will not be needed for the rest of the run). You know that a rack is fully processed when the corresponding LED starts flashing. Removing fully processed racks is necessary, for instance, if you want to reload new samples on Continuous Loading (► *Chapter 9.6.2 Preparing and Loading the New Patient Samples, p. 159)*

If the rack is fully processed (and the LED is flashing):

1) Pull out the rack(s) designated by a flashing LED.

If the rack is not yet fully processed (the corresponding red LED is not flashing) you **should NOT remove it**. If there is a specific problem and you absolutely have to remove it, do so as described above (except that no LED is flashing).

NOTE

However, please note that if you remove and reload a sample rack that was not fully processed, any sample that will be pipetted from that rack after you have removed and reloaded it will be flagged and the respective results will not be calculated (► *Chapter 8.9.2 Result Interpretation, p. 115*).

8.10.3 Unload Reagent Racks

Basically, the rules that apply to reagent racks are equivalent to those described for sample racks, i.e.:

- Technically, it is always possible to remove a reagent rack, even while the run is being performed.
- You should not remove a reagent rack before it is fully processed (i.e. the corresponding LED is flashing) unless you absolutely need to do so or are prompted to do so by the software (see below).

However, the following differences apply:

- If you remove a reagent rack before it is fully processed, all the samples which had not yet been pipetted when the rack was removed will be flagged but the corresponding results will still be calculated.
- If you need to load an unstable reagent, the system will direct you to do so as described in ► *Chapter 8.7.4 Load Unstable Reagents, p. 97* and the samples will not be flagged.

Unloading a reagent rack (during or at the end of a run) is done as described above for sample racks.

8.10.4 Unload Tip Racks and Dilution Plates

The cover is normally locked during the whole run (it can be unlocked only for a short time when it is necessary to reload tip racks (► *Chapter 8.7.6 Load Tip Racks, p. 99*).

You will have to wait until the end of the run to unload dilution plates and tip racks.

Unloading of tip racks and dilution plates

1) Open the cover.

2) Take dilution plate(s) or empty tip racks out of the respective holding devices.

3) Close the cover.

NOTE

If you are using the Re-use partial tip racks or/and the Re-use partial dilution plates option(► *Chapter 9.4 Worklist Options, p. 142*).remove tip racks only if they are completely empty and the dilution plates only if they are completely used. DO NOT remove partially empty racks and partially used dilution plates! The system monitors the number of tips and dilution wells left and will include them in planning the next worklist.

8.10.5 Unload other Resources

Wash buffer, cleaning fluid and system liquid do not need to be emptied or unloaded after each run. For wash buffers, follow the storage conditions in assay kit inserts.

For additional information, refer to the maintenance plan and procedures.

8.10.6 Waste Disposal

- Dispose of microplates, dilution plates and sample tubes in accordance with legal regulations for biologically hazardous waste.
- Visually check the contents of the tip ejection waste container. There is no sensor for this container. If full or nearly full, empty it as described in ► *Chapter 11.2.3 Shut down, p. 205.*
- Check the liquid waste level in the liquid waste container. If full or nearly full, empty and clean as described in ► *Chapter 11.2.2 After each run, p. 204*.

8.11 Shutdown / End of Day Maintenance

NOTE

Before shutting down the system see Maintenance procedures in ► *Chapter 11.2.3 Shut down, p. 205*.

NOTE

Always shutdown the computer (Windows shutdown) before switching off the system! Otherwise, the computer could lose data or could have hard-disk failures.

1) Click on the FILE > Exit menu item to terminate the EUROIMMUN Analyzer I-2P software.

2) Click on the Start > Shutdown menu item of the Windows operating system.

3) Select the Shutdown item.

4) Click on the OK button.

5) The software system is shut down and the PC is switched off automatically.

6) Switch off the EUROIMMUN Analyzer I-2P system.

7) Inspect and clean the instrument as described in ► *Chapter 11.2.3 Shut down, p. 205*. Observe the complete maintenance instructions (► *Chapter 11 Maintenance and Cleaning, p. 201)*

8.12 Processing of emergency primary samples

On the instrument, emergency primary samples are processed in the same way as in routine operation.

1) If urgently required, interrupt any worklist running in routine operation.

2) Prepare the worklist as usual.

3) Rate the urgency of the emergency primary sample(s) and reduce the volume of the worklist, if necessary.

4) Start the worklist.

9 Advanced functions

This chapter describes further functions of the EUROIMMUN Analyzer I-2P Software.

9.1 Initialisation and Self-test

Required access rights: Nothing

ATTENTION

MOVEMENT OF THE BARCODE-SCANNER

Damage to the barcode scanner.

> Never use the loading bay as storage space!

WARNING

MOVEMENT OF THE BARCODE-SCANNER

Risk of impact, crushing, stabbing

> Only load or unload in the specified lane.
> > Wait until you are prompted to load/unload.
> > Wait until the barcode scanner stops.

WARNING

BACKWARD MOVEMENT OF THE BARCODE-SCANNERS

Risk of impact, crushing, stabbing

> Never reach into the rack loading area to the right of the barcode scanner.

A self-test is performed each time you start the EUROIMMUN Analyzer I-2P software. The system is initialised and checks all instrument modules. These are checked as follows:

Check	Description
COP (Command Operating Processor)	An EEPROM checksum is created. The serial connection to all modules of the EUROIMMUN Analyzer I-2P is verified.
Pipettor	The pipettor is initialised. The movement in x-, y-, z-axis is checked, the encoders and the home sensors in these directions are tested. The pipettor is primed with system liquid five times.
Wash unit	The home sensors, encoders, aspirate and dispense pump are checked.

Check	Description
Photometer	An EEPROM checksum is created. The reference voltages of the front end and also the photodiode dark background signals is measured. Each filter is tested to choose the optimum read gain and for noise at optimum gain. The optic channel transmissions are measured.
Plate transport unit	A EEPROM checksum is created. The movement in x-, y-, z-axis is checked and the encoders in these directions are tested.
Incubators	A EEPROM checksum is created. The temperature sensors are tested and it is checked that the heater drives are not in open circuit.

Tab. 33: Self-test checked module

The results of this instrument check are then displayed on the screen:

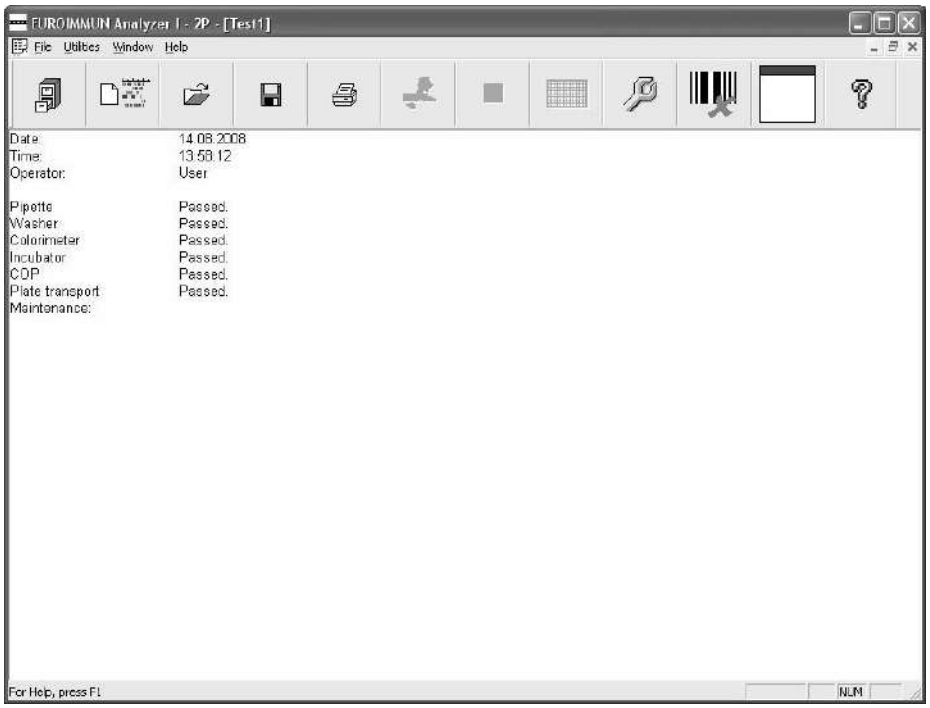


Fig. 43: Self-test report

The result of the instrument is satisfactory if the word "Passed" is displayed for each instrument module.

The Maintenance field remains empty unless you have defined specific maintenance checks to be performed by the system (► *Chapter 11.5 Maintenance Jobs, p. 209*).

Under default settings, self-tests are performed only each time you start the software. But other options are available.

9.1.1 Manually Start Self-test

The EUROIMMUN Analyzer I-2P system allows the user to request a self-test at any other time (not, however, while a worklist is being processed). This is useful, for example, if you suspect that an instrument module is not responding or functioning correctly.

Proceed as follows:

1) Select Utilities > Selftest.

→ After a confirmation dialog, a self-test will be immediately performed and the results shown as above.

9.1.2 Self-test before each Run

Required access rights: Change system setup

1) Select the Utilities > System Setup... to open the SYSTEM tab of the SYSTEM SET-UP dialog (► *Chapter 10.2.1 System tab, p. 177*).

2) Check the Perform self-diagnostics before a run item in the SELF-DIAGNOSTICS area.

This dialog also lets you program the software to automatically print a report each time a self-test is performed.

Proceed as follows:

3) Check the Auto print self-diagnostics report item in the Self-diagnostics area.

NOTE

Performing a self-test check before each run is a good safety procedure. However, it takes time (approx. 2 minutes), and is recommended mostly for operators who are not familiar with the system.

9.1.3 Self-test errors

If one or more of the instrument modules that are checked during the self-test are found to be not responding correctly, a corresponding error message will be displayed in the self-test report.

Before interfering with the faulty or non-responding module, try to perform the self-test again by selecting Self-test in the Utilities menu.

If this also fails, refer to the error message list in ► *Chapter 12.1 Error messages, p. 217* and check what corresponding action can be undertaken to solve the problem.

9.2 Complete Patient Editor

Required access rights: Edit patient details

The complete PATIENT EDITOR dialog allows the direct input of patient data and the assignment of assays. It is required in the following situations:

- If you prefer to assign tests before loading the patient samples on the instrument.
- If you have already created a new worklist (► *Chapter 9.3 Create your own worklist, p. 131)* and have not yet assigned tests to some patients.
- If you are reusing a formerly saved worklist and want to assign the tests to some new patients.
- If only patient samples without barcoded tubes are used.
- If additional patient data (e.g. name, sex, date of birth etc.) are to be entered.
- If you are using the software in demo mode.

Enter patient data manually:

1) Select Utilities > Patient Details... .

→ The PATIENT EDITOR dialog is displayed:

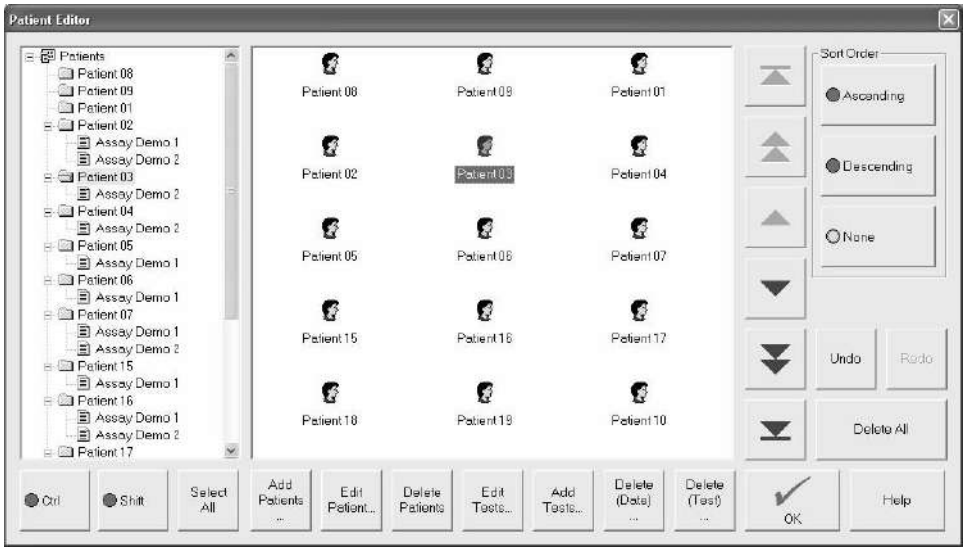


Fig. 44: Complete Patient Editor dialog

Option	Description
Left list	Shows all patients and their assigned assays as a tree. (Click on the plus sign to display the assays.)
Right list	Shows all patients. Select only one patient to: ▪ edit the patient details or ▪ edit the assigned tests. Select one or more patients to: ▪ delete the patient(s) or ▪ add tests.

Option	Description
Add Patients...	New patient IDs can be created with this function (► *Chapter 9 Advanced functions, p. 123 /► Chapter 9.2.4 Assign Assays to the Patient Samples (Complete Patient Editor), p. 130.*
Add Tests...	This function allows the assignment of patients and assays (► *Chapter 9.2.4 Assign Assays to the Patient Samples (Complete Patient Editor), p. 130.*
Delete All	All created patients and test assignments can be deleted with this function.
Delete (Date)…	This function allows the deletion of patients already created which were created before a certain date.
Delete Patients	Patients already created and selected can be deleted with this function.
Delete (Test)	Allows the deletion of the assignment of a certain assay to the patient.
Edit Patient...	This function allows to enter additional details (e.g. name, sex) for a selected patient (► *Chapter 9.2.3 Edit Patient Details, p. 128).*
Edit Tests...	With this function, the assignment of a selected patient and the assigned assay can be changed (► *Chapter 9.2.5 Edit the assigned tests, p. 131)*
Select All	All created patients can be selected with this function.
Sort Order	The Sort Order field allows you to define the order in which the samples will be pipetted from the tubes. The Sort Order selected also serves to determine: the sample order for the Auto Arrange function in the Load dialog (► *Chapter 8.7.1 Load Dialog, p. 89)* the order in which samples are listed in the results (in the Combined Report) the order in which sample IDs will be sorted in the Patient Editor after a successful worklist import. Selectable sort order: **Ascending:** Sorted in alphanumeric ascending order (based on the sample IDs entered or read by the barcode scanner). **Descending:** Sorted in alphanumeric descending order (based on the sample IDs entered or read by the barcode scanner). **None (default):** The samples will be pipetted from the tubes in the order in which they are placed in the racks.

⚠ WARNING

INCORRECT SAMPLE ALLOCATION

Wrong analysis result

- > Do not change the “Sort Order” to Ascending or Descending if CSF assays are being processed.
- > The order in which the samples and CSF are placed in the rack must be maintained.

9.2.2 Add new Patient

If the button Add Patients has been clicked in the complete PATIENT EDITOR dialog, the ADD PATIENT(S) dialog is displayed:

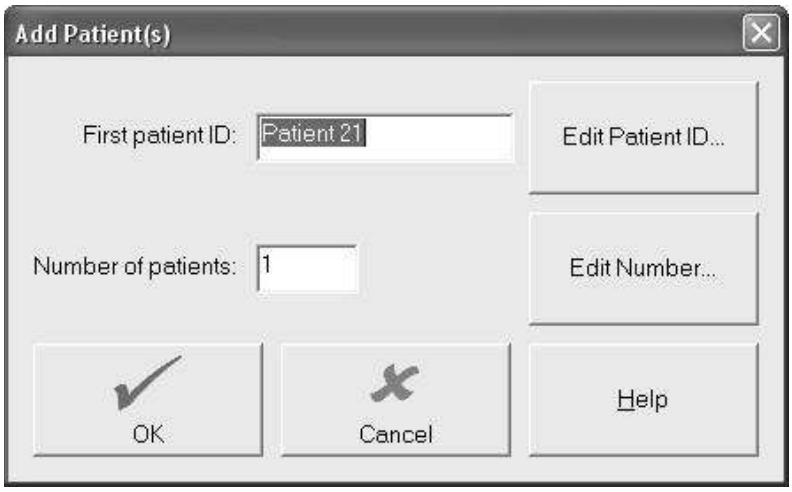


Fig. 45: Add Patient(s) dialog

Function	Description
First patient ID	In this box, the (first) patient ID number can be entered. For the input of the patient ID, the Edit Patient ID dialog can be used (► *Chapter 7.6.1 Edit Text Dialog, p. 63*).
Number of patients	In this box, the number of patients to be created with a consecutive patient ID can be entered. Example: Input: ID: P0001; Number: 5 Result: P0001, P0002, P0003, P0004, P0005 For the entry of the value, click on the Edit Number button (► *Chapter 7.6.2 Enter a Number Dialog Window, p. 64*).

NOTE

The entered patient IDs must be unique! If non-unique patient IDs are used (e.g. same ID for different persons on different worklists), the patient database is incorrect. In this case, features like patient history or patient result report must not be used.

9.2.3 Edit Patient Details

Only the Patient ID is absolutely needed to process a test run. However, the EUROIMMUN Analyzer I-2P system also allows the user to enter and store the following patient details:

- last name
- birth date
- sex

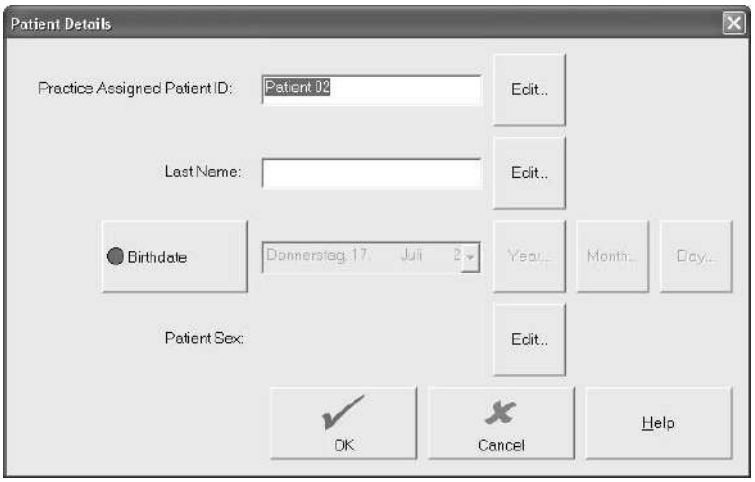


Fig. 46 Patient Dialog

Function	Description
Practice Assigned Patient ID	In this box, the selected patient ID number can be changed. Please note that the patient ID must remain unique. It is also possible to click on the Edit button to open the Edit Text dialog (► *Chapter 7.6.1 Edit Text Dialog, p. 63*).
Last Name	In this box, the last name of the patient can be entered. It is also possible to click on the Edit button to open the Edit Text dialog (► *Chapter 7.6.1 Edit Text Dialog, p. 63)*
Birthdate	After the activation of this option, the date of birth of the patient can be selected in the adjoining box. For a simplified entry of the date of birth, a calendar is available which is opened after clicking on the arrow.
Year, Month and Day	The date of birth can also be entered by pushing the buttons. After pushing, the Enter Number dialog is opened (► *Chapter 7.6.2 Enter a Number Dialog Window, p. 64*).
Patient Sex	After pushing the button Edit, a dialog appears for selecting the sex of the patient. The following selection options are available: **F**: female **M**: male **U**: undefined/unknown

NOTE

If you are using barcodes or importing test orders from a host computer, the patient details can be entered automatically provided the pertinent information is included in the barcode or in the imported file/data.

9.2.4 Assign Assays to the Patient Samples (Complete Patient Editor)

Before a patient sample can be tested, an assay must be assigned to the sample. This assignment is made in two steps:

- In the first step, all patients must be selected which are to be assigned to an assay.
- In the second step, the required assays are selected.

1) Select all involved patients in the complete patient editor.

2) Press on the Add Tests... button.

→ The SELECT ASSAY(S) dialog opens:

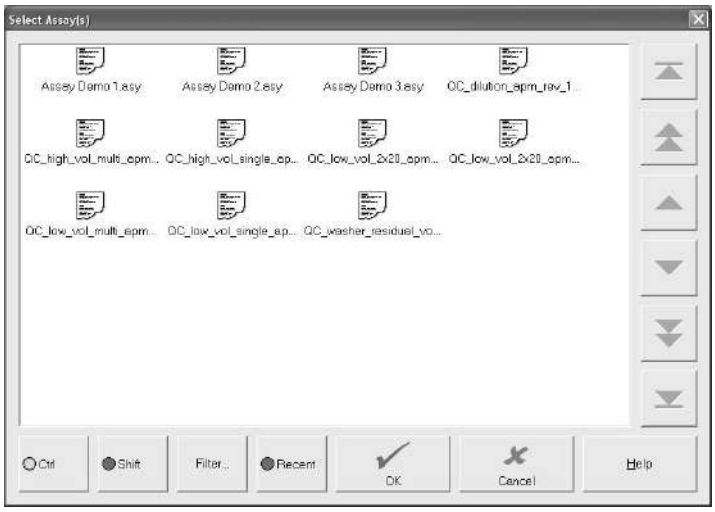


Fig. 47: Select Assay(s) dialog

Function	Description
Filter	With this function, the number of assays displayed can be limited. After pushing the button, the EDIT TEXT dialog (► *Chapter 7.6.1 Edit Text Dialog, p. 63*) is opened. After the entry, only those assays containing the entered text are displayed. The filter ignores capitalisation. Example: Filter input: igg Displayed Assays: CMV IgG, HSV IgG, MUMPS IgG, Toxo IgG
Recent	After clicking on this function, only assays that have already been used once in a worklist are displayed. If this function is clicked on again, all assays are displayed again.

After the selection of the assays and the pushing of the OK button, the PATIENT EDITOR dialog appears again. The assignment of patients and assays is now executed.

9.2.5 Edit the assigned tests

With this function, the assignment of a selected patient and the assigned assay can be changed.

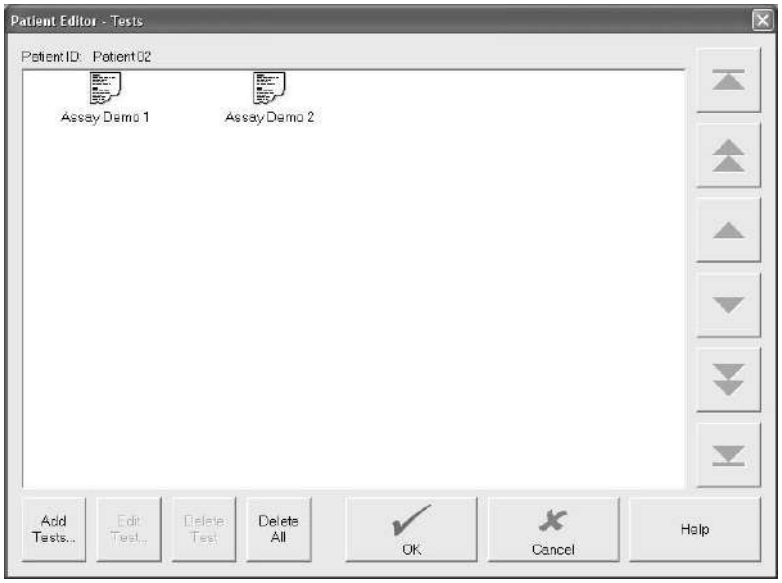


Fig. 48: Patient Editor – Tests

Option	Description
Add Tests...	This function allows to assign tests to the patient ► *Chapter 9.2.4 Assign Assays to the Patient Samples (Complete Patient Editor), p. 130*.
Edit Test...	Shows the TEST ORDER DETAILS dialog to add/edit the collection date of the selected assay.
Delete Test	Selected tests can be deleted with this function.
Delete All	All assigned assays can be deleted with this function.

9.3 Create your own worklist

Required access rights: Start Worklists

The worklist is at the core of how the EUROIMMUN Analyzer I-2P system operates.

In the PATIENT EDITOR dialog, you defined the tests (assays) to be performed for each patient (e.g. patient 000001 must be tested for Borrelia and HSV, patient 000002 must be tested for Borrelia only, patient 000003 must be tested for Borrelia, HSV and toxoplasmosis, etc.).

Now, you will use the worklist to define how these tests will actually be implemented on the test plates (e.g. Plate 1 will be used to test patient 000001, 000002 and 000003 for Borrelia, Plate 2 will be used to test patient 000001 and 000003 for HSV, and Plate 3 will be used to test patient 000003 for toxoplasmosis ...).

Once the worklist is defined, the system checks all parameters and signals any error. Errors must be corrected before you start a run.

A new worklist is generally created for each test run but if similar test runs are performed regularly, the system allows the user to save and re-use previously defined panels.

The main element of worklist definition is the SET-UP PANEL dialog. Here, the user organizes the test run to be performed: which assay on which plate and the order of the plates.

The SET-UP PANEL dialog is blank when it opens, i.e. when the system does not yet have the required information on the patients or on the tests to generate a suggested worklist.

Use this method particularly if:

- you create a worklist before loading the sample racks onto the instrument.
- you do not import data from a host computer.
- you are using the system in demo mode (► *Chapter 9.10 Simulation mode/demo mode, p. 166*).

If you have already loaded the sample racks and assigned assays to patients as described in ► *Chapter 8.3 Loading patient samples and assigning tests, p. 68*, or if you have imported patient data and test orders from a host computer, the system will automatically suggest a worklist; you can refer directly to ► *Chapter 8.4 Create a worklist, p. 74*.

Create a worklist

1) Click on the New Worklist button.

→ An empty SET-UP PANEL dialog is shown (► *Chapter 9.3.1 Set-up Panel Dialog, p. 134*).

2) Click on the Add Plate... button.

→ A new plate is added.

3) Click on the Add Assay... button.

→ The OPEN dialod is shown (► *Chapter 7.3 Loading (Open), p. 57)*.

4) Select the desired assay file.

→ The assay is added.

5) Click on the Add Patient... button.

→ The SELECT PATIENT(S) dialog is shown (► *Chapter 9.3.2 Add Patients, p. 137*).

6) Select the desired patient(s) and click on the OK button

The patient(s) are shown in the SET-UP PANEL dialog.

7) Optional:

   a) Click on the Add Assay... button to add a further assay to the (selected) plate.

   b) Click on the Add Patient... button to add further patients to the (selected) plate.

c) Click on the Add Plate... button to add further plate.

d) Click on the Edit... button to change the name of the (selected) plate.

e) Move the plate order:

The EUROIMMUN Analyzer I-2P will process plates in order from top to bottom as shown in the list. The order of the plates can be edited by clicking on the Move Up / Move Down buttons

8) When you are finished, click OK.

✓ The EUROIMMUN Analyzer I-2P -Software shows the LOT-SPECIFIC VALUES FOR: dialog (► *Chapter 8.5 Lot-specific Values, p. 75*).

NOTE

The EUROIMMUN Analyzer I-2P is a two-plate system. However, in order to provide a longer walk-away time, a third plate can be initially loaded, which will be processed usually after the processing of the first plate is finished. Furthermore, it is possible to load more plates during the run. Please refer to the section on continuous loading (► *Chapter 9.6 Continuous Loading, p. 158*) if you add plates during a run.

Maximum number of plates included in a worklist at the same time:

It is normally possible to add up to 3 plates in the same worklist. This depends, however, on the assays and on the number of samples to be processed.

In most cases, the system will then schedule the run so that the processing of the last plate begins only when the processing of the first plate is finished.

If you need to process heavy workloads, it is sometimes preferable to do two consecutive runs (see the end of ► *Chapter 8.6.2 Schedule, p. 79* on how to optimise your workflow) or to rely on continuous loading (► *Chapter 9.6 Continuous Loading, p. 158*) rather than add a maximum number of plates in the same worklist.

9.3.1 Set-up Panel Dialog

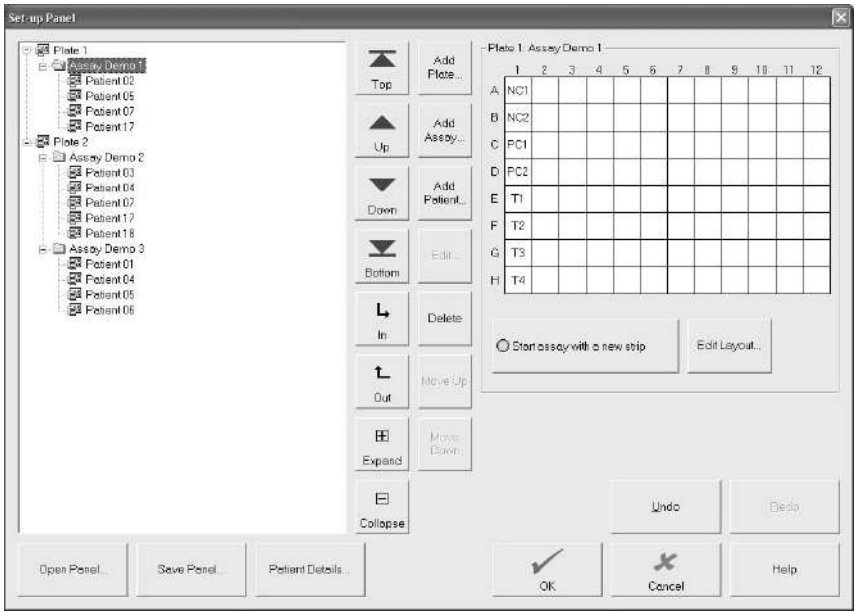


Fig. 49: Set-up Panel dialog with two plates

Function	Description
Plates, assay and patients	In the tree, all plates are displayed which will be used in the worklist. Later, they are processed in top-down sequence. The individual plates can be selected by clicking on them. After the selection, the assignment is indicated in the plate layout. After clicking on the ⊞ sign of a plate or double clicking on the plate, all assays are displayed which will be used on the selected plate. The individual assays can be selected by clicking on them. After clicking on the ⊞ sign of an assay or double clicking on the assay, all patients are displayed which will be processed with the selected assay. The individual patients can be selected by clicking on them.
Add Assays...	With this function, you can add a new assay to the (selected) plate. After clicking on the function, an OPEN dialog for the selection of assays is opened automatically (► *Chapter 7.3 Loading (Open), p. 57*).
Add Patient...	With this function, you can add a new patient to the (selected) assay. After clicking on the function, the Select Patient(s) dialog for selecting the patient(s) is opened automatically (► *Chapter 9.3.2 Add Patients, p. 137*).
Add Plate...	With this function, you can add a new plate to the worklist. After clicking on the function, the new plate is added.
⊟ Collapse	Closes the complete plates/assays/patients tree.
Delete	With this function, you can delete a selected plate, assay, or patient from the worklist.

Function	Description
Edit...	This function allows you to change the plate ID (name) of a (selected) plate. Take care that the plate ID is clear and unique, i.e. is not used by another plate in this worklist.
Edit Layout...	This function opens the ASSAY LAYOUT dialog for a selected assay (► *Chapter 8.6.3*). The software ignores any plate layout given by the "Assay Layout" after import of a plate layout when processing the plate (also recalculation of the results).
Expand	Opens the complete plates/assays/patients tree.
In	Opens the lower part of the selected plates/assays/patients tree.
Move Down	This function changes the sequence of the plate processing. A plate can be processed **after** another one.
Move Up	This function changes the sequence of the plate processing. A plate can be processed **before** another one.
Open Panel...	Opens a saved worklist (► *Save or Open a Worklist, p. 141*).
Out	Closes the lower part of the selected plates/assays/patients tree.
Patient Details...	Opens the dialog PATIENT EDITOR (► *Chapter 9.2 Complete Patient Editor, p. 125*).
Save Panel...	Saves the created worklist (► *Save or Open a Worklist, p. 141*).
Start assay with a new strip	By activating this function, you can make sure that the selected assay starts in a new column, even if there are unused wells left in the previous column (► *Chapter 9.3.3 Processing Several Assays per microplate, p. 137* and ► *Strip Management /Optimising the Plate Layout, p. 139*). This function is activated by default.

Plate Layout

The upper right-hand side of the Set-Up Panel dialog shows the plate layout. The 96 cells in this table represent the actual test plate with its 96 wells. Columns are numbered from 1 to 12, and rows are lettered from A to H so that each individual cell/well has a unique location (e.g. E5).

Click on a test name to see how many strips are needed for the assay and where they should be placed. We recommend performing the plate setup as shown. Complete all required strips with empty wells.

In the plate layout, sample types are precisely labelled (B1, NCQ1, T3, etc.).

Label	Description
B	Blank value
S	Standard (calibrator)
T	Sample

Label	Description
NCQ / NCS	Negative control
PCQ / PCS	Positive control
C	Cut-off calibrator

Tab. 34: Plat layout

To help distinguish them visually, a set colour is generally assigned to each sample type, e.g. S well are red, PC wells are blue, NC wells are green, T wells are black, etc. These colours are assigned when the assay is defined.

Editing the Plate Layout

The PLATE LAYOUT is the way in which the different samples (patient samples (T) but also negative control (NC), positive control (PC), standards (S), etc.) are arranged on a test plate.

This arrangement is specifically defined for each assay when the assay is created, as described in the (*Assay Programming Manual* (or ask your EUROIMMUN-service engineer)).

NOTE

If you are using a EUROIMMUN pre-defined assay, you should not attempt to edit the Plate Layout at this stage.

NOTE

Even if you are using your own assays, it is generally not recommended to alter the Plate Layout at this stage as any changes made will apply only to this run (the assay file itself will not be changed so that if you process the assay again later, the original layout will be applied).

NOTE

If you are not processing full plates, the best way to optimize the Plate Layout at this stage is to process several assays per plate and eliminate "empty" wells as explained in ► *Chapter 8.6.3 Plate Layouts, p. 81.* This is possible whether you are processing EUROIMMUN pre-defined assays or any other assays.

9.3.2 Add Patients

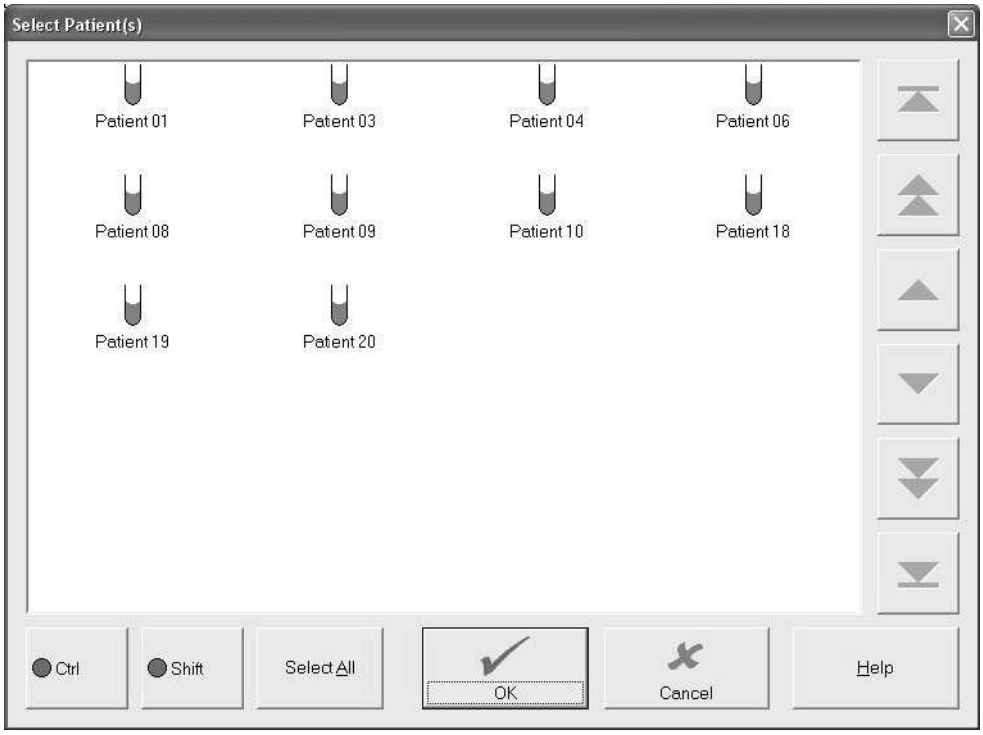


Fig. 50: Select Patient(s) dialog

Function	Description
Select All	This function allows you to automatically select all samples that have already been assigned to a test.

NOTE

If the SELECT PATIENT(S) dialog is empty when it opens, this means that you have not yet assigned this particular assay to any patients as explained in ► *Chapter 9.2 Complete Patient Editor, p. 125* . You can click the Patient Details button in the SET-UP PANEL dialog and do this now. If necessary, refer first to the explanations given in that section.

9.3.3 Processing Several Assays per microplate

Combining several assays on the same plate is a way to save time (and test plates) if you intend to test several different assays on a fairly small number of patients (e.g. 8 assays on 20 patients). It is also done on a regular basis for some tests, e.g. Toxo IgG and Toxo IgM.

The EUROIMMUN Analyzer I-2P system allows you to combine several assays on the same test plate but only if the following conditions are met:

Assays can be combined on the same plate only if they have a compatible assay structure, i.e. the same parameters for incubation steps, shake steps,

the same wash reagents, reading parameters, etc. and belong to the same assay group.

NOTE

If one of the assays you intend to combine requires the use of unstable reagents, it is best to place it as the first assay on the plate.

NOTE

Avoid combining assays with Plate wash mode and assays with Strip wash mode on the same plate! This could result in a delayed final aspiration including on the Plate wash mode assay.

Compatible Assay Structure /-Parameters

To check whether the assays you intend to combine on the same plate have compatible assay structures, you can either open these assays and review their respective parameters as described in ► *Chapter 8.3 Loading patient samples and assigning tests, p. 68* or use the system to check their compatibility automatically.

If the assays you have tried to combine on the same plate are compatible, the Worklist window is displayed normally (plate status is Not Loaded).

NOTE

The EUROIMMUN Analyzer I-2P software does not check compatibility of shake steps. If an assay that does not need shaking is combined with a second assay that needs shaking, the plate will be shaken.

If the assays you have tried to combine are not compatible, a warning message is displayed telling you why these assays cannot be combined on the same plate.

If you click on the OK button on the warning message an Error will appear as the status of the respective plate in the Worklist window. To correct the worklist definition and assign each assay to a different plate, go back to the SETUP PANEL dialog (► *Chapter 9.3 Create your own worklist, p. 131*).

Assay-Combination Groups

Assay combination groups are intended for assays that are commonly processed together. Assigning assays to the same assay group serves to confirm to the system that these assays can be combined on the same plate. If assays belong to different combination groups, the system will never allow them to be processed on the same plate (even if their parameters are compatible).

For detailed information see *EUROIMMUN Analyzer I-2P Assay Programming Manual* (or ask your EUROIMMUN service engineer).

Automatic Worklist Definition

If you import worklist/test orders from the LIS and you use barcoded samples, as soon as you load new samples on the instrument, the system automatically suggests a suitable worklist to process the samples you just loaded (► *Chapter 8.4 Create a worklist, p. 74*). This also applies when you reload samples in an on-going worklist using the continuous loading procedure (► *Chapter 9.6 Continuous Loading, p. 158*).

With the default settings, whenever a worklist is automatically generated by the system, the system always tries to combine as many assays as possible on each plate (provided, of course, that the assay parameters are compatible and that the assays belong to the same assay combination group).

NOTE

Note, however, that this redefinition applies to the current worklist only. If you decide that there are some assays which you never want to combine on the same plate (even though they have compatible structures), you have to change their combination group as described in the *EUROIMMUN Analyzer I-2P Assay Programming Manual* (ask your EUROIMMUN service engineer) so that they belong to different groups.

Strip Management /Optimising the Plate Layout

If you use coated microplates with removable strips, when combining several assays on the same plate, you have to make sure that:

- In the software, each assay starts on a new strip.
- You rearrange the microplate you intend to load so that the strips correspond exactly to what has been defined in the software.

New Strip

The SET-UP PANEL dialog includes a Start assay with a new strip checkbox (► *Chapter 9.3.1 Set-up Panel Dialog, p. 134*).

If you enable the Start assay with a new strip (default), you can see that Assay2 now starts on Strip 5 only. This is required if you use coated plates with removable strips. You can then prepare your microplate accordingly.

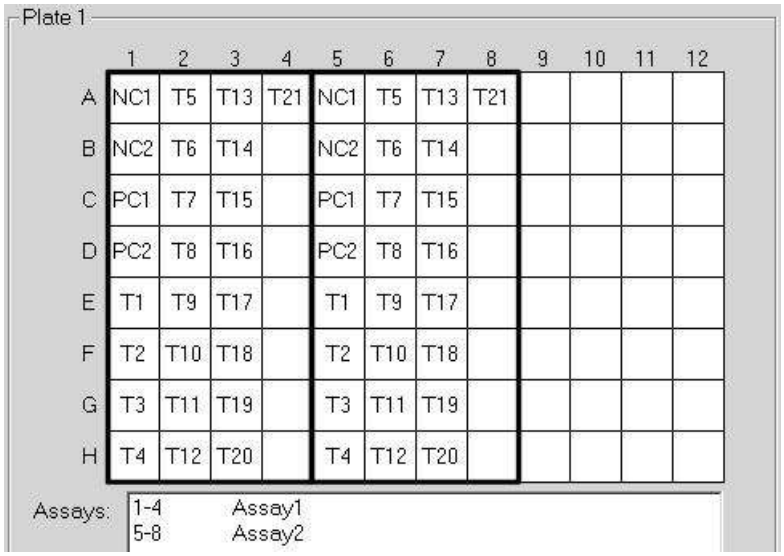


Fig. 51: Two Assays on a plate (start assay with a new strip)

If you combine two assays on the same plate **without** checking this box, the second assay starts immediately after the last well of the first assay as shown below: Assay2 starts in well B4, immediately after the last sample well for Assay1.

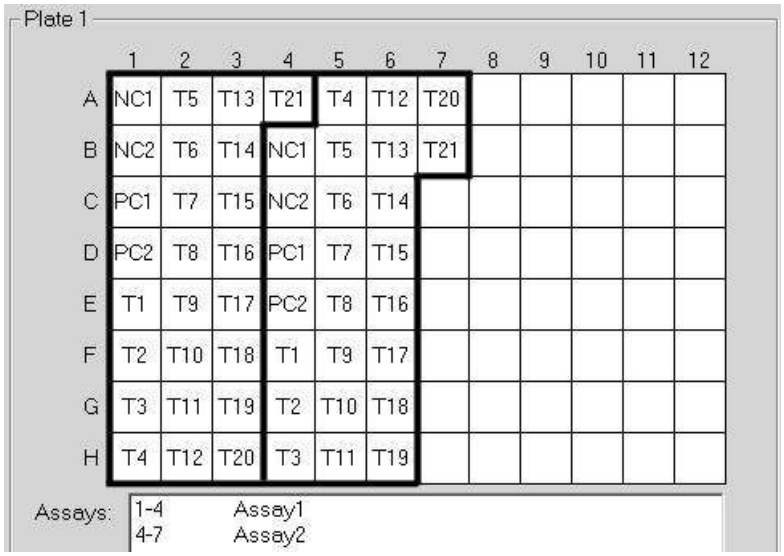


Fig. 52: Two Assays on a plate (start assay without a new strip)

Layout Optimisation

However, starting each assay on a new strip means you may have unused wells on a test plate, as in the example above where only one well is used respectively on Strip 4 and Strip 8. This means that you will "loose" the seven unused wells located on each of these strips. In that case, it might make sense to decide to test sample T21 (for each assay) in a later run. If you use microplates with break-off wells, you can complete the strip with empty wells or wells that have already been used (dummies).

See ► *Chapter 9.3.1 Set-up Panel Dialog, p. 134* to remove sample T21 from the worklist/plate

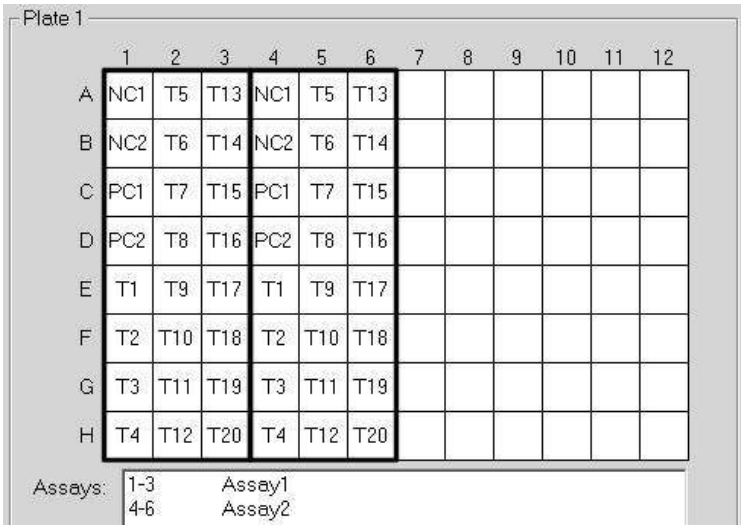


Fig. 53: Two Assays on a plate (without sample T21)

You now have an optimised layout and you can prepare your microplate accordingly.

Results

Even if you run several tests on one plate, the system will only generate one results file per plate. The results for each test are listed in this file in sequence, in the same order as on the plate (i.e. the full results for Assay1, then the full results for Assay2, etc.).

9.3.4 Save or Open a Worklist

If you generally use the EUROIMMUN Analyzer I-2P system for the same assays or for repetitive jobs, you can shorten the worklist creation process by reusing previously defined (and saved) worklists (also called panels).

NOTE

When a worklist is saved, the system stores only the plate and assay arrangements but not the Patient IDs. This is because it is assumed that if the worklist file is used again in a new worklist and for a new test run, it will normally be for a new set of patients. This is why, even if you use an existing worklist file to create a new worklist, you have to redo the Add patient step.

Save a worklist

1) Create a worklist with your plate and assay arrangement.
2) In worklist window:
   a) For new or changed worklists:

Click on the Save button or select the File > Save Panel menu item.

b) For changed worklists with changed file name:

Select the File > Save Panel as menu item.

3) Enter the file name and save the worklist (► *Chapter 7.4 Save, p. 60*).

Load a worklist

1) Click on the Open button.

2) Click on the Worklist Files (*.wor) symbol.

3) Select your desired worklist file and load it (► *Chapter 7.3 Loading (Open), p. 57*).

4) Select patient(s) for the plates.

5) Start the worklist.

9.4 Worklist Options

Required access rights: Edit Worklist Options

After a worklist has been prepared and before it is started it is possible to check and/or edit the worklist processing options. By default, the system uses the previously defined worklist options. Some options are locked and cannot be changed even by supervisors (users with full access rights).

Click on the Edit Options... button or select the Edit > Panel Options... menu item to open the WORKLIST OPTIONS dialog.

The WORKLIST OPTIONS dialog is shown with several registers:

- **Scheduling** (► *Chapter 9.4.1 Worklist Options: Scheduling, p. 142*)
- **Before**: Before worklist is started (► *Chapter 9.4.2 Worklist Options: Before Worklist is started, p. 144*)
- **During**: During worklist processing (► *Chapter 9.4.3 Worklist Options: During Worklist processing, p. 146*)
- **After**: After worklist is finished (► *Chapter 9.4.4 Worklist Options: After Worklist is finished, p. 147*)

9.4.1 Worklist Options: Scheduling

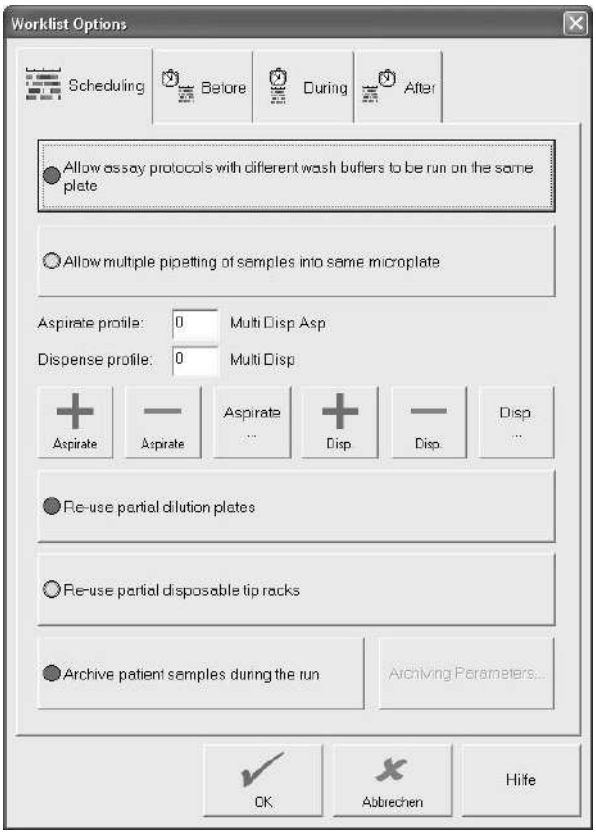


Fig. 54: Worklist Options dialog - register Scheduling

Option	Description
Allow assay protocols with different wash buffers to be run on the same plate	Worklist definitions are permitted where different wash buffers are being used. This option should always be disabled.
Allow multiple pipetting of samples into same microplate	If a sample is to be pipetted into more than one well on a plate, this option allows this sample to be pipetted with only one tip into all wells required together. Risk: Drift constraints! See note below!
Archiving Parameters	Not used
Archive patient sample during the run	Not used
Aspirate profile	Only used for multipipetting: Select the desired aspirate profile. The aspirate profile you define here will apply to both samples and reagents (controls, standards or sample buffer).
+ Aspirate	Shows next aspirate profile.

Option	Description
— Aspirate	Shows previous aspirate profile.
Aspirate...	Shows the selection dialog with all aspirate profiles.
Dispense profile	Only used for multipipetting: Select the desired dispense profile. The dispense profile you define here will apply to both samples and reagents (controls, standards or sample buffer).
+ Disp.	Shows next dispense profile.
— Disp.	Shows previous dispense profile.
Disp. ...	Shows the selection dialog with all aspirate profiles.
Re-use partial dilution plates	Partially used dilution plates are registered and re-used for later worklists. (default)
Re-use partial disposable tip racks	Partially used tip racks are registered and re-used for later worklists. See ► *Chapter 8.7.6 Load Tip Racks, p. 99* on when to select this option and when not to select it (default).

Multi Pipetting

NOTE

Do not use the multipipetting function if you use EUROIMMUN assays or other assays where the functions Eliminate assay drift caused by this operation (pipette or dispense step) or Time incubation from start to previous assay step (incubate step) are enabled; see *Assay Programming Manual* (ask your EUROIMMUN service engineer)!

Note that if this option has been selected, samples that are pipetted in parallel within the plate are pipetted before all other samples on the same plate.

This makes this option strictly incompatible with all assays that include the "assay drift compensation" feature (see *Assay Programming Manual* (ask your EUROIMMUN service engineer).

This can also create unsuitable pipetting sequences when:

- only some samples are assigned to both tests.
- the multiple determination option (► *Chapter 9.3.2 Add Patients, p. 137*) has been used for some or all samples.
- the assays include a predilution step.
- the order in which the controls have to be dispensed (i.e. strictly before or strictly after the samples) must not be changed.

If in doubt, do not select this option or call your EUROIMMUN Application Engineer for assistance.

9.4.2 Worklist Options: Before Worklist is started

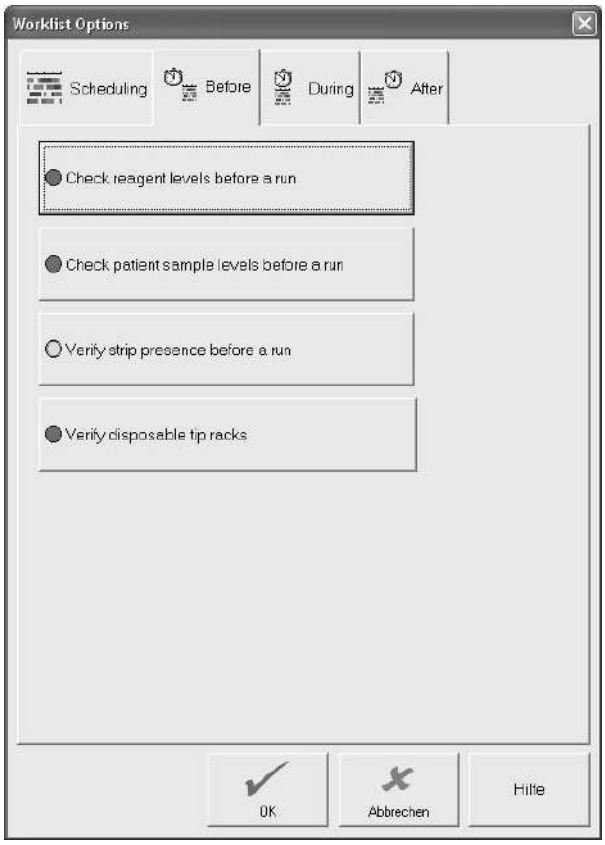


Fig. 55: Worklist Options dialog - Before

Option	Description
Check patient sample levels before a run	► *Sample Volume Check , p. 107*
Check reagent levels before a run	► *Reagent Volume Check, p. 106*
Verify disposable tip racks	When starting to process the worklist, the system checks the size of the first tip of each rack to make sure the racks have been loaded as displayed in the Load dialog box (i.e. long tips and short tips have not been mixed up). ► *Sample Volume Check, p. 107* .
Verify strip presence before a run	Each time a test plate is loaded, it is first moved into the photometer so that the system can check that it includes the correct number of strips. This is useful especially when using plates with removable strips. This item is checked by default and may not be unchecked (even by users with supervisor status).

9.4.3 Worklist Options: During Worklist processing

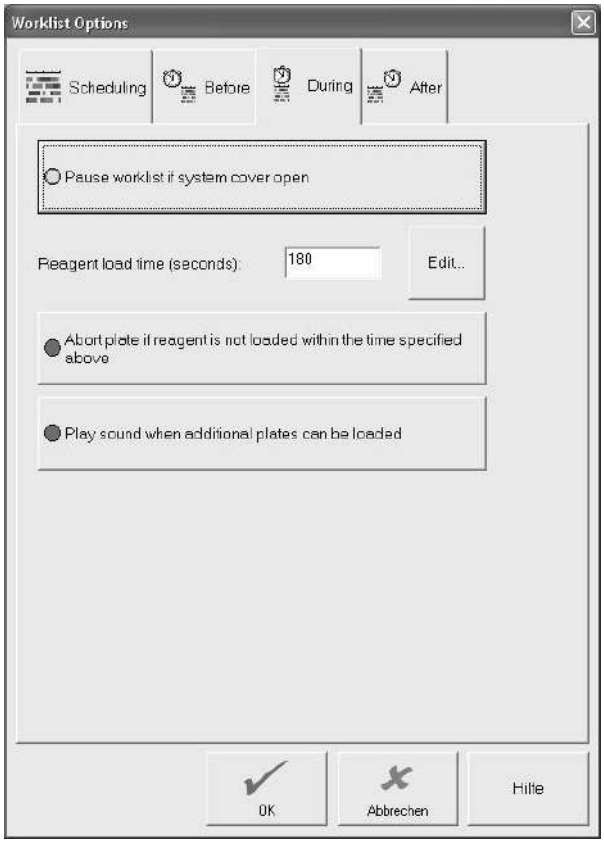


Fig. 56: Worklist Options dialog - During

Function	Description
Abort plate if reagent is not loaded within the time specified above	Aborts the respective plate processing if the reagent is not loaded within the time specified above. Check this item if you intend to use EUROIMMUN Analyzer I-2P as a "walk away" system (e.g. at night). That way, the respective plate will be aborted but the rest of the run will continue.
Pause worklist if system cover open	Stops the instrument immediately when the instrument cover has been opened. This item is checked by default and may not be unchecked (even by users with supervisor status).
Play sound when additional plates can be loaded	An acoustic signal will warn the operator when additional plates can be loaded to a running worklist (► *Chapter 9.6 Continuous Loading, p. 158*).

Function	Description
Reagent load time	Enter the maximum reagent load time in seconds. This applies when unstable reagents have to be loaded while a worklist is being processed (► *Chapter 8.7.4 Load Unstable Reagents, p. 97*). The system will warn the operator beforehand (warning message in the software and acoustic signal) and pauses during the specified load time. This load time should be long enough to allow correct loading but not so long as to affect the processing of the run. Recommended time is 180 seconds (3 minutes). Entries between 0 and 1000 are accepted.

9.4.4 Worklist Options: After Worklist is finished

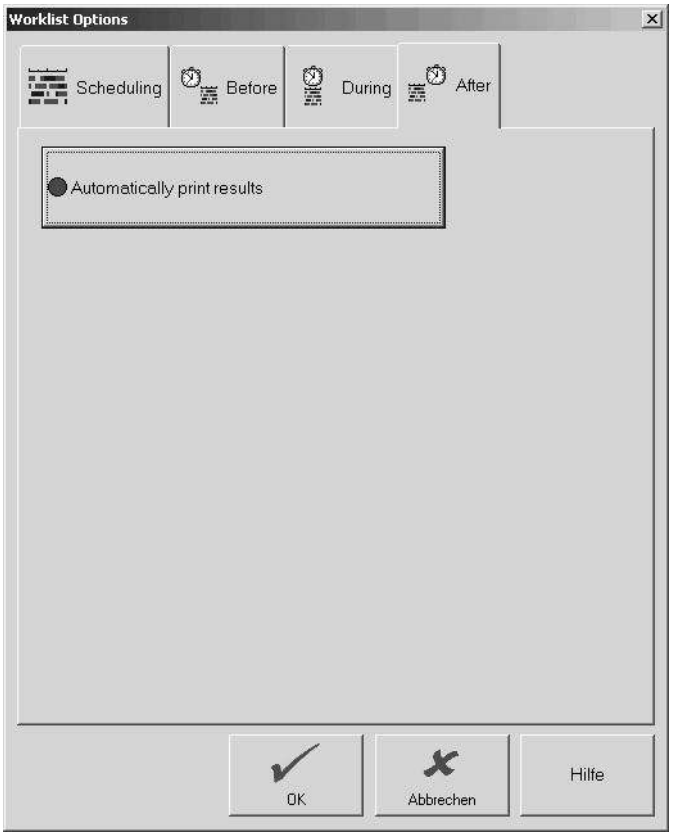


Fig. 57 Worklist Options dialog - After

Options	Description
Automatically print results	Check this option if you want the system to print the result file as soon as it is generated, i.e. as soon as the processing of the respective plate is over.

9.5 Advanced Options

9.5.1 Optimise the Schedule

When you have finished defining your worklist (in the SET-UP PANEL dialog) and your worklist options, the EUROIMMUN Analyzer I-2P software calculates the best way to combine the various steps of each process, while maintaining the plate processing sequence you defined.

If you want to optimise this process even further by changing the processing order of the various plates, proceed as follows:

1) Select Edit > Optimise or click the buttons Other Options... > Optimise. The system tries all possible plate orders and automatically reschedules the run using the plate order with the shortest overall processing time.

NOTE

For very complex worklists, the optimisation process may take a long time while the system calculates all possible combinations. If no solution has been reached within a few minutes, it is recommended to abort the process (click on the Abort button in the OPTIMISING dialog) and reschedule the worklist manually if necessary.

Manual optimisation

If you want to optimize the processing manually:

1) Go back to the SET-UP PANEL dialog by selecting Edit > Panel Definition....

2) Edit the worklist by selecting the elements you want to change and using the Edit, Delete, Move Up / Move Down buttons (► *Chapter 9.3.1 Set-up Panel Dialog, p. 134* for more information on these buttons).

3) Click the OK button.

Planning a Daily Workload

Optimising the schedule is particularly important if you want to process a large number of samples in a minimum time (e.g. processing 100 samples with several assays and within an 8-hour work shift). In such cases, determining the best schedule may require you to try out many different solutions (Some assays are easier to combine than others. Sometimes it is better to do two runs. Sometimes you want to avoid operator intervention at a certain time of day, etc.). If the right schedule is not obvious, you can use Demo Mode (► *Chapter 9.10 Simulation mode/demo mode, p. 166*) to do all your planning/optimising and to simulate the various possibilities.

9.5.2 Advanced Load Options

Save/Open Reagent Layout

If you are using non-barcoded reagent bottles and if you are generally repeating the same tests over and over again, you may try to shorten the

reagent allocation process by using the Save Reagent Layout... and Open Reagent Layout... function. The system will not check opened reagent layouts.

⚠ WARNING

Incorrect reagent layout

Incorrect analysis result

> Make sure that positions are correct!

Save

The first time you use the desired worklist, load the reagents on the instrument and allocate them manually in the LOAD dialog as described in ► *Allocate Non-barcoded Racks and Samples, p. 152*

1) Click on the Save Reagent Layout... button.

2) After clicking on the function, the SAVE AS dialog is opened (► *Chapter 7.4 Save, p. 60*). Enter an appropriate file name and save the reagent layout. (Reagent layout files have the extension *.rea.)

Open

1) The next time you want to process exactly the same tests with the same reagents (and new patients samples of course), in the LOAD dialog, click on the Open Reagent Layout... button.

2) In the OPEN dialog (► *Chapter 7.3 Loading (Open), p. 57*) which is then displayed, select the desired (*.rea) file and open it. All the reagents are automatically allocated. Now fit the reagent bottles in the racks making sure you reproduce exactly the layout that is displayed in the Load dialog.

ⓘ NOTE

If you intend to use this function on a standard basis, include small labels on the rack itself or copy and fill in the rack layout forms in order to keep a "reference picture" of each saved layout.

Scanner Configuration

Sample Rack Tab

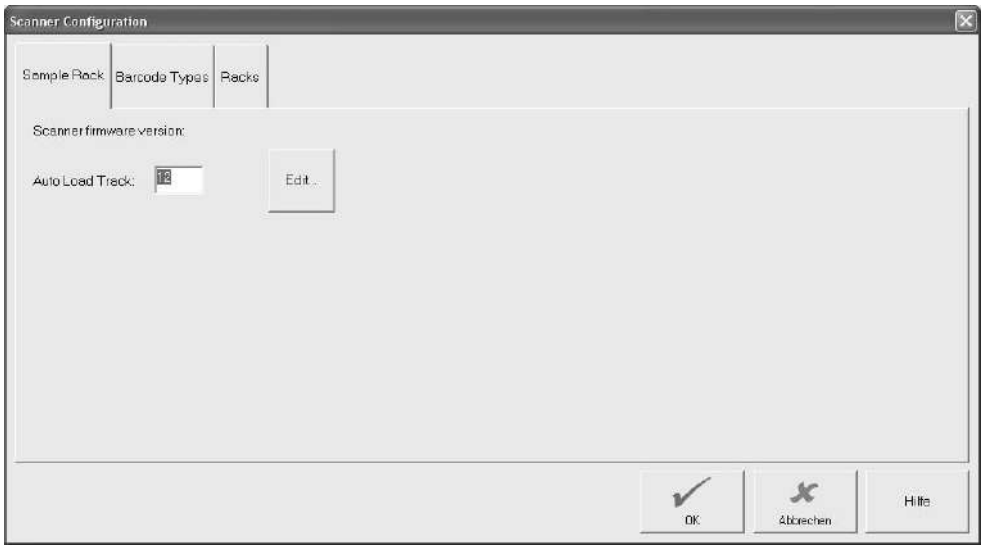


Fig. 58: Scanner Configuration dialog: Sample Rack tab

Option	Description
Auto Load Track	Enter the first line to be loaded. Also refer to ► *The system requires the loading process to be carried out from right to left., p. 233* .

Barcodes Type tab

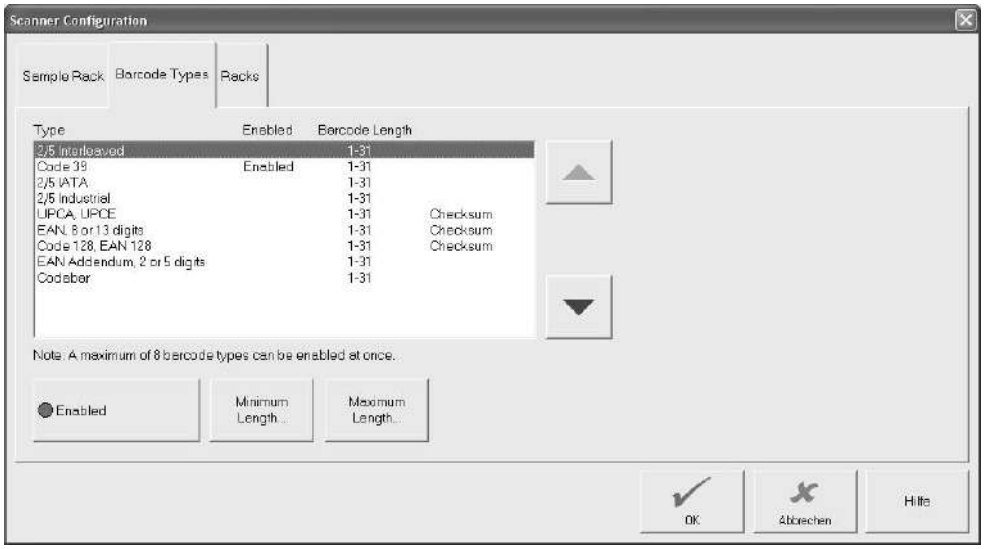


Fig. 59: Scanner Configuration dialog: Barcode Types tab

Option	Description
List	List of all barcode types that can be read by the integrated barcode scanner. If a barcode type is selected, the scanner is able to read the respective barcode type. It is possible to select several barcode types but the more checkboxes are selected, the slower and less accurate the reading will be. One barcode type is always selected and cannot be deselected (barcode type code 39 used for EUROIMMUN Analyzer I-2P racks). The following barcode types can be used for samples and reagents to be processed on the EUROIMMUN Analyzer 2P system: 2/5 Interleaved Code 39 (used for EUROIMMUN racks), 2/5 IATA 2/5 Industrial UPCA, UPCE EAN 8 or 13 digits, Code 128, EAN 128 (used for EUROIMMUN reagents), EAN Addendum, 2 or 5 digits Codabar Typically, when the system is installed, your EUROIMMUN service engineer configures the barcode scanner to accept the barcode types you generally use on the samples you process. If you need to change the preconfigured barcode settings later on, see ► *Using several Barcode Types, p. 190* .
Enabled	Enables a barcode type in the list.
Minimum Length... / Maximum Length...	Minimum and maximum character length of each barcode type. **NOTE** Generally, if you do not know these values, you can leave the default values. **NOTE** Wrong settings could lead to incorrect barcode values. For example: **Max.** = 6 Barcode 1: 2007P45 Barcode 2: 2007P48 Result: 2007P4 for both barcodes!

⚠ WARNING

Changing the barcode setting

Incorrect analysis result

> Only use the software-supported barcodes.
> If you change the barcode settings (e.g. length) these must be validated for your barcodes.

Racks tab

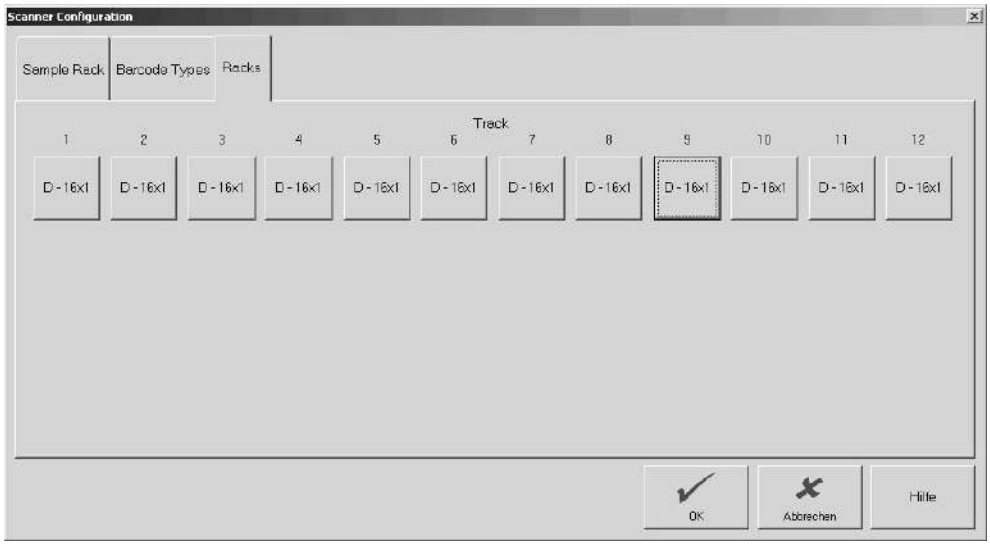


Fig. 60: Scanner Configuration dialog: Racks tab

Number	Description
Racks	If a rack is identified through barcodes, the rack type is automatically displayed. If identification via barcodes was not possible (damaged or dirty barcodes), you have to select the rack type manually. With three-track racks the same rack type must occupy the respective tracks.

Allocate Non-barcoded Racks and Samples

If you are using non-barcoded racks (or racks with damaged or dirty barcodes), the central section of the Load dialog is empty when it opens:

1) Click on the Scanner Setup... button at the bottom of the LOAD dialog. This will open the SAMPLE RACK tab in the SCANNER CONFIGURATION dialog (► *Scanner Configuration, p. 149*).

2) In the Rack tab, use the lane buttons to specify which type of rack you have loaded or intend to load on which track.

3) Confirm with OK.

NOTE

Make sure that the position to which the system or the user allocates a sample on the screen corresponds exactly to the real position of the corresponding patient tube in the rack! This is very important as wrong allocation is equivalent to mixing up samples.

Now the racks are depicted as empty (rows of blank dots) in the rack system area of the Load dialog. The required samples are depicted as unallocated resources. Allocate the samples as described in ► *Chapter 8.7.2 Functions of the Load, p. 92*.

Replacement barcode labels for sample racks can be ordered from EUROIMMUN.

9.5.3 Test Plate Removal

NOTE

There is no need to use this function (► *Chapter 8.8.7 Emergency Stop/Cancelling a Run, p. 112*).

If you notice a serious problem on one plate while the run is being processed, you can use a special procedure to remove this plate from the instrument.

This is an emergency procedure only. It should not be used on a standard basis. Removing the plate may affect the results.

Removing the test plate

1) From the Worklist window select Utilities > System Utilities....

→ The SYSTEM UTILITIES dialog is displayed.

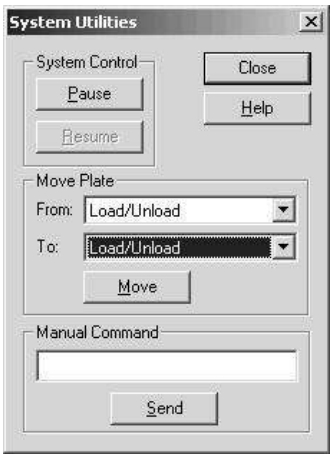


Fig. 61: System Utilities dialog

2) In the System Control field, click on the Pause button.

3) In the Move Plate field, use the two drop-down lists to specify how to move the plate.

- In the From field, select the present location (washer, photometer, incubator, pipetting area...) of the plate you want to remove from the system.
- In the To field, select Load/Unload so that the plate transport unit brings the plate to its unloading position.

4) Click on the Move button.

5) In the System Control field, click on the Resume button.

6) Close the SYSTEM UTILITIES dialog with the Close button.

If you are able to correct the problem rapidly enough and you think it is worth reloading this plate and processing it further:

7) From the Worklist window, select System Utilities in the Utilities menu.

→ The SYSTEM UTILITIES dialog is displayed.

8) In the System Control field, click on the Pause button.

9) In the Move Plate field, use the two drop-down lists to specify how to move the plate.

- In the From field, select Load/Unload.
- In the To field, select the module where the transport unit should move the plate to resume its processing (if you did not close the SYSTEM UTILITIES dialog after unloading the plate, the From and To fields should already be correctly set - by default, the system reverses the locations selected when unloading the plate).

10) Click on the Move button.

11) In the System Control field, click on the Resume button.

12) Close the SYSTEM UTILITIES dialog with the Close button.

9.5.4 Editing/Recalculating the Results

If you think the results are not entirely satisfactory, the EUROIMMUN Analyzer I-2P software allows you to edit and/or recalculate them before saving, printing or exporting them.

To edit the results, select one of the following functions:

- Outliers
- Parameters/Lot-specific Values
- Assays

These items are enabled only when a result file is open.

Editing Outliers

NOTE

Required access rights: Manually remove outliers

The Outliers function allows you to manually remove from the results some OD values which you think are not consistent with the test (e.g. if some samples were not properly treated or processed) and should not be taken into account when calculating the results.

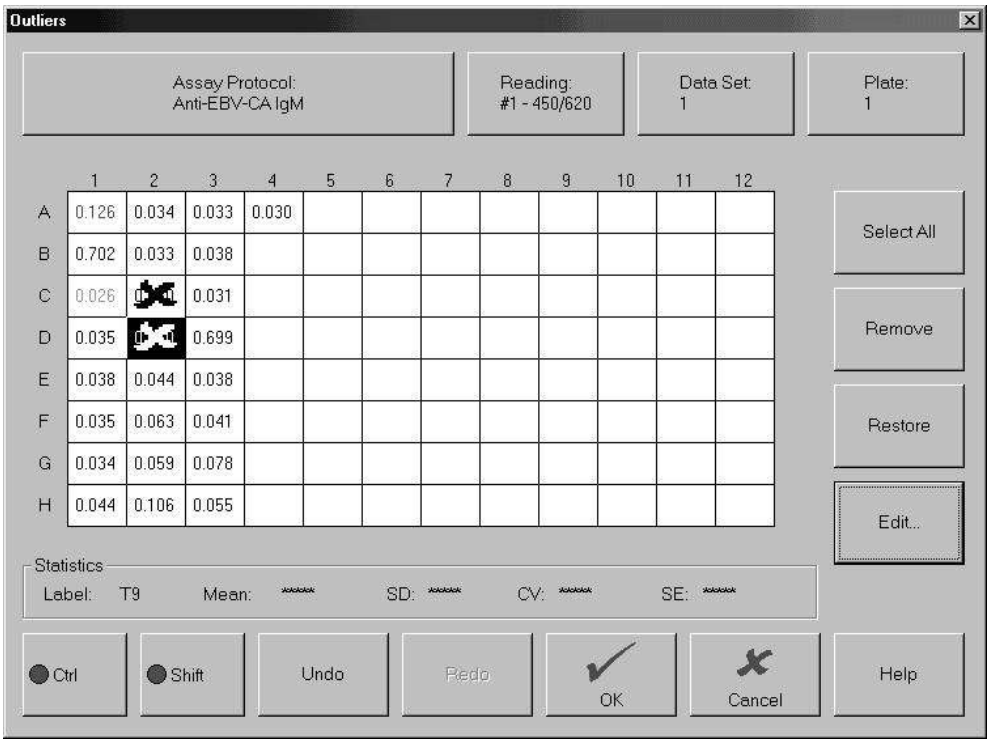


Fig. 62: Outliers dialog

Option	Description
Test name	Opens the Select dialog to choose a specific assay to change or edit the assay outliers. After the change, the Outliers dialog shows the measured wells for the selected assay.
Reading	The Reading button shows the filter(s) used for the reading.
Data Set	Not used
Select All	Selects all wells of the plate.
Remove	Removes the selected well from the calculation process.
Restore	Restores the removed well.
Edit...	Allows the user to change outliers. (password-protected)

A removed value is displayed crossed out. Conversely, if a value was removed from the calculation automatically by the software (for example, because of bad pipetting or dispense verification errors), you can choose to restore it.

Use

1) Click on the Outliers... button in the Result window.

2) Remove/edit the desired wells (► *Chapter 9.5.4 Editing/Recalculating the Results, p. 154).*

3) Click on OK.
The new result report includes the following comment: "Removed wells: ..."

4) Click on the Recalculate button to recalculate the results taking into account the changes you made. The new result report includes the following comment: "WARNING! Results have not been processed using the original assay."

Recalculating flagged Results

The Restore button of the OUTLIERS dialog can be used to force the system to calculate results for flagged samples or reagents that have automatically been removed from result calculation (e.g. when clicking the Ignore button if the liquid for a reagent or sample has not been identified during a run).

To do so:

1) In the original Result Report, display the Combined Report part.

2) Select the samples with a "NOTE" (flag).

3) If you want to recalculate some of these flagged samples, note their locations on the plate (layout labels).

4) Open the Outliers dialog and restore the corresponding wells (layout labels) as described above.

5) Recalculate the Result Report as described above. In the recalculated Result Report, the selected flagged results are now calculated but the original flags remain. It is the user's responsibility to check and validate such recalculated results.

Changing the Lot-specific Parameters

The Lot Data function (Lot Data button) opens the LOT-SPECIFIC VALUES DIALOG FOR: (► *Chapter 8.5 Lot-specific Values, p. 75*), by displaying the data of the reagents used for the individual assays. This lets you correct possibly incomplete lot data or edit some parameters.

When you click OK, the results are recalculated taking into account the changes you made. The new result report includes the following comment: "WARNING! Results have not been processed using the original assay."

Recalculation with another Assay

The Assay(s) button opens the CHANGE ASSAY PROTOCOL dialog.

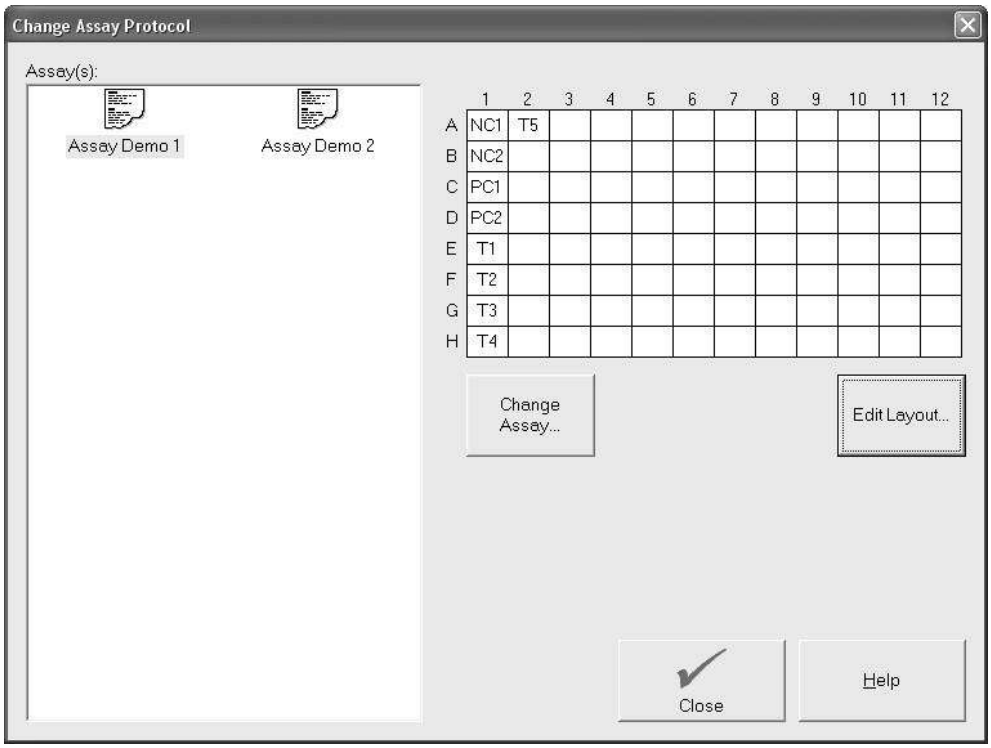


Fig. 63: Change Assay Protocol dialog

Option	Description
Assay(s)	Shows all used assay for the plate. After the change, the CHANGE ASSAY PROTOCOL dialog shows the used wells for the selected assay.
Change Assay...	Opens a dialog to select a different assay for calculation. After the change, the Change Assay Protocol dialog shows the labels of the used wells for the selected assay.
Edit Layout...	Opens the ASSAY LAYOUT dialog (► *Editing the Plate Layout, p. 136*).

This function allows you to recalculate the results with another assay protocol while retaining the original OD values of your plate. This can be useful, for instance, if you have several versions of the same assay, all with the same processing steps but with different evaluation steps or validation criteria.

1) Click on the Assays... button in the Result window.

2) Click on the Change Assay... button and change the assay protocol.

3) Click on ✓ Close.

When you click the on ✓ Close button in the CHANGE ASSAY PROTOCOL dialog, the results are recalculated. The new result report includes the following comment: “WARNING! Results have not been processed using the original assay."

Recalculating the Results

A recalculation of the results is performed automatically each time you use some of the editing functions described above.

But the EUROIMMUN Analyzer I-2P software also allows you recalculate results independently from the above editing operations.

To do so:

Click on the Recalculate button in the Result window. The new result report includes the following comment: “WARNING! Results have not been processed using the original assay."

This function is useful if you are editing or defining an assay. If you change the assay evaluation parameters and recalculate, the data processing of the raw data will be done using the new parameters (you need to save your assay changes before recalculating).

9.6 Continuous Loading

Required access rights: Edit running Worklists

Continuous loading is the process by which new patient samples and new test plates are inserted into the instrument while the instrument is running a worklist. The EUROIMMUN Analyzer I-2P allows this but only at certain times and under specific conditions.

The main advantage of continuous loading is that it allows the user to test more samples and/or to use more than 3 test plates in a single test run.

NOTE

An absolute maximum of 3 plates can be in the instrument at the same time. If you want to process more than three plates in the same run, you will first have to unload completely processed plates (the system will prompt you to do so).

Change of worklist options during continuous loading:

The only worklist option (► *Chapter 9.4 Worklist Options, p. 142*) that cannot be changed during continuous loading is the Reagent load time (which is greyed out). But any changes that are made are only applied to the new plates. So, the already loaded plates will continue to use the multipipetting mode in force at the time that they were scheduled.

9.6.1 Check Reloading Time(s)

The first thing to do if you intend to add new samples and new plates to an already running worklist is to check when this will be possible.

Reloading sample racks can be done at any time as soon as a LED opposite an already loaded sample rack is flashing. But the actual reloading process, in which the system recalculates the worklist and directs the operator to load (and allocate) the other required resources and the test plates, and unlocks the instrument accordingly, can only be done when the pipettor is not busy. The only time this is allowed is when all the plates on the current worklist are incubating.

Checking the reloading intervals

1) In the Worklist window of the current worklist, click on the Schedule button (► *Chapter 8.6.2 Schedule, p. 79*).

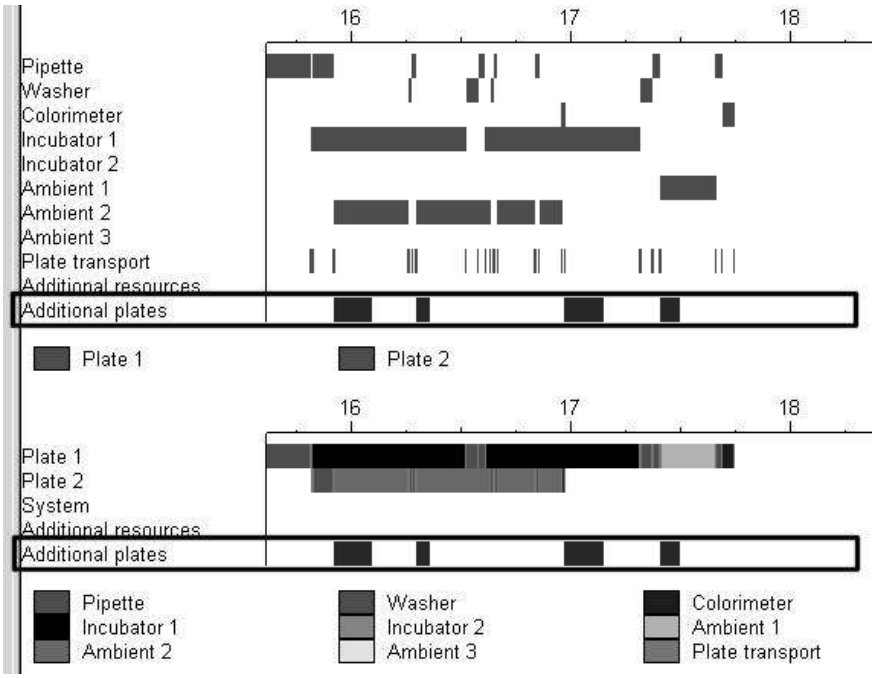


Fig. 64: Schedule (example)

2) In the Additional Plates line, the brown sections indicate the time intervals when reloading will be possible. This line is seen both in the module view and in the plate schedule view.

The more complex your current worklist, the more restrictive the available reloading intervals will be.

9.6.2 Preparing and Loading the New Patient Samples

1) Place your new samples in sample racks. If you are using barcoded sample tubes, make sure the barcode labels face right so that they can be scanned by the barcode reader when the rack is inserted.

2) As soon as an LED opposite a sample rack is flashing, you can remove the respective rack (the flashing LED indicates that the pipetting is over for this rack) and load a new rack at this position.

3) Repeat this step if you are loading more than one additional sample rack.

4) The system displays the tabular PATIENT EDITOR dialog (► *Chapter 8.6.2 Schedule, p. 79*). If the samples were barcoded, the Patient IDs are already entered in the first column. If samples were not barcoded or the barcodes could not be read, you have to enter the Patient IDs manually.

5) Using the drop-down lists, select the appropriate assays and assign them by checking the corresponding lines (► *Chapter 8.7.2 Functions of the Load, p. 92*).

6) Click on OK. If you reload more than one new sample rack, the system will display the tabular Patient Editor dialog again for each rack.

For this step, you do not need to wait until all the currently loaded plates are incubating. Therefore:

- Make sure all your sample racks are ready before you remove it.

9.6.3 Redefining the Worklist

Once you have loaded the additional sample racks and assigned assays in the Patient Editor dialog boxes as described above, the system automatically reschedules the current worklist to include the additional plates.

If the additional samples you loaded correspond to samples included in test orders downloaded from the LIS, assays are already assigned in the successive Patient Editor dialog boxes and you just need to close these dialog boxes by clicking the Close button.

You now need to confirm the automatically redefined worklist and specify the reagent lots for the additional tests.

To do so:

1) Click on the Edit Panel button. This opens the Set-up Panel dialog (► *Chapter 8.4 Create a worklist, p. 74*). In the left-hand side window, you can see the new plates that have been automatically added to the worklist.

NOTE

By default, when the systems reschedules the worklist to include the additional samples you have loaded it systematically tries to combine several assays on each plate (provided these assays have compatible processing parameters).

2) If you are satisfied with the automatically redefined worklist, click on the OK button to close the Set-up Panel dialog. If not, edit the worklist and then click on the OK button. The Lot-specification dialog is displayed for the first additional plate.

3) Check the lot numbers and expiration data for all assay kits and assay components for this plate and all additional plates and click on the OK button. Check the lot numbers and expiration data for all assay kits and assay components for this plate and all additional plates and click on the OK button.

9.6.4 Reloading other Resources

After you have clicked on the OK button in the Lot-specific Values dialog, the system checks its current status:

- If it is currently going through an incubation phase (for all plates), reloading is allowed and the Load dialog box appears. In that case:
  - Refill or add the resources (reagents, dilution plates, tip racks, wash buffer) required for the additional processing as shown in the Load dialog.

- Allocate them as if you were starting a new run. The new samples should already be allocated. If not, allocate them manually if they are not barcoded. If they are barcoded, open the door of the rack unit, withdraw the new racks and insert them again (► *Chapter 9.6.2 Preparing and Loading the New Patient Samples, p. 159)*
- After loading and allocation of all required resources, click on the OK button. The Load Plate dialog is displayed.

- If the system is currently (or will soon be) performing other steps of the running worklist (e.g. pipetting), a system busy warning message appears. In that case:
  - Click on the OK button to close the warning NOTE.
  - When you reach the allowed reloading time, click on the Edit Panel button once more and confirm it with OK. The Load dialog is displayed.

9.6.5 Reloading Test Plates and Further Processing of the Worklist

Load the required additional test plate(s) identical to the start of run (► *Chapter 8.7.9 Load Test Plates, p. 102*) and confirm with OK.

NOTE

If some of the plates of the initial worklist are already fully processed when you are ready to reload additional test plates, the system automatically brings them forward to the loading/unloading compartment so that you can remove them before loading the additional plates.

When you click on the OK button in the Load Plate dialog, the system recalculates and reschedules the worklist (interlacing or adding new plates/assays to be processed).

Further processing is then carried out in accordance with this new rescheduled worklist.

9.7 Patient result report

The patient result report shows a compact summary of the patient results of all selected assays.

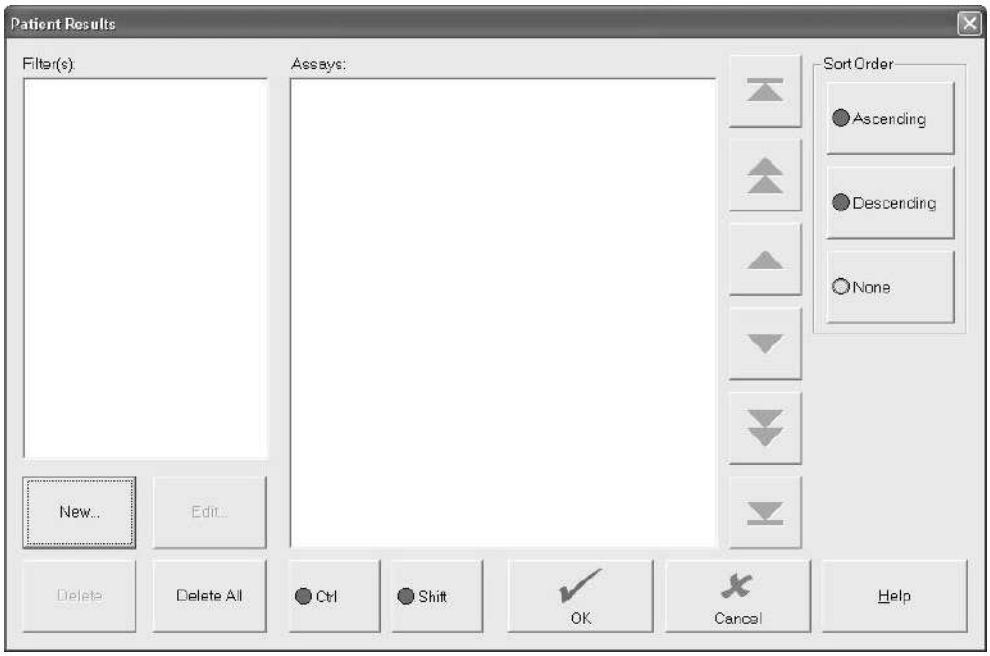


Fig. 65: Patient Results dialog

Option	Description
Assays	Shows all processed assays.
Delete	Deletes a selected filter.
Delete All	Deletes all filters.
Edit...	Allows a selected filter for the patient result report to be edited (► *Chapter 9.7 Patient result report, p. 161*).
Filter(s)	This area shows all existing filters for the patient result report. With a filter, the number of reported patients can be limited. Select a filter to use them. Click on a free position on the area to deselect the filter.
New...	Adds a new filter for the patient result report (► *Chapter 9.7 Patient result report, p. 161*).
Sort Order	The Sort Order field allows you to define the order in which the samples will be shown in the report. Selectable sort order: **Ascending** Sorted in alphanumeric ascending order (based on the sample IDs entered or read by the barcode scanner). **Descending** Sorted in alphanumeric descending order (based on the sample IDs entered or read by the barcode scanner). **None** The samples will be shown in the order in which they were added.

Proceed as follows:

1) Select File > New.

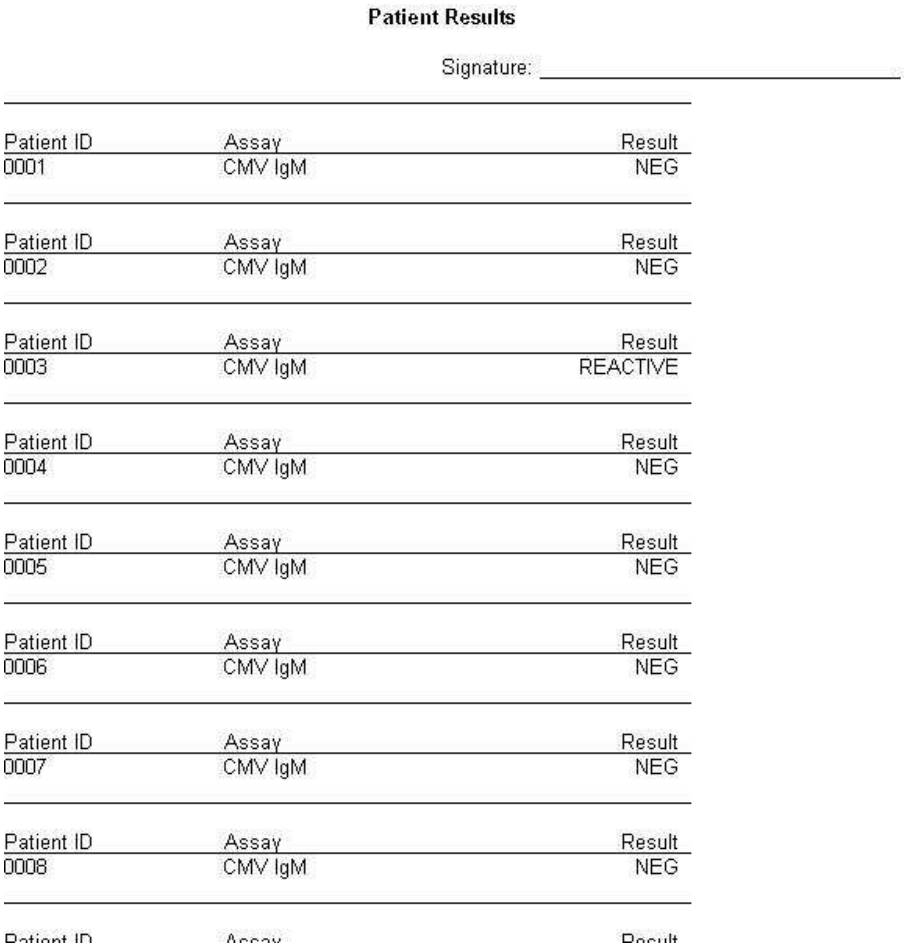
2) In the MAKE A SELECTION dialog, select the Patient Results Report symbol. This shows the PATIENT RESULT dialog.

3) Click on the New button to create a filter (e.g. only patient IDs between 0070 and 0100)

4) Select one or more assays.

5) Select the sort order (sorting) (► *Chapter 9.2 Complete Patient Editor, p. 125*).

6) Click OK to confirm the entries. The system shows you the patient result report.



Patient Results

Signature: _____

Patient ID	Assay	Result
0001	CMV IgM	NEG
0002	CMV IgM	NEG
0003	CMV IgM	REACTIVE
0004	CMV IgM	NEG
0005	CMV IgM	NEG
0006	CMV IgM	NEG
0007	CMV IgM	NEG
0008	CMV IgM	NEG

Fig. 66: Patient result report

9.7.1 Filter Configuration

This function lets you limit the number of reported patients.

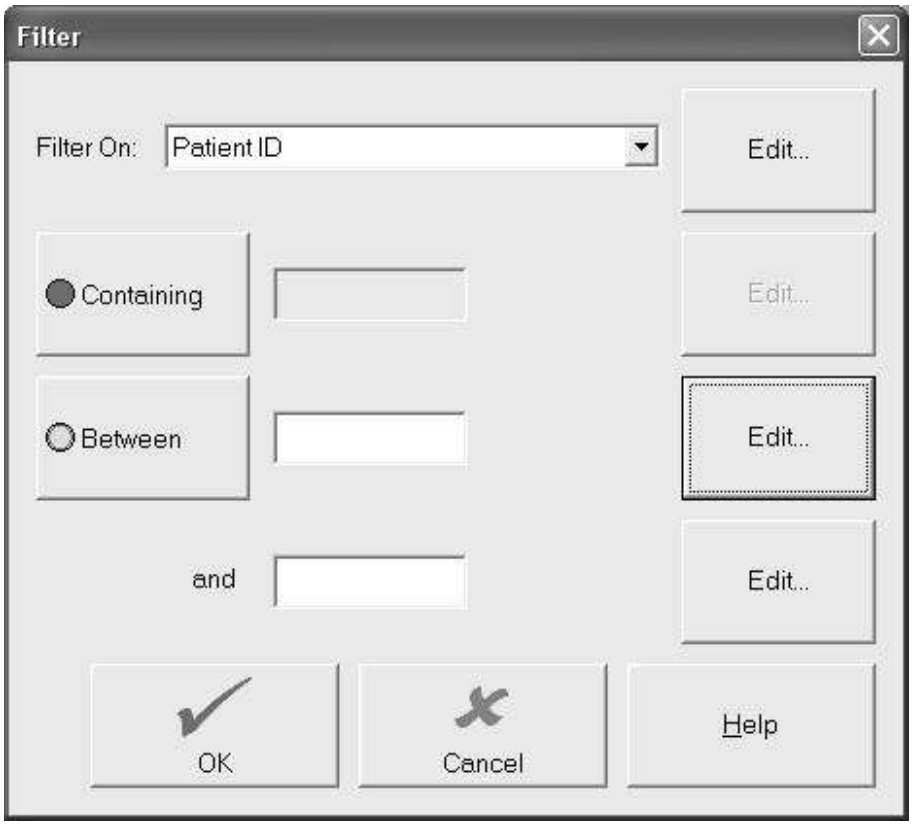


Fig. 67: Filter dialog

Option	Description
Filter On	Shows the selected filter argument (e.g. Patient ID, Birthdate, Date). Click on the Edit... button to change the argument.
Containing	The selected filter contains a definable argument. For example: Filter: Patient ID, Containing: 10 Report: Patient 10, Patient 101, Patient 1030, Patient 310, etc.
Between	The selected filter is between two arguments. For example: Filter: Date, Between: 2008-07-01 and 2008-07-30 Report: All patients tested between 2008-07-01 and 2008-07-30

9.8 Quality Control Analysis Report (Levey Jennings Plot)

The quality control analysis report (Levey Jennings plot) shows the results of a selected reagent over a period of time.

To generate a QA Analysis Report you have to activate the QA analysis by defining Quality Control labels in the LOT-SPECIFIC VALUES FOR dialog while preparing a worklist (► *Chapter 8.5 Lot-specific Values, p. 75*).

Proceed as follows:

1) Select File > New.

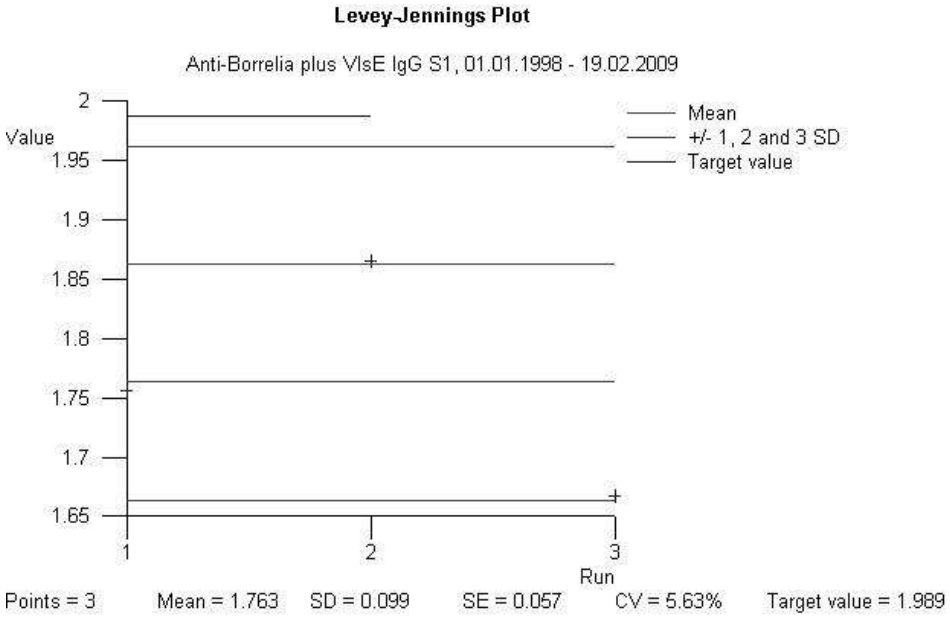
2) In the MAKE A SELECTION dialog, select the QA Analysis Report symbol.

3) In the Q.A. ANALYSIS dialog, select in the Controls list the respective reagent.

4) Select in the Batch Numbers list the respective batch number.

5) Select the period of time in the boxes Date from and to.

6) Click OK to confirm the entries. The system shows you the quality control analysis report (Levey Jennings plot).



Anti-Borrelia plus VlsE IgG S1, 01.01.1998 - 19.02.2009

Batch No.	Date	Value	Variance	%
E080305BQ	19.02.2009	1.756	-0.231	-11.63%
E080305BQ	19.02.2009	1.865	-0.122	-6.14%
E090121AL	19.02.2009	1.667	-0.326	-16.36%

Fig. 68: Levey Jennings plot

9.9 Software Language

Required access rights: None

It is possible to choose the language in which to use the EUROIMMUN Analyzer I-2P software. This will affect the software layout (menus, dialogs, buttons) but also the documents (assay files, result reports, event logs...) used or generated by the system.

To select the language:

1) Select File > Close to close all open windows (including the self-test report). You should see only the menu bar and toolbar above a grey screen.

2) From the Utilities menu, select the Select Language function. The SELECT LANGUAGE dialog opens.

Fig. 69: Select Language dialog

3) In the Select Language dialog, select one of the available languages from the drop-down list.

4) Click on OK.

5) Close the EUROIMMUN Analyzer I-2P software and restart it.

NOTE

If you have changed the software language but some elements continue to be displayed in English, this may be because you are using an English-language version of Windows (in this case, some buttons will be in English), or you are using assays that were defined in English.

9.10 Simulation mode/demo mode

The simulation/demo mode allows you to work with the EUROIMMUN Analyzer I-2P software even if no instrument is connected or turned on.

- To do this, check the Demo Mode item in the LOG-ON dialog (► *Chapter 8.2 Start-Up, p. 67*).

The COM port between the PC and the instrument is then disabled.

Required access rights: The demo mode allows you to access and use all the functions that you would normally use.

You can, for instance, use it to create a worklist and check on the Schedule view how it would actually be performed on the instrument. The only difference is that the time scale is changed (one minute of a real process is rendered as one second in demo mode) and that no reading values are returned in the results.

You can also use the demo mode to edit the system parameters, edit assays, create worklists, access and print former results, etc. Changes made or files created while in demo mode are saved on the system just as they would be normally.

It is therefore a very useful (and safe) mode to use for all operations for which you do not need to use the instrument.

10 System configuration

10.1 System Options

The SYSTEM SET-UP dialog (► *Chapter 10.1 System Options, p. 168*) and the OPTIONS dialog allow you to adapt the EUROIMMUN Analyzer I-2P to your specific circumstances and needs.

The OPTIONS dialog lets you specify software options.

NOTE

If tabs in the Options dialog aren't shown, this means that you belong to a user group with restricted access rights. For more information on access rights and user groups, see ► *Chapter 10.1.1 Access Control tab, p. 168* .

Click on Utilities > Options... to open the OPTIONS dialog.

10.1.1 Access Control tab

Required access rights: Nothing or password (if set)

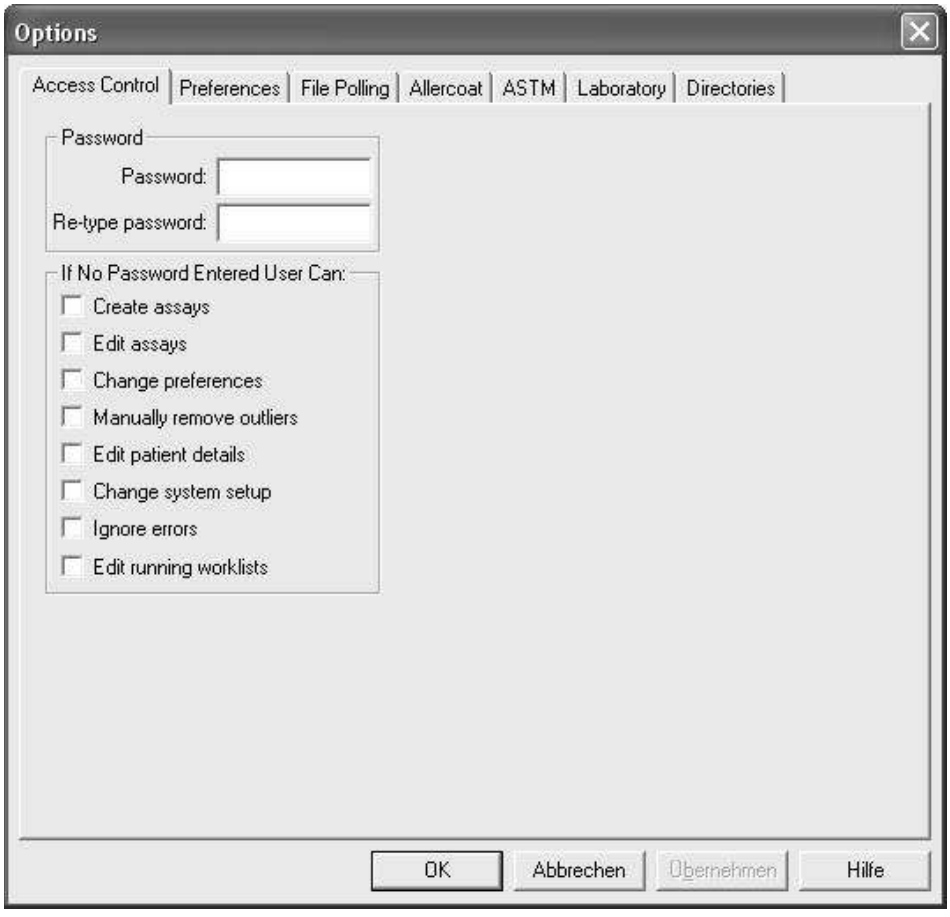


Fig. 70: Options dialog: Access Control tab

The purpose of this tab is to allow the laboratory supervisor to define the rights of the users without a password. For example, it makes it possible to specify that some technicians will only be allowed to use the EUROIMMUN Analyzer I-2P system to process pre-defined assays but not to program new assays or change the system settings. It also makes it possible to ensure that only authorised personnel can access patient data or validate results before they are exported to a host computer.

Enter a password to set access rights:

Option	Description
Password	Field for your new password. Any alphanumeric chain of characters can be used as password.
Re-type Password	Field to retry your new password.

Tab. 35: Functions of the Options dialog

This tab also includes a list of access control items (user rights). When an item is checked, this means that users without an entered a password can use this function.

Items	When item is checked, user without entered password can...
Create assays	...create new assays.
Change preferences	...access the Preferences tab in the OPTIONS dialog and change the settings on this tab (► *Chapter 10.1.2 Preferences tab, p. 170*).
Change system setup	....open the SYSTEM SET-UP dialog and change the settings on any of the tabs (► *Chapter 10.2.1*)
Edit assays	...edit assays. Note however that even if a group of users is allowed to edit assays, assays themselves can be individually protected by a specific password set by the person or company that created the assay (e.g. EUROIMMUN pre-defined assays are password protected).
Edit patient details	...access and edit patient personal information (► *Chapter 9.2 Complete Patient Editor, p. 125*).
Edit running Worklists	...access the Edit > Panel Definition menu item in order to change the settings of an existing worklist (e.g. to add new plates - see ► *Chapter 9.6 Continuous Loading, p. 158*).
Ignore errors	....click the Ignore button when error messages are displayed. Ignoring errors is not recommended. However, in some cases, it allows the worklist to continue (even if some wells are flagged) whereas otherwise it would have to be completely aborted. Ignored error messages are traced in the event log.
Manually remove outliers	... ...edit outliers manually (► *Editing Outliers, p. 154*).

Tab. 36: List of definable access control items

10.1.2 Preferences tab

Required access rights: Change preferences

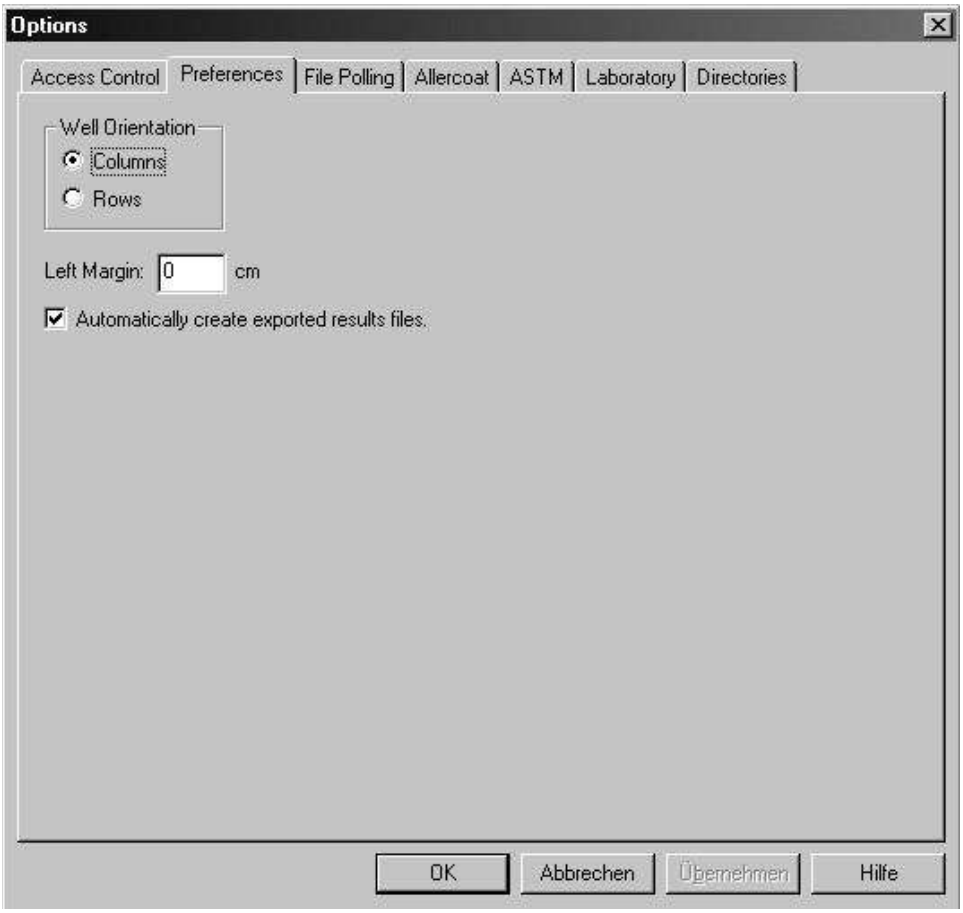


Fig. 71: Options dialog: Preferences tab

Option	Description
Columns	Displays the results column wise.
Rows	Displays the results row wise.

Tab. 37: Functions of the Well Orientation area

NOTE

This option is a software option. It does not change the way the pipettor operates. It changes the way the results are displayed. Default is columns.

NOTE

The pipetting direction must be changed in the ASSAY LAYOUT dialog. (Assay Programming Manual, please contact your EUROIMMUN service engineer ► *Chapter 1.10 Technical Service, p. 24*)

General

Option	Description
Automatically create exported results files	Check this option to automatically generate result files (*.res). These will be saved in the result folder under the chosen plate name. The result report applies both to ASCII and ASTM exports. A prerequisite for these exports, however, is that the appropriate settings have been defined at the assay level (Assay Programming Manual, please contact your EUROIMMUN service engineer ► *Chapter 1.10*) and, for ASTM exports, that the connection has been enabled as described in ► *Chapter 10.1.5* .
Left Margin	Defines the left paper margin for printout of the assay protocols and the result report.

Tab. 38: General functions

10.1.3 File Polling Tab

See ► *Automatic Import (File Polling), p. 247* .

10.1.4 EUROIMMUN Allercoat tab

Required access rights: None

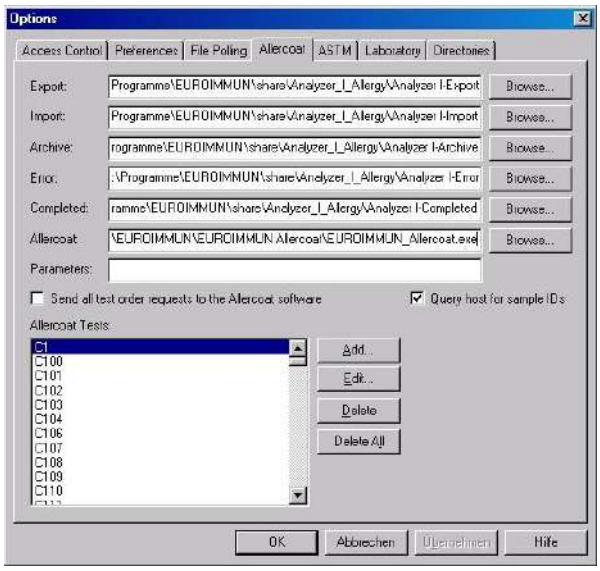


Fig. 72: Options dialog: EUROIMMUN Allercoat tab

Option	Description
Add	Allows you to add a new allergen to the allergen list.
Allercoat	Shows the path/folder and filename of the Allercoat software.
Allercoat Tests	Shows the added Allercoat tests.
Archive	Shows the path/folder for the Allercoat archive files.
Browse...	Enables the path/folder to be changed: Click on Browse. In the Browse dialog, find the desired directory. In this directory, select any file and click on the Open button (see NOTE below). Back in the EUROIMMUN tab, check that the corresponding change has been taken into account.
Completed	If the Allercoat result report meets the quality criteria, the related plate layout file is transferred to a subfolder named "completed".
Delete	Deletes a selected Allercoat allergen.
Delete All	Deletes all Allercoat allergens.
Edit...	Allows you the edit the name of a selected Allercoat allergen.
Error	In case of an error during plate layout import, the layout file is moved into the “error” folder.
Export	Shows the storage location of the Allercoat export files.
Import	Shows the storage location of the Allercoat import files (*.lay files) used for the EUROIMMUN Analyzer I-2P.

Option	Description
Parameters	Shows parameters to start the EUROIMMUN Allercoat software (see 'EUROIMMUN Allercoat Software Manual').
Query host for sample IDs	Unselected: Clicking the EUROIMMUN Allercoat software button starts the 'EUROIMMUN Allercoat software'. Selected: After clicking the EUROIMMUN Allercoat software button, the EUROIMMUN Analyzer I-2P software sends a "Query all" request to LIMS. After a response, the 'EUROIMMUN Allercoat software' will start.
Send all test order requests to the Allercoat software	If selected, all LIMS requests will be sent via export files to the 'EUROIMMUN Allercoat software'.

Tab. 39: Functions of the EUROIMMUN Allercoat tab

NOTE

If this new target directory is empty just copy or create any file into it, so you can select it for that purpose (you can later delete it). If you select only the directory (and no file) and click on the Open button, the change will not be saved.

10.1.5 ASTM Tab

Required access rights: None

The connection setting of the delimiter and the interface are defined in accordance with the ASTME standard.

ASTM E 1394

Option	Description
…Delimiter	These fields specify the set of delimiters used for transmissions.
Compact Mode	If this item is checked, each patient result is sent in a separate package.
ID	Instrument ID is included in the result record.
Query Host For Test Order Requests	If this item is checked, the Query to Host mode is enabled (see below).
Time Out	If no response is received to the query within the time out specified in the field, then the software will send no further query requests.
Baud Rate	Specifies the baud rate used for transmissions between the EUROIMMUN Analyzer I-2P and the host; any values from 110 to 56,000 can be chosen. Default is 9600.

Option	Description
COM Port	This field specifies the serial port used for host transmissions. Please make sure that you do not select the internal COM Port 1 between PC and instrument.
Create Log File	If this item is checked, a log file (yyyymmdd.txt) of the ASTM communication is created in the `C:\ProgramData\Euroimmun Analyzer I - 2P\EventLogs` directory.
Data Bits	7 or 8, default is 8.
Parity	None, odd, even, mark, space. Default is None.
Stop Bits	1 or 2, default is 1.

Tab. 40: Functions of the ASTM E 1394 area

General

Option	Description
Assay Links	Click this button to check or link the LIMS names to the corresponding test names (► *Chapter 16.1.7 Definition of LIS Assay Names, p. 253*).
ASTM E 1381/1394	Select this item if you wish to activate communication with a host computer.

Tab. 41: Functions of the ASTM E 1381 area

10.1.6 Laboratory Tab

Required access rights: None

The laboratory details entered here are included in the result reports (► *Chapter 8.9 End of Run/Result Report Window, p. 112*).

Option	Description
Address	Laboratory address (no specific format is required by the system).
FAX	Fax number of your laboratory (no specific format is required by the system).
Name	Name of your laboratory (no specific format is required by the system).
Telephone	Telephone number of your laboratory (no specific format is required by the system).

Tab. 42: Functions of the Laboratory tab

10.1.7 Directories tab

Required access rights: None

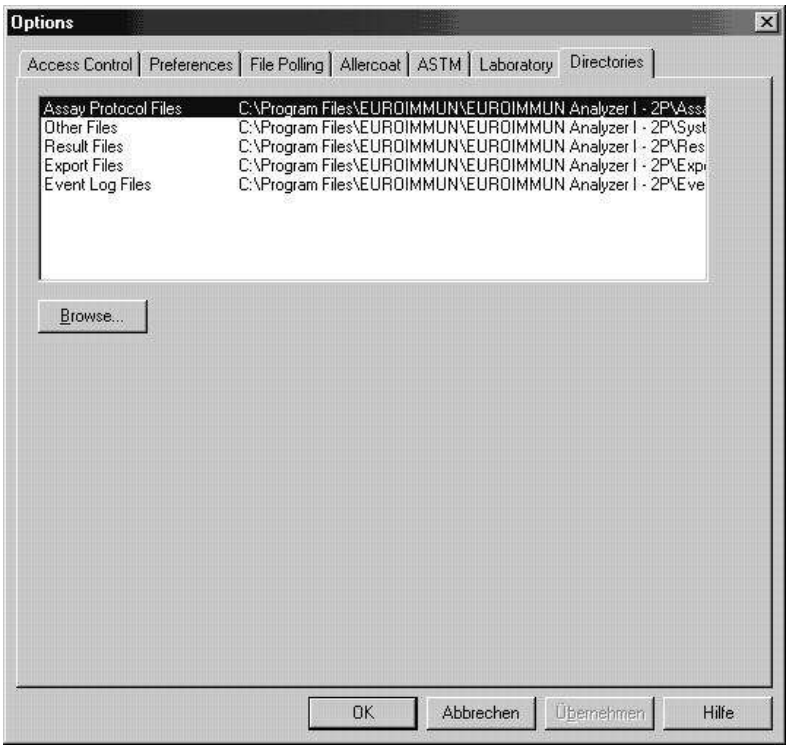


Fig. 73: Options dialog: Directories tab

Option	Description
Directories	Shows all file types and the path/folder where they are saved.
Browse...	Enables the path/folder of the file types to be changed: Select a file type in the directories list. Click on Browse... . In the BROWSE dialog, find the directory where you want to save this file type. In this directory, select any file and click on the Open button (see NOTE below). Back in the Directories tab, check that the corresponding change has been taken into account. Confirm with OK . Repeat this procedure for the other file types if necessary.

Tab. 43: Functions of the Directories tab

NOTE

If this new target directory in which you want to save certain file types is empty just copy or create any file into it, so you can select it for that purpose (you can later delete it). If you select only the directory (and no file) and click on the Open button, the change will not be saved.

10.1.8 File types and locations

The EUROIMMUN Analyzer I-2P software uses a number of different file types. Under default settings these files are saved in the following directories:

Extension	File types	Path/Folder
*.apm	Import files for host systems.	C:\ProgramData\Euroimmun Analyzer I - 2P\System
*.asy	Assay protocol files.	C:\ProgramData\Euroimmun Analyzer I - 2P\Assays
*.dat	Only one file: Koordina.dat (file containing the system coordinates).	C:\ProgramData\Euroimmun Analyzer I - 2P\System
*.log	Active event log files (documenting daily data steps performed by the EUROIMMUN Analyzer I-2P as well as error messages).	C:\ProgramData\Euroimmun Analyzer I - 2P\EventLogs
*.mpc	Coordinate files for test plates or dilution plates.	C:\ProgramData\Euroimmun Analyzer I - 2P\System
*.pan	Worklist files.	C:\ProgramData\Euroimmun Analyzer I - 2P\Assays
*.rac	Coordinate files for rack types.	C:\ProgramData\Euroimmun Analyzer I - 2P\System
*.rea	Reagent allocation files	C:\ProgramData\Euroimmun Analyzer I - 2P\System
*.res	Result files.	C:\ProgramData\Euroimmun Analyzer I - 2P\Results
*.spe	Spectrum files (contain data of a spectrum acquisition)	C:\ProgramData\Euroimmun Analyzer I - 2P\System
*.tst	Self-test report files with information about the self-tests that were performed	C:\ProgramData\Euroimmun Analyzer I - 2P\System
*.txt	Export files in ASCII format	C:\ProgramData\Euroimmun Analyzer I - 2P\Export

Extension	File types	Path/Folder
*.txt	ASCII patient data import files can be downloaded from a host computer to the EUROIMMUN Analyzer I-2P software (patient with associated assays).	C:\ProgramData\Euroimmun Analyzer I - 2P\Import or selected directory on host computer
*.txt	Duplicate log file in (*.txt) format.	C:\ProgramData\Euroimmun Analyzer I - 2P\Event logs
*.ver	Photometer verification report files.	C:\ProgramData\Euroimmun Analyzer I - 2P\System
*.wor	Worklist files.	C:\ProgramData\Euroimmun Analyzer I - 2P\Assays

Tab. 44: File types and storage locations

NOTE

The system also uses some other file types (*.db, *.mdb, *.lsv, *.con) but these are hidden for the user.

If, when installing the software, you have chosen to install it in a different directory than the default directory, you will have to manually edit the default directory for each file type as described below. This can be a source of errors. Therefore, unless you have a specific reason to do otherwise, it is recommended that you install the EUROIMMUN Analyzer I-2P software in the default directory.

10.2 System Set-up

Required access rights: Change system setup

The SYSTEM SET-UP and OPTIONS dialogs (► *Chapter 10.2 System Set-up, p. 177*) allow you to adapt the EUROIMMUN Analyzer I-2P to your specific circumstances and needs.

The SYSTEM SET-UP dialog allows you to define the parameters of each instrument module (incubators, pipetting system, wash unit, etc.).

Click on Utilities > System Set-up to open the SYSTEM SET-UP dialog.

10.2.1 System tab

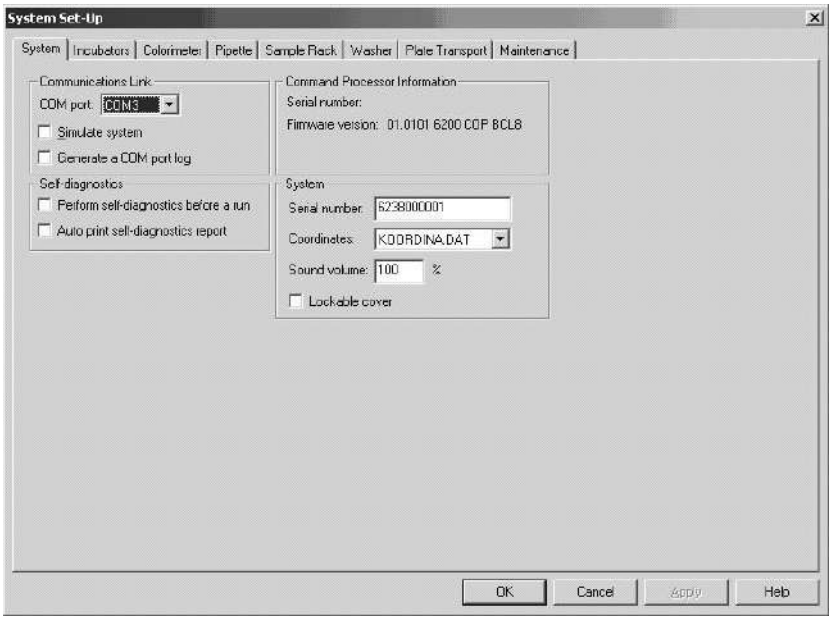


Fig. 74: System Set-up dialog: System tab

Communication Links area

Defines the PC's communication link to the EUROIMMUN Analyzer I-2P.

Option	Description
COM port	Select the COM port for the computer-to-instrument link. The default is COM port 3 (► *Chapter 16.1.6 ASTM Link Set-Up, p. 253*).
Simulate system	This item is automatically checked when you check the Demo mode item in the Log-On dialog (► *Chapter 8.2 Start-Up, p. 67*).
Generate a COM port log	Select this item to document communication via the selected COM port in a log file.

Tab. 45: Functions of the Communications Links area

Self-diagnostics

Enables an additional check of the EUROIMMUN Analyzer I-2P.

Option	Description
Perform self-diagnostics before a run	Select this item to automatically perform a self-test before running a worklist (► *Chapter 9.1 Initialisation and Self-test, p. 123*).
Auto print self-diagnostics report	Select this item to print automatically the self-test result report.

Tab. 46: Functions of the Self-test area

System

Option	Description
Coordinates	Shows the used coordinates file.
Lockable cover	Activates the cover lock. This means that the cover is locked during a run.
Serial number	Serial number of the EUROIMMUN Analyzer I-2P instrument. This number will be needed if you call your EUROIMMUN representative for support or service. The serial number is also printed on the type label (► *Chapter 1.5 Type label, p. 20*).
Sound volume	Volume of the audible signal.

Tab. 47: Functions of the System area

Command Processor Information

Information on the EUROIMMUN Analyzer I-2P central operation processor (COP).

Option	Description
Serial number	Shows the COP serial number
Firmware version	Shows the COP firmware version.

Tab. 48: Functions of the Command Processor Information area

10.2.2 Incubators tab

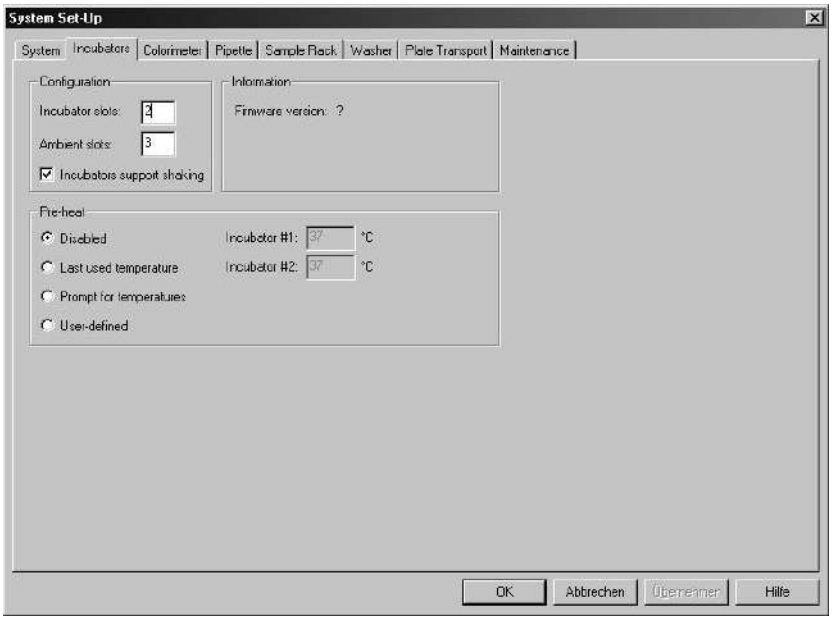


Fig. 75: System Set-up dialog: Incubators tab

Configuration

Option	Description
Incubator slots	Specify how many heatable incubators are to be used.
Ambient slots	Specify how many room-temperature incubators are to be used.
Incubators support shaking	Enable the shaking function of the heatable incubators.

Tab. 49: Functions of the Configuration area

Pre-heat

Setting for the incubators preheat function on power-up. The incubators take some time to reach high temperatures. The system will not start a run if the temperatures required for the assays to be processed are not reached. If you intend to process assays with high incubation temperatures, it is a good idea to select a pre-heating on power-up option.

Option	Description
Disabled	Incubators are not preheated on power-up
Last used temperature	Incubators are preheated to the last used temperature on power-up (default setting).
Prompt for temperatures	During the self-test you will be asked to define the temperature of each individual incubator. The system immediately starts to preheat the incubators.

Option	Description
User-defined	Incubators are preheated to the temperature defined in the fields for Incubator #1 and Incubator #2 on power-up (values between 21 and 55 can be entered).
Incubator #1, Incubator #2	(see User-defined)

Tab. 50: Functions of the Pre-heat area

Information

Incubators information

Option	Description
Firmware version	Shows the firmware version number for the incubators.

Tab. 51: Functions of the Information area

10.2.3 Colorimeter tab

In the software and in this manual, the terms "photometer" and "colorimeter" are used synonymously.

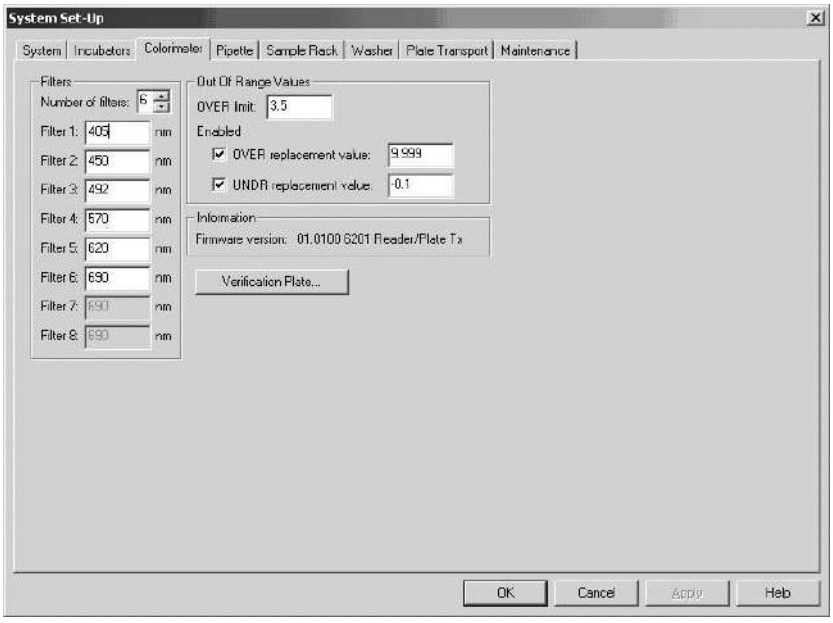


Fig. 76: System Set-up dialog: Photometer tab

Filters

By default, the photometer in the EUROIMMUN Analyzer I-2P is equipped with six filters. Two more filters can be added to suit the user-specific needs. To add filters, contact your EUROIMMUN service engineer.

NOTE

The system is not able to check automatically in which position each filter is installed. When the system is installed, the appropriate data is entered in the software by your Service Engineer using the Colorimeter tab below. If you ever add or change filters, always make sure the parameters specified in the software (number of filters, order, wavelengths) strictly correspond to the filters that are on the instrument.

Option	Description
Number of filters	Number of filters used in the instrument (default is 6).
Filter 1 - Filter 8	The number of boxes that are enabled depends on the number that has been specified above. Shows the wavelength of each filter in nm. The numbering of the filter in the instrument must match the numbering on this tab! Defaults: Filter 1: 405 nm Filter 2: 450 nm Filter 3: 492 nm Filter 4: 570 nm Filter 5: 620 nm Filter 6: 690 nm Filter 7: - Filter 8: -

Tab. 52: Functions of the Filters area

Out Of Range Values area

Option	Description
OVER limit	Enter the upper limit value (OD) for the photometer (e.g. 2.5). The maximum value that can be set is 3.5. The lower limit value is equal to the negative value of the upper limit value. The photometer is linear up to 2.000. For other specifications, see ► *Chapter 13 Technical specifications, p. 236*.
OVER limit replacement value, LOWER limit replacement value	When the value read by the photometer is OVER the upper limit (or UNDER the lower limit), you can choose to replace, in the results, the actual value by another character string, e.g. a wildcard (*), a digit or a comment. In this case, check the item and enter the replacement string in the respective field (default is a wildcard sign).

Tab. 53: Functions of the Out Of Range Values area

Information

Option	Description
Firmware version	Shows the firmware version number.

Tab. 54: Functions of the Information area

General

Option	Description
Verification plate	Enables the reference values of the reader verification plate to be entered. You don't need this function if you use the verification plate data disk from Stratec. See 'Reader Verification Plate Manual' for photometer verification.

Tab. 55: General functions

10.2.4 Pipette tab

NOTE

The Pipette tab is used to define the pipetting parameters at system level, i.e. to define how the pipettor works. Do not confuse it with the Pipette dialog or the Dispense dialog (see "Assay Programming Manual" (ask your EUROIMMUN service engineer)) which are used to define, at assay level, which aspirate/dispense steps the pipettor should execute.

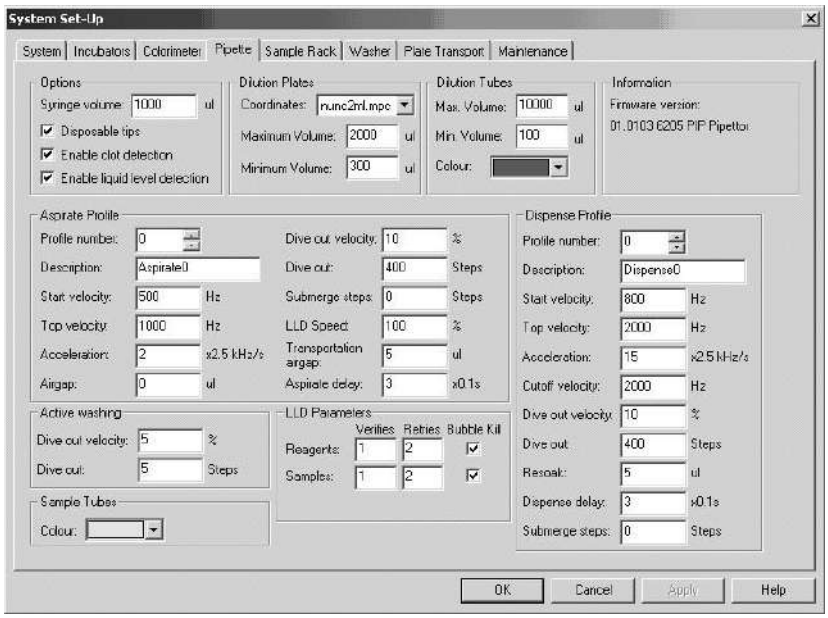


Fig. 77: System Set-up dialog: Pipettor tab

Options

Option	Description
Syringe volume	Shows the syringe volume of the pipettor pump in micro-litres (1000 µl).
Disposable tips	This item is always checked (it ensures that a warning message is displayed if a problem occurs when the pipettor picks up or ejects a tip).
Enable clot detection	This item is always checked. It ensures that a warning is displayed if a clot is detected.
Enable liquid level detection	This item is always checked. The liquid level detection process enables the system to monitor the height at the surface of the respective liquid. It then calculates how the pipettor should move during aspiration/dispense in relation to the surface of the liquid and the volume to be aspirated/dispensed.

Tab. 56: Functions of the Options area

Dilution Plates

Also refer to ► *Chapter 8.7.5 Load Dilution Plate, p. 98* .

Option	Description
Coordinates	The dilution plates offered here are based on one file (nunc2ml.mpc). Here you can select the dilution plates to be used. The respective file must be in the EUROIMMUN Analyzer I-2P system folder (`C:\ProgramData\Euroimmun Analyzer I - 2P\System`).
Maximum Volume	Enter the maximum volume of a well of the dilution plate.
Minimum Volume	Enter the minimum detectable volume of a cavity of the dilution plate.

Tab. 57: Functions of the Dilution Plates area

Dilution Tubes

Information about the dilution tubes. Dilution tubes can be used for sample archiving and for dilution steps (for assays that require such a step). However, dilution plates, not tubes, are always used for dilution steps for predefined EUROIMMUN assays.

Option	Description
Max.	Enter the maximum volume of a dilution tube.
Min.	Enter the minimum detectable volume of a dilution tube.
Colour	Select the colour in which dilution tubes are displayed in the Load dialog.

Tab. 58:Functions of the Dilution Tubes area

Information

Pipettor information.

Option	Description
Firmware version	Shows the current firmware version of the pipetting system.

Tab. 59: Functions of the Information area

Aspirate Profile

Also refer to ► *Pipetting Profiles, p. 187* .

Option	Description
Profile number	Select the profile which you want to view or edit.
Description	Name of the aspirate profile.
Start velocity	Velocity at the start of aspiration (in Hz).
Top velocity	Maximum aspirate velocity (in Hz).
Acceleration	Enter the acceleration of the aspirate velocity in kHz/s.

Option	Description
Airgap	This airgap is aspirated before a reagent and blown out after the reagent to ensure the full dispensing of the reagent.
Dive out velocity	Velocity in percent of the maximum velocity used to move the tip out of the liquid.
Dive out	Distance the tip has to travel up when being moved out of the liquid (in steps of the stepper motor).
Submerge steps	Number of steps the tip is to submerge into the liquid following liquid detection.
LLD velocity	Velocity of liquid detection in percent of the maximum velocity.
Transportation airgap	This airgap is aspirated after a reagent.
Aspirate delay	Delay time after aspiration to allow the liquid to settle.

Tab. 60: Functions of the Aspirate Profile area

Dispense Profile

Also refer to ► *Pipetting Profiles, p. 187* .

Option	Description
Profile number	Select the profile which you want to view or edit.
Description	Name of the dispense profile.
Start velocity	Velocity at the start of dispensing (in Hz).
Top velocity	Maximum dispense velocity (in Hz).
Acceleration	Enter the acceleration of the dispense velocity (in kHz/s).
Velocity limit	Cut-off velocity in Hz (stop velocity).
Dive out velocity	Velocity in Hz with which the tip is moved up out of the liquid.
Dive out	Distance the tip has to travel when being pulled out of the liquid (in steps of the stepper motor).
Resoak	Define how much liquid in l is resoaked again after dispensing.
Dispense delay	Delay time before dispensing (the pipettor moves from the reagent bottle to the test plate and waits) to allow the liquid to settle.
Submerge steps	Number of steps the tip is to submerge into the liquid following liquid detection.

Tab. 61: Functions of the Dispense Profile area

Active washing

Pipette parameters for washing: Do not use for EUROIMMUN instruments.

Option	Description
Dive out velocity	Velocity in Hz with which the tip is moved up out of the liquid. This should be set slower than the normal velocity.
Dive out	Distance the tip has to travel when being pulled out of the liquid (in steps of the stepper motor).

Tab. 62: Functions of the Active washing area

Sample Tubes

Also refer to ► *Allocate Barcoded Racks and Non-barcoded Individual Samples, p. 92* .

Option	Description
Colour	Select the colour in which sample tubes are displayed in the Load dialog.

Tab. 63: Functions of the Sample Tubes area

LLD Parameters

Liquid Level Detection parameters:

Option	Description
Verifies	Do not change the default settings.
Retries	Do not change the default settings.
Bubble Kill	Do not change the default settings.

Tab. 64: Functions of the LLD Parameters area

Pipetting Profiles

The purpose of pipetting profiles is to optimise the pipetting process (e.g. increase accuracy and precision, avoid dripping, air bubbles, splashing, hanging drops, etc.) by adjusting the pipetting parameters to the type of liquid (samples, controls, reagents) which is aspirated/dispensed and to other specific circumstances (e.g. multishots, low volumes, large volumes, etc.).

Defining Pipetting Profiles

Defining pipetting profiles is done at system level, using the Aspirate Profile and the Dispense Profile fields in the Pipette tab (see above). However, defining pipetting profiles is a fairly complex process which requires a good knowledge of how the pipettor operates and adequate testing. This is why the software includes some pre-defined profiles.

Profile Number:	Description:
0 to 4 (inclusive)	Pre-defined profiles. These profiles are protected (read-only). They cannot be edited but the profile parameters can be viewed in the Pipettor tab.
5 to 19 (inclusive)	User-definable profiles. To define a new profile, select one of these profiles (e.g. Aspirate 6), rename it and enter the desired values.

Tab. 65: Profile description

This adds up to a total of 20 possible aspirate profiles and 20 possible dispense profiles.

Using a Pipetting Profile

If you are using pre-defined assays, the profiles to be used for each aspirate or dispense operation are already specified in the assay.

If you are creating your own assays, you have to specify the profiles you want to use:

- when you define your Pipetting steps (see "Assay Programming Manual" (ask your EUROIMMUN- service engineer))
- and when you enter your reagent data in the reagent database (see "Assay Programming Manual" (ask your EUROIMMUN service engineer)).

NOTE

Because of wrong profile settings (problem spillages) it is necessary to validate assays!

Trouble Shooting

Defining profiles or even selecting the right profile to use can be difficult in some cases. If in doubt, contact your EUROIMMUN application engineer.

10.2.5 Sample Rack Tab

Scanner Firmware Version area

Option	Description
Scanner firmware version	Information on the scanner firmware installed on the system.

Tab. 66: Functions of the Scanner Firmware area

Barcode Type

Option	Description
Barcode Type	List of all barcode types that can be read by the integrated barcode scanner. If a checkbox is selected, the scanner is able to read the respective barcode type. It is possible to select several checkboxes but the more checkboxes are selected, the slower and less accurate the reading will be. Some barcode types are always selected and cannot be unchecked (barcode types used on EUROIMMUN Analyzer I-2P racks and EUROIMMUN reagents). The following barcode types can be used for samples and reagents to be processed on the EUROIMMUN Analyzer I-2P system: 2/5 Interleaved Code 39 2/5 IATA 2/5 Industrial UPCA, UPCE EAN 8 or 13 digits, Code 128, EAN 128 (used for EUROIMMUN reagents), Pharmacode EAN Addendum, 2 or 5 digits Codabar Typically, when the system is installed, your EUROIMMUN service engineer configures the barcode scanner to accept the barcode types you generally use on the samples you process. If you need to change the preconfigured barcode settings later on, see ► *Using several Barcode Types, p. 190* .
Lengths Min. Max.	Minimum and maximum character length of each barcode type. NOTE: Generally, if you do not know these values, you can leave the default values. However, if you also use the Prefix and Suffix options to exclude some digits (see below), you should enter in the Min. and Max. fields exactly the number of significant digits (including the prefix and suffix) in the respective barcode type. For example, if you use a barcode format with 14 digits altogether and exclude the date suffix (6 digits), enter "14" in both the Min. and Max. fields. NOTE: Wrong settings could lead to false barcode values. For example: Max. = 6 Barcode 1: 2007P45 Barcode 2: 2007P48 Result: 2007P4 for both barcodes!

Tab. 67: Functions of the Barcode Type area

⚠ WARNING

Changing the barcode setting

Incorrect analysis result

> Only use the software-supported barcodes.
> If you change the barcode settings (e.g. length, checksum) it is necessary to validate these settings with your barcodes.

NOTE

For better reading accuracy, select only those barcode types which you actually use. Never check all the barcode types.

NOTE

To edit the barcode settings just before a run (e.g. to select a barcode type which you specifically need for this run) you can access this dialog by clicking the Scanner Setup button in the Load dialog.

Auto Load

If a rack is identified through barcodes, the rack type is automatically displayed. If identification via barcodes was not possible (damaged or dirty barcodes), you have to select the rack type manually.

With three-track racks the same rack type must occupy the respective tracks.

Option	Description
Track	Lane of the sample and reagent unit.
Type	Rack type.

Tab. 68: Functions of the Scanner Firmware area

Using several Barcode Types

You will frequently have to select several barcode types, e.g. when a laboratory uses one set of barcodes for racks and patient sample tubes differ from one customer to the other.

In this case, click the corresponding checkboxes. The scanner will work faster and more precisely if you choose fewer barcode types. Choose only those you will use. Never check all the barcode types.

If you don't know the type of barcode used

In most cases, the types of barcodes used are specified by the suppliers of the various accessories or products. It is possible that the operator may not be aware of the barcode type in use: for example, if a laboratory receives barcoded patient samples or reagent containers, but is not sure which barcode type was used.

What you can do to identify the barcode type:

1) Fit the barcoded sample(s) in a rack.

2) Select Utilities > System Setup and click on the Sample Rack tab.

3) Select three deselected barcode types (notice them).

4) Click on OK.

5) Insert the rack in its lane.

When the PATIENT EDITOR dialog opens, check the first column.

6) If the system has not been able to read the barcodes, the first column is blank. In this case, click on the Close button in the Patient Editor dialog, remove the rack, open the SAMPLE RACK tab again, and repeat the procedure for three other barcodes (deselect the previous barcodes).

7) If the system has been able to read the barcodes, the Patient IDs are already displayed in this first column. In this case, click on the Close button in the Patient Editor dialog, remove the rack, open the Sample Rack tab again, and select each of these three barcode types one at a time and, for each type, pull out the rack and then re-insert it until you determine which of the three barcode types is correct.

Rack Barcodes

All EUROIMMUN Analyzer I-2P sample and reagent racks are barcoded. The barcode labels are located on the right-hand side of each rack. They serve to identify both the rack type and individual positions on each rack.

The system is preconfigured to be able to read the rack barcodes. It is recommended not to use racks with missing or damaged barcodes. Replacement barcode labels for EUROIMMUN Analyzer I-2P racks can be ordered from EUROIMMUN. ► *Chapter 4 Scope of delivery and equipment features, p. 30* . However, if you need to use non-barcoded racks (or racks with damaged labels), follow the instructions in ► *Allocate Non-barcoded Racks and Samples, p. 152* and allocate the on-board samples or reagents manually.

NOTE

Rack barcodes are used by the system to identify different rack types but not individual racks. For example, the system can differentiate a reagent rack from a sample rack or a "T" sample rack from a "Z" sample rack but it cannot differentiate one "T" sample rack from another "T" sample rack.

Reagent Barcodes

All reagents included in EUROIMMUN kits are barcoded. The barcode settings of the EUROIMMUN Analyzer I-2P are preconfigured so that the system can read all barcode types used on EUROIMMUN reagent bottles.

10.2.6 Washer tab

The parameters of the washer are entered by your EUROIMMUN service engineer when the EUROIMMUN Analyzer I-2P system is first installed.

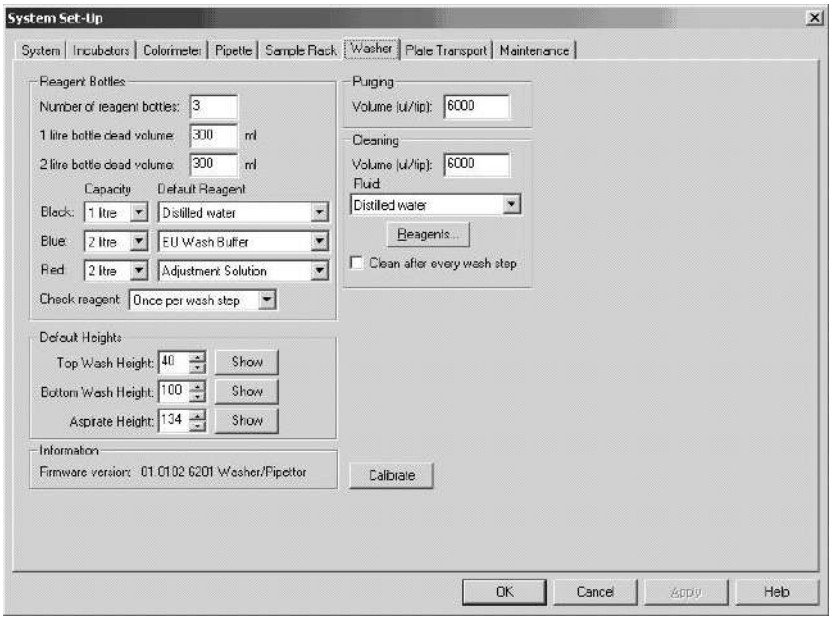


Fig. 78: System Set-up dialog: Washer tab

If you find that the washer is not operating correctly, please refer to the procedures described in chapter ► *Chapter 11.6.4 Washer Malfunction, p. 211* .

On defining wash steps in an assay, see "Assay Programming Manual (ask your EUROIMMUN service engineer)".

Reagent Bottles

Parameters for the wash buffer and cleaning fluid containers.

Option	Description
Number of reagent bottles	Number of wash buffer/cleaning fluid containers used (default is 3).
1 litre bottle dead volume	Dead volume of each wash buffer/cleaning fluid container in ml (150 ml).
2 litre bottle dead volume	Dead volume of each wash buffer/cleaning fluid container in ml (300 ml).
Capacity	Use these items if you want to use a 1-litre bottle or a 2-litre bottle for the Red, Blue, or Black channel. The change is reflected in the Load dialog of the wash buffer/cleaning fluid bottles (► *Chapter 8.7.1 Load Dialog, p. 89*). In any case, always make sure what is specified in the software corresponds to the actual wash buffer/cleaning fluid bottles loaded on the instrument.

Option	Description
Default Reagent	With these drop-down lists, you can change a default reagent so that a given wash buffer should always be assigned to a specific bottle for the red, blue or black channel. The change is reflected in the Load dialog of the wash buffer/cleaning fluid bottles (► *Chapter 8.7.1 Load Dialog, p. 89*).
Check reagent	The wash buffer volume sensor (float switch) is checked at the beginning of each wash cycle.

Tab. 69: Functions of the Reagent Bottles area

Default Heights

Set the height of the dispensing needle during washing.

Option	Description
Top Wash Height	Aspiration needle on the level of the upper edge of the plate.
Bottom Wash Height	Aspiration needle on a level slightly above the well bottom. On this level, the dispense tip is also in the liquid for intense washing of the wells (simultaneous aspiration during dispensing).
Aspirate	Aspiration needle on the same level as the well bottom. Notches in the aspiration needles prevent the washer heads getting stuck.
Show	You can check the exact height setting as follows: Enter a height (0 means: highest position of the dispensing needle) and click on Show The dispensing needle is then moved to the defined height. If the setting is not yet adequate, correct the height and click the Show button again. Should be done only by your EUROIMMUN service engineer.

Tab. 70: Functions of the Default Heights area

Information

Washer information.

Option	Description
Firmware version	Shows the current firmware version of the washer

Tab. 71: Functions of the Information area

Purging

Purge parameters (= cleaning before the first wash step of the worklist).

Option	Description
Volume	Purge volume in µl per tip.

Tab. 72: Functions of the Purging area

Cleaning

Cleaning parameters.

Option	Description
Volume	Cleaning volume (µl per tip)
Fluid	Select a reagent/buffer for cleaning.
Reagents	If the desired buffer is not available in the drop-down list, you may define or load another wash buffer by clicking the Reagents button (this opens the Buffer section of the reagent database and lets you select or create the desired buffer, see "Assay Programming Manual" (ask your EUROIMMUN service engineer).
Clean after every wash step	Select this item if you want to clean after each wash step.

Tab. 73: Functions of the Cleaning area

General

Option	Description
Calibrate	Click this button to perform an internal calibration of the 3 dispensing pumps of the wash system.

Tab. 74: General functions

10.2.7 Plate Transport tab

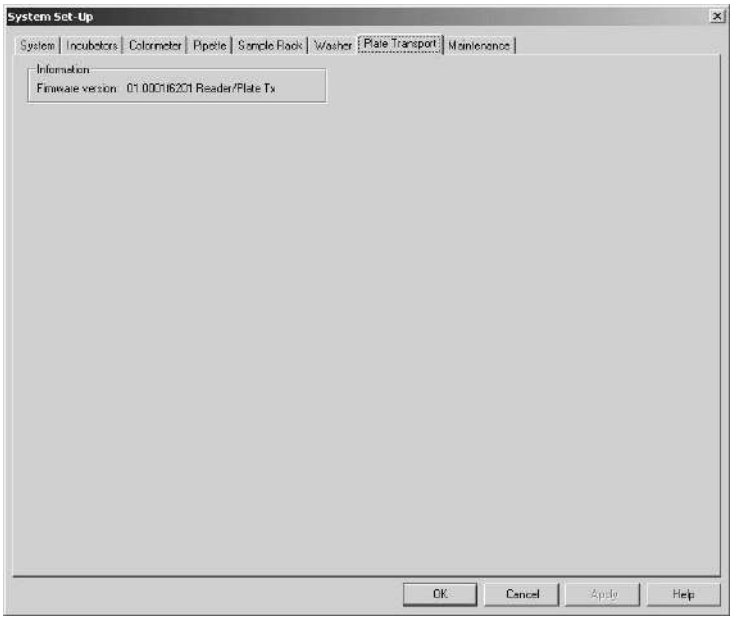


Fig. 79: System Set-up dialog: Plate Transport tab

Information

Plate transport information.

Option	Description
Firmware version	Shows the current firmware version of the plate transport unit.

Tab. 75: Functions of the Information area

10.2.8 Maintenance tab

As part of its normal operating routine, the EUROIMMUN Analyzer I-2P performs a number of maintenance jobs automatically. For example:

- During each self-test (► *Chapter 9.1 Initialisation and Self-test, p. 123*), the system checks the status of all instrument modules.
- During each run, the pipettor is primed with system liquid.
- Following each wash step, the washer is purged with cleaning fluid (deionised water).

These maintenance jobs are controlled automatically without any user intervention.

But the EUROIMMUN Analyzer I-2P system also includes a feature allowing users to predefine some maintenance tasks and maintenance reminders.

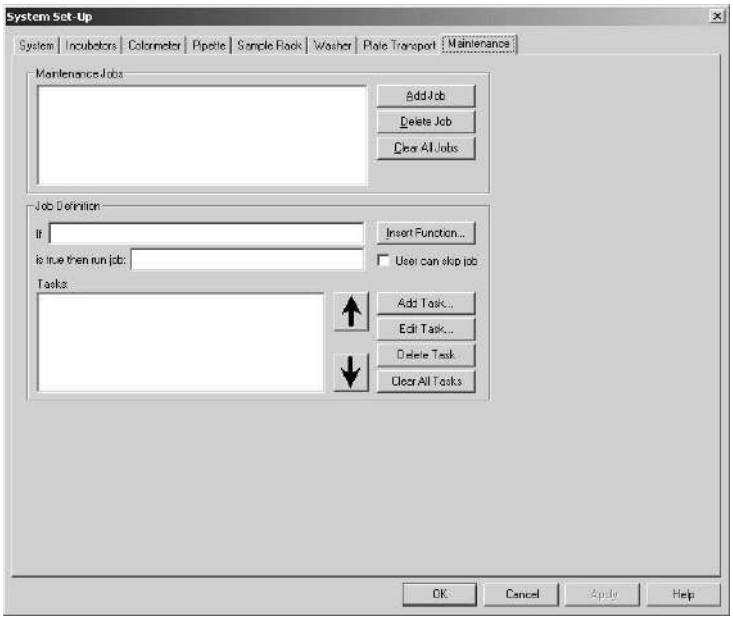


Fig. 80: System Set-up dialog: Maintenance tab

Maintenance Jobs

Option	Description
Maintenance Jobs	Shows the name of all created maintenance jobs.
Add Job	Adds a new maintenance job to the maintenance job list.
Delete Job	Deletes a selected maintenance job.
Clear All Jobs	Deletes all maintenance jobs.

Tab. 76: Functions of the Maintenance Jobs area

Job Definition

Option	Description
If	Specifies the condition to be fulfilled to perform a certain maintenance job.
is true then run job	Name of the maintenance job to be performed if the specified condition is fulfilled.
Insert Function	Shows the Insert Function dialog to select a function.
User can skip job	This option allows the user to skip an incidental maintenance job. The maintenance job can then be performed later.
Tasks	Indicates all actions to be performed if the maintenance job is started.

Option	Description
Arrows	By means of the arrows, the position of a selected action can be changed. The actions are performed according to their sequence.
Add Task	Inserts a new task. Possible tasks: **Display message:** With the action **Display message**, a message can be displayed on the screen during the performance of a maintenance job. The user must acknowledge this message. **Prime pipettor:** This action allows the cleaning of the pipettor. With an input dialog, the volume to be aspired can be specified. **Purge washer:** With this action, the washer can be cleaned. With an input dialog, the bottle to be used and the volume can be entered. **Verify colorimeter:** Allows the verification of the reader. The filters to be checked can be selected with an input dialog.
Edit Task	Allows the editing of a selected action.
Delete Task	Deletes a selected task.
Clear All Tasks	Deletes all tasks.

Tab. 77: Functions of the Job Definition area

Functions for Maintenance Jobs

Option	Description
IF(	`IF(condition;then;else)` If the condition is true the "then" expression is evaluated, otherwise the "else" expression.
AND(	`AND(condition;...)` Returns true if all of the conditions evaluate to true, otherwise returns false.
OR(	`OR(condition;...)` Returns true if any of the conditions evaluate to true, otherwise returns false.
Days	The number of days since this reminder was last displayed.
Plates	The number of plates processed since this reminder was last displayed.
Samples	The number of samples processed since this reminder was last displayed.

Option	Description
Tips	The number of tips used since this reminder was last displayed.
Worklists	The number of worklists processed since this reminder was last displayed.
abs	`ABS(value)` Returns the absolute value of the value argument.
log	`LOG(value)` Returns the base 10 logarithm of value.
alog	`ALOG(value)` Returns the base 10 anti-logarithm of value.
ln	`LN(value)` Returns the natural logarithm of value.
exp	`EXP(value)` Returns the natural anti-logarithm of value.
Int	`INT(value)` Returns the integer part of value.

Tab. 78: Functions of the Insert Function dialog

Definition of Maintenance Jobs

Example 1

Defining a conditional maintenance reminder:

In this example you want to define a maintenance message that will remind the operator, every morning when starting-up the system, to check the system liquid level (full), liquid waste and tip waste levels (empty).

To do so:

1) Click on the Add Job button to define a new maintenance job.

2) In the is true then run job: field enter the general name of the maintenance reminder you want to define, e.g. "General level checking prompt". This text is automatically entered in the maintenance jobs list.

3) Click on the Add Task button to define the job(s) included in this maintenance job. This opens the ADD MAINTENANCE TASK dialog.

4) Select Display message and click on the OK button. This opens the DISPLAY MESSAGE TASK dialog.

5) In the blank space, enter the text of the message prompt. For example: "Check the fill level of the system liquid container and waste container."

6) Click on the OK button to close this dialog and to return to the Maintenance tab.

7) Now you have to specify when this message prompt should be displayed. To do this, click on the Insert Function button. This opens the INSERT FUNCTION dialog.

8) In the current example, you want to specify that the message prompt should be displayed every day upon start-up. Define the condition (`Days>=1`) in the If edit box by using the INSERT FUNCTION dialog (e.g. `Days` and the keyboard for `>=1`).

9) When done, click on the OK button to confirm and close the MAINTENANCE tab.

Now every morning when you start-up your EUROIMMUN Analyzer I-2P instrument, the entered prompt is displayed.

Example 2

Defining an automated maintenance task

In this example you want to predefine an additional "Purge washer routine" that can be launched easily when needed (e.g. after using specific wash buffers...).

To do so:

1) Start as described in the previous example. In the is true then run job field enter "Purge washer routine".

2) When you get to the ADD MAINTENANCE TASK dialog, select Purge washer and click on the OK button.

3) You are then prompted to select the container and how much liquid is to be used to purge the washer (e.g. “Black” for the cleaning fluid container and “10 ml/tip”). It is useful to define a message to inform the user about the function of this maintenance job (see example 1 and complex jobs).

4) When done, click on the OK button to confirm and close the Maintenance tab.

In this case, you have defined the task but you have not defined a condition upon which the system would automatically perform the maintenance routine. You must start this maintenance job manually (► *Chapter 11.5 Maintenance Jobs, p. 209*).

Complex Jobs

More elaborate maintenance routines:

From these two relatively simple examples, you can program all sorts of more complex maintenance checklists or conditional routines such as:

- Start-up checklist: add several consecutive "Display message" tasks and a `Days>=1` condition.
- Weekly maintenance routine reminder: condition `Days>=7`.
- Prime / Purge routine if the system has not been used for over 2 weeks: Condition `Days>=15 AND Worklists=0`.
- Empty tip waste reminder if 900 or more tips have been used: condition `Tips>=900`.

- Rinse all four washer lines: combine messages to prompt user to fill all four wash buffer bottles with rinse fluid and 3 purge washer tasks, one for each wash buffer bottle. End with a message.

NOTE

Note however that the maintenance status and conditions are checked only each time the instrument is initialised. So, if, for example, you define a message to remind you to empty the tip waste container when you have used more than n tips, the message will not be displayed as soon as tip n + 1 is used but only the next time the instrument is initialised (i.e. upon start-up or when a self-test is performed).

Log and Skip

Logged maintenance jobs / skipped maintenance jobs

Each time you perform (or allow the system to execute) a predefined maintenance routine, this is recorded in the log file.

The log file also keeps track of all cases where the operator was prompted to execute a conditional routine but decided to skip it.

In the log file, performed routines are displayed in black, skipped routines in red.

A required maintenance routine can only be skipped by the operator if the person who defined it selected the User can skip job checkbox in the Maintenance tab.

11 Maintenance and Cleaning

Maintenance jobs, which are listed in the maintenance schedule, are necessary to ensure reliable operation of the instrument. Perform all steps in the maintenance wizard to achieve the best possible maintenance result.

Pay attention to the safety note in the Safety chapter (► *Chapter 2 Safety, p. 25*).

Independent of the maintenance work carried out by the user, semi-annual and annual maintenance is prescribed for the instrument. This is carried out by the EUROIMMUN technical service department or an authorised EUROIMMUN service engineer.

11.1 Safety and notes about cleaning/decontamination

⚠ WARNING

NON-COMPLIANCE WITH THE SAFETY NOTES

Personal injury and property damage

> Observe all safety notes before performing maintenance work on the instrument.

⚠ WARNING

FAULTY OR LEAKING TUBES, SYRINGES, VALVES OR PUMPS

Incorrect analysis result

> Pay attention to the maintenance intervals.
> If anomalies or ambiguities arise, contact the responsible service engineer.

⚠ WARNING

TYPE OF HAZARD
BIOLOGICAL SUBSTANCES AND REAGENTS

Potential risk of infection/skin irritation

> Avoid skin/mucous membrane contact with the biological substances and reagents used as well as instrument parts that come into contact with biological substances and reagents.
> Treat the aforementioned parts as potentially infectious material.
> Wear suitable protective clothing (protective gown, protective gloves and if needed, safety goggles).
> Pay attention to safety indications!
> Dispose of all waste in accordance with legal regulations for biological hazardous waste.

⚠ WARNING

HAZARDOUS INGREDIENTS

Danger to health

> Use decontamination products as instructed (as indicated on the bottle).
> Read the instructions for the decontamination products before use.

Please follow closely the steps contained in the individual instructions to achieve a perfect function of the instrument.

- Disinfectants must not come into contact with bearings and guides, as otherwise the greasy film may dissolve!
- Disinfectants must not be used in the vicinity of circuit boards, light barriers and Plexiglas surfaces!
- Take care not to touch any optic surfaces (e.g. scanners, lenses, sensors)!
- The operator may only perform the maintenance work described in these instructions for use.
- Only clean the glass panel of the barcode scanner with a soft and lint-free cloth. Do not use any aggressive detergents (e.g. acetone).
- We recommend Gigasept®, Liquinox® or Rivascop® to decontaminate the instrument. Do not use the decontamination liquid undiluted!
- Do not use bleach or decontamination liquid with alcohol!
- Use soft cloths with neutral detergent or with ethanol to clean the touch screen. Do not use any chemical solvents, or acidic or alkali solutions. Do not allow liquid to soak into the joint of film and glass as this may result in peeling or malfunctioning.
- DO NOT autoclave containers or parts of the instruments!

When the instrument is turned off, mobile modules such as the pipettor guide rail or the plate transport unit may be moved manually so as to get better access to certain parts of the instrument. This is to be done as gently as possible so as not to damage or align the modules.

Spare wash buffer bottles (with normal caps) can be ordered from EUROIMMUN. If you have spare bottles, you can remove and store partially empty bottles while performing the cleaning procedure with spare bottles. (This means that you do not need to transfer the buffer to storage containers at night and re-transfer it back into the bottles later).

11.2 Daily Maintenance

11.2.1 Start-up

	Maintenance	Power supply	Also refer to
System liquid container	Check the level of system liquid in the system liquid container. If low, refill with distilled water.	OFF	► *Chapter 11.5 Maintenance Jobs, p. 209*

	Maintenance	Power supply	Also refer to
Waste liquid container	Check the level of waste liquid in the waste liquid container. If full or nearly full, empty and decontaminate it. Dispose waste liquid in accordance with legal regulations for biological hazardous waste.	OFF	–
Pipettor	Perform self-test and check pipettor tubing and syringe for air bubbles or leakages as these can cause pipetting errors.	ON	► *Chapter 11.6.1 Visual inspection of the tube system, p. 209* ► *Chapter 11.6.2 Visually Check Syringe and Three-Way-Valve, p. 210*
Washer bottles	Prepare wash buffer and adjustment solution in the required quantities. Discard any residual solution from previous runs and clean the container with distilled water. Ready for use wash buffer and adjustment solution are stable for up to three days if stored in the system and unchilled.	ON	–
Washer	Start the “Washer Check-2P” assay to check the washing performance (equal liquid level in the first 6 strips or dryness of the last 6 strips). The first 6 strips are filled as follows: strip 1-2 EU wash buffer, 3-4 adjustment solution, 5-6 distilled water. If the washer check result is unsatisfactory, check / clean the washer head needles and repeat the washer check. To access the washer head needles remove the aluminium cover using a screwdriver.	ON	–

Tab. 79: Daily maintenance: System start

11.2.2 After each run

	Maintenance	Power supply	Also refer to
Inspect instrument	Inspect instrument deck, plates, racks, etc. for spillages. If there are spillages, check instrument for leakages.	ON	► *Chapter 11.6.1 Visual inspection of the tube system, p. 209* ► *Chapter 11.6.2 Visually Check Syringe and Three-Way-Valve, p. 210*
Remove racks	Remove patient sample and reagent racks. Dispose of tubes and bottles in accordance with legal regulations for biological hazardous waste.	ON	► *Chapter 8.10.1 Unloading of Test plates, p. 118* ► *Chapter 8.10.3 Unload Reagent Racks, p. 120*
Remove plates	Unload used microplates and (full) dilution plates. Dispose of microplates and dilution plates in accordance with legal regulations for biological hazardous waste.	ON	► *Chapter 8.10.1 Unloading of Test plates, p. 118* ► *Chapter 8.10.4 Unload Tip Racks and Dilution Plates, p. 120*
Waste bag for disposable tips	Check the waste bag for disposable tips. If full or nearly full, replace it. Dispose of the waste bag in accordance with legal regulations for biological hazardous waste.	ON	–
System liquid container	Check the level of system liquid in the system liquid container. If low, refill it.	ON	► *Chapter 11.5 Maintenance Jobs, p. 209*

	Maintenance	Power supply	Also refer to
Waste liquid container	Check the liquid waste level in the liquid waste container. If full or nearly full, empty and decontaminate it. Dispose waste liquid in accordance with legal regulations for biological hazardous waste. Observe all safety notes and tips about cleaning/decontamination (► *Chapter 11 Maintenance and Cleaning, p. 201* and ► *Chapter 11.1 Safety and notes about cleaning/decontamination, p. 201*)	ON	–

Tab. 80: Daily maintenance: After every run

11.2.3 Shut down

	Maintenance	Power supply	Also refer to
Inspect instrument	Inspect instrument deck, plates, racks, etc. for spillages. If there are spillages, check instrument for leakages.	ON	► *Chapter 11.6* ► *Chapter 11.6.2*
Remove racks	Remove patient sample and reagent racks. Dispose of tubes and bottles in accordance with legal regulations for biological hazardous waste.	ON	► *Chapter 8.10.2* ► *Chapter 8.10.3*
Remove plates	Unload used microplate and dilution plates. Partially used dilution plates may remain on the instrument overnight, particularly if you are using the "Re-use partially dilution plates" option. Dispose of plates in accordance with legal regulations for biological hazardous waste.	ON	► *Chapter 8.10.1* ► *Chapter 8.10.5*
Wash buffer container	Remove all storage containers that contain wash buffer. Now place the spare containers filled with distilled water in the instrument and start the “Rinse_daily-2P” assay.	ON	–
Close worklist and files	Close all finished worklists and opened files (assay files, result files, etc.)	ON	► *Chapter 9.4*
Exit user software	Close the EUROIMMUN Analyzer I-2P software (select File > Exit from the menu).	ON	–
Shut down windows	Close all windows and properly shut down the Windows software	ON	–
Switch off	Switch off the instrument.	OFF	–

	Maintenance	Power supply	Also refer to
Waste bag for disposable tips	Check the waste bag for disposable tips. If full or nearly full, replace it. Dispose of the waste bag in accordance with legal regulations for biological hazardous waste.	OFF	► *Chapter 8.10.6*
System liquid container	Check the level of system liquid in the system liquid container. If low, refill it.	OFF	► *Chapter 11.5*
Waste liquid container	Check the liquid waste level in the liquid waste container. If full or nearly full, empty and decontaminate it. Dispose of the waste liquid in line with the legal requirements for biological hazardous waste. Observe all safety notes and tips about cleaning/decontamination (► *Chapter 11.1*).	OFF	–
Disposable tip racks	Unload disposable tip racks. Partially used tip racks may remain on the instrument overnight (particularly if you are using the "Re-use partially disposable tip racks" option (► *Chapter 8.7.6*).	OFF	–
Reagent and control bottles	If they are not empty and can be re-used, remove the reagent and control bottles from the racks or instrument, close them (be careful not to mix the caps!) and store them in a refrigerator. Otherwise, dispose of them in accordance with legal regulations for biological hazardous waste. NOTE: Do not store racks in a refrigerator!	OFF	–

	Maintenance	Power supply	Also refer to
Testing/ Cleaning/ Decontamination	Every evening after shut down, inspect the instrument for stains or spills. Make sure to inspect all individual surfaces, compartments and work areas: Outer surfaces, particularly around the handle of the cover. Open the cover to check the upper work areas. Pipettor wash station Sample and reagent unit Make sure no tips have remained blocked in the waste slide (ramp). If necessary, pull out the slide to do so. Do not forget to check for liquid underneath the wash buffer bottles. If you discover spots, small puddles or generally dirty areas, decontaminate them (► *Chapter 11.3)* . Observe all safety notes and tips about cleaning/decontamination (► *Chapter 11.1*).	OFF	–

Tab. 81: Daily maintenance: Shut-down

11.3 Weekly maintenance

	Maintenance	Power supply	Also refer to
Washer Cleaning	Procedure: Empty all storage containers (3) and clean them thoroughly, e.g. using a bottle brush. Then rinse the containers with distilled water. Fill them with distilled water and reconnect them to the system. Start the “Maintenance_weekly-2P” assay to flush the channels and the wash head with distilled water. Decontaminate the pipettor washing station by filling approximately 5 ml of disinfectant (e.g. Mikrozid) into the station and leaving to act for at least 15 minutes. Initiate the self-test under «Utilities» to aspirate off the solution. Then clean the washing station using a paper towel. Decontaminate and clean the tip waste tunnel. Empty, disinfect and rinse the waste liquid container.	ON	–

	Maintenance	Power supply	Also refer to
Instrument and accessories cleaning/decontamination	Clean and decontaminate all individual surfaces, compartments, work areas and accessories: Outer surfaces All work areas Tip eject station Loading bay Loading bay barcode scanner Plate transport unit Touch screen (only with soft cloths with neutral detergent or ethanol) Racks Plate carriers Observe all safety notes and tips about cleaning/decontamination (► *Chapter 11.1*).	OFF	–

Tab. 82: Monthly maintenance

11.4 Monthly maintenance

	Maintenance	Power supply	Also refer to
Washer cleaning/decontamination	Fill all three storage containers with the EUROIMMUN Setup Clean cleaning solution and dilute it 1:5 (e.g. 100ml Setup Clean + 400ml distilled water per container). Subsequently, add 500 µl of EUROIMMUN defoamer for Setup Clean to 500 ml of cleaning solution. Start the “Maintenance_monthly-2P” assay to flush the channels and the wash head with the solution. Then empty the storage containers. Prepared cleaning solution can be stored and reused at a later stage. Thoroughly rinse the storage containers with distilled water. Fill all storage containers with distilled water and perform the “Rinse_monthly-2P” assay to remove the cleaning solution from the tubes. Empty and disinfect / clean the system liquid container (e.g. using Mikrozid / Mucasol). Then rinse thoroughly using distilled water to remove all cleaning agent residues from the container. Empty, disinfect and clean the system liquid container. Then rinse thoroughly using distilled water to remove all cleaning agent residues from the container.	ON	► *Chapter 11.1*

	Maintenance	Power supply	Also refer to
Cleaning/decontaminating the instrument and accessories	Use a soft lint-free cloth, moistened with ethanol, to gently clean the head of the pipettor. Observe all safety notes and tips about cleaning/decontamination (► *Chapter 11.1*).	OFF	–

Tab. 83: Monthly maintenance

11.5 Maintenance Jobs

- As part of its normal operating routine, the EUROIMMUN Analyzer I-2P performs a number of maintenance jobs automatically. For example:
- During each self-test (► *Chapter 9.1 Initialisation and Self-test, p. 123*), the system checks the status of all instrument modules.
- During each run, the pipettor is primed with system liquid.
- Following each wash step, the washer is purged with cleaning fluid (deionised water).

11.6 Special Maintenance Procedures/Emergencies

This section describes maintenance procedures that are not to be performed on a regular basis but as needed depending on events/incidents affecting the instrument or its environment.

For an emergency stop (cancelling a run) and emergency test plate removal, see ► *Chapter 8.8.7 Emergency Stop/Cancelling a Run, p. 112* and ► *Chapter 9.5.3 Test Plate Removal, p. 153*

11.6.1 Visual inspection of the tube system

⚠ WARNING

FAULTY OR LEAKING TUBES, SYRINGES, VALVES OR PUMPS

Incorrect analysis result

> Pay attention to the maintenance intervals.
> If anomalies or ambiguities arise, contact the responsible service engineer.

⚠ WARNING

POORLY FLUSHED TIPS

Mixing of sample material

> Pay attention to the maintenance intervals.
> If anomalies or ambiguities arise, contact the responsible service engineer.

Make sure all tubing is in good condition and properly connected to connectors.

1) Switch the EUROIMMUN Analyzer I-2P off.
2) Disconnect main power from the system.
3) Check all tubing connections thoroughly.
   - If they are poor or loose tighten them properly.
4) Check tubing for any signs of wear or leaking.
   - Call service to change worn or leaking tubing.
5) Make sure tubing insides are clean and free from any deposits, residues or clogs.
   - If the tubing seems to contain residues, deposits or air bubbles, flush the system. If necessary, decontaminate the system as described in the decontamination procedures.
   - If there are still deposits, residues or clogs, contact the Service department to change the tubing.

11.6.2 Visually Check Syringe and Three-Way-Valve

⚠ WARNING

FAULTY OR LEAKING TUBES, SYRINGES, VALVES OR PUMPS

Incorrect analysis result

> Pay attention to the maintenance intervals.
> If anomalies or ambiguities arise, contact the responsible service engineer.

⚠ WARNING

POORLY FLUSHED TIPS

Mixing of sample material

> Pay attention to the maintenance intervals.
> If anomalies or ambiguities arise, contact the responsible service engineer.

1) Switch the EUROIMMUN Analyzer I-2P off.
2) Disconnect main power from the system.
3) Check the syringe connections thoroughly.
   - If they are poor or loose tighten them properly by hand.
   - Syringes have to be leak free and clean.
   - If they are leaking or the glass barrel is scratched call service to change it.
4) Check the valve connection thoroughly.
   - If after inspecting the liquid paths, dripping is observed at the end of the tip adapter, the valve may require replacement.
   - Call service to change the valve.

11.6.3 Heavy Liquid Overflow

In case liquid overflows into the instrument modules while the system is running:

1) Immediately switch the EUROIMMUN Analyzer I-2P off.
2) Disconnect the power cord.
3) Using absorbent paper, clean up all excess liquid.
4) Be sure to check all areas that may have been affected. Unload the racks from the sample and reagent units, check the various modules (including incubators, photometer).
5) Dispose of used absorbent paper in accordance with legal regulations for biological hazardous waste.
6) Decontaminate the affected areas as described in the maintenance sections.
7) Allow to dry.
8) Before turning the system on again, identify the source of the problem (damaged tubing, faulty washer...) and take appropriate actions. If in doubt, call your EUROIMMUN service engineer.

The procedure is identical if the liquid overflow is noticed only some time after the incident has occurred. Even if the instrument is already turned off, do not forget to disconnect the power cord.

11.6.4 Washer Malfunction

Cleaning a Clogged Wash Head

⚠ WARNING

BIOLOGICAL SUBSTANCES AND REAGENTS (WASH HEAD)

Potential risk of infection/skin irritation

> Avoid skin/mucous membrane contact with the biological substances and reagents used as well as instrument parts that come into contact with biological substances and reagents.
> Treat the aforementioned parts as potentially infectious material.
> Wear suitable protective clothing (protective gown, protective gloves and if needed, safety goggles).
> Pay attention to safety indications!

If the wash function is no longer adequate, you have to clean the needles of the wash head.

1) Open the service cover of washer (6) and remove it.
2) Using the supplied cleaning needle to clean the 8 dispensing and the 8 aspirate needles of the wash head.

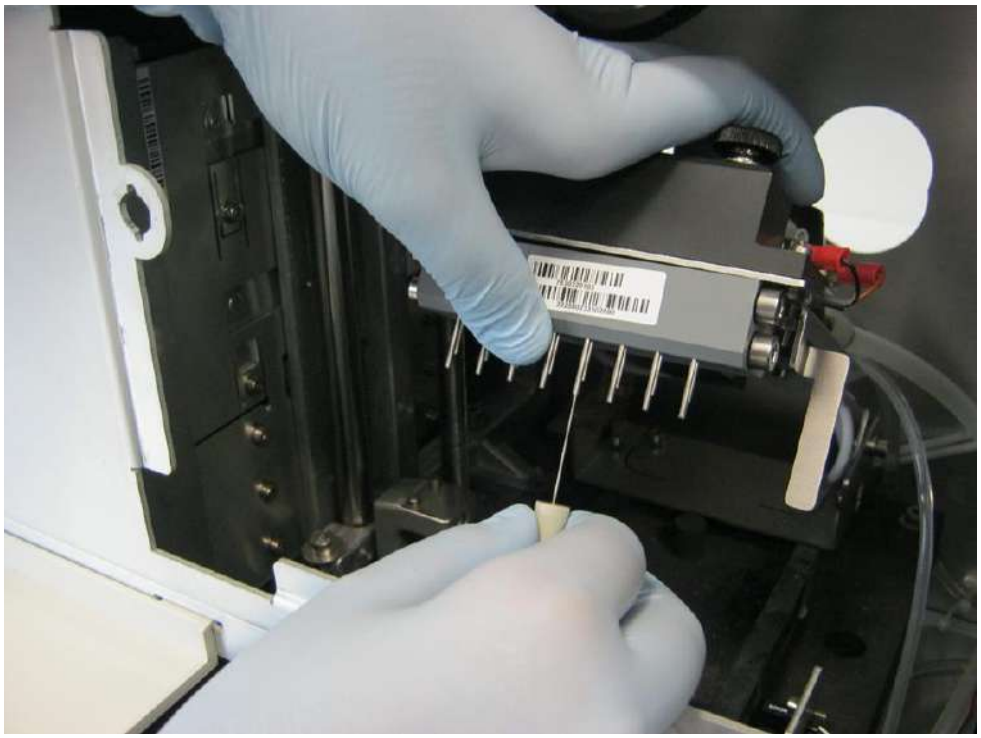


Fig. 81: Cleaning the wash head needles

3) Install the service cover of washer (6).

Other Problems

If you have performed all the above actions but the washer still does not operate correctly, other parts such as filters or pumps may be involved. Call your EUROIMMUN service engineer for assistance.

11.6.5 Power Supply Malfunction

Power Cuts/Outages

If a power cut occurs during a run, the system can rely on a recovery file to resume the run automatically when the power cut is over.

When the power supply is reset, the EUROIMMUN Analyzer I-2P will normally prompt the operator to continue the run from where it was interrupted (your decision to continue the run will depend on the duration of the power cut). Note, however, that if only a part of a plate has been processed, the system does not keep track of the sample locations and you may have to reselect the patient samples to be tested.

If the power cut occurs outside of a run, turn off the instrument.

If you frequently experience power supply fluctuations, it is recommended that you install a UPS (Uninterruptible Power Source) device to protect your EUROIMMUN Analyzer I-2P.

Replacement of Main Fuses

⚠ WARNING

ELECTRIC VOLTAGE

Electric shock

> Spare fuses must match the values (nominal voltage, nominal current, and type) specified by the manufacturer.
> Never short-circuit the fuse holder.
> Always replace burned fuses, never repair them.

The EUROIMMUN Analyzer I-2P operates with two fuses that are located in a fuse holder at the right side of the instrument, just above the power supply cord.

If the instrument does not power on when you press the ON/OFF switch, the power fuses may be blown. Spare fuses are supplied with the instrument or can be purchased from EUROIMMUN.

To replace a blown fuse:

1) Switch off the instrument.

2) Disconnect main power from the system.

3) Pull out the fuse carrier with a screwdriver.

Fig. 82: Fuse carrier

4) Change the faulty fuse(s): Fuse: 3.2 AT, 250 V

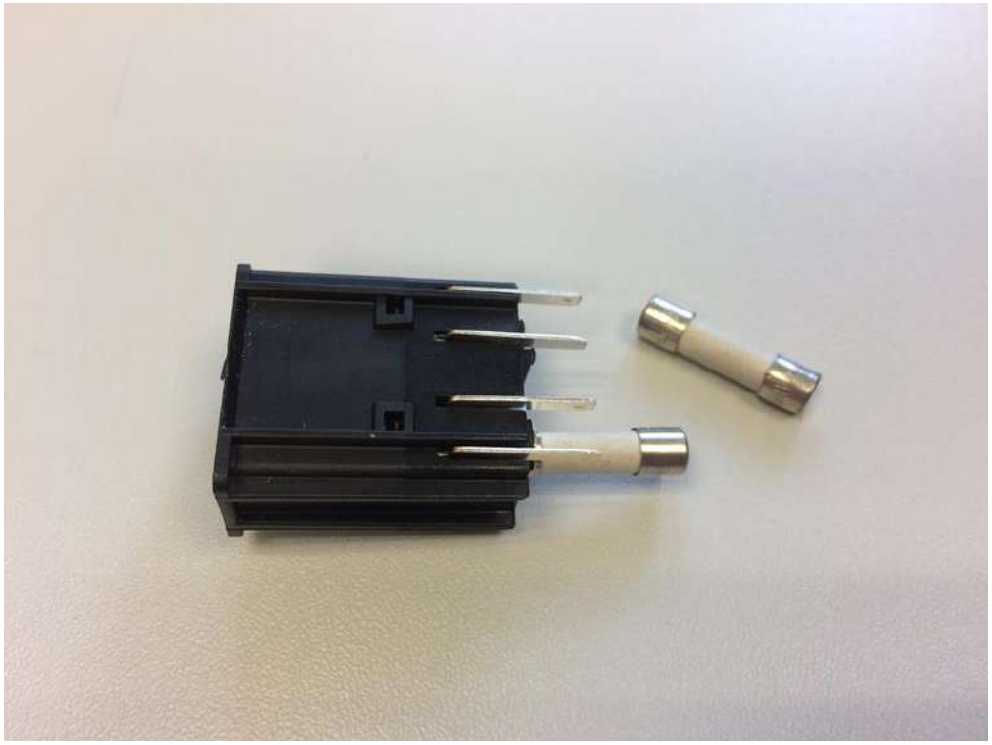


Fig. 83: Fuse carrier with fuses

5) Insert the fuse carrier.

6) Connect the main power.

7) 3 Switch on the instrument.

NOTE

Although spare fuses are provided with the instrument and the replacement procedure is described above, you should be aware that blown fuses are very often indicators of other malfunctions that may be affecting instrument modules, components or wires. If in doubt or if the fuse blows again shortly after you have replaced it, please call your EUROIMMUN service engineer for assistance.

11.6.6 Photometer Malfunction

Replacement of Photometer Lamp

Module uses halogen lamp, it will be hot even after short periods of use and takes time to cool down.

⚠ WARNING

HOT SURFACE

Risk of burns

> Leave the halogen lamp to cool before touching it.
> Take care not to touch any optical surfaces (e.g. bulb, mirror)!

Removing the lamp

In the event of a lamp failure, replace the lamp with the recommended part only. Use of other lamps is not acceptable.

1) Shut down the computer and switch off the system.

2) Disconnect main power from the system.

3) Remove both retaining screws (2) and the photometer service cover (1).

Fig. 84: Photometer service cover

4) Lift the lamp retaining clip (3) and remove the lamp (4).

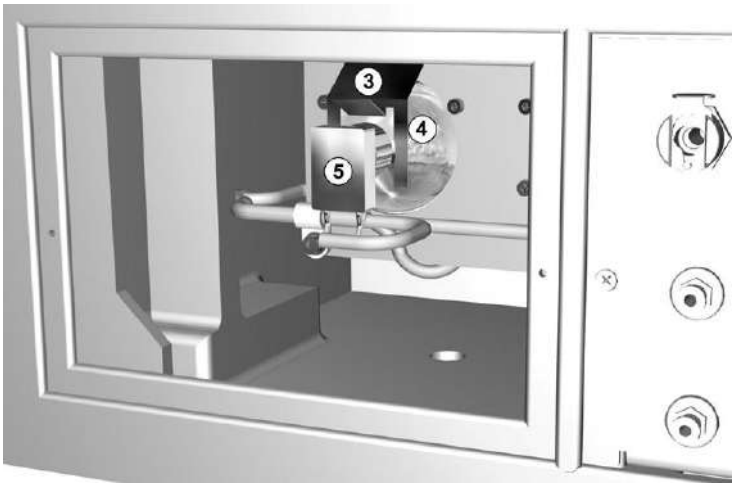


Fig. 85: Photometer lamp

5) Disconnect the lamp connector (5).

Installation

1) Plug the new lamp (4) into the lamp connector (5).

2) Lift the lamp retaining clip (3) and insert the lamp (4).

3) Install the photometer service cover (1) and tighten both retaining screws (2).

4) Execute the verification plate process to verify the new lamp.

11.7 Damaged Parts

In most cases, repairing and/or replacing damaged parts will require the assistance of your EUROIMMUN service engineer.

If in doubt, please call before trying to repair/change the part yourself.

However, two specific cases need to be mentioned.

Parts damaged during shipment:

If you have ordered parts that are shipped directly to you, examine them carefully when unpacking. Although they are packed to provide maximum protection, damage can occur. In this case, report the damage in the first place to the carrier/shipping company and then to the supplier.

Decontamination

If you want to return damaged parts to EUROIMMUN or to your local supplier (e.g. if under guarantee), please note that the parts must be decontaminated first. Follow the maintenance procedures to decontaminate the instrument and accessories (► *Chapter 11.1 Safety and notes about cleaning/decontamination, p. 201*).

12 Troubleshooting

This chapter sets out solutions to technical problems with the instrument. If these solutions do not rectify the problem, please contact the EUROIMMUN Technical Service department.

► *Chapter 1.9 Information on IT security, p. 23*

► *Chapter 1.10 Technical Service, p. 24*

12.1 Error messages

If the EUROIMMUN Analyzer I-2P does not work, this is often due to minor problems which you can deal with yourself.

This chapter describes error messages and the associated error recovery measures.

System messages appear in the status bar of the EUROIMMUN Analyzer I-2P software. Error messages are displayed in a separate window, which has to be confirmed. Some of these messages are also written into the result report.

'%1' and '%2' are place holders for a system module or the designation of a plate, a reagent or an error number.

Error message	Cause	Measure
A result file already exists for plate "xxxx"	The system will automatically generate a result file not for each worklist but for each plate included in a worklist. This result file will be named after the Plate ID displayed in the Load Plate dialog (e.g. "HBc01.res"). Therefore, if you choose a Plate ID that has already been used in a former worklist, when you click on the OK button, the system will display this warning message.	Unless you specifically want to overwrite the former result file, click on the No button and go back to the Load Plate dialog to change the Plate ID. To do so just delete the name shown in the Plate ID field and enter a new name. Therefore, when choosing a Plate ID, try to find a precise name that will differentiate each test from previous or future tests. Do not keep the default ID “Plate 1”, “Plate 2”, etc., and do not simply enter the test ID “Adeno”, “B2”, etc. The system does not expect a specific format, any sequence of alphanumeric characters (with or without spaces) can be entered. To replace the existing result file, click on the Yes button. Note that the overwritten result file will be lost.
ABORT button pressed	The Stop button has been clicked during a run.	The run has been interrupted and may be continued or aborted completely (► *Chapter 8.8.7*).

Error message	Cause	Measure
Plate “xxx” will be aborted	The operator clicked the Stop button during a run and then, in the Pause dialog, requested that the processing of one or more plates be aborted	You can decide to resume the run for the remaining plates or abort it completely (► *Chapter 8.8.7*)
Argument error in command	During initialisation procedure. Faulty firmware is installed.	Call service to reinstall the firmware for the module concerned. If error recurs the PCB of concerning module has to be checked.
Clot detected in patient sample %1	During the run. Clots were detected in patient sample %1. Inaccurate teaching. Deficient sample preparation Incorrect tracking due to wrong sample rack type Incorrect tracking due to wrong tube diameter Tip touches the (wet) wall of a tube.	Recovery options: Skip Sample button: system will skip the affected sample and continue with the work list. Abort Plate button: Plate will be aborted. Continue button: system continues but affected sample will be flagged. Error Recovery: Check if correct tubes were used. If error recurs, call service to check the teaching.
Colorimeter fatal error %2: A/D error	During initialisation procedure or during the run. Error of the analogue/digital converter of the photometer.	Restart the system again. If the error recurs, call service to check the photometer module.
Colorimeter fatal error %2: A/D over range	During initialisation procedure or during the run. Upper limit of analogue/digital converter of the photometer has been exceeded due to the signal height of the pre-selected resolution.	Recovery options: Retry button: System will try to repeat the last step. Ignore button: Not advisable, as the system cannot go on without this leading to sequence errors. Click the Retry button. If the error recurs, abort the work list and check the filters and the photometer lamp. Error Recovery: If error recurs after checking the filters and the lamp, call service to check the whole photometer module.

Error message	Cause	Measure
Colorimeter fatal error %2: A/D under range	During initialisation procedure or during the run. Too little light reaches the electronic of photometer.	Recovery options: Retry button: System will try to repeat the last step. Ignore button: Not advisable, as the system cannot go on without this leading to sequence errors. Abort button: the worklist will be aborted. Click the Retry button. If the error recurs, abort the worklist. The whole photometer module has to be checked. Error Recovery: The halogen lamp of the photometer is faulty and has to be replaced. If the error persists, the optical components in the photometer (filter, upper or lower optic block) may be dirty. Call service to clean or replace the photometer.
Colorimeter fatal error %2: Background light detected. Values out of range	During initialisation procedure or during the run. Typically occurs when light entered the measurement chamber.	Restart the software to initialise the photometer again. Check if the photometer cover, all instrument sheet metal covers and the deck top are installed correctly and all filters are installed. If this error recurs, call service.
Colorimeter fatal error %2: EEPROM read failure	During the communication between colorimeter and PC.	Initialize the module again. If the error recurs, the PCB of the photometer must be checked. Plate transport fatal error %2:
Colorimeter fatal error %2: Invalid filter	During initialisation procedure. The gain factor for the respective filter cannot be identified.	Restart the software to initialize the photometer again, after checking the filter configuration. If the error recurs, the relevant filter must be replaced. Plate transport fatal error %2:
Colorimeter fatal error %2: Drive not moving	During initialisation procedure. The system does not recognize the current position of the filter motor.	Restart the software. If the error recurs, the filter wheel must be checked. Plate transport fatal error %2:
Colorimeter fatal error %2: Lamp error	During initialisation procedure. Halogen lamp of photometer is faulty.	Replace halogen lamp and restart the software to initialise the photometer again.
Colorimeter fatal error %2: Optic channel error	During initialisation procedure. One of the optical channels is faulty.	The lower or upper optic block must be cleaned, or the fibre optics have to be replaced. Plate transport fatal error %2:

Error message	Cause	Measure
Colorimeter fatal error %2: Positioning error	Plate movement is faulty.	If the error recurs, call service to check the plate transport teaching of the reader position, the guide rails and the plate carriers.
Command execution error	During initialisation procedure. Faulty firmware is installed.	Call service to reinstall the firmware for the module concerned.
Command not implemented	During initialisation procedure. Faulty firmware is installed.	Call service to reinstall the firmware for the module concerned.
COMGEN error '%1'	At start-up. Cable connection between PC board and instrument CU board is faulty.	Start instrument again. If this error recurs, call service.
Crash cover file of a worklist detected. Do you want to try and recover the work list?	After power failure.	ATTENTION: It is not recommended to use the crash recovery. Any results produced in a recovered run should be discarded. Details on recovery procedure: Message: "Do you want to try and recover the work list?" No button: Software continues with initialising the system. Old worklist will be deleted. Yes button: The following message appears: "Is the system still running?" No button: The system first initialises the modules before continuing with the next worklist step. Yes button: System will continue with the next worklist step.

Error message	Cause	Measure
Pipettor error 0x70 - Disposable tip dropped '%1	The disposable tip has fallen off the adaptor unexpectedly. Possible causes: Defective tip Insufficient tip pick-up force due to excessive friction inside the z drive. Insufficient tip pick-up force due to excessive flexibility in the tip tray or deck top.	The user should pick up the dropped tip, check for possible contamination and for what could have caused the problem and select the appropriate recovery option. ATTENTION: Especially, if the error occurred while the pipettor was moving across any wells, vials or tubes, the affected plate must be aborted. The error is logged in the event log. Recovery options: Retry button: The system will repeat the pipetting step where the error occurred after initialisation of the pipettor arm. Abort Plate button: Plate will be aborted. Ignore button: The affected sample will be flagged. System goes on with the next pre-dilution.
Scanner fatal error %2: Drive not moving	Motor error in scanner of reagent and sample rack. Scanner firmware not working correctly. Electrical or mechanical problems of scanner.	If error occurs use the option of allocating the reagents and samples manually. The loading bay barcode scanner must be checked. Plate transport fatal error %2:
Duplicate patient ID %1 Edit the patient IDs so that only one tube is used per patient.	Two loaded sample tubes with identical barcodes.	Remove the sample tubes and use another barcode for one of these tubes (► *You want to process two tubes of each sample (*duplicate sample tubes)*, p. 233*).
%1 fatal error: Argument error in command	During initialisation procedure. Component cannot be actuated.	Restart software and analyser. If the error recurs, the affected module must be checked. Plate transport fatal error %2:
Error during assay layout reduction. Reduce the number of patient samples. Check that the assay layout is reducible.	After adding assay and patient to the plate. Too many samples are used on this plate.	Click the OK button and reduce the number of patients, so that a maximum of 96 wells are used per plate.
Error opening '%1'	Error during reading or writing a file (network down or directory moved/deleted).	Check or change the target directory in the Directories tab of the Options dialog (► *Chapter 10.1.7*).
Error scheduling plate '%1'	After adding plate and assay. The assay programming is not correct or the combination of different plates cannot be scheduled.	Click the OK button and modify the assay list or worklist.
%1 fatal error %2: Illegal parameter (length/type)	During initialisation procedure. Faulty firmware is installed.	Call service to reinstall the firmware for the module concerned.

Error message	Cause	Measure
Incubator fatal error %2: Heater drive failure	During initialisation procedure or during the run. The heater foil of incubator box %1 is faulty.	The heater of the incubator box concerned must be checked. Plate transport fatal error %2:
Incubator fatal error %2: Temperature sensor failure	During initialisation procedure or during the run. The temperature sensor of the incubator box is faulty.	The temperature sensor of the incubator box concerned must be checked. Plate transport fatal error %2:
%1 fatal error %2: Initialisation position not reached or Init not in init direction	During initialisation procedure of the plate transport (can also be initiated by washer or reader). Error of the plate transport init light barrier or plate transport drive.	Restart the software and system. If the error occurs during a run, click the Abort button to cancel the worklist. After this error occurs a recovery is not possible. If the error recurs the plate transport drive and its Init light barrier have to be checked. Plate transport fatal error %2:
Insufficient volume of reagent %1	At reagent check if volume of reagent is insufficient.	Recovery options: Abort button: reagent check will be aborted. The system goes on with the work list. Refill bottle button: software jumps back to the loading window where reagents can be filled up. Continue button: The system checks the volume of the next reagent. To make sure that worklist will run without pipetting errors, click Refill bottle and make sure that enough reagent liquid is available. Error Recovery: If this error occurs although there is enough liquid provided in the reagent bottle, check if the bottle type used is correct. Call service to check the teaching.
Insufficient volume of sample %1	During the run if volume of sample is insufficient.	Recovery options: Retry button: The system will try to repeat the last measurement of the fill level. Abort button: The sample will be aborted. Abort Plate button: Plate will be aborted. Ignore button: The affected sample will be flagged. System continues with the next sample.

Error message	Cause	Measure
Invalid pipettor coordinate on plate %1, label %2! Check that the dispense and aspirate labels are consistent.	After adding plate and assay. The assay programming is faulty. A label of a sample is undefined.	Click on OK. Modify the assay definition and restart the worklist.
No disposable tips left	During the run. No more tips available or found.	Automatic appearance of the loading window after system message occurs. Load the correct tips to the suggested position. After clicking the OK button the worklist will continue.
No liquid detected for reagent %1	During the run. No liquid for reagent %1 is detected if reagents check was disabled.	Recovery options: Retry button: The system checks the regent level again. Abort Plate button: Plate will be aborted. Abort button: the worklist will be aborted. To make sure that the worklist will run without pipetting errors, click Abort and enable the Reagent check in the worklist options. After that, you have to start the work list again. The old work list cannot be recovered. Error Recovery: If this error occurs although there is enough liquid provided in the tube, check if the tube size used is correct. Call service to check the teaching.
No liquid detected for sample %1	During the run. No liquid for sample %1 is detected if sample check was disabled.	Recovery options: Retry button: System will check level of sample again. Ignore button: System continues but affected sample will be flagged. NOTE: Air can be pipetted if you click Ignore. Abort Plate button: Plate will be aborted. Abort button: The affected sample will be aborted.

Error message	Cause	Measure
No response to command '%1'	System cannot communicate with PC.	Recovery options: Retry button: PC will try to connect to system again. Abort button: the worklist will be aborted. If the error message recurs after clicking Retry, restart the system. Error Recovery: Check the cable between PC board COP. Please call service to check the electronics.
Tip eject failure.		Remove tip manually from pipettor or trigger eject mechanism manually. Click the OK button after manually removing the tip. Click Retry. The system logs the failure in the event log and continues with the next step. If the error recurs call service to check the teaching and the friction force of the Z drive
%1 fatal error %2: Parameter not allowed	During initialisation procedure. Faulty firmware is installed.	Call service to reinstall the firmware for the module concerned.
Pipettor error 0X0E-LY (or LX) position not reached	During a pipettor movement. Pipettor crashes or mechanical problems.	Recovery options: Retry button: After initialisation, the system will try to reach the position again. Ignore button: Not advisable, as the system cannot go on without this leading to sequence errors. Abort button: the worklist will be aborted. Error Recovery: Click the Retry button to repeat the last step. If the error recurs, open system flap and check if there are any obstacles that disturb the pipettor movement. If no obstacles are present, the pipetting module must be checked. Plate transport fatal error %2:

Error message	Cause	Measure
Pipettor error 0x82 - Open loop/overload error '%1'	Pipettor crash during a run.	Recovery options: Retry button: After initialisation, the system will try to repeat the former pipetting step. Ignore button: System will continue with the next pipetting step. Abort button: Plate will be aborted. Error Recovery: Click the Retry button to repeat the last step. If the error recurs, open system flap and check if there are any obstacles that disturb the pipettor movement. If no obstacles are present, the pipetting module must be checked. Plate transport fatal error %2:
Plate carrier not detected	During plate transport movement. A plate carrier is not detected where it is expected. Possible causes: Wrong teaching Plate carrier does not interrupt a "plate in" light barrier in an incubator (or room temperature) slot: Defective light barrier, tolerance issue in the room temperature slots with the guiding rails (try to push the guiding rails farther to the back or exchange the plate carrier). Defective shake mechanism.	Recovery options: Retry button: Plate transport will try to load / unload the plate again. Ignore button: Not advisable cause system cannot go on without sequence errors. Abort button: The system aborts the plate processing. Error Recovery: Plate transport and incubator slots must be checked, please call service. Plate transport fatal error %2:
Plate transport fatal error %1: Positioning error	During initialisation procedure or during the run. Possible reasons for the error: Possible causes: Inaccurate control In particular, the control of the Z position of the incubator drive and the "plate in" Y position are critical for loading and unloading plate carriers. Defective encoders. Wrong belt tension misadjustment of the incubator slots Insufficient lubrication	Recovery options: Retry button: System will try to repeat the last movement step. Ignore button: Not advisable, as the system cannot go on without this leading to sequence errors. Abort button: Plate will be aborted. Error Recovery: After the error message occurs, make sure that there are no obstacles that have jammed the movement of the plate transport unit. Click Retry. If the error recurs, please call service to check the plate transport module.
Plate transport unit fatal error %1: EEPROM read failure	EEPROM error while reading / writing procedure.	Restart the system again. If the error recurs, please call service to change the instrument CU board.

Error message	Cause	Measure
Please close the system cover	During initialisation or when resuming from pause. System cover isn't closed.	Close the system cover and click the OK button. If the error recurs after closing the cover, call the Service department to check the cover sensor.
Please remove the plate from the system	During starting or stopping of a worklist. In order to save time in case OK is accidentally clicked before the plate is actually loaded, the software will not close the Load Plate dialog if no opening and closing of the cover for loading a plate has been detected.	Open the system cover and (after approx. one second) close it again. Then the dialog can be closed by pressing OK.
%2 fatal error %1: Positioning error	Motor error in scanner of reagent and sample rack. Electrical or mechanical problems of scanner.	If error occurs, please call service to check the barcode scanner of the loading bay.
%1: Rack scanner focusing error	During a reading step of barcoded sample/reagent rack. The barcode scanner cannot be focused.	If error occurs use the option of allocating the reagents and samples manually. The barcode scanner must be checked. Plate transport fatal error %2:
%1: Rack scanner motor error	Motor error in scanner of reagent and sample rack. Scanner firmware does not work correctly. Electrical or mechanical problems of scanner.	If error occurs use the option of allocating the reagents and samples manually. The barcode scanner must be checked. Plate transport fatal error %2:
%1: Rack scanner not connected	During initialisation procedure. Scanner of loading bay is not connected.	If error occurs use the option of allocating the reagents and samples manually. The barcode scanner must be checked. Plate transport fatal error %2:
Reagent '%1' is undefined	After adding plate, assay and sample. A reagent has not been defined. An assay was loaded for which the reagent is missing in the reagent database.	Open assay and add the missing reagent into reagent database. Restart the worklist. NOTE: the changes have to be saved with the Save Button before they become active.
Some resources have not yet been allocated to a position	After the loading dialog. Not all required reagents have been allocated to a position.	Click on OK. Load all resources from the unallocated resources field into the appropriate position (reagents, samples, dilution tubes/plates, tips, buffers).

Error message	Cause	Measure
Suspect tip pickup	During tip pick up. The disposable tip adapter reached the Zmax position, the tip sensor detects a tip, but the pick-up force was not as high as expected.	This WARNING is logged in the event log. No results are flagged. The software continues pipetting with the tip without user interaction. If the error recurs frequently, the positions in the tip rack must be checked. Plate transport fatal error %2:
System fluid low	During initialisation procedure or during the run.	Fill up the system liquid container with deionised water and click OK. If the error recurs after filling up the container, the level sensor has to be checked. Plate transport fatal error %2:
%2 fatal error %1: Waste full Empty waste container	During initialisation procedure or during the run.	Empty the waste container and click OK. If the error recurs after emptying the waste container, the level sensor has to be checked. Plate transport fatal error %2:
The disposable tips have been incorrectly loaded.	During the tip type detection. Software detected a wrong type of tip.	After clicking OK, the software displays the loading dialog in which you can check whether the correct type of tips (300 µl or 1100 µl) are loaded to the correct position.
Tip eject failure. Remove the tip from the pipettor.	Error during the tip ejection in the tip eject station. The tip could not be ejected (the tip sensor still detects a tip although the pipettor performed a tip eject movement)	Remove tip manually from pipettor or trigger eject mechanism manually. Click the OK button after manually removing the tip. The system logs the failure in the event log and continues with the next step. If the error recurs, the disposable tip adapter and the control must be checked. Plate transport fatal error %2:
Unable to create text file '%1'.	Error during writing a file (network down or directory moved/deleted).	Check or change the target directory in the Directories tab of the Options dialog (► *Chapter 10.1.7*).
Unknown colorimeter error: %1	Unknown photometer error.	Restart system and software. If the error recurs, the entire photometer module must be checked. Plate transport fatal error %2:
%2 fatal error %1: Unknown command	During initialisation procedure. Faulty firmware is installed.	Call service to reinstall the firmware for the module concerned.
Unknown incubator error :%2 %1	Unknown incubator error.	Restart system and software. If the error recurs, the entire incubator module must be checked. Plate transport fatal error %2:

Error message	Cause	Measure
Unknown plate transport error. %1	Unknown plate transport error.	Abort the worklist, and restart software to initialize the plate transport unit. Restart the worklist. If the error recurs, the plate transport unit must be checked. Plate transport fatal error %2:
Unknown washer error: %1	Unknown washer error.	Restart system and software. If the error recurs, the entire washer module must be checked. Plate transport fatal error %2:
Verification failed:	During the photometer verification.	If the error occurs, change the lamp and check the filter configuration. Repeat the colorimeter verification test. If the error recurs, the photometer module must be checked. Plate transport fatal error %2:
WARNING! Incubator tolerance of +/-%1°C was exceeded (%2°C)	For elevated temperature incubation, if the incubation temperature monitored during the run does not correspond to the incubation temperature defined in the assay.	See ► *Chapter 12.3.2*
Washer fatal error %2: Vacuum sensor error	During the initialisation procedure or during a wash step. Poor vacuum quality is detected.	Recovery options during wash step: Retry button: Software will try to activate the aspirate pump again. Abort Plate button: Plate will be aborted. Before clicking the Retry button, check that all tubes are connected correctly. Check that there are no kinks in the tubing. Check the bottle seals. Are the bottle lids closed correctly? If the error recurs, please call service to check the vacuum sensor and the washer aspiration pump.
Washer fatal error %2: Aspirate pump error. Pump cannot be enabled	During the initialisation procedure or during a wash step. The aspirate pump is faulty.	Recovery options: Retry button: Software tries to repeat the dispensing step. Abort Plate button: Plate will be aborted. Click Retry. If this error recurs, call service.

Error message	Cause	Measure
Washer fatal error %2: Dispensing pump error	During the initialisation procedure or during a wash step. One of the wash buffer pumps is faulty.	Recovery options: Retry button: Software tries to repeat the dispensing step. Abort Plate button: Plate will be aborted. Click Retry. If the error recurs, please call service to check the wash buffer pumps.
Washer fatal error %2: EEPROM read failure	EEPROM error while reading / writing procedure.	Restart the system again. If the error recurs, the washer PCB must be replaced. Plate transport fatal error %2:
Washer fatal error %2: Reagent level low	After loading dialog or during the run. One of the washing liquids is empty.	Recovery options: Retry button: Software checks the level sensor again. Abort button: the worklist will be aborted. Ignore button: the worklist continues without filling up the buffer. Refill the washer reagent and click the Retry button. If the error recurs after refilling, check the cables connections of level sensors or call service.
Washer fatal error %2: Strip error	Before wash step. One of the strips of microplate is not inserted correctly.	Retry button: Strip check will be repeated. Abort Plate button: Plate will be aborted. After the error occurs, click the Retry button. The system will continue. If the error recurs abort the plate.
Washer fatal error %2: Waste full	During initialisation procedure or during the run. Waste bottle is full.	Recovery options: Retry button: System will check the level sensor again. Abort Plate button: Plate will be aborted. Empty waste container manually and click the Retry button. If the error recurs, the fill level sensor in the container must be checked. Plate transport fatal error %2:

Tab. 84: General error messages

12.2 Troubleshooting while Loading

This section describes the possibilities for troubleshooting while loading patient samples, reagents, microtiter plates or other resources.

12.2.1 Troubleshooting while Loading Patient Samples

Unreadable barcodes

If the system has not been able to read one or several barcodes of patient samples:

1) Close the displayed tabular PATIENT EDITOR dialog by clicking the OK button.

2) Remove the inserted rack.

Check the barcode labels on the tubes that the system failed to read. Make sure the labels are facing on the right-hand side and are not damaged or dirty. Make sure the barcode type is the same as on the tubes that were correctly read, otherwise you may need to change your barcode settings. (see ► *Rack* Barcodes*, p. 191*).

3) Try to insert the rack again. The tabular PATIENT EDITOR dialog is displayed again.

4) If the system still fails to read these barcodes, remove the rack once more (without closing the tabular Patient Editor dialog).

5) Enter the unreadable Patient IDs manually. Do not remove or exchange any of the barcoded samples (the system compares successive readings).

6) Insert the rack again.

7) Assign the assays (► *Chapter 8.3.2 Assign assays to patient samples (Tabular patient editor), p. 70*).

Problems with reinserted sample rack

Each time you reinsert a sample rack on the same lane, the system compares the data read by the barcode scanner during two successive readings. If any difference is found between the first and the second reading, the system assumes that tampering may have occurred and:

- All Patient IDs entered manually in the tabular PATIENT EDITOR dialog between the first and second reading are deleted.
- Rack positions that returned discrepancies between the first and the second reading are signalled visually (see below) and the corresponding data is cleared.
- Rack positions for which the second reading is identical to the first are retained.

For example:

You insert a rack with 8 barcoded sample tubes for Patient IDs. The barcode scanner fails to read the barcode label on Position 6. When the tabular Patient Editor dialog is displayed, the first Patient ID is missing.

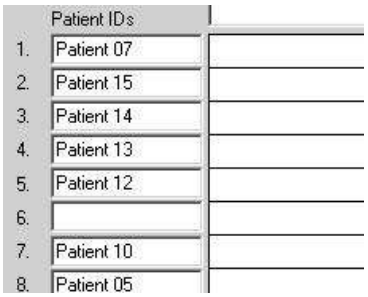


Fig. 86: Result of the first reading

You remove the rack, type in the missing Patient ID (e.g. "Patient 11") (or scan it with the hand-held scanner) and click on the OK button to close the tabular Patient Editor dialog.

Then you reinsert the rack on the same lane. When the tabular Patient Editor dialog is displayed again, if nothing else has changed, all 8 Patient IDs are listed in the Patient ID column.

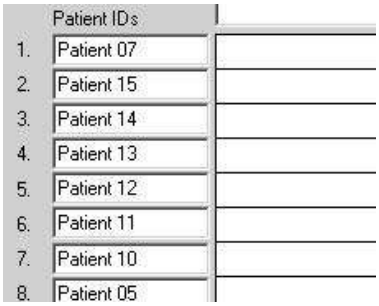


Fig. 87: Result of the second reading (no errors)

But, if you changed anything else on that rack, the manually entered ID(s) are deleted and any sample for which the barcode read in the second reading is not identical to the first barcode is corrected and marked. For example, if you inadvertently exchanged sample tubes "Patient 10" and "Patient 12" between the first and second readings, the tabular Patient Editor dialog displayed after the second reading looks like this:

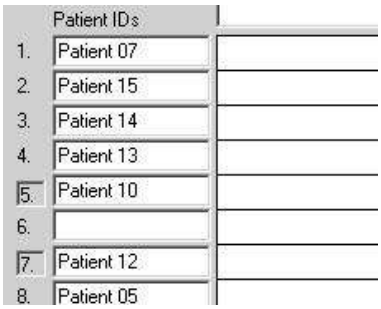


Fig. 88: Result of the second reading (with errors)

You can see that the manually entered ID "Patient 11" has been deleted. Changed Patient IDs "Patient 10" and "Patient 12" have also been corrected

and small boxes around position numbers 5 and 7 indicate that these positions have been changed between the first and the second readings.

To correct this:

1) Click on the OK button, remove the rack and insert it once more.

2) Enter the missing IDs manually without changing anything else.

3) Click on the Ok button and reinsert the rack. All Patient IDs should now be displayed. You can assign assays to each patient sample as described below.

Racks tend to tip over sideways

When inserting a sample rack onto a lane, make sure to keep your rack strictly level while pushing it in. If you push down on the end that you are holding, the other end may lift out of the lane and the rack may tip over. If this happens, refer to the cleaning and decontamination procedure in ► *Chapter 11.6*

Using different sizes of sample tubes

The standard T sample racks (► *Chapter 10.2.5)* usually accommodate tubes with a diameter between 9 and 16 mm and a height not exceeding 10 cm.

If you need to use smaller tubes (e.g. Eppendorf tubes), narrower tubes or tubes with a specific shape, contact EUROIMMUN technical support to adapt and re-align your racks accordingly. The adapted racks will be identified by coloured stickers and, in the Load dialog, these racks will be displayed in the corresponding colour and identified by a different code letter (U, V, W, Y and Z).

The EUROIMMUN Analyzer I-2P cannot accommodate sample tubes that exceed 10 cm in height; therefore, these samples must be transferred into smaller tubes to be processed.

There is not enough space to fit all the sample tubes

Each rack can accommodate 16 tubes. The sample and reagent unit includes 12 rack tracks, some of which are reserved for the reagents. Therefore, the maximum number of sample tubes that you may load at the beginning of a run is:

- 144 tubes (9 racks) if you intend to process 2 or 3 plates;
- 96 tubes (6 racks) if you intend to process 1 or 2 plates.

The continuous loading system may allow you to insert new samples at a later stage. The continuous loading system is explained in ► *Chapter 9.6 Continuous Loading, p. 158.*

Sample tubes with unknown barcode label types

See chapter ► *Rack Barcodes, p. 191* on how to set the scanner parameters and determine the type of barcode used.

The system has not been able to read some of the patient sample barcodes

Either the problem exists in the barcode settings (i.e. the barcode scanner has not been set to read the type of barcode that is actually used on the tubes), in which case the answer is the same as in ► *You want to process two tubes of each sample (*duplicate sample tubes*), p. 233*, or the settings are correct but the scanning fails for another reason (e.g. the barcode printing is fuzzy); in this case, see ► *Chapter 8.3.2*

The system requires the loading process to be carried out from right to left.

Under standard scanner settings, loading will always be directed from right to left, i.e. the LED to the very right will light up.

The standard direction can be changed in the System Setup, under the Sample Rack tab in the Auto Load field (► *Chapter 10.2.5 Sample Rack Tab, p. 188*).

You want to process two tubes of each sample (duplicate sample tubes)

You are not allowed to load sample tubes with identical barcodes. If you do, an error message is displayed:

`Duplicate sample ID %1 present .....!`

Process the sample ID so that it only occurs once.

If you really want to process two tubes of each sample, you have to use different barcode labels for each tube.

However, the system permits the same sample to be tested twice with the same assay on the same plate (replicate wells). This can take place using the multiple determination option in the Assay Layout dialog (see Assay_Programming_Guide_02). In this case, the sample is pipetted twice out of the same tube and dispensed into two consecutive wells of the same plate.

12.2.2 Troubleshooting while Loading Reagents

Non-barcoded unstable reagents

If the unstable reagent you loaded is not barcoded (or has an incorrect barcode), an error message is displayed:

`"Error! Barcode "..." is not correct for reagent "(reagent name)".`

You can click on the `OK` button to close the message but it will appear again and again until the end of the preset preparation time. When the preparation time is over, the system assumes that you have not loaded the required unstable reagent and that you need to abort the plate for which this reagent was required. The System Paused dialog opens as a result (► *Chapter 8.8.5 System Paused Dialog, p. 110*), to allow you to abort this plate.

At this stage, if you have actually loaded the required unstable reagent, DO NOT abort any plates and simply click on the Resume button. The run continues normally (the system actually dispenses the unstable reagent), but in the log file a warning is included stating that the reagent was not loaded on time, and the volume of the unstable reagent is not checked. This procedure is therefore not satisfactory. This is why it is recommended to always use barcoded unstable reagents.

12.3 Troubleshooting with regard to worklist

12.3.1 Error detection when creating a worklist

If, while conducting its verification process (click on the OK button in the LOT-SPECIFIC VALUE dialog), the system does not identify any problems, the worklist window is displayed and the status of the plates in the Worklist Parameters is Not loaded (► ► *Chapter 8.6.3 Plate Layouts, p. 81*).

Conversely, if the system detects a problem, a corresponding error message will be displayed.

If the error is related to the way you defined your worklist (e.g. if you tried to combine too many assays and patients and the system cannot find a way to schedule them adequately), correcting the source of the error will involve going back to the Set-up Panel dialog. To do so:

1) Click on the OK button in the error message box. The worklist window appears but “ERROR” is displayed (instead of Not loaded) as the status for that plate. If the status for a plate appears as Error, the respective plate cannot be processed.

2) Click on the Edit Panel button in the worklist window to re-open the SET-UP PANEL dialog.

3) Carry out the necessary changes and click on the OK button again. If you have successfully corrected the problem, the worklist window is displayed again but this time the status for this plate in the WORKLIST PARAMETERS is Not loaded.

If the error is related to the assay file you are using (e.g. if the reading parameters refer to a photometer filter not available on the instrument or if one of the reagents required for the assay has not been entered in the reagent database (see "Assay Programming Manual" (ask your EUROIMMUN service engineer)), open your assay file and check it thoroughly (edit it if necessary). If you use only EUROIMMUN pre-defined assays validated for the EUROIMMUN Analyzer I-2P, you should not encounter this kind of problem.

If the error is related to a problem in the system itself, please refer to the error message list (► *Chapter 12.1 Error messages, p. 217*).

12.3.2 Monitoring of the Incubation Temperature

For elevated temperature incubation, if the incubation temperature monitored during the run does not correspond to the incubation temperature defined in the assay:

- A general warning note is included in the title block of the report (“WARNING! Incubator tolerance of +/-%1°C was exceeded %2°C”) (► *Chapter 8.9.1 Structure of the Result Reports, p. 114).*
- In the Combined Report, all affected samples are flagged (IncKo - Incubation overrun, ► *Chapter 8.9.1 Structure of the Result Reports, p. 114 and ► Laboratory Details , p. 114*) and the results for these samples are not calculated.

Example

If the temperature defined in the assay is 37 °C +/- 1 °C, there is a flag and no result calculation when:

- the mean incubation temperature is < 36 °C or > 38 °C or
- the maximum incubation temperature is > 38 °C.

If the temperature defined in the assay is 37 °C +/- 1 °C, there is no flag and the results are calculated when:

- the minimum incubation temperature is < 36 °C and
- the mean incubation temperature is > 36 °C and < 38 °C.

Temperature			
Min.	Mean	Max.	
36.3	37	37.5	No Flag, Result calculated
35.5	36.5	37.5	No Flag, Result calculated
36.3	37.5	38.2	Flagged, Result not calculated
34.3	35.8	37.5	Flagged, Result not calculated

The same warning and flags apply if there is a discrepancy between the actual duration of an incubation step during a run and the incubation duration defined in the assay. Incubation duration errors apply both to room-temperature and elevated-temperature incubations.

Using the OUTLIERS dialogs, it is possible to calculate results for samples invalidated because of incubation errors (see "Instructions for use"). This, however, should only be done for reference purposes and under the laboratory supervisor's sole responsibility.

13 Technical specifications

13.1 Mechanical Data

Dimensions

Width x Depth x Height	120 cm x 75 cm x 115 cm (160 cm width with lateral monitor)

Weight

EUROIMMUN Analyzer I-2P	100 kg without accessories

13.2 Electrical and operating data

Instrument

Supply voltage	100 – 240 V +/- 10 %
Power consumption	max. 320 VA
Mains frequency	50 – 60 Hz
Main fuse	Main fuse T4A
Pollution degree	2
Maximum noise level	70 dB A (distance 1 m (39.37 inch))

Laser of the Barcode Scanner

Class	Class 2 laser product Class II laser product
Maximal output radiation:	1.3 mW
Pulse duration	70 µs
Emitted wavelength:	650 – 690 nm
Standards	DIN EN 60825:1 2003-10 Complies with 21 CFR 1040.10

Electromagnetic compatibility

This equipment is not intended for use in domestic applications and cannot ensure adequate protection of the wireless reception in these environments.

This instrument was developed and tested in accordance with CISPR 11, Class A. It can cause radio interference in domestic environments. In this case, you may need to take measures to eliminate the interference.

13.3 Environmental conditions

The system is only suitable for use indoors (laboratory environment).

Operation

Permissible ambient temperature	15 - 30 °C
Permissible relative humidity (no condensation)	30 - 80 % non-condensing
Operating height	Up to 2000 m above sea level
Installation area	Storage: as required for air cargo
Sunlight	dry, level, clean
Location of use	no direct sunlight
Mains current	as dust-free as possible, no vibrations or shocks
Installation class	earthed wall socket

Transport and storage

The unit must be packed for transport and storage. ► *Chapter 15 Transport and storage requirements, p. 241*

Permissible ambient temperature	5 – 50 °C
Permissible relative humidity (no condensation)	10 – 85 % non-condensing

Packaging

Dimensions (WxDxH)	125 cm x 90 cm x 115 cm
Weight	143 kg

13.4 System

Number of plates	Up to 3 plates
Number of samples	Up to 144 samples
Number of tests per plate	Up to 12 (depending on combinability)
Number of tests per worklist	Up to 36
Sample tube size	Outer diameter up to 16 mm
Dilution range	Height 30 mm - 100 mm
Safety function	2 x 96-2 ml Deepwell Plates

13.5 Computer

Technical data of the computer supplied can be found in the instruction manual of the computer manufacturer.

Integrated Computer

Processor	Intel 1,86 GHz Atom Dual-Core
Working memory (RAM)	2 GB
Hard disk	320 GB
Connections	4 USB ports 1 external monitor connector 2 serial RS 232 ports 1 RJ11 connection 1 LAN RJ45(Gigabit) 3 audio connections
Integrated monitor	15-Inch-Touchscreen
Operating system	Microsoft® Windows ® 7 32 bit (US-Englisch)

External Computer

Processor	Intel® Core™ i3-8100 Processor
Working memory (RAM)	8 GB
Hard disk	256 GB M.2 SATA SSD hard-drive

Connections	4 x USB 3.0 2 x USB 2.0 1 x VGA connection for external monitor 2 x Display port 2 x serial interfaces RS232 via SUNIX card 1 x serial interface RS232 COM1 (disabled) 1 x LAN RJ45 (Gigabit) 2 x PS2 for keyboard/mouse 1 x Loudspeaker connection
External monitor	22-Zoll Monitor
Operating system	Microsoft® Windows ® 10 64bit LTSC 2019 Enterprise

14 Disassembly and disposal

14.1 Disassembly

The product may only be disassembled by EUROIMMUN. For disassembly, contact the Technical Service department.

14.2 Disposal

The product may only be disposed of by EUROIMMUN. For disposal, contact the Technical Service department.

15 Transport and storage requirements

The instrument may only be transported in the packaging supplied by EUROIMMUN.

If a change to the place of installation is necessary, contact Technical Service.

Secure the product against vibration during storage.

The ambient conditions for transport and storage are defined in the Technical Data chapter.

► *Chapter 13 Technical specifications, p. 236*

This equipment is not intended for use in domestic applications and cannot ensure adequate protection of the wireless reception in these environments.

This instrument was developed and tested in accordance with CISPR 11, Class A. It can cause radio interference in domestic environments. In this case, you may need to take measures to eliminate the interference.

► *Chapter 13.3 Environmental conditions, p. 237*

16 Connection to a Host Computer

The EUROIMMUN Analyzer I-2P has been designed to easily integrate into a laboratory environment. The integrated PC that operates the instrument then has to be additionally connected to a host computer. This connection enables data to be imported or exported from the host to the EUROIMMUN Analyzer I-2P system, and back (e.g. download of patient data to the system, upload of test results to the host computer).

For connection, two different methods of exchanging data between the EUROIMMUN Analyzer I-2P and a host computer are supported:

- Transmission of ASCII files (import patient files or worklists to the EUROIMMUN Analyzer I-2P and export patient assay results to the host computer) – ► *Chapter 16.1*
- Transmission via an ASTM connection (download assay orders to the EUROIMMUN Analyzer I-2P and upload patient findings to the host computer) – ► *Chapter 16.1.5*

These two methods are described in the following chapters.

NOTE Please note that it is not possible to import absorption data, pipetting data or other file types from other systems or photometers.

The imported patient ID must be unique! If non-unique patient IDs are used (e.g. same ID for different persons on different worklists), the patient database is incorrect. In this case, features like patient history or patient result report must not be used.

16.1 ASCII File Transfer

The EUROIMMUN Analyzer I-2P can import (*.txt) worklists or patient data files and export (*.txt) result files from and to a network server.

The import of worklist files can be performed manually by the user or automatically with a polling sequence. Export files are generated and transmitted automatically if this has been defined in the respective assay.

16.1.1 Hardware Configurations

The communication between the EUROIMMUN Analyzer I-2P computer and the host system is established using an Ethernet card or the serial connection.

If the EUROIMMUN Analyzer I-2P computer should be connected to another host system, please install the necessary protocol or client and configure it according to the specifications for this host.

File name restrictions:

1) For all types of servers, note the following restrictions:

- File names should not include more than 20 characters.
- File names should not include special characters except "-" and "_".

1) Characters allowed in file names are:

- Numbers from 0 to 9.
- Letters from A to Z (supper and lower case).

16.1.2 Importing patient data and worklist files (types of import files)

Import files are (*.txt) files generated by a host computer, which include information about patients and test orders for these patients. The EUROIMMUN Analyzer I-2P can import and process these files only if their structure and contents are arranged in a certain order.

Standard Data Fields:

The standard data fields that can be expected by the EUROIMMUN Analyzer I-2P in an import file are: the Patient ID, the Patient Name, the patient's Birthday, the patient's Sex, the Test Name(s) and the Collection Date.

Not all these fields have to be included in the imported files. For instance, you can import worklist files that include only the Patient IDs and the Test Name for each Patient ID (see examples below).

For certain fields, a specific format has to be obeyed (e.g. birth dates must have a YYYYMMDD format, collection dates a YYYYMMDDHHMMSS format.

Header/No Header:

The EUROIMMUN Analyzer I-2P is able to analyse import files with or without header. A file has a header if the first line of the file lists the various data fields included in the file.

Examples of import files with header:

a)

`Patient ID, assay name, assay name, assay name, assay name`	Has Header Row
`001,Borr IgG,Borr IgM,Adeno IgG,CMV IgG`	Data fields
`002,Borr IgG,Borr IgM,Adeno IgG,CMV IgG`	
`003,Borr IgG,Borr IgM,Adeno IgG,CMV IgG`	
`004,Borr IgG,Borr IgM,Adeno IgG,CMV IgG`	
`005,Borr IgG,Borr IgM,Adeno IgG,CMV IgG`	
`1001,Borr IgM,HSV-IgM`	
`1002,Borr IgM,HSV-IgM`	
`1003,Borr IgM,HSV-IgM`	

b)

`Patient ID, patient name, assay name, date of birth, gender, sampling date`	Has Header Row

```
001,David,Borr IgG,19690330,,20020330102944                    Data fields
324,Marco,Borr IgM,19770119,M,20020330103344
BF221,Dupont Jean,Adeno IgG,19661101,M,20020330112121
33SD321,Durand Sophie,Adeno IgG,19770202,F,20020324120229
```

Using headers makes it easier if several Test Names are included for each patient. Otherwise, a new line has to be included for each Test Name (see below).

Without a header row, file **a)** above would have to be structured as follows:

```
001,Borr IgG,Borr IgM,Adeno IgG,CMV IgG                        Data fields
002,Borr IgG,Borr IgM,Adeno IgG,CMV IgG
003,Borr IgG,Borr IgM,Adeno IgG,CMV IgG
004,Borr IgG,Borr IgM,Adeno IgG,CMV IgG
005,Borr IgG,Borr IgM,Adeno IgG,CMV IgG
1001,Borr IgM,HSV-IgM
1002,Borr IgM,HSV-IgM
1003,Borr IgM,HSV-IgM
```

For file **b)**, things would be easier since only one Test Name is included per Patient ID:

```
001,Borr IgG,Borr IgM,Adeno IgG,CMV IgG                        Data fields
002,Borr IgG,Borr IgM,Adeno IgG,CMV IgG
003,Borr IgG,Borr IgM,Adeno IgG,CMV IgG
004,Borr IgG,Borr IgM,Adeno IgG,CMV IgG
005,Borr IgG,Borr IgM,Adeno IgG,CMV IgG
1001,Borr IgM,HSV-IgM
1002,Borr IgM,HSV-IgM
1003,Borr IgM,HSV-IgM
```

Separator:

The header fields and the data fields are separated by a special character. In the examples above it is a comma (,) but the system lets you specify which character you intend to use as a separator: colon (:), semi-colon (;), vertical bar (|) ...

No space should be included between the separator and the data.

Note that if for a given patient all data fields are not filled (e.g. in example b) the birthdate of Patient 001 is not known), the data field remains empty but there must still be the same number of separators.

This is true except for the fields at the end of a line (e.g. in example a) for patients 1001, 1002 and 1003 for which only two tests are assigned).

Several tests for patients in one line:

Example file header row:

```
...,assay name,assay name, ...
```

Example file data rows:

```
...,Borr IgG,Borr IgM,...
```

16.1.3 Defining Import Parameters

The ASCII Patient Information Import dialog allows the user to "tell" the EUROIMMUN Analyzer I-2P what type of import file it should expect.

This dialog is displayed each time you import files or when you define your file polling (automatic import) parameters.

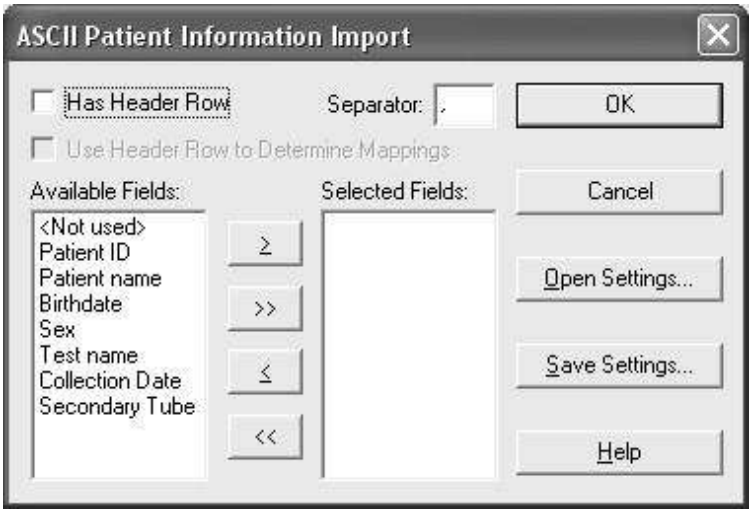


Fig. 89: ASCII Patient Information Import dialog

Option	Description
Has Header Row	Select this item if the import file has a header. In this case, the next item is enabled.
Use Header Row to Determine Mappings	If you select this item, the system will automatically use the header row to interpret the data fields. In this case, you do not have to specify which data fields are included; the Available Fields list and the Selected Fields list are disabled. If you do not select this item, you are telling the system to disregard the header row and to interpret the data fields according to your selection
Separator	Enter the character used as separator ► *Chapter 16.1.2 Importing patient data and worklist files (types of import files), p. 243* .
Available Fields	Shows the available fields. Select the fields that the patient ASCII file includes from this list. If you need additional fields, you can load them from a file by clicking on the Open Settings button. This file must include the fields row-wise in the ASCII format. If necessary, you have to create a file with the field names and copy it to the respective subdirectory. See below for a field description.

Option	Description
> , >> , < , <<	Use these buttons to transfer data fields from the Available Fields list to the Selected Fields list (or back). You can also transfer fields from one list to the other by double-clicking on them.
Selected Fields	Shows the data fields which the system should expect to find in the import file. Make sure that the order of the data fields in the Selected Fields list is in accordance with the order of the data fields in the import file! You can move a field in the list by selecting it with the mouse and dragging it upwards or downwards without releasing the mouse button. See below for a field description.
Open Settings Save Settings	If the files you import from the host computer always have the same structure and include the same data fields, you do not have to redefine the import parameters each time. Once you have defined the parameters (header row or not, separator, selected data fields), click on the Save Settings button. This creates an ASCII Patient Information Mappings file (*.apm) which you can re-use for later imports. To do so, click on Open Settings. However, this is useful mainly if your import files do not have header rows that can be used for mappings.

Tab. 85: Functions of the ASCII Patient Information Import dialog

Field description:

Field	Description
<Not used>	If there are unused field(s) in the file, you can use this item to hide the unused field(s).
Patient ID	ID number of the patient. Alphanumeric strings accepted.
Name	Name of the Patient. No limits on patient name.
Birthdate	YYYYMMDD (year, month, day)
Sex	ASTM states M, F, or U but no actual restrictions
Test name	If you have defined LIS assay names ► *Chapter 16.1.5* , the software can use these as assay names (both in case of manual import and in case of import by file polling). Otherwise, the imported test name must correspond exactly to the name of the assay file stored in the directory but without the (*.asy) extension.
Collection Date	YYYYMMDDHHMMSS (year, month, day, hour, minutes, seconds) Secondary Tube

Tab. 86: Fields

NOTE After importing all patient information, the file is deleted automatically!

Manual Import of a Patient Information

To import a worklist file manually:

1) Select the menu item File > Open.

2) Click on the ASCII Patient Information (*.txt) entry.

3) Search and select your file.

4) This opens the ASCII PATIENT INFORMATION IMPORT dialog. Define your import parameters as described in ► *Chapter 16.1.3 Defining Import Parameters, p. 245* .

5) Click on the OK button to import the patient information.

Automatic Import (File Polling)

The EUROIMMUN Analyzer I-2P software allows the user to define specific addresses that the software will poll on a regular basis to look for ASCII patient information files. When a valid file is found, it is automatically imported into the software, interpreted and the patient database is updated with the new patient details.

To specify the file polling intervals and the structure of the files to be imported:

1) Select the Utilities > Options... menu item to open the OPTIONS dialog.

2) Click on the File Polling tab.

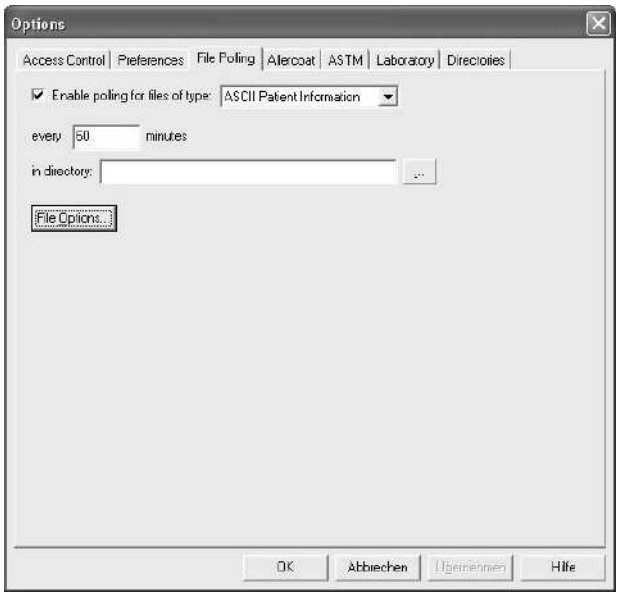


Fig. 90: Options dialog: File Polling tab

Option	Description
Enable polling for files of type	Select this item if the EUROIMMUN Analyzer I-2P computer is connected to a host computer. If you select this item, the other boxes on this tab are enabled. In the drop-down selection list you can select the file type for the patient information. Currently, the only available format is the ASCII format.
Every *n* minute(s)	Enter the intervals (in minutes) in which information is to be polled from the host computer.
in directory	Specify the folder (directory in the host computer) to be polled. Enter the full path (including a filename). To browse/search, click on the... button. Find the desired directory and select a file name in that directory.
File Options	Opens the ASCII Patient Information Import dialog and you can enter the structure of the ASCII files to be imported (► *Chapter 16.1.3 Defining Import Parameters, p. 245*).

3) Activate the Enable polling for files of type checkbox.

4) Enter the intervals to request for files.

5) Enter the desired directory.

6) Click on the File Options button to open the ASCII PATIENT INFORMATION IMPORT dialog. Define your import parameters as described in ► *Chapter 16.1.3 Defining Import Parameters, p. 245* .

7) Click on the OK button twice.

NOTE The system time of the server and the system time of the EUROIMMUN Analyzer I-2P computer must be synchronised! If the system time of the server is ahead of the system time of the EUROIMMUN Analyzer I-2P computer and they deviate more than the defined polling time, the patient information files will never be imported!

Successful Import / Import Failure

If you import a patient data file manually, once you have clicked on the OK button in the ASCII PATIENT INFORMATION IMPORT dialog, the system displays a successful import message.

This message just confirms that the file has been imported. It does not confirm the correct import of all the data fields!

To make sure that all the data included in the file have been successfully and correctly imported into the EUROIMMUN Analyzer I-2P, you have to check the PATIENT EDITOR dialog (► *Chapter 9.2 Complete Patient Editor, p. 125*). The same method can be used to check if an automatic file polling and import process has been successfully carried out.

NOTE If the patient data that you imported (manually or automatically) correspond to patient samples that you are loading or have loaded on the EUROIMMUN Analyzer I-2P, the system will automatically display the imported data in the Patient Editor tabular format (► *Chapter 9.2 Complete Patient Editor, p. 125*).

Import Failure

If the patient data was not correctly imported:

- Check that the import parameters that you defined in the ASCII PATIENT INFORMATION IMPORT dialog correspond to the actual structure and contents of the file you tried to import.
- Check that the file polling path you specified in the OPTIONS dialog / File Polling tab is correct.
- Check that network communication is not down.
- Check that the system times of the EUROIMMUN Analyzer I-2P computer and of the host computer are synchronised.

Deletion of Imported *.txt Files

To prevent imported worklists from remaining for ever in the import directory, imported *.txt files are automatically deleted by the system after importing (whether by manual import or file polling). Before the file is deleted a copy is made in the Backup folder (► *Chapter 10.1.7 Directories tab, p. 175*). The filename of the copy is the same as the filename of the original import file but with a prefix "Copy of", e.g. if the import file is named "worklist4.txt", then the backup copy will be named "copy of worklist4.txt". If the import file always uses the same filename, then the name of the backup copy will be incremented, e.g. "Copy (2) of worklist4.txt", "Copy (3) of worklist4.txt", etc.

Importing of Multiple Test Order Requests for the Same Patient

The software uses a registry setting to control what happens when a duplicate test order request is received for the same patient. The registry setting either allows or ignores the duplicate test order request. The default setting is that the duplicate test order request is ignored (and processed as an individual test order). If the duplicate test order request is allowed then, after a successful import, multiple test order requests are shown for the respective

patient in the PATIENT EDITOR dialog (► *Chapter 9.2 Complete Patient Editor, p. 125*).

Then, when a worklist is created for this patient a number of wells equal to the number of test order requests will be allocated to the patient sample. These will be combined by the software and given the same layout label ID (e.g. patient 000001 (x2)).

NOTE This only applies when importing from text files. Duplicate ASTM test order requests will always be ignored.

16.1.4 Export of Test Results

Individual Export Requests

Each time a (*.res) result report is calculated and displayed on the screen, you can decide to export it.

To do so:

1) Select the Utilities > Export Results menu item.

If the Utilities > Export Results menu item is disabled, it means that the EUROIMMUN Analyzer I-2P software has already been configured to automatically export the results as described below.

Automatic Export

See ► *Chapter 10.1.2 Preferences tab, p. 170* .

Contents of ASCII Export Files

The structure and contents of the ASCII export files depend on what has been defined for each assay (see "Assay Programming Manual" (ask your EUROIMMUN service engineer)).

Examples of ASCII Export Files

[Borr IgG]
No header data

[Borr IgG]	
[Results] Patient ID|Assay|Outliers Measured value|Qual. Value ""|"CMV IgG"|"0.009"|"NCS1" ""|" CMV IgG"|"0.011"|"NCS2" ""|" CMV IgG"|"0.093"|"NCS3" ""|" CMV IgG"|"1.455"|"PCS1" ""|" CMV IgG"|"1.465"|"PCS2" "001"|" CMV IgG"|"0.004"|"-" "002"|" CMV IgG"|"0.011"|"-" "003"|" CMV IgG"|"0.011"|"-" "004"|" CMV IgG"|"0.002"|"-" "005"|" CMV IgG"|"0.987"|"+" "006|" CMV IgG"|"0.009"|"-" "007 CMV IgG"|"0.075"|"?" "008 CMV IgG"|"0.011"|"-" Header with data fields, separate is a vertical bar (|) [End of results]	Header with data fields, separate is a vertical bar (|)

Tab. 87: Export file without header field

[CMV IgG]	
Time:;11:15:00 Date:;27/09/07 OVER limit:;3.5 User:;User Wavelengths:;450nm/620nm	Assay header data
-0.01<=NCS1<=0.50; -0.01<=0.010<=0.50; -0.01<=0.009<=0.50; -0.01<=0.011<=0.50; -0.01<=0.093<=0.50;Removed Valid(NC)>=2;2>=2 PCi>=0.550; 1.460>=0.55; 1.455>=0.55; 1.465>=0.55; valid(PC)=2;2=2	Header with validation criteria

[CMV IgG]	

`If 'Sample<(NC+0.05)*0.9' Then`
`Result:='-'`
`If 'Sample>=(NC+0.05)*1.1' Then`
`Result:='+'`
`Default result := equ`
`[Results]`
	Qualifying header data

`Patient ID, assay, outliers, qual. Value`
`"","CMV IgG","0.009","NC1"`
`"","CMV IgG","0.011","NC2"`
`"","CMV IgG","0.093","NC3"`
`"","CMV IgG","1.455","PC1"`
`"","CMV IgG","1.465","PC2"`
`"001","CMV IgG","0.004","-"`
`"002","CMV IgG","0.011","-"`
`"003","CMV IgG","0.011","-"`
`"004","CMV IgG","0.004","-"`
`"005","CMV IgG","0.987","+"`
`"006,"CMV IgG","0.009","-"`
`"007 CMV IgG","0.075","?"`
`"008 CMV IgG","0.011","-"`
`[End of results]`
	Header with data fields, separator is a comma (,)

Tab. 88: Export files with header field

Target Directory for Export Files

Under default settings:

- Result files (*.res) are saved in the C:\ProgramData\Euroimmun Analyzer I - 2P\Results directory.
- Result Export files (*.txt) are saved in the C:\ProgramData\Euroimmun Analyzer I - 2P\Expor directory.

To change the directory where export files are to be saved (for example if you want them to be saved on a host computer and not on the EUROIMMUN Analyzer I-2P computer), see ► ► *Chapter 10.1.7 Directories tab, p. 175*

Opening ASCII Result Export Files

Result export files are ordinary (*.txt) files which can be opened with any standard word processor or spreadsheet software.

But they cannot be opened with the EUROIMMUN Analyzer I-2P software! If you try to open a *.txt result export file with the EUROIMMUN Analyzer I-2P software, the system will assume that it is a *.txt worklist import file and will automatically display the ASCII Patient Information Import dialog, as if you wanted to define import parameters

(► *Chapter 16.1.3 Defining Import Parameters, p. 245*). Just click on the Cancel button in this dialog and use the correct software to open the export file.

16.1.5 Communication through an ASTM Link

Communication between the EUROIMMUN Analyzer I-2P and an external host computer then takes place via an RS232 connection and follows the ASTM 1394 (high level) and 1381 (low level) standards for communication.

ASTM stands for American Society for Testing and Materials. The ASTM has developed standards on data transfer to/from host computer in the medical field. For more information on ASTM standards, see www.astm.org.

The EUROIMMUN Analyzer I-2P host interface is comprised of:

- ASTM -1381 low-level transfer protocol used to transmit or receive messages
- Interpretation of received data from the intermediate files and entry in the EUROIMMUN Analyzer I-2P database

The ASTM 1394 defines how the data to be transmitted is represented as a structured message consisting of several records. These messages are then translated into one or more frames that will actually be transmitted according to ASTM 1381.

16.1.6 ASTM Link Set-Up

NOTE It is possible to configure the ASTM connection settings if the software is in Demo Mode but the ASTM connection cannot be used.

To set-up the connection parameters according to ASTM specification for connection to a host computer:

1) Select the Utilities > Options menu item.

2) Click on the ASTM tab.

3) Click the Enable ASTM E 1381/1394 checkbox. Then all boxes on this tab are enabled. The connection setting of the delimiter and the interface are defined in accordance with the ASTME standard. For other settings, ► *Chapter 10.1.5 ASTM Tab, p. 173 .*

4) Select the correct COM port.

5) Confirm with OK.

NOTE Please make sure that you do not select the internal COM Port between PC and instrument.

16.1.7 Definition of LIS Assay Names

Because the actual assay file names are often relatively long, it is sometimes not convenient or not technically possible to use them for file transfer purposes (for file transfers between the EUROIMMUN Analyzer I-2P software and the host computer/LIS).

In this case, shorter code names or "LIS assay names" can be defined. Once defined, these LIS assay names can be used either for ASTM file transfers (► *Chapter 16.1.8*) or for ASCII file transfers (see chapter ► *Chapter 16.1.3* [import] and "Assay Programming Manual" (ask your EUROIMMUN service engineer) [export]).

To define LIS assay names:

1) Select the Utilities > Options... menu item.

2) Click on the ASTM tab.

3) In this tab, click on the Assay Links... button. This opens the following dialog showing the list of previously defined LIS assay names and the corresponding assay file names. If you have not yet defined any LIS names, the list is empty.

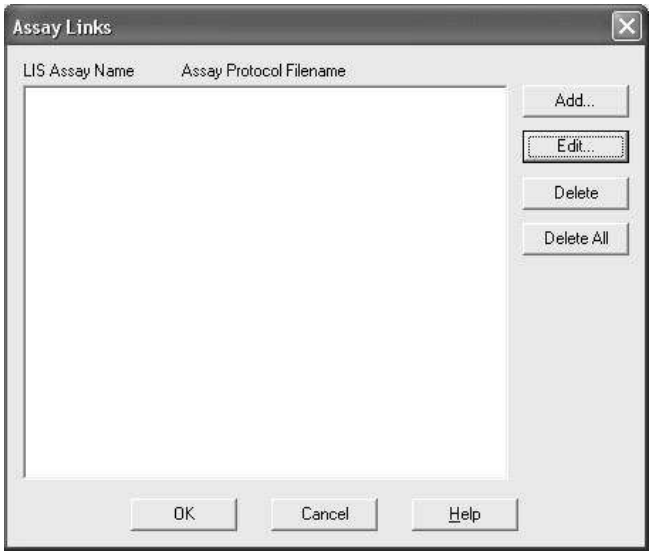


Fig. 91: Assay Links dialog

4) Add a new name.

a) To define a new LIS assay name, click on the Add... button. This opens the following dialog.

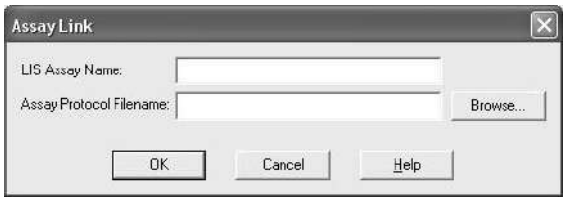


Fig. 92: Assay Link dialog

b) Click on the Browse... button to open the assay file directory and select the assay file for which you want to define a LIS assay name.

c) Click on the Open button to close the assay file directory and insert the selected file in the Assay Name field.

d) We recommend always using the Browse... button instead of entering the assay file name via the keyboard to avoid spelling mistakes.

e) In the LIS Assay Name field, enter the short name you want to use as LIS assay name for this assay.

f) Then click on the OK button. This takes you back to the ASSAY LINKS dialog and you can check that the newly defined LIS name is now in the list.

g) Click on the OK button again to close this dialog and go back to the ASTM tab of the OPTIONS dialog.

5) Click on the OK button to close this dialog.

LIS assay names can include letters, digits and blank spaces. Capitals and lower-case letters are visually different but are treated by the system as the same character. For example, if "HSV1IgG" is an existing LIS assay name, you cannot define another LIS assay name as "HSV1IgG". If you try, a message is displayed saying: "A link already exists for this assay name. Do you want to overwrite the existing link?"

Edit a Name

To edit an existing LIS assay name, select it in the ASSAY LINKS dialog and click on the Edit... button.

Delete a Name

To delete an existing LIS assay name, select it in the ASSAY LINKS dialog and click on the Delete button. If you click on the Delete All button, you will be prompted to confirm that you really want to delete all existing LIS assay names.

16.1.8 Communication

Communication sessions between the EUROIMMUN Analyzer I-2P and a host computer can be initiated upon request by the EUROIMMUN Analyzer I-2P operator or automatically.

Importing test order requests

When patient samples are loaded on the instrument, all tests previously ordered for these samples at host computer level and downloaded to the EUROIMMUN Analyzer I-2P computer will appear on the Patient Editor tabular dialog (► *Chapter 8.3 Loading patient samples and assigning tests, p. 68*).

If you have checked the Query Host For Test Order Requests item in the ASTM tab, each time you load new samples on the system the software will automatically query the host computer to know if test order requests are available for these samples.

When a test order request is received from the LIS, a search is first made within the list of LIS assay names/assay protocol filename pairings. If a matching LIS assay name is found, then the software uses the linked assay protocol filename when the test request is affected. If no match is found, the software assumes that the assay name received from the LIS is the exact assay protocol filename.

Export of Test Results

It is possible to export test results manually (via the Utilities > Export Results menu item, available when a result report is displayed on the screen) or to configure the EUROIMMUN Analyzer I-2P software to create and export test results automatically. For ASCII files, this takes place as described in ► *Chapter 16.1.4 Export of Test Results, p. 250* .

The ASTM format and the data included in the transmission are defined as described in ► *Chapter 16.1.6 ASTM Link Set-Up, p. 253* and ► *Chapter 16.1.7 Definition of LIS Assay Names, p. 253* . Additional assay-specific data fields may be included at assay level.

16.1.9 Low-Level Protocol

Physical Layer

► *Chapter 16.1.5 Communication through an ASTM Link, p. 253* .

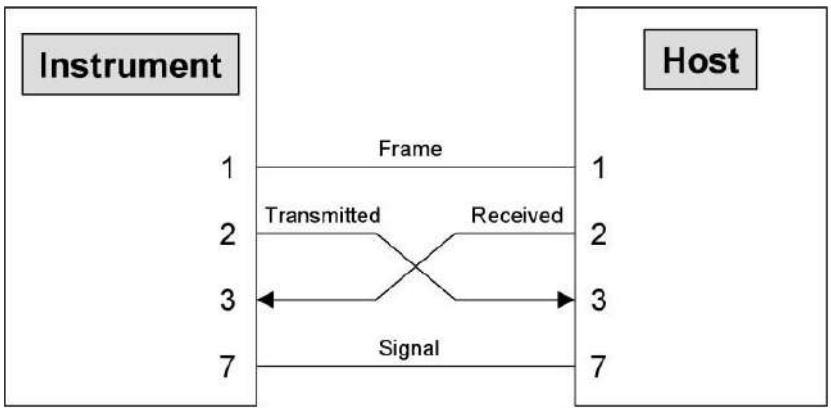


Fig. 93: RS232 connection to host

Data Link Layer

Establishment phase

(see ASTM 1381 Standard, ► *Chapter 10.1.5 ASTM Tab, p. 173*)

Transfer phase

(see ASTM 1381 Standard, ► *Chapter 10.1.5 ASTM Tab, p. 173*)

The checksum is encoded as two characters sent after the <ETB> or <ETX> character. The checksum includes the first character after <STX> (the frame number) up to and including <ETB> or <ETX>. It is computed by adding the binary values of the characters, keeping the least significant eight bits of the result.

During the transfer phase, if the LIS responds to a frame with an <EOT> the EUROIMMUN Analyzer I-2P does NOT stop transmitting and chooses to ignore the interrupt request.

Termination phase

(see ASTM 1381 Standard, ► *Chapter 10.1.5 ASTM Tab, p. 173*)

After the EUROIMMUN Analyzer I-2P transmits or receives the <EOT>, indicating that all messages have been sent, the line is considered to be in the neutral state.

Trouble Shooting

(see ASTM 1381 Standard, ► *Chapter 10.1.5 ASTM Tab, p. 173*)

The EUROIMMUN Analyzer I-2P checks every frame it receives to guarantee its validity and sends an <ACK> for a valid frame, or a <NAK> for an invalid frame. Frames are invalidated when:

- Any character errors are detected (i.e. parity error, framing error).
- The frame checksum does not match the checksum computed on the received frame.
- The frame number is not the same as the last accepted frame or one number higher.

When the EUROIMMUN Analyzer I-2P receives a <NAK> for a frame rejected by a host it resends the frame. If a single frame is sent and rejected six times, the EUROIMMUN Analyzer I-2P proceeds to the termination phase.

During the establishment phase, the EUROIMMUN Analyzer I-2P expects to receive a reply within 15 seconds after sending <ENQ>. During the transfer phase, the EUROIMMUN Analyzer I-2P expects to receive a reply within 15 seconds after transmitting the last character of a frame. If a time-out occurs, the EUROIMMUN Analyzer I-2P proceeds to the termination phase.

During the transfer phase, the EUROIMMUN Analyzer I-2P expects to receive a frame or <EOT> within 30 seconds after first entering the transfer phase or replying to a frame. After a time-out, the last incomplete message is discarded and the line is considered to be in the neutral state. The EUROIMMUN Analyzer I-2P will also time-out if a reply to a frame is not received within 15 seconds.

16.1.10 Logical Structure of the Message Level Protocol

The blocked stream of data sent between a host computer and the EUROIMMUN Analyzer I-2P at a given time is called a message.

Messages consist of a hierarchy of records of various types:

Level	Segment Name	Identifier (record type ID)	Comments
0	Message Header Record	H	
0	Message Terminator Record	L	
1	Patient Information Record	P	
1	Request Information Segment	Q	

Level	Segment Name	Identifier (record type ID)	Comments
1	Scientific Record	S	not allowed for EUROIMMUN Analyzer I-2P
2	Test Order Record	O	
3	Result Record	R	
General	Comment Record	C	
1	Manufacturer Information Record	C	not allowed for EUROIMMUN Analyzer I-2P

Tab. 89: Message Level Protocol

A record is identified by the first field of a record, the RecordTypeID.

Most of the various record types are related to each other in a definite hierarchy:

A lower level record may never appear without the preceding higher level record (i.e. order records must be preceded by a patient record, result records must be preceded by an order record...).

A sequence of records at one level is terminated by the appearance of a record of the same or higher level.

In some other descriptions a record might also be called segment.

16.1.11 Incoming and Outgoing Transmission Examples

Host to EUROIMMUN Analyzer I-2P (Test Orders)

The host response includes patient demographics, Patient ID, sample ID, and test orders according to the following record hierarchy.

The response to requests for test orders is expected to be received within <Timeout> seconds after the request has been sent. <Timeout> is to be specified on the ASTM tab.

Structure according to ASTM 1394	Structure according to ASTM 1381
(several records form a single message)	(every record is sent as one or more frames)

Structure according to ASTM 1394		Structure according to ASTM 1381
Message Header Record		
Patient Information Record 1		
Test Order Record 1		
:		
Test Order Record n		Frame 1
:	=>	:
Patient Information Record n		Frame n
Test Order Record 1		
:		
Test Order Record n		
Message Terminator Record		

Tab. 90: Structures

In case there are no test orders available the LIS should respond with an empty message containing header and terminator records only. The terminator record should contain an 'I' (no information available) flag in the Termination Code Field.

For example:

```
H|\^&|||EDVLab||||||||1|19941115202738
P|1||PatID01||Anderson^Anna||19741001|F|||||MARTINEZ
O|1|Sam-
pleID01||^^^AFP^1:10||19980506||||||||S|||||||||X
P|1||PatID02||Newman^Tony||19741001|F|||||MARTINEZ
O|1|SampleID02||^^^AFP||19980506||||||||S|||||||||X
O|1|SampleID02||^^^TSH||19980506||||||||S|||||||||X
O|1|SampleID02||^^^T3||19980506||||||||S|||||||||X
O|1|SampleID02||^^^T4||19980506||||||||S|||||||||X
P|1||Barcode15||Palmer^John||19741001|F|||||MARTINEZ
O|1|                                                Bar-
code15||^^^AFP^1:10||19980506||||||||S|||||||||X
P|1||12345|||||F|||||MARTINEZ
O|1|12345||^^^AFP^1:10||19980506||||||||S|||||||||X
L|1|N
```

After the EUROIMMUN Analyzer I-2P receives all test orders from the host, the records are interpreted. Valid test orders are entered into the load list database, while invalid test orders are not.

EUROIMMUN Analyzer I-2P to Host (Test Results)

Only the final calculated result (Abs, concentration or interpretation) is transferred per test. For multiple replicate results the mean is transmitted only.

EUROIMMUN Analyzer I-2P to host: (transmit sample information with corresponding tests and results)

Structure according to ASTM 1394		**Structure according to ASTM 1381**
(several records form a single message)		(every record is sent as one or more frames)
Message Header Record		
Patient Information Record 1		
Test Order Record 1		
Result Record 1		
Comment 1		
:		
Result Record n		
Comment 1		
:		
Test Order Record n		
Result Record 1		
Comment 1		
:		
Result Record n		
Comment 1		Frame 1
:	=>	:
Patient Information Record n		Frame n
Test Order Record 1		
Result Record 1		
Comment 1		
:		
Result Record n		
Comment 1		
:		
Test Order Record n		
Result Record 1		
Comment 1		
:		
Result Record n		
Comment 1		
Message Terminator Record		

Tab. 91: Structures

For example:

```
H|\^&|||EDVLab|||||||1|19941115202738
P|1||PATID01||ANDERSON^ANNA||19741001|F|||||MARTINEZ
O|1|SampleID01||^^^AFP||19980506|||||||||S||||||||||F
R|1|^^^AFP|13.1|IU/ml||H||F||||19980506123145|
```

L|1|N

Data Record Usage:

(Refer to the ASTM Standard 1394, particularly sections 6 through 13)

Each record sent by the EUROIMMUN Analyzer I-2P contains all of the fields used by the EUROIMMUN Analyzer I-2P, which may or may not be all the fields possible for the record. An 'O' in Required or Sent field indicates optional. The first <MaxLength> characters are significant only. Any more characters transmitted for a specific field are ignored.

Message Header Record

Field no.	ASTM field	Description	Valid content	Max. length	Required
1	Record Type ID	Character identifying the record as a message header	H	1	J
2	Delimiter Definition	Any received delimiter set is accepted. The delimiters defined in ASTM Setup dialog are sent.		4	J
3	Message Control ID				N
4	Access Password				N
5	Sender Name / ID			20	N
6	Sender Street Address				N
7	Reserved Field				N
8	Sender Telephone No.				N
9	Characteristics of Sender				N
10	Receiver ID				N
11	Comment				N
12	Processing ID				N
13	Version No.		1	1	N
14	Date and Time of Message	Format is YYYYMMDD HHMMSS		14	N

Tab. 92: Message Header Record

Patient Information Record

Field no.	ASTM field	Description	Valid content	Max. length	Required
1	Record Type ID	Character identifying the record as a patient information record	P	1	J
2	Sequence Number				J
3	Practice Assigned Patient ID				N
4	Laboratory Assigned Patient ID	Becomes our PatientID			J
5	Patient ID No. 3				N
6^1	Patient Name				O
6^2	Patient First Name				O
7	Mother's Maiden Name				N
8	Date of birth			8	O
9	Patient Sex			1	O
10	Patient Race - Ethnic Origin				N
11	Patient Address				N
12	Reserved Field				N
13	Patient Telephone Number				N
14	Attending Physician ID	Becomes our SenderID			N
15	Special Field 1				N
16	Special Field 2				N
17	Patient Height				N
18	Patient Weight				N
19	Diagnosis				N
20	Active Medications				N
21	Diet				N
22	Practice Field No. 1				N
23	Practice Field No. 2				N
24	Admission and Discharge Dates				N
25	Admission Status				N
26	Location				N

Field no.	ASTM field	Description	Valid content	Max. length	Required
27	Nature of Alternative Diagnostic Code and Classifiers				N
28	Alternative Diagnostic Code and Classification				N
29	Religion				N
30	Marital Status				N
31	Isolation Status				N
32	Language				N
33	Hospital Service				N
34	Hospital Institution				N
35	Dosage Category				N

Tab. 93: Patient Information Record

Test Order Record

Field no.	ASTM field	Description	Valid content	Max. length	Required
1	Record Type ID	Character identifying the record as a test order record	O	1	J
2	Sequence Number				J
3	Specimen ID				N
4	Patient ID				J
5^4	Universal Test ID	Test Abbreviation			J
5^5	Dilution				N
6	Priority				N
7	Requested/Ordered Date and Time				N
8	Specimen Collection Date and Time	YYYYMMDDHHMMSS		14	J
9	Collection End Time				N
10	Collection Volume				N
11	Collector ID				N
12	Action Code				N

Field no.	ASTM field	Description	Valid content	Max. length	Required
13	Danger Code				N
14	Relevant Clinical Information				N
15	Date/Time Specimen Received				N
16	Specimen Descriptor (Type)				N
17	Ordering Physician				N
18	Physician's Telephone Number				N
19	User Field No. 1				N
20	User Field No. 2				N
21	Laboratory Field No. 1				N
22	Laboratory Field No. 2				N
23	Date/Time Results Reported or Last Modified				N
24	Instrument Charge to Computer System				N
25	Instrument Section ID				N
26	Report Types				N

Tab. 94: Test Order Record

Result Record

Field no.	ASTM field	Description	Valid content	Max. length	Required
1	Record Type ID	Character identifying the record as a result record	R	1	J
2	Sequence Number				J
3	Test ID				N
4	Data or Measurement Value			depends on the value	J
5	Units				J
6	Reference Ranges				J
7					N

Field no.	ASTM field	Description	Valid content	Max. length	Required
8	Nature of Abnormality Testing				N
9	Result Status				N
10	Date of Change in Instrument Normative Values or Units				N
11	Operator Identification				N
12	Date/Time Test Started				N
13	Date/Time Test Completed				N
14	Instrument ID				N

Tab. 95: Result Record

Comment Record

Comment Records are used either to describe reasons for rejected test orders or to supply additional result information.

One comment record is used for the kit/reagent/control batch number.

Another comment record is used for the relevant flags.

Comment records begins with a C character.

Request Information Record

Not applicable.

Message Terminator Record

Field no.	ASTM field	Description	Valid content	Required	Sent
1	Record Type ID	Character identifying the record as the last record in the message	L	J	J
2	Sequence Number			J	J
3	Termination Code			N	N

Tab. 96: Message Record

Scientific Record

Must not be sent.

Manufacturer Information Record

Must not be sent.

17 Glossary

Term	Meaning
2D barcode scanner	Barcode scanner installed in the instrument for identifying materials
Hand-held 2D barcode scanner	External, can be operated manually
Request	Analysis/assay to be carried out for a certain patient sample
Aqua dest.	Distilled water
Worklist	Procedure that prepares and (post-)processes all assays
ASTM	American Society for Testing and Materials
ASTM protocol	Communication protocol based on ASTM standards
Lot information	Data on a reagent lot
ELO	EUROLabOffice (EUROIMMUN AG laboratory management software)
ID	Identification number
IEC	International Electrotecnical Commission
Incubator	Instrument in which plates are incubated
Conjugate class	Bundling of conjugate types (IgA, IgG, IgM, IgE) in a class
Combination group	Group of different assays that are processed in the same manner
Laboratory information system	A socio-technical system that produces, procures, distributes and processes data.
Run	Complete processing of a worklist
LCD	Liquid crystal device
LED	Light-emitting diode
LIMS	Laboratory Information and Management System
LIS	Laboratory information system
MTP	Microtiter plate
Pipetting platform	Part of the instrument in which pipetting takes place
Photometers	Instruments in which the optical density of the microtiter plate is measured
Sample ID	Sample identification number
Quality control certificate	Document enclosed with the assay record that contains the lot information
Service software	Software for instrument maintenance
TCP/IP	Transmission Control Protocol/Internet Protocol
UPS	Uninterruptible power supply

Term	Meaning
VC	Variation coefficient
Well	E.g. well in a microtiter plate

Tab. 97: Glossary