Elisys Quattro

| User Manual

CE

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Human

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System

Manufacturer:

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

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Table of Contents

1 Intended Use

The **ELISYS QUATTRO** system consists of the **ELISYS QUATTRO** instrument and the **Phoenix** software. It is a fully automated microplate analyzer performing the complete sample processing (sample dilutions, sample and reagent dispensing, incubations, wash processes, plate transports) as well as the photometric measurement and evaluation.

For in Vitro Diagnostics only!

Prior the use of the **ELISYS QUATTRO** system for IVDs, any test methods (assays) and kits must be validated by the user in combination with the system according to common clinical laboratory practice, local legislation, and the state of the art.

1.1 Typographical Conventions

Please consider the following typographical conventions.

1.1.1 Warning Messages

Warning messages are indicated with a safety symbol and printed in special types. For special situations the following security symbols were used.

Caution, risk of danger! Consult instructions for use!

Biohazard!

Electrical hazard!

Caution, hot surface!

Mechanical hazard!

Automatic start-up!

Laser hazard!

1.1.2 Notes

Notes are indicated with a symbol and printed in special types. For special situations were used the following symbols.

Consult instructions for use!

Notes are indicated by this symbol and printed in special types.

Disconnect mains power connector before servicing!

1.1.3 Symbol Keys

Manufactured by

IVD In Vitro Diagnostic Medical Device

LOT Lot Number

EXP CCYY-MM-DD Expiration Date

Storage Temperature

CE CE Mark

REF Catalogue Number

SN Serial Number

1.1.4 Special Types

LEDs   LEDs (light emitting diode) are printed in special type.

Example: PWR LED, ERR LED

Menu items and fields	Menu items and fields are printed in bold type.
	Example: **File** Menu
Buttons	Buttons are printed in spaced type.
	Example: Open button.
Keys	Keys are printed in slanted type.
	Example: Press *Enter*

1.2 Safety Instructions

Read all of these instructions! Save these instructions for later use!

Please always act according to the following safety instructions, before as well as during operation of the system!

The operating manual must be kept near the system and must be accessible for the user at any time.

ELISYS QUATTRO is a fully automated microplate analyzer including functions such as sample preparation, test performance, photometric measurement and data evaluation.

ELISYS QUATTRO is designed and manufactured in accordance with the safety requirements for electronically and IVD measuring devices. If the local law lays down regulations on the installation and/or operation of microplate analyzers, then it is the operators responsibility to adhere to them.

The manufacturer has done everything possible to guarantee that the equipment works safely, both electrically and mechanically. The systems are tested by the manufacturer and supplied in a condition that allows safe and reliable operation.

The user has to observe the information and warnings contained in this operating manual in order to ensure safe operation of the instrument.

1.2.1 General Safety

Follow all warnings and instructions marked on the instrument and in this manual.

The instrument must only be operated by personnel who have been trained on the use of the system.

It is strongly recommended that all first time personnel read this manual prior to use.

Use the system only for the designated application.

Use only the consumables and accessory prescribed herein (e. g. microplates, tubes, disposable tips etc.).

The manufacturer assumes no liability for any damages, including those to third parties, caused by improper use or handling of the system.

The operator may only perform the maintenance work described in this manual.

Use only the parts prescribed in this manual for servicing.

The tests and maintenance work defined by the manufacturer should be performed to make sure that the operator remains safe and that the instrument continues to function correctly.

Any service and maintenance work not described in this manual must be performed by authorised service personnel and technicians.

Any changes on the system which are not authorised by the manufacturer lead to the loss of guarantee obligation.

The system was developed and tested according to the regulations of the IvD directive

Any changes on the system which are not authorised by the manufacturer lead to the loss of the validity of the conformity with the applicable regulations the manufacturer has declared. In this case, the customer is responsible for the fulfilment of the applicable regulations.

The instrument should be opened, serviced and repaired by qualified and authorised service personnel only.

1.2.2 Electrical Safety

Country-specific regulations regarding safe electrical operation of the installed system have to be observed.

Check that the operating voltage is set correctly on all system components before you connect the system to the mains supply.

This product must be operated from the type of power source indicated on the type label. If you are not sure of the type of power available, consult an authorised sales person or your local electric power company.

Use a 3-wire grounding type plug to connect all instrument and peripherals to mains supply.

Use only extension cables with a protective conductor and grounded contact.

Grounding of the instrument, computer and its peripheral devices to the same protective earth potential must be ensured.

Never knowingly interrupt the grounding contacts.

There is the risk of an electrical shock if the protective conductor is interrupted within or outside the device, or has been disconnected.

The instrument must be connected with a delivered connection cable to dedicated socket. The use of a multi plug is not allowed!

Do not allow anything to rest on the power cord.

If you can see that the instrument has become unsafe to use, switch it off and disconnect it from the mains supply.

If liquid gets inside the instrument, switch it off and disconnect it from the mains supply. Clean, and dry the respective parts.

Surfaces (floors, work table) must be dry when you are working with the system.

Only use the bottles, tubing and components supplied and recommended for containing liquids on the instrument.

Spare fuses must match the values (nominal voltage, nominal current, and type) specified by the manufacturer.

Always replace blown fuses, don't try to repair them.

Never short-circuit the fuse holder.

Switch the instrument off and disconnect it from the mains supply before servicing.

Only when directed to do so, should power be applied. If power is applied while any covers are removed, use extreme caution while servicing the system.

Never remove protective guards or secured components since you could expose live parts in this way.

Electrical connection contacts (plugs, sockets etc.) can be electrically live.

Even after the device has been switched off, components (e. g. capacitors) can be under voltage as the result of an electrical charge.

All current-carrying parts are sources of danger for an electrical shock.

Don't position the instrument so that it is difficult to operate the disconnecting device (power supply switch, mains power connector)!

1.2.3   Laser Safety

Care must be taken when operating and testing the bar code scanners as they use a laser class 2. Never look directly into the laser beam!

Output causes iritations of the eye if stared into the beam for long periods of time.

See for technical data of the laser (bar code scanner).

For operating and testing the laser, no optical devices may be used.

For operating and testing the laser, watches and mirroring jewellery should be removed.

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

1.2.4   Mechanical Safety

Do not place the instrument on a unstable table, cart, or similar.

The instrument may fall, causing serious damage to the system or injure the user.

Don't load the complete opened drawer! The instrument could tip forward!

Never open screw-attached housing parts while the instrument is on.

There is a risk of injury due to moving parts (fan, motor drives).

Only when directed to do so, should power be applied. If power is applied while any covers are removed, use extreme caution while servicing the system.

Do not take off the protective cover during a run and do not reach into the working area.

Improper handling may cause serious damage to the instrument or injure the user.

If you open the flap or cover, verify that the movement of the pipettorhas stopped before you reach in the working area.

Avoid touching the pipettorand other moving parts while the system is in operation.

Notice that it is possible that the instrument continues processes independently, even without computer.

Slots and openings are provided for ventilation.

To ensure reliable operation of the instrument and to protect from overheating, these openings must not be blocked or covered.

1.2.5 Biological Safety

Risk of infection! Handling of samples and reagents:

Avoid contact between skin/mucous membrane and samples/test reagents or parts of the instrument which were in contact with samples/test reagents.

The above-mentioned parts are to be treated as being potentially infectious.

Reagents can lead to irritation of the skin and mucous membranes.

Use appropriate gloves!

Observe the instructions in the package inserts for a correct use of the reagents.

If sample material is spilled in the system, clean and disinfect it immediately by the use of a validated method.

For reagent containers and tubings (system liquid and waste), no guarantee can be provided for any resistance against organic solvents.

For this reason, do not use any organic solvents unless such solvents are expressly authorised.

It is not possible to autoclave the containers for liquids and waste!

1.2.6 Cleaning the System

Switch the instrument off and disconnect it from the mains supply before cleaning, disinfection or decontamination.

Liquid detergents, disinfectants or decontamination liquids may not be poured into the instrument or sprayed inside the system.

For the cleaning, disinfection or decontamination, a cloth moistened with detergent, disinfectant or decontamination liquid should be used.

Only approved detergents, disinfectants or decontamination liquids may be used.

Only approved cleaning, disinfection or decontamination methods may be used.

For cleaning, disinfection or decontamination, the regulations of the local authorities must be observed.

1.2.7 Disposal

Potential infectious material and all parts that may come in contact with potential infectious material must be disposed according to national legislation.

All parts which have been replaced, must be disposed according to national legislation.

Disposal of the instrument according to national legislation.

Disposal of the packaging material according to national legislation.

Containers intended for single-strip use may not be used repeatedly.

1.3 Positions of Safety Labels and Type Label

If any label gets lost, replace it by an equivalent label!

1.3.1 General Warning Labels

General waring labels are positioned on:
• Patient sample and rack unit flap

1.3.2 Biological Hazard Labels

Biological hazard labels are positioned on:
• Waste bag cover
• Waste container
• Waste bottles (positioned in the drawer)

1.3.3   Electrical Hazard Labels

Electrical hazard labels are positioned on:
*   Rear side of the instrument (near the mains switch)

1.3.4   Laser Hazard Labels

Laser hazard labels are positioned on:
*   Patient sample and reagent unit bar code scanner on the right side at the front).
*   Test plate compartment (near the bar code scanner on the left side at the front).

1.3.5   Type Label

The type label in positioned on:
*   Rear side of the instrument (near the mains switch)

2 System Basics

2.1 Overview

The **ELISYS QUATTRO** is a fully automated microtiter plate analyzer performing the complete sample processing (sample pre-dilutions, sample and reagent dispensing, incubations, wash processes, plate transports) as well as the photometric measurement and evaluation. The instrument is controlled via the Windows PC software **Phoenix**. This software, which was specifically designed for this purpose, allows the user to process the pre-defined assays as well as assays programmed by the user. The clear structure with intuitive user-guidance allows simple and quick operation of daily routine jobs as well as programming of user-specific assays.
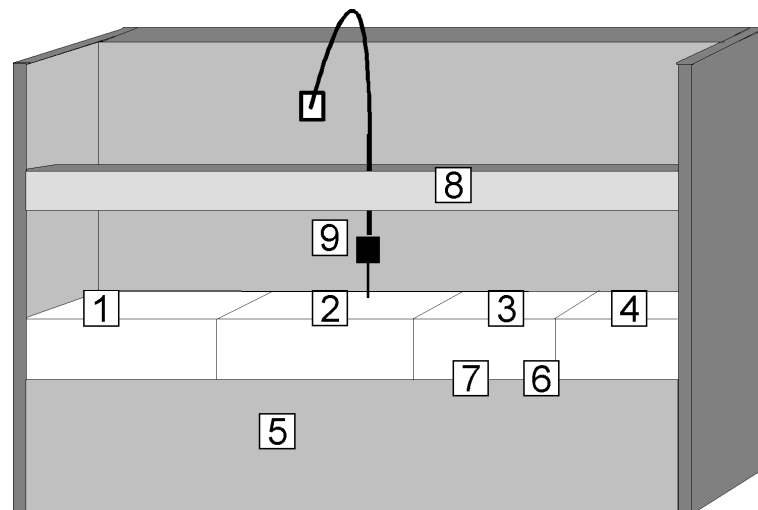
Figure 2-1: **ELISYS QUATTRO** *- Instrument modules*

1	Tray for tip racks and dilution tubes
2	Patient sample and reagent rack unit with bar code scanner
3	Tip eject station, pipettor wash station, pipetting station
4	Test plate compartment, plate transport unit
5	Drawer with wash unit and photometer
6	Position of incubators (below test plates), heated and for room temperature (dark)
7	Waste bag for tips
8	Guide rail for pipettor (X and Y movement)
9	Pipettor (movement in Z-direction)

2.2 Top Level Instrument Modules
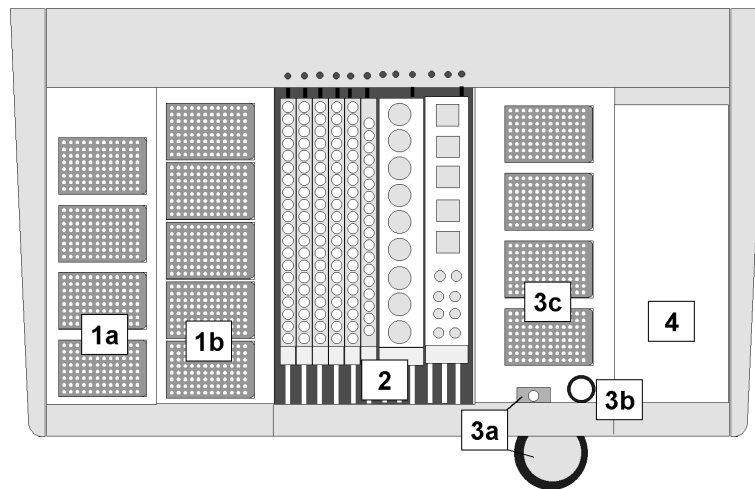
Figure 2-2: **ELISYS QUATTRO** *- View on top level*

1a Dilution plates (see chapter 2.2.1 on page 2-3)selftest

1b Tip racks (see chapter 2.2.1 on page 2-3)

2 Patient sample and reagent unit (see chapter 2.2.2 on page 2-4)

3a Tip ejection station and waste bag (see chapter 2.2.3 on page 2-4)

3b Pipettor wash station (see chapter 2.2.3 on page 2-4)

3c Pipetting station (see chapter 2.2.3 on page 2-4)

4 Test plate compartment with plate transport unit (see chapter 2.2.4 on page 2-5)

2.2.1 Tray for Tip Racks and Pre-dilution

The tray is accessible via a drawer which is locked automatically as soon as a run has been started. The tray includes 5 positions for tip racks (300 μl or 1100 μl tips, see figure 2-2: position 1b) as well as a position for the dilution rack see figure 2-2: position 1a. 6 additional reagent positions are also available.

Move the tip rack from above straight into the specific position, the groove must fit into the pin (see figure 2-3: and see chapter 5.1 on page 5-1). The clamp shall fix the tip rack.
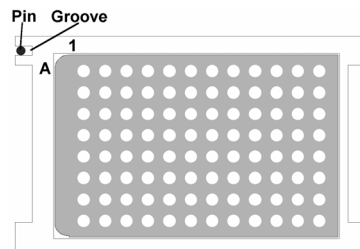
Figure 2-3:   Placement of tip racks: A1 is on the top left

2.2.2 Patient Sample and Reagents Unit with Bar Code Reader

(See figure 2-2: position 2)

CAUTION: Laser radiation - do not stare into beam!

The bar code scanner is located on the right side at the front of the patient sample and reagent unit.

The patient sample and reagent unit, accessible via a flap, includes 12 tracks for sample and reagent racks.
The following racks are supplied:

T: Sample rack for 20 patient samples (occupies one track).

R: Reagent rack for 18 bottles for reagents (occupies 1 tracks).

5:   Reagent rack for 5 large bottles for reagents and 8 small bottles for reagents (occupies 3 tracks).

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 red 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 limit stop. The respective LED on the rear panel goes off (Loading/Unloading see chapter 5 on page 5-1).
Reloading of patient and reagent racks is possible when the instrument is in the incubation mode.

Keep the flap of this unit closed during a run. It may be opened only for re-loading (see chapter 5.2 on page 5-6). Opening the flap while transfer steps are being performed results in an immediate stop of the pipettor and entry in the event log.

2.2.3 Tip Ejection Station, Pipettor Wash Station, Pipetting Station

Tip ejection station and waste bag (see figure 2-2: position 3a)
The opening serves as ejection station for disposable tips. The ejected tip is transported into the waste bag via a slide which is attached to the front side of the instrument. The ejection station is closed by a cover plate which can be pulled off by hand. With the cover plate removed, the waste bag can be taken out of the holding device and replaced (Disposal see chapter 5.3 on page 5-7).

Pipettor wash station (see figure 2-2: position 3b)
The pipettor wash station is located next to the tip ejection station.

Pipetting station (see figure 2-2: position 3c)

The test plates are positioned by the system. Up to 4 plates can be positioned in this station. A transport unit automatically moves them from the plate compartment to the correct position where they are processed further (Loading/Unloading see chapter 5 on page 5-1).

2.2.4 Test Plate Compartment with Bar Code Scanner

(See see figure 2-2: position 4 or figure 2-5: position 4)

CAUTION: Laser radiation - do not stare into beam!

The bar code scanner is located on the left side at the front of the test plate compartment.

The test plate compartment can be opened only on request by the software. The LED indicator LD lights up green.

Open the door and place the respective (bar coded) test plate with the holding frame onto the transport unit so that both pins of the holding frame sit in the openings of the slide. Position A1 is at the top left (see figure 2-4:). The plate is moved to the pipetting station following the respective command on the screen.
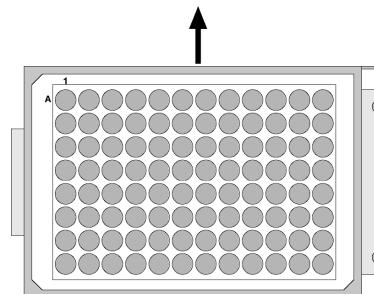
Figure 2-4:   Inserting a test plate with holding frame

From there the plate is transported - depending on the defined assay - to the various instrument modules and then back again to the plate loading position (Loading/Unloading see chapter 5 on page 5-1).

2.3 Drawer Instrument Modules

The drawer is automatically locked during a run. The green LED INSTR goes off.

Figure 2-5:   **ELISYS QUATTRO** *- Bottom drawer pulled out*

4	Test plate compartment with plate transport unit (see chapter 2.2.4 on page 2-5)
5a	Wash buffer container (square) and waste bottles (round) (see chapter 2.3.1 on page 2-6)
5b	Wash unit for test plates (see chapter 2.3.2 on page 2-6)
6	Incubators (see chapter 2.3.3 on page 2-6)
7	Photometer (see chapter 2.3.4 on page 2-7)

2.3.1   Wash Buffer Container and Waste Bottles

(See figure 2-5: position 5a)

A maximum of 3 bottles (1 x 1 litre, 2 x 2 litres) can be used for various wash buffers; another position has to be reserved for the cleaning fluid (distilled water) to clean the washer head.

The connection fitting consists of 4 colour-coded connection pairs: one tubing and one level sensor each per bottle (Loading see chapter 5.1 on page 5-1).

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

2.3.2   Wash Unit for Test Plates with Window

(See figure 2-5: position 5b)

The test plates are moved into the wash unit by the system. The wash process and the height adjustment of the washer head can be checked via the window.

2.3.3   Incubator Unit

(See figure 2-5: position 6)

Below the pipetting area for the test plates there are four independent heatable and shakeable incubator chambers; the test plates are automatically transported into these incubators and out again according to the assay protocol.

The instrument is equipped with a light-protected storage magazine accommodating four plates for room temperature incubation. It is located below the incubators in front of the photometer.

2.3.4 Photometer (Back of Bottom Drawer)

(See figure 2-5: position 7)

The photometer (400 - 700 nm) is installed at the back of the bottom drawer. The photometer can be equipped with up to 8 filters (end point or kinetic evaluation possible). The photometer is moved out with the bottom drawer.

2.4 Other Instrument Modules

2.4.1 Guide Rail for Pipettor

(See figure 2-1: position 8)

It is used to move the pipettor in the X- and Y-direction.

2.4.2 Pipettor (Z-Direction)

(See figure 2-1: position 9)

The pipettor includes a complex sensory mechanism. It works with disposable tips. The pipettor is connected to the system liquid port (See figure 2-6: position 10) via tubing.

A plastic cover with hinged flap protects the visible working area. The closed position of this flap is monitored by a contact switch. The ELISYS QUATTRO cannot be operated without this cover or flap, in order to avoid getting in contact with the working area during a run. If these safety precautions are not observed strictly, the operator may get hurt or contract an infection, or the instrument may get damaged.

The system will stop immediately when the instrument cover or the lockable flap is opened during a run!

2.5 Connections
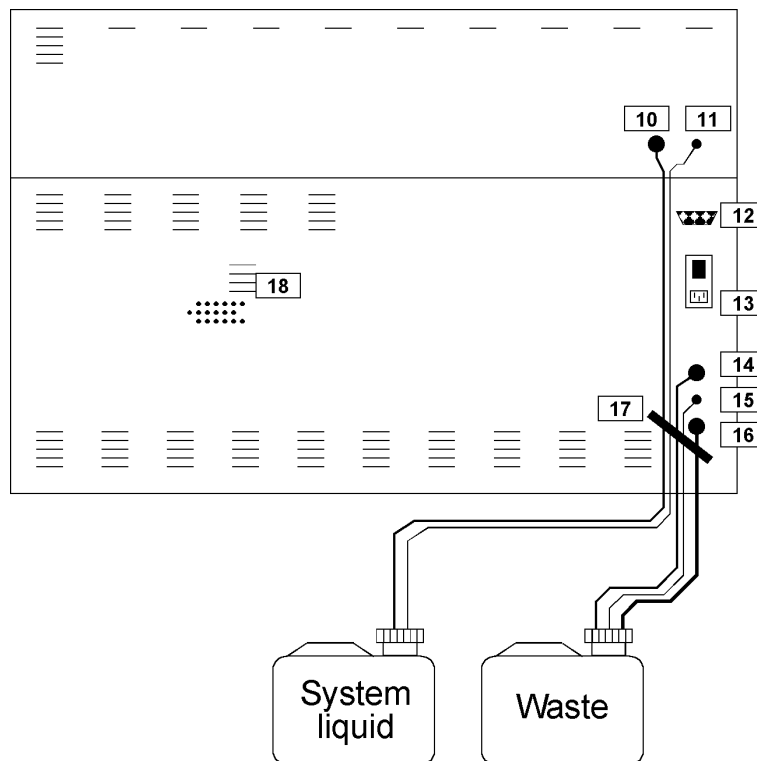
Figure 2-6:   **ELISYS QUATTRO** *- Instrument rear panel with connections*

10   Tubing connection for system liquid

11   Electrical connection for system liquid level sensor

12   PC port (RS232, 9-pole)

13   Mains fuses, mains switch and mains connection

14   Liquid waste outlet

15   Electrical connection of waste container level sensor

16   Waste from pipettor wash station

17   To protect tubings and cables

18   Ventilation channels

Pass tubings and cables through below the bow.

Don't position the equipment so that it is difficult to operate the discon-necting device!

The ventilation channels must not be blocked. Observe minimum distance of 15 cm!

The level sensors inform you about the status of the respective container (full/ empty). A corresponding message appears on the screen. Before starting a run, check both containers.

2.6   LED Displays

The LED displays on the instrument front panel (next to the left and right door) have the following meaning:

Left

PWR	Power	**Green**, when turned on, otherwise **off**.
RDY	Ready	**Green**, when ready for a run, otherwise **off** (e.g. in case of Error or during initialisation)
ERR	Error	**Yellow**, when instrument error has occurred, otherwise **off**.

| | DWR | Drawer | **Green**, when left drawer has been cleared for loading and unloading of pre-dilution plates and tips, otherwise **off**. |

Right

| | LD | Load | **Green**, when plate compartment can be opened, otherwise **off**. |

| | INSTR | Instrument | **Green**, when instrument drawer (bottom drawer, see figure 2-1: position 5 can be opened. |

2.7 Principles of Methods

2.7.1 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 for the concentration of the substance under investigation. The photometer consists of a polychromatic or monochromatic light source. In the case of the *ELISYS QUATTRO*, this is a halogen lamp which emits a 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.

2.7.2 Bichromatic Measurement

In the case of the bichromatic measurement principle measurements are performed at two wavelength, 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 subtracted 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.

3 Software Structure and Operation

3.1 Basic Information about Operation

ELISYS QUATTRO

The user program ***Phoenix*** is a PC program running under Microsoft Windows 95 as well as Windows 2000. The usual Windows conventions apply. Deviations from these conventions are described where appropriate.
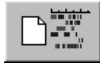
Explorer Tree

Some windows show an explorer tree on the left-hand side and the selected item on the right-hand side. Clicking on the plus sign of a folder on the explorer tree opens the respective options, clicking on the minus sign closes the respective folder. Clicking on an item shows the respective page of the corresponding file.

This presentation is used for the windows:

- **Assay Protocol**
  To define assay process steps (pipetting, washing, incubating, measurement, etc.).
- **Panel Definition / Set-up Panel**
  To combine assays and samples on test plates to create a worklist for routine.
- **Worklist**
  To check the conditions for a certain worklist.

3.2 Menu Guidance

3.2.1 General Menu Guidance

Menu	Item	Icon	Function
File	New		Creates a new file, e. g. a worklist or an assay. The New dialogue box opens and the following file types can be selected: **Assay**, **Worklist**, **Spectral Response**, **Patient Results Report**, **QA Analysis Report**, **Job List**.
	New | Worklist		Creates a new worklist.
	Open		Opens an existing file, e. g. an assay protocol or a report file (file types see File | New).
	Close		Closes the displayed file.
	Save		Saves the active file (e. g. worklist, report).
	Save As		Saves active file (e. g. worklist, report) under a new name.
	Print...		Prints the active document.
	Print Preview		Shows the active document as print preview.
	Print Setup...		Defines the printer and printing options.
	Recent Protocols >		Shows the last opened and already saved assay protocol files for selection.
	Recent Results >		Shows the last opened and already saved result files for selection.
	Recent Worklists >		Shows the last opened and already saved worklist window for selection.
	Exit		Terminates the program.
View	Toolbar		Shows/hides toolbar.
	Status Bar		Shows/hides status bar at the bottom of the screen.
Utilities	System Setup...		Definition of instrument parameters.
	Selftest		Performance of a selftest (initialisation).
	Verify		Checks the photometer

Menu	Item	Icon	Function
	Patient Details...		Definition of detailed patient data.
	Options...		Definition of software parameters.
Window	New Window		Opens a new window.
	Cascade		Cascades the active windows.
	Tile		Tiles the active windows.
	Arrange Icons		The icons can be re-arranged.
	.		Shows the names of all currently active windows.
Help	Help Topics	▶?	Calls on-line help.
	About Phoenix...		Shows the version number of the **Phoenix** software.

Table 3-1:   General menu guidance

3.2.2　　Worklist Menu Guidance

Menu	Item	Icon	Function
Edit	Panel Definition...		Opens the Set-up Panel dialogue box (only possible with open worklist) with editing options of the current worklist.
	Panel Options...		Settings for processing the worklist.
	Optimise		Optimises processing of the defined run.
	Lot specific values		Display and input of the lot specific information and the required reagents for the displayed worklist.
	Start		Starts the loading dialogue; once the loading dialogue has been completed, a run using the current worklist can be started.
	Stop		Stops the current run. The run can be continued again and one or several plates can be removed from processing. Or the entire run can be aborted completely.
	Load additional tips		Allows the reloading of pipette tips.
View	Module Schedule		Graphical display of the processing of a worklist (module-specific).
	Plate Schedule		Graphical display of the processing of a worklist (plate-specific)
Utilities	System Utilities		Manual plate control.

Table 3-2:　　Worklist menu guidance

3.2.3   Result Menu Guidance

Menu	Item	Icon	Function
Edit	Outliers...		Shows the Outliers dialogue. This dialogue shows all result values. Changes of these values are marked in the result report.
	Parameters...		Shows the Lot Specific Values dialogue. This dialogue shows all data of the reagents. Changes of these datas are marked in the result report.
	Assays...		Shows the Change Assay Protocol dialogue. This dialogue shows the used assay. Change of these assays are marked in the result report.
	Retest...		Shows the Retest dialogue. This dialogue shows all tested patients. Select one or more patients you want to test it with these assays again.
	Copy to clipboard		Copy selected Quantitative Results to the windows clipboard.
View	Recalculate		After having changed the parameters for the assay this function starts the recalculation. The data reduction of the raw data will be done using the new parameters.
Utilities	Export Results		Shows a dialogue to start the export of the results to a file and/or to LIMS.

Table 3-3:   Result menu guidance

3.3 File Types

File	Extension	Path
File polling format setting of the import file for host systems. For detailed information see *ELISYS QUATTRO* 'Connectivity Manual' Cat.No.: 16300/4, available on request.	***.apm**	C:\Phoenix
Assay protocol files	***.asy**	C:\Phoenix\Assays
Files documenting daily data communication between PC and *ELISYS QUATTRO* instrument as well as error messages.	***.log**	C:\Phoenix\Eventlogs
Coordinate files for e.g. pre-dilution plates	***.mpc**	C:\Phoenix
Coordinate files for the racks	***.rac**	C:\Phoenix
Result files	***.res**	C:\Phoenix\Results
Spectrum files (contain data of a spectrum acquisition)	***.spe**	C:\Phoenix
selftest files with information about the selftests that were performed.	***.tst**	C:\Phoenix
Export files in ASCII format	***.txt**	C:\Phoenix\Export
ASCII patient data import files can be downloaded from a host computer to the *Phoenix* software (patient with associated assays).	***.txt**	For host connection
Verification report files	***.ver**	C:\Phoenix
Worklist files	***.wor**	C:\Phoenix

Table 3-4: File types

4 Performing a Test Run

4.1 System Start

1. Start the ***ELISYS QUATTRO*** instrument.
2. Start the computer.

3. Start the ***Phoenix*** software by clicking on the respective icon on the desktop or choosing Start | Phoenix.
4. Click on the OK button.
   You don't need a User Name or Password

ℹ️ *To run the **Phoenix** software in demo mode tick the* Demo mode *check box. The **Phoenix** software can be run without the **ELISYS QUATTRO** instrument.*

---

5. After that a system selftest is performed and checks all instrument functions. The result of this instrument check is then displayed on the screen.
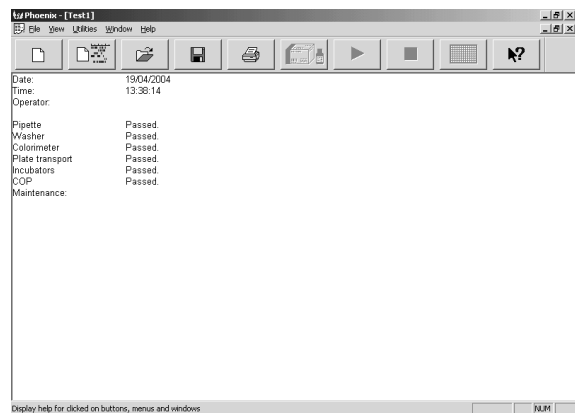
4.2 Input of Patient Data

4.2.1 Manual Input of Patient Data

1. Select Utilities | Patient Details or click on the icon on the tool bar and define the patients and the associated tests in the Patient Editor.
2. Click on the Add Patient(s) button to open the Add Patient(s) dialogue box.

3. Enter the first sample name in the First patient ID.
4. Optionally, consecutive sample numbering may be entered blockwise. To do this, the number of the following samples has to be entered in the Number of patients text box. The software numbers the following samples con-secutively.
5. Click on the OK button.
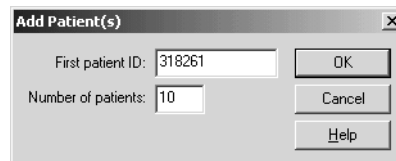
> *The patient editor only accepts letters and numbers as patient ID. The use of any spe-cial characters such as "%", "-", "$", "€","", "|", "/", "\", ";", "," or "." when creating a patient ID or receiving from the host computer is forbidden.*

The software returns to the Patient Editor and shows the patients that were entered new.

Repeat this step, if necessary, for further patient IDs.
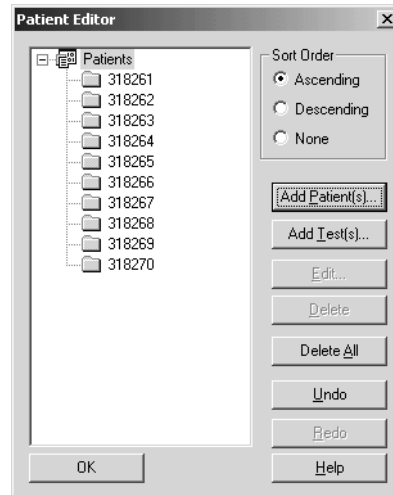
6. Click on the Add Test(s) button in the Patient Editor.
7. In the following Add Tests dialogue assign the patients to the assays.
   To do this, select the patients and then the assay(s).
8. Click on the OK button.
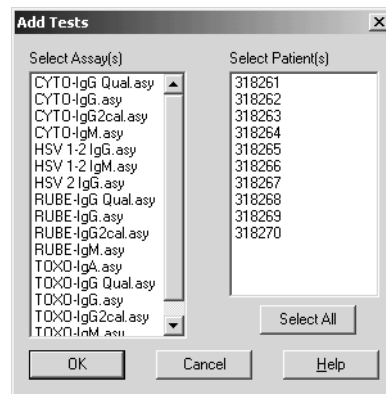
> *You will find further information to the tests in the manual of the respective test.*

4.2.2   Input of Bar Coded Patient Samples

1. Insert samples into the **ELISYS QUATTRO** with the worklist closed.
   The patient bar codes are read.
   The dialogue box depicted to the right appears on the screen, showing the identified bar codes.
2. From the respective list box (with all available assays), select the respective assay by clicking on the column header.
3. Then assign the samples by clicking on the field in the respective assay column.
4. Click on the `Close` to accept the selection.
5. Proceed accordingly for each further sample rack.
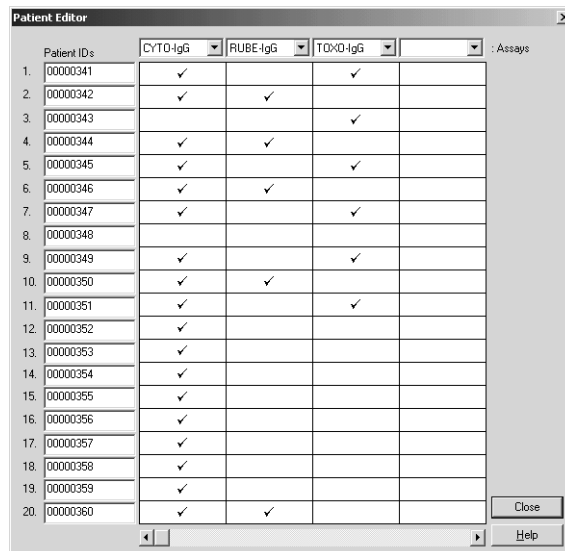
	Patient IDs	CYTO-IgG	RUBE-IgG	TOXO-IgG		: Assays
1.	00000341	✓		✓		
2.	00000342	✓	✓			
3.	00000343			✓		
4.	00000344	✓	✓			
5.	00000345	✓		✓		
6.	00000346	✓	✓			
7.	00000347	✓		✓		
8.	00000348					
9.	00000349	✓		✓		
10.	00000350	✓	✓			
11.	00000351	✓		✓		
12.	00000352	✓				
13.	00000353	✓				
14.	00000354	✓				
15.	00000355	✓				
16.	00000356	✓				
17.	00000357	✓				
18.	00000358	✓				
19.	00000359	✓				
20.	00000360	✓	✓			

The patient editor only accepts letters and numbers as patient ID. The use of any spe-cial characters such as "%", "-", "$", "€",""", "|", "/", "\", ";", "," or "." when creating a patient ID or receiving from the host computer is forbidden.

*As an alternative, patients may be entered via host. In this case you may start directly with creating a worklist (see chapter 4.3.1 on page 4-5).*

You will find further information to the tests in the manual of the respective test.

4.3 Worklist Definition

4.3.1 Create New Worklist

1. Click the New| Worklist button (or select File | New and then select Worklist in the dialogue box).
2. The Set-up Panel dialogue box is displayed.
- In case of **non-bar coded** samples this dialogue box is empty, as shown in the figure to the right.
- With **bar coded** samples a worklist with plates, assays and patients is suggested in accordance with the assignment of the assays to the samples and displayed in the Explorer tree, using one assay per plate.
Click on the OK button to accept this proposal and proceed with defining several plates (see chapter 4.3.3 on page 4-8) or with input of reagent data (see chapter 4.3.4 on page 4-8).
If the proposal is modified, the plate panel has to be deleted with Delete and a new plate panel has to be defined.
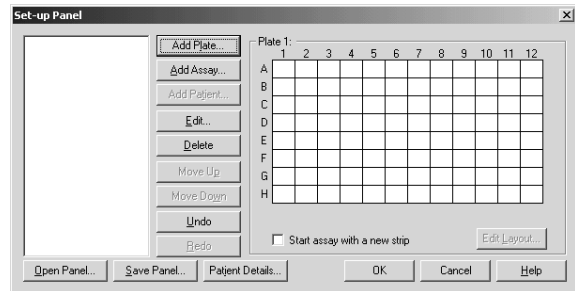
In the Set-up Panel dialogue box the plate(s) and the plate layout are defined for the selected worklist via the top 3 buttons. Click on the Undo button to undo the last step. Click on the Open Panel button to open a stored plate panel. Click on the Save Panel button to save the defined plate panel. The assigned patients are not stored.

3. Click on the Add Plate... button.
Plate 1 is entered in the Explorer tree.
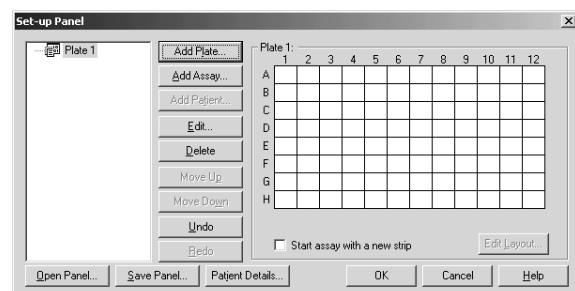
4. Click on the Add Assay... button.
   The Open dialogue box shows all available
   assay files (*.asy) in the selected subdirectory.
5. Select the desired assay file.
6. Click on the Open button.
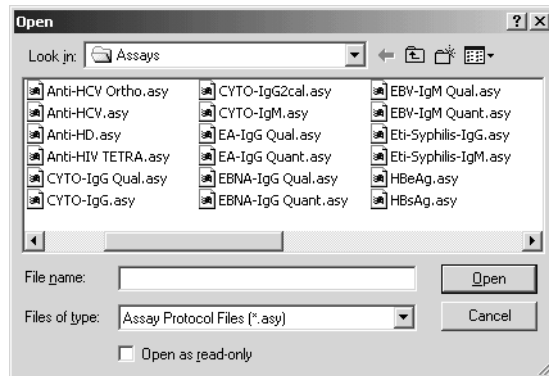
The plate panel pre-defined in the selected assay
protocol is entered into the plate depicted in the
Set-up Panel dialogue box (except tests). In the
Explorer tree the assay protocol is displayed as a
folder.
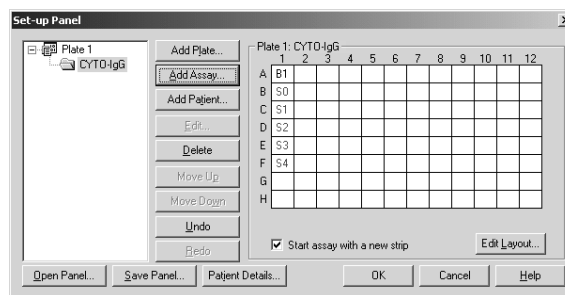
7. Click on the Add Patient... button to assign
   the patients to the selected assay.
   The Select Patient(s) dialogue box
   appears. It contains only the patient IDs for which
   the respective assay has been selected in the
   Patient Editor.
   The dialogue indicates all patients with a '*',
   which are already loaded on the instrument.
8. Select patients with the mouse or press on the
   Select All button to select all of the loaded
   samples to the worklist.
9. Click on the Ok button.
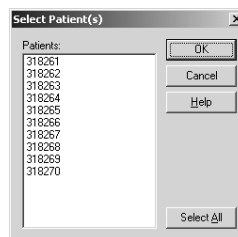
> ℹ️ *If you did not enter any patient codes before creating the worklist this window*
> *does not contain any patients. In this case you can assign assay/patients via*
> *the* Patient Details... *button in the* Set-up Panel *dialogue box.*

> ℹ️ *If a sample is already assigned to the worklist it disappears from the* Select
> Patient(s) *dialogue.*

> ℹ️ *To run the same patient with the same assay on more then one plate the op-*
> *tion* Allow multiple determinations *must be selected.*

The selected patients are listed in the Set-Up Panel dialogue box as contents of the assay folder.
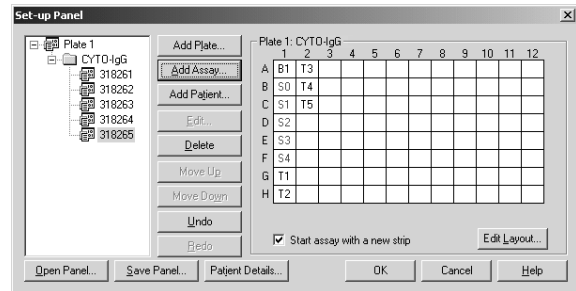
4.3.2 Defining Several Assays per Plate

1. The respective plate must be active.
   If not: click on the plate name in the Explorer tree.
2. Click on the Add Assay... again to place a second assay on the same plate.
   The panel of the first assay is hidden.
3. Select assay and patients as described in the steps before (see chapter 4.3.1 on page 4-5).

---
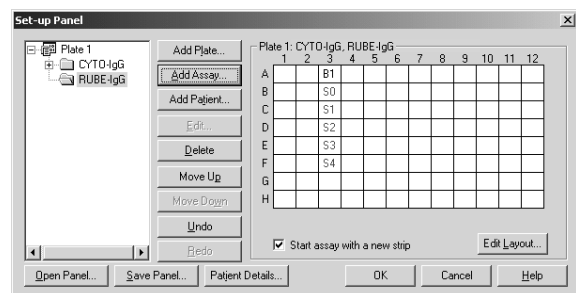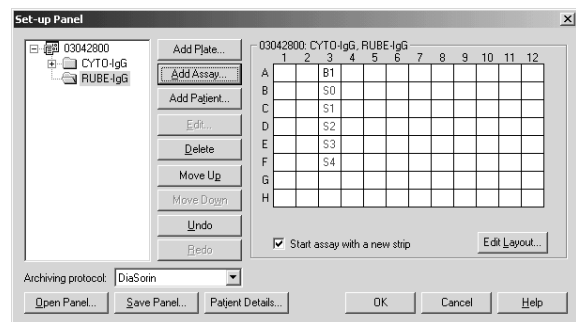
i   *Only possible with identical incubation parameters!*

---

i   *The item* Start assay with a new strip *must always be enabled!*

4.3.3   Defining Several Plates

1. Click on the Add Plate... button.
2. Click on the Add Assay... button and select
   an assay protocol (see chapter 4.3.1 on page 4-5).
3. Click on the Add Patient... button and select
   patients.
   The expanded Explorer tree is displayed along
   with plate 2 showing the panel of the active
   assay.
4. Repeat this steps for further plates.
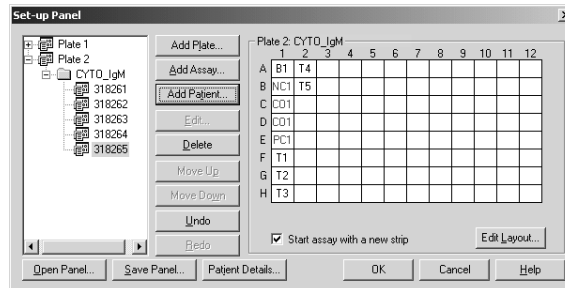
Further possibilities:

• Click on the plus sign of an plate folder to view
  the respective assays in the Explorer tree.
• Click on the plus sign of an assay folder to view
  the respective patient IDs in the Explorer tree.
• Change the order of plates via the Move Up
  and Move Down buttons.

4.3.4   Input of Reagent Data

1. After all required plates have been defined in the
   Set-up Panel dialogue box, click OK to
   close the dialogue box.
   The Lot Specific Values For: Plate 1
   dialogue box for of the active worklist is dis-
   played. It includes a tab for each assigned assay,
   listing the required reagents for the respective
   assay
2. For this assay and - if available - for the other
   assays on this plate, that are located **on further
   tabs**, you have to enter the lot-specific data.
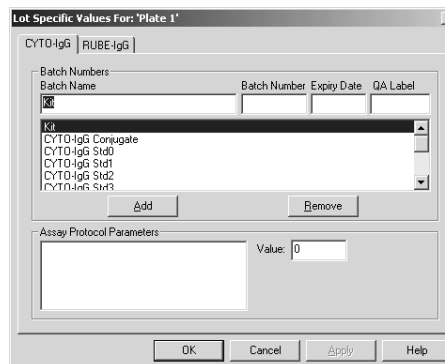
The different assay tabs must be selected by hand!

---

3. Click on the OK button.
   The first assay of the next plate is displayed. This
   and possibly following assays and plates have to
   be treated as described above.
   After the last plate the Worklist window is dis-
   played (see next chapter).

4.4 Start a Worklist

4.4.1 The Worklist Window

When all dialogues have been processed as described above, the Worklist window with the Worklist parameters and the Explorer tree appear.

The start time and end of the run as well as the plate status (loaded/not loaded/error), the selected assays and the number of patients are displayed.

In the Explorer tree click the plus sign of the work-list folder and then the respective item.

- Click on the Start button to start the worklist and open the Load dialogue (see chapter 4.4.2 on page 4-12).

4.4.1.1 Schedule

The Schedule shows the process diagram for the worklist. It can be presented as Module Sched-ule (see figure) or as Plate Schedule. The selection is made via the View menu.

The individual plates and process steps are displayed in different colors.
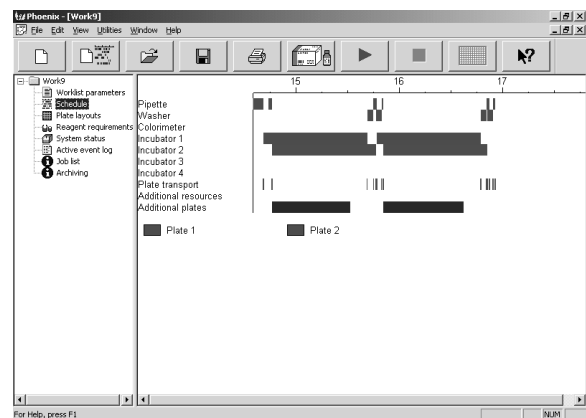
4.4.1.2 Plate Layout

The Plate layout shows the exact plate layout. All plate layouts defined in the current worklist are displayed one below the other.

The view can be switched between Layout Label (e. g. T1, T2 ...) and Patient IDs (e. g. 318261, 513255 ...)
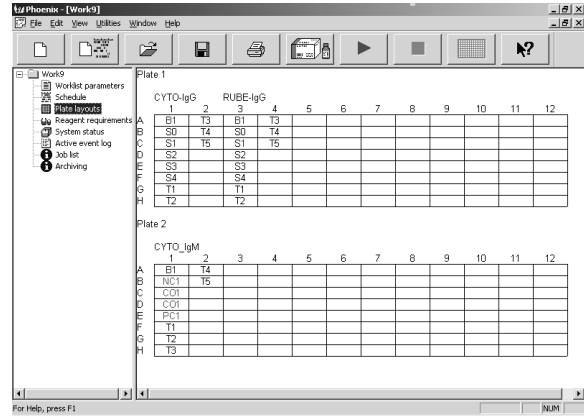
4.4.1.3 Reagent Requirements

The Reagent requirements shows the required reagents (Example).

Make sure the required reagents are available and there is sufficient space in the liquid waste container.
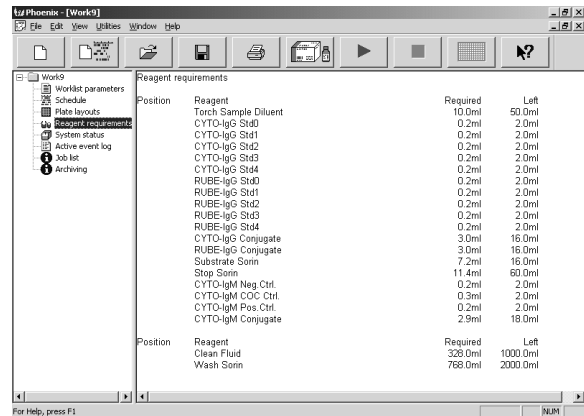
4.4.1.4 System Status

The System status shows the working area including status messages. Depending on the type of loading (bar coded, non-bar coded samples or host connection), this presentation differs:

- Bar coded samples:
  Sample and reagent racks are depicted.
- Non-bar coded samples and host connection:
  No racks are depicted yet.
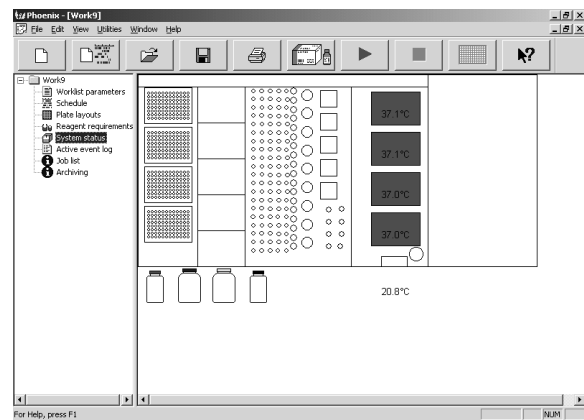
4.4.1.5 Active Event Log

The Active event log shows the communication protocol, listing all steps of the *ELISYS QUATTRO* (Example).

- Important actions in this context are warning and error messages; they are displayed in red.
- Reactions by the user on these actions are displayed in green.
- User actions such as manual definition of reagents are also displayed in red.
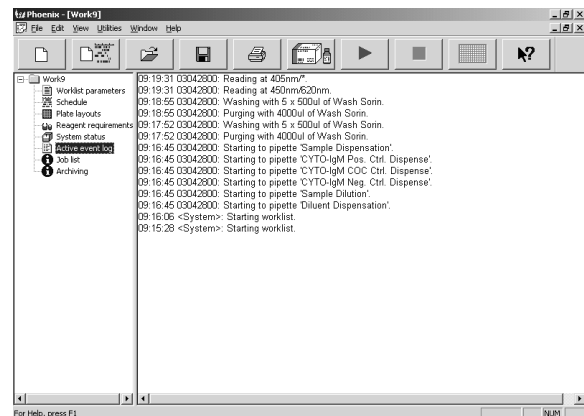
4.4.1.6 Job List

The `Job list` shows the allocation of patient IDs
and tests to be performed in a list.
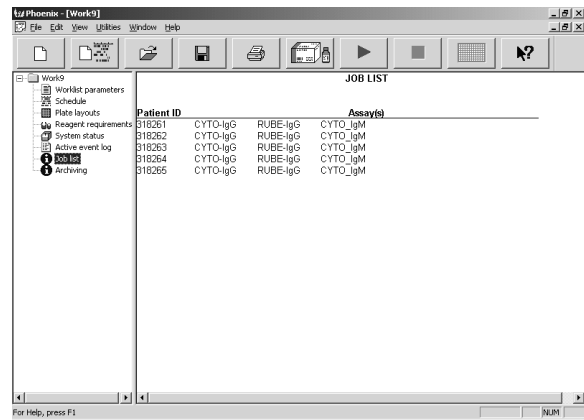
4.4.2 Loading Samples and Reagents

CAUTION: Laser radiation - do not stare into beam!

Allocate the vials only into suitable locations. An incorrect allocation may cause errors in dispensing.

Samples having particulate matter, turbity, lipaemia, foam, or erythrocyte debris may require clarification by filtration or centrifugation before testing.

The use of primary tubes with gel separator requires a careful check of the sample volume above the gel to avoid any possible errors in dispensing.

When refilling a reagent bottle never exceed the bottle shoulder. An over-filling may lead to an incorrect dispensing.

4.4.2.1 Loading Bar Coded Patient Samples and Reagents

The sample and reagent area on the screen are empty.

The required resources are displayed as circles in different colours in the top right corner of the screen. You can view the respective name by moving the cursor over these circles. An inserted rack is depicted graphically and the loaded resources are **automatically** allocated.
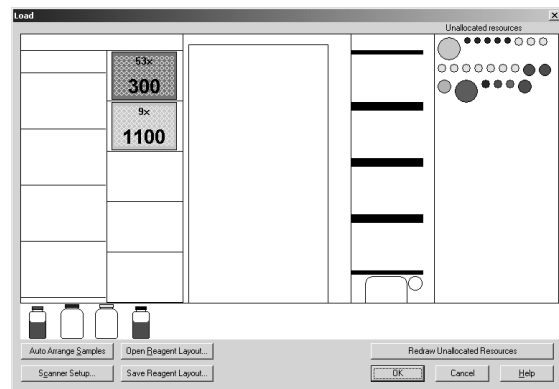
1. Right LED lights up red.
2. Insert first rack into the right track.
3. The bar codes are read and the rack and the available reagents are identified.
4. If the rack has been inserted properly up to the limit stop the LED goes off. On the screen, the loaded resources from the pool of unallocated resources are allocated to the inserted rack (marked with a cross in the rack position), since they are bar coded and are therefore identified.
5. The next empty track is marked by a red LED. Proceed as described in the preceding step (see chapter 5 on page 5-1).
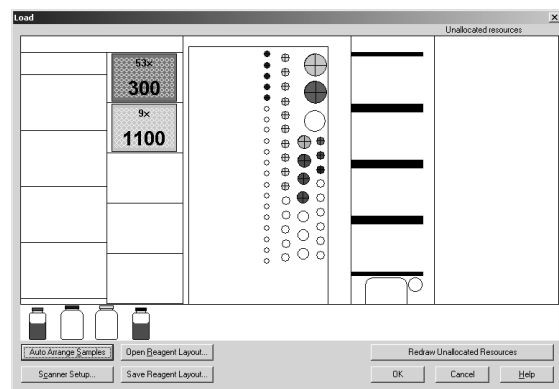
> ℹ️ *Always load racks from right to left.*

4.4.2.2 Allocation of Non-bar Coded Reagents and Samples

The sample and reagent area on the screen is empty.

After insertion of the racks **only the rack types** with empty positions are depicted. Unallocated but required resources are displayed as circles in different colours in the top right corner of the screen. You can view the respective name by moving the cursor over these circles.
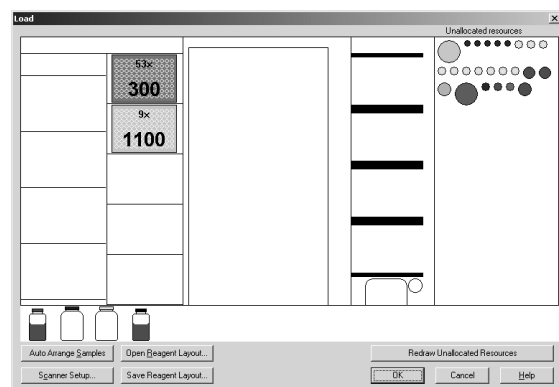
1. Right LED lights up red.
2. Insert first rack into the right track.
3. Allocate the non-bar coded reagents on the screen by dragging the mouse - corresponding to the actual loading - to the reagent rack.
   Each dot clearly corresponds to one reagent.
4. Insert the required racks one by one into the tracks marked by the red LED and allocate the resources as described above (from right to left).
5. On the screen, allocate the samples by dragging the mouse - corresponding to the actual loading - to the sample racks. Each dot clearly corresponds to one patient tube or one reagent.

---
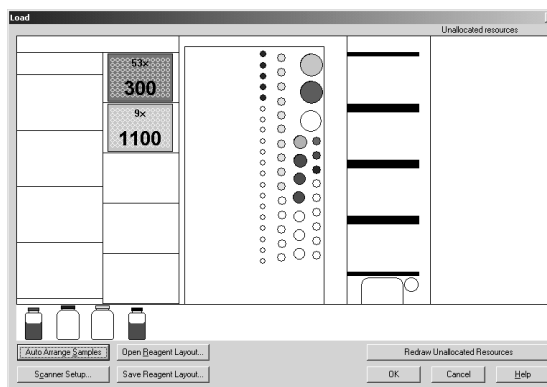
i   *"Dragging" means clicking with the mouse on a resource, keeping the mouse button pressed down, moving it to the desired location, and releasing the mouse button again.*

Auto Arrange Samples:

- **Load procedure 1:**
  Load all sample racks and press on the Auto Arrange button. The fill direction of the samples starts at position one of the rack placed in the far left side.

- **Load procedure 2:**
  Load the first sample rack and press on the Auto Arrange button. The fill direction of the samples starts at position one of the sample rack just inserted.
  Proceed this sequence with the remaining racks.

---

i   *The Auto Arrange function always arranges the samples by using the None sort order as selected in the Patient Editor. After its use, it is recommended to perform a random manual verification of the sample IDs in the rack. This type of verification is also recommended when working with a job list manually created for sample tubes without barcodes.*

4.4.3   Loading other Required Resources

Load disposable tips and dilution plates as well as wash buffer and distilled water as shown on the screen. The number and size of the required tips is displayed.

Observe defaulted positioning!

Tip racks depicted in dark grey and light grey must be loaded in addition.

- 300 μl tips are depicted in dark grey.
- 1100 μl tips are depicted in light grey.

Only complete tip racks should be loaded.

Tip racks depicted in red are already available on the instrument, tips may have been removed already. The number of tips that are still available is taken into account by the software.

You can view the respective name of the dilution plate by moving the cursor over this plate.
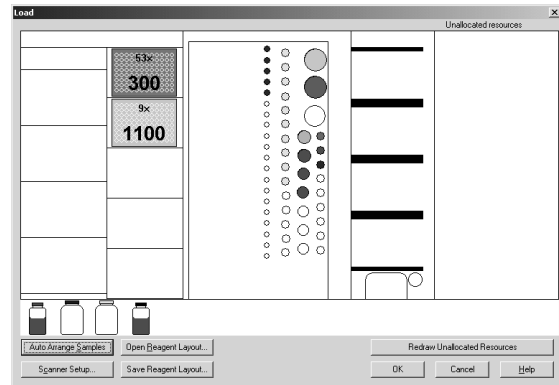
Check if sufficient tips are available and if the tip size displayed agrees with the position on the instrument!

Please carefully check the tip racks allocation, following the specific color code and type in the software. A tip misplaced can not be recognized by the instrument and may cause mechanical damage!

4.4.4 Reagent Volume Check

After loading and allocation of all required resources, press on the OK button. A volume check of all reagents is carried out automatically.

If the reagent check shows that the volume of one reagent is low, a System Error dialogue box appears alerting you about any insufficient volume.

To refill the respective reagent or to replace it by a new bottle, the respective reagent rack has to be moved out, reagent has to be refilled or the bottle replaced, respectively and the rack has to be inserted again.

- If you press on the Refill Bottle... button, the volume is checked once more.
  If the reagent was identified manually, the position in the rack has to be allocated once more (see above).
- If the reagent cannot be supplied, press on the Abort Worklist button.
  This will abort any further volume check.
- The Ignore button skips the reagent check for this specific reagent (the insufficient volumne is logged) and continues with the reagent check for the next one.
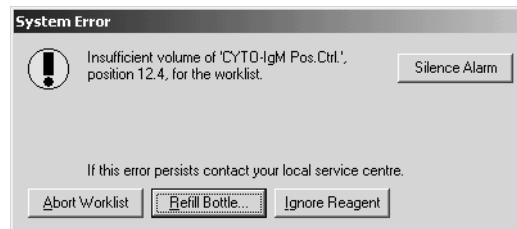
Do not change any reagent positions!

4.4.5 Plate Loading

Plate loading may be started as soon as all reagents are available in sufficient quantity.

4.4.5.1 Plate Loading

The plate compartment LED lights up green, the dia-logue box depicted to the right appears on the moni-tor. Open door and place test plate (position A1 on the rear left) with the holding frame correctly on the plate transport unit (see chapter 5.1 on page 5-1).

1. Enter the plate name in the field `Plate ID`.
2. Click on the `OK` button.

The test plate is first moved into the photometer to check for an adequate strip filling for the perform-ance of this assay. Then the plate is placed on the pipettor station. The plate transport unit moves back to the home position and the `Load Plate` dia-logue box requests the 2nd plate.

3. Repeat procedure until all plates of the worklist have been inserted.
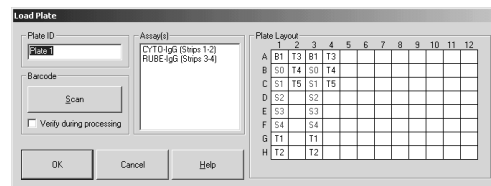
ℹ️ *At this point the system does only recognise if a holding frame has been load-ed!*

4.4.6   Starting and Processing a Run

As soon as all plates have been loaded, the system starts the run. All loading doors must be closed so that the run can be started!

The plates are processed in accordance with the defined process steps of the selected assays.

During the run all worklist options (see chapter 4.4.1 on page 4-9) can be viewed. In the Schedule mode the current time and thus the current operation is marked by a vertical indicator.

At the end of the entire run the system prompts you to unload plates. Unload plates one by one. Results can be viewed as soon as all plates have been unloaded.
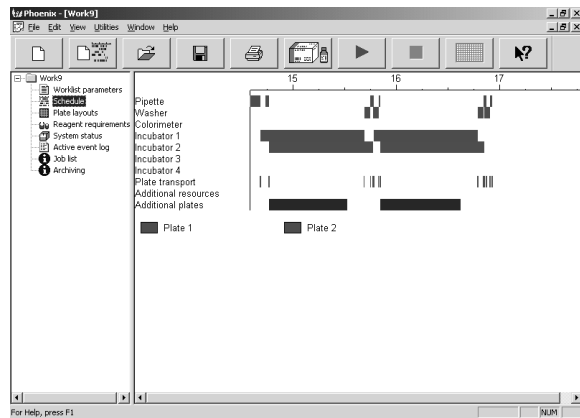
4.4.6.1   Clot Detection Error Handling

Dependent on the attitude in the test definition ("Raise alarm and stop", "Log and continue" or "Manual pipette at end of step") the error handling is different at a clot detection.

Action on error "Raise alarm and stop"

If a clot is detected, the system stops and shows a message with the following buttons:

Skip Sample:
• The pipettor moves to the eject position to remove the tip.
• Entry in the Eventlog.
• The next sample will be pipetted.
• The result file flags all samples with "Clot detected" where a clot was detected.

Abort Plate:
• An additional message comes up to confirm the plate abort process.
• The pipettor moves to the Eject position to remove the tip.
• If available, the next sample of the next plate will be pipetted.

Continue:
• The sample is pipetted into the appropriate well of the micro plate.
• The result file flags all samples with "Clot detected" where a clot was detected.
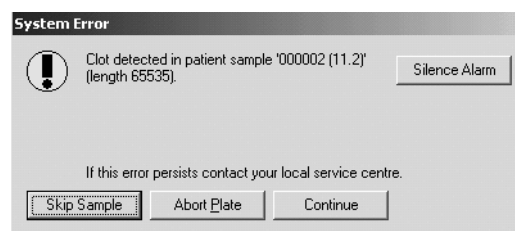
Action on error "Log and continue"

If a clot is detected, the system does not show a message and continues with:

- The pipettor moves to the eject position to remove the tip.
- Entry in the Eventlog.
- The next sample will be pipetted.
- The result file flags all samples with "Clot detected" where a clot was detected.

Action on error "Manual pipette at end of step":

If a clot is detected, the system does not show a message and continues with:

- The pipettor moves to the eject position to remove the tip.
- Entry in the Event log.
- The next sample will be pipetted.
- At the end of the pipetting step, a message comes up and shows you all samples which were not pipetted or were a clot was detected.
- The result file flags all samples with "MP" where a clot was detected.

4.4.7 Pausing or Cancelling a Run

Click the Stop button to stop the current run.

The *ELISYS QUATTRO* system stops and shows the System Paused dialogue box.

- Click Resume to continue the run.
- Select a plate and click Abort Plate(s) to remove the plate.
- Click Abort All Plates to remove all plates.

Any interruption of a run is documented with the time of its occurrence.

If an error occurs, a run is automatically stopped. A dialogue box with a message describing the error is displayed. Error messages have to be confirmed accordingly and you may then continue or abort the run.
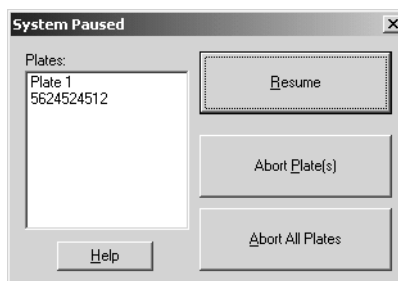
> *The **ELISYS QUATTRO** unloads an aborted plate at the next appropriate moment. You must unload this plate, otherwise the worklist will be paused! An already started process step with another plate will be finished first.*

4.5 Results of a Run

Upon complete processing of a plate, the results are saved to a result file and displayed on the screen, which can be printed in individual parts or as a whole.

- Click on the plus sign in front of file name to open the folder tree of the result file.
- Click on the individual symbol of the folder to display its contents in the right window.

> *Don't approve results without reviewing the original results printout and the events of the run!*

4.5.1 Results Report

4.5.1.1 Laboratory Details

Select the item Laboratory Details to open
the window depicted to the right, showing informa-
tion about the laboratory (e.g. name, address, etc.)

This information can be entered and edited via the
menu items Utilities | Options | Labora-
tory.

4.5.1.2 Title Block

The Title Block identifies the assay respective
assay definition file the results have been generated
with. It provides information on the plate ID and the
person responsible for running the test, specifies the
assay used, saves date and time the test has been
finished and shows certain default settings of the
photometric measurement such as the overflow limit
and the wavelength as well as the reference wave-
length. Furthermore, important error messages that
came up in the course of processing the assay
respective the worklist are already displayed at this
point.

4.5.1.3 Reader

The blank value is displayed in the Reader result
section. This section can also be used to show the
raw data.

4.5.1.4 Quantitative Results

The window Quantitative Results shows the
graph which is created with the standards defined in
the assay.

4.5.1.5 Combined Report

The Combined Report shows all patient IDs, results, flags etc. in one table. It gives a short overview about all relevant data.

The samples are identified by the patient ID. The individual wells are identified (alphanumerically), evaluated, calculated and, if necessary, flagged.

4.5.1.6 Validation Criteria

The window Validation Criteria indicates if the control values of the test meet the defaulted criteria.

If the values of the control well 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 criterias is failed, the test will not be evaluated.

4.5.1.7 Qualitative Results

The window Qualitative Results provides information regarding the cut-off value of the test.

Three options are available:

- Pos: positive result
- Neg: negative result
- Eqv: result in the greygreygrey range.

4.5.1.8 Events

The Events window shows information on important actions performed by the analyzer and subsequent reactions by the user.

- Important actions in this context are warning and error messages; they are displayed in red.
- Reactions by the user on these actions are displayed in green.
- User actions such as manual definition of reagents are also displayed in red.

4.5.1.9   Lot Specific Values

The window Lot Specific Values, if selected in the assay-protocol, includes the lot data entered before the start of the worklist, the reagents used and the test kits.

4.6   Re-Loading

To insert a new plate during a running worklist, this can be done by re-loading.

1. **Input of additional patient (bar coded or non-bar coded):**
   Bar coded patients:
   First, insert the bar coded patient samples and then assign the assays in the Patient Editor (see chapter 4.2.2 on page 4-4). Processed sample racks (red flashing LED) may be removed.
   Non-bar codedNon-bar coded patients:
   First, enter the additional patients in the Patient Editor (see chapter 4.2.1 on page 4-2).
2. Select the item Edit | Panel Definition. The Set-up Panel dialog box appears showing the current plate panel.
3. Define additional plate panel via the Add Plate, Add Assay and Add Patient buttons (see chapter 4.3.3 on page 4-8).
4. After definition of the additional plate panel, click on the OK button.
5. Enter all Lot Specific Values (see chapter 4.3.4 on page 4-8).

After confirmation of the lot-specific data, the Load dialogue box appears (possible during incubation phases) or the system specifies that the system is currently busy. The times for loading resources and plates are depicted in the worklist schedule.

When the specified time is over, select the item Edit | Panel Definition once more. The Load dialogue box appears.

6. **Patient samples**:
   Insert sample racks and allocate sample symbols with the mouse to the new sample rack (see chapter 4.4.2 on page 4-12).
   Processed sample racks (flashing red LED) can be removed.

7. **Reagents:**
   Refill or add additionally required reagents as shown on the screen (see chapter 4.4.2 on page 4-12). The reagent symbols are automatically allocated to the respective positions.

8. **Disposable tips and dilution plates**:
   Refill disposable tips, dilution plates, wash buffer and distilled water as shown on the screen (see chapter 4.4.3 on page 4-15).

i	*Allocate the vials only into suitable locations. An incorrect allocation may cause errors in dispensing!*

i	*When refilling a reagent bottle never exceed the bottle shoulder. An over-filling may lead to an incorrect dispensing!*

i	*Never remove a rack while still in use. Remove it only when the related LED is flashing. If a sample rack is removed which is still in use, all samples not already pipetted out of this rack will be flagged with* `Removed` *and not calculated.*

i	*Make sure that the flap of the reagent unit is closed after re-loading.*

9. After loading and allocation of all required resources confirm the dialogue with OK. A volume check of all reagents is carried out automatically (see chapter 4.4.4 on page 4-16).

After the volume check the worklist is calculated new (interlacing or adding new plates/assays to be processed). Further processing is then carried out in accordance with the new worklist.

4.7 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 QA-Labels in the Lot Specific Values while preparing a worklist (see chapter 4.3.4 on page 4-8).

A QA-Label is the label which is used in the assay layout definition (e. g. NC, NC1, PC2 etc.).

1. Select File | New.
2. In the New dialogue box select the file type QA Analysis Report.
3. In the Q.A. Analysis dialogue box select in the box Controls the respective reagent.

4. Select in the box Batch Numbers the respective bach 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).
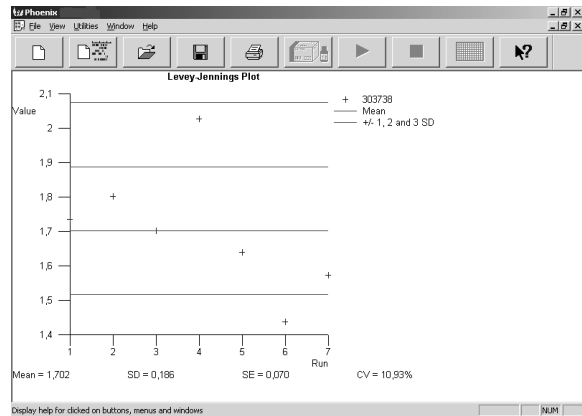
4.8 Patient Result Report

The patient result report shows a compact summary of the patient results of all selected assays.

1. Select File | New.
2. In the New dialogue box, select the file type Patient Result Report.
3. In the Patient Result dialogue box, select All Patients or IDs between.
   If you selected IDs between than enter the first ID and the last ID in the two boxes.
4. Select up to five assays.
5. Select the period of time in the boxes Date from and Date to.

6. Select the Sort Order.
7. Click OK to confirm the entries.
   The system shows you the patient result report.
8. Select View | Detail to show a detailed list, including the Batch Number of the Kit (if entered, see chapter 4.3.4 on page 4-8).

5 Loading - Unloading - Disposal

5.1 Loading (Instrument at Hold)

5.1.1 Refill System Liquid

1. Open screw cap of system liquid container and refill system liquid or replace container.
2. Close screw cap again and watch for correct seat of level sensor and connections.

5.1.2 Refill Wash Liquid

1. Hold bottom drawer with both hands at the bottom edge and pull it out. The LED INSTR must light up green.
2. Open cap of wash container and refill the respective liquid or replace bottle.
3. Close cap again and watch for correct seat of level sensor and connections.
4. Close bottom drawer again, so it clicks into place (audible click).

5.1.3 Position Dilution Plates

1. Pull very left drawer out. The LED DWR must light up green.
2. Place dilution plate(s) in the respective positions as shown in the Load dialogue box. The position 1 is on the rear.
3. Push in drawer again up to the limit stop (audible click), overcoming a slight resistance.

5.1.4 Load Tip Racks

1. Pull very left drawer out. The LED DWR must light up green.
2. Place tip rack - as illustrated in the drawing below - into the holding device of the instrument, so that the pin sits in the groove of the tip rack.
3. Push in drawer up to the limit stop (audible click), overcoming a slight resistance.

ℹ️ *Please carefully check the tip racks allocation following the specific colour code and type in the software. A tip misplaced can not be recognized by the instrument and may cause mechanical damage!*
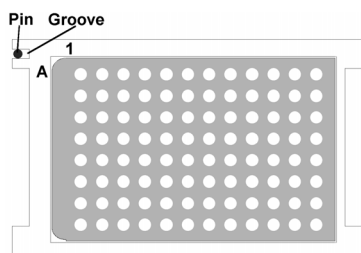
Figure 5-1:   Inserting a tip rack

5.1.5   Load Sample and Reagent Racks

CAUTION: Laser radiation - do not stare into beam!

The red LED indicates the track where the rack is to be inserted. When loading reagent racks that occupy three tracks it must be ensured that the rack with its right track (= position of contact tappet) is placed on the tracks with the red LED. The bar code labels must face right the bar code reader.

Samples having particulate matter, turbity, lipaemia, foam, or erythrocyte debris may require clarification by filtration or centrifugation before testing.

The use of primary tubes with gel separator requires a careful check of the sample volume above the gel to avoid any possible errors in dispensing.

Never remove a rack while still in use. Remove it only when the related LED is flashing. If a sample rack is removed which is still in use, all samples not already pipetted out of this rack will be flagged with Removed *and not calculated.*

> **i** *If reagents were not identified or placed without barcode, the user has to make sure that the manually allocated positions correspond to the actual placement on the reagent rack. Manually allocated reagents are identified in the result printout and in the log file.*

5.1.5.1   Loading Reagent Racks

1. Insert rack on **that** track that is marked by the red LED on the rear panel. Place rack in front of the track and then push evenly up to the limit stop (with the pin in the contact pin hole on the rear panel). **The bar code labels must face right towards the bar code scanner**.
2. The LED goes off and jumps to the next position that can be loaded. (A red flashing LED indicates that the rack wasn't identified correctly. Pull out the rack and insert it once more.) A graphical representation of the correctly inserted rack appears on the screen. From the pool of unallocated resources in the right-hand side of the screen, the loaded reagents are allocated to the rack in accordance with the identified loading. Place the mouse pointer on the reagent to check the ID.
3. Insert the next racks as described.

The software shows all resources prior to allocation in the area Unallocated resources in their respective colour (as defined in the reagent database).

All **automatically** allocated samples and reagents are crossed, all **manually** allocated samples and reagents are not crossed.

Loaded reagents which are identified by a bar code and which are not needed for the current worklist are presented in black.

Reagents that have not been identified are not displayed in the reagent area, the position remains white. The symbols of these reagents can be allocated from the area Unallocated resources to the respective positions with the mouse.

> **i** *See notes on page 5-2*

5.1.5.2 Load Patient Sample Racks with Bar Coded Samples

1. Insert the rack on that track that is marked by the red LED on the rear panel. Place rack in front of the track and then push evenly up to the limit stop (with the pin in the contact opening on the rear panel).
2. The LED goes off and jumps to the next position that can be loaded. (A red flashing LED indicates that the rack was not identified correctly. Pull out the rack and insert it once more.) A graphical representation of the correctly inserted rack appears on the screen. From the pool of unallocated resources in the right-hand side of the screen, the loaded samples are allocated to the rack in accordance with the identified loading. Place the mouse pointer on the sample to check the patient ID.
3. Insert the next racks as described.
4. After loading, close the flap again (audible click).

See notes on *page 5-2*

5.1.5.3 Load Patient Sample Racks without Bar Coded Samples

1. Insert the rack on that track that is marked by the red LED on the rear panel. Place rack in front of the track and then push evenly up to the limit stop (with the tappet in the contact opening on the rear panel).
2. The LED goes off and the rack type is identified by the bar code scanner and depicted on the screen with empty sample positions.
3. Insert the next racks in the track marked by the red LED.
4. Once you have loaded all racks distribute the unallocated samples displayed on the screen on the individual rack positions with the mouse in accordance with the identified loading.
5. Close the flap again (audible click).

See notes on *page 5-2*

5.1.6 Load Test Plates

CAUTION: Laser radiation - do not stare into beam!

1. When the software requests a plate the LD LED lights up **green** (on the instrument front panel next to the right flap) and the Load Plate dialogue appears.
2. Open flap (very right). The plate transport unit is already in a position directly next to the plate compartment.
3. Place test plate in holding frame (see chapter 2.2.4 on page 2-5) and push it in, overcoming a slight resistance.

Check if the plate has been inserted correctly and make sure no strip extends beyond the edge of the frame.

4. Place holding frame onto the plate transport unit such that both pins of the holding frame on the right sit in the openings of the slide on the plate transport unit (see chapter 2.2.4 on page 2-5).
5. Close flap.
6. In the Load Plate dialogue, enter the plate ID and click OK (or Scan, when using bar coded plates).
7. The test plate is first transported into the photometer to check for an adequate strip filling; then the plate is placed in the pipettor area.
8. Repeat this process to load several plates in succession.

5.2   Unloading

5.2.1   Remove Dilution Tubes / Take Tip Racks off

1. Pull very left drawer out. The LED DWR must light up green.
2. Take dilution tube(s) and/or empty tip racks out of holding devices.
    Partially used tip racks must remain in the original position. The information regarding the number and position of the available tips is stored in the ***Phoenix*** software and this information is used for the subsequent run.
3. Push drawer in again (audible click).

5.2.2   Remove Racks with Patient Samples and Reagents

1. As soon as a LED starts flashing the respective rack can be removed.

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i   *Never remove a rack while still in use! Remove it only when the related LED is flashing! If a sample rack is removed which is still in use, all samples not already pipetted out of this rack will be flagged with* Removed *and not calculated.*

---

2. Open flap (see figure 2-1: on page 2-1).
3. Pull racks out.
4. After removal close flap again (audible click).

5.2.3   Remove Test Plate

1. Open flap. The plate transport unit with the test plate is already in a position directly next to the plate compartment.
2. Remove plate with holding frame and take plate off the holding frame.
3. Close flap again (audible click).
4. Process plate further manually or dispose off plate.

5.3 Disposal

5.3.1 Liquid Waste from Pipettor and Wash Unit

1. Open screw cap on liquid waste container.
2. Dispose liquid waste in accordance with the legal provisions and clean the container.
3. Close screw cap again and check proper seat of level sensors and connections.

5.3.2 Disposable Tips

1. Disposable tips are automatically ejected at the tip ejection station. Via a slide they go directly into the plastic waste container at the instrument front panel.

5.3.3 Replace Waste Container for Disposable Tips

1. Pull cover plate next to the plate compartment out horizontally from the front.
2. Take waste container off the retaining ring and close it using the supplied lid.
3. Place new waste container with plastic reinforcing onto the retaining ring and push it down.
4. Attach cover plate again.
5. Dispose off the closed waste container in accordance with the legal requirements.

Potentially infectious material and all parts that may come in contact with potentially infectious material must be disposed off according to the legal requirements of the relevant country.

5.3.4 Disposal of Instrument

Disposal of the instrument according to national legislation.

5.3.5 Disposal of Packaging Material

Disposal of the packaging material according to national legislation.

6 Service and Maintenance

The user must perform the maintenance work described in this chapter. Any service work described in the service plan (see chapter 6.2 on page 6-2) or not described in the user manual must be performed by authorised service engineers.

These maintenance procedures must be performed to keep the instrument in a proper working condition. Any deviations may lead to false results.

6.1 Maintenance Schedule

The maintenance work described below has to be performed by the user **whenever necessary**, at least, however, in the intervals specified below.

6.1.1 Daily Maintenance Procedure

Start up
1. Check the system liquid container level.
2. Empty and clean the waste container for tips (see chapter 5.3.3 on page 5-7).
3. Check the waste container liquid level, empty and clean if necessary.
4. Check the level of washing solution and distilld water in the washer bottle.
5. Check the needles of the washing head and clean using the cleaning tools if necessary.
6. Clean the instrument surface if necessary.
7. Start the system first and then the Computer.
8. Start the *Phoenix* software only when the RDY LED on the instrument is ON.
9. Perform the selftest:
   The selftest starts and will be executed automatically.
10. Check if selftest is passed.

End of work
1. Close the finished worklist.
2. Close the *Phoenix* software.
3. Close Windows 95/2000 and shut off computer, monitor and printer.
4. Switch the *ELISYS QUATTRO* off.
5. Remove reagent and patient racks.
6. Remove all used dilution tubes.

6.1.2 Weekly Maintenance Procedure

Procedure
1. Change the system liquid fluid.

Where a disinfecting is required use always a non alcoholic type!

---

2. Clean the following areas:

- Dilution area
- Reagent and patient rack area
- Pipetting station
- Pipettor wash station
- Tip eject station

3. Clean and disinfect waste container.

6.1.3 Monthly Maintenance Procedure

i *Where a disinfecting is required use always a non alcoholic type!*

i *Do not use any disinfectants containing alcohol for Plexiglas surfaces and for the manifold (e.g. cover)!*

i *Disinfectants must not come into contact with bearings and guides, as otherwise the greasy film may dissolve!*

i *Disinfectants must not be used in the vicinity of circuit boards and light barriers!*

1. Clean reagent and patient racks.
2. Clean all four washer buffer bottles with distillated water.
3. Check the internal waste bottle '2' and empty it if necessary.
   Clean the system liquid container with distillated water.
4. Clean and disinfect the external waste container.
5. Clean plate carriers.

⚠ ***Do not clean heated incubators!***

6.2 Service Plan (to be performed by authorised Service Engineers)

Periodically, during the year, a specific preventive maintenance can be run by the authorised technical personnel.

A specific procedure will be followed to ensure a good check on all the instrument parts, which are:

- Photometer
- Washer
- Incubator
- Plate transport

- Pipettor

6.3   Cleaning and Disinfecting the Instrument

Clean or disinfect the following instrument parts of the *ELISYS QUATTRO* in accordance with the maintenance plan:

1.   Housing surface
2.   Interior of instrument:
    - magazine for tip racks and dilution tubes (1),
    - sample and reagent unit (2),
    - test plate area (3),
    - test plate compartment surface (4),
    - incubators (6),
    - drawer with wash unit and wash buffer (5)
3.   Manifold in washer unit (5)

> **i** *Disinfectants must not come into contact with bearings and guides, as otherwise the greasy film may dissolve!*

> **i** *Disinfectants must not be used in the vicinity of circuit boards and light barriers!*

> **i** *Do not use any disinfectants containing alcohol for Plexiglas surfaces and for the manifold (e.g. cover)!*
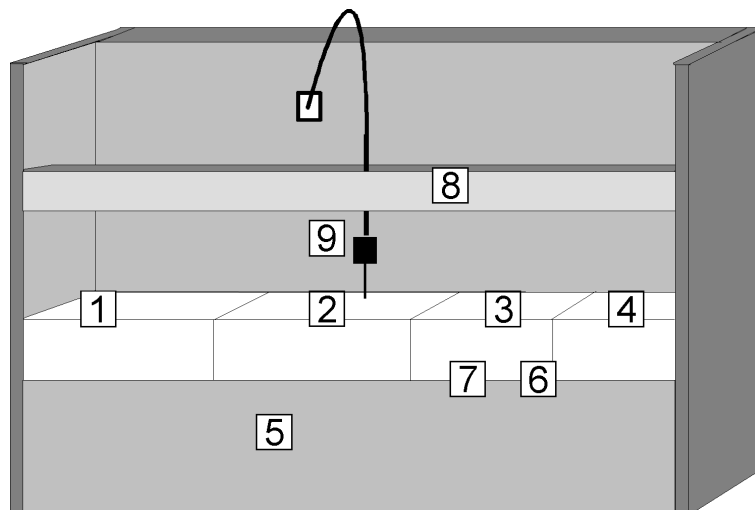
*Figure 6-1:   **ELISYS QUATTRO** - Instrument modules*

6.3.1 Cleaning and Disinfecting the Housing Surface

Proceed as follows:
1. Apply disinfectant on instrument housing surface.
2. Let it take effect according to the manufacturer's specifications.
3. Wipe instrument off with a cloth.

6.3.2 Cleaning and Disinfecting the Interior of the Instrument

If liquid got inside the drawers or individual modules, turn the instrument off immediately. Clean the affected areas as quickly as possible using an appropriate cleaning agent; take all sensitive parts and all parts that are relevant for operation into account: guide rails, door edges, plate transport unit, drawers, racks etc.

The actions listed in the maintenance schedule (see chapter 6.1 on page 6-1) have to be performed regularly and have to be documented.

6.3.3 Maintenance of Pipettor System

The pipettor systems is automatically primed with system liquid during a run; this process is controlled by the *Phoenix* software.

Further actions are also provided by daily and weekly maintenance.

6.3.4 Maintenance of Washer System

The washer system is automatically flushed with distilled water following each wash step; this process is controlled by the *Phoenix* software.

The 4 containers with wash buffer/distilled water and the complete washer unit (including manifold, pumps, valve, tubing) are cleaned during the daily and weekly maintenance.

6.4   Cleaning the Wash Head Needles

The wash head could have had contact with dangerous material. Pay attention to safety regulations! Always wear gloves!

The wash head is part of the wash unit located in drawer (5) (see figure 6-1: on page 6-4). If the wash function is not longer adequate, you have to clean the needles of the wash head.

1.   Open drawer.
2.   Using the supplied cleaning needle, clean the 8 dispense and the 8 aspirate needles of the wash head.
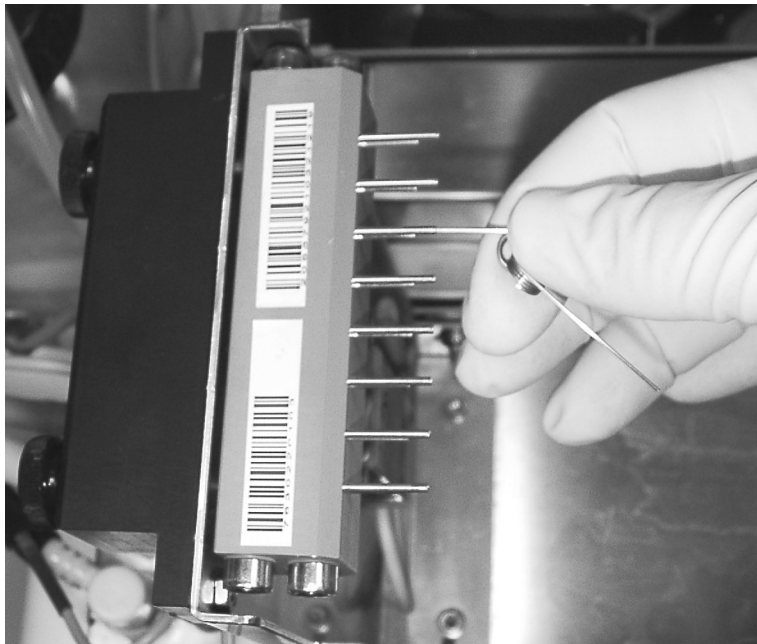
Figure 6-2:   Cleaning the wash head needles

6.5 Replacement of Mains Fuse

The mains fuse is on the back of the analyzer.

1. Switch off the system.
2. Disconnect the system from the mains power.
3. Pull out the fuse carrier with a screw driver.

Figure 6-3:   Fuse carrier

4. Change the faulty fuse(s):
   Fuse: 4 A T, 250 V
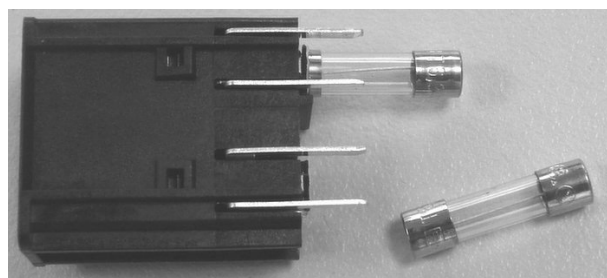
Figure 6-4:   Fuse carrier with fuses

5. Insert the fuse carrier.
6. Connect the main power.
7. Switch on the system.

6.6 Backup of Result Files

A backup of result files is recommended on regular time bases (e. g. weekly). This backup cannot be carried out directly from the *Phoenix* software menu.

Proceed as follows:

1.   Open the Windows explorer.
2.   Select the Phoenix folder.
3.   Select the Results folder.
4.   Select the result files (.res) to save.
5.   Copy them on the desired data drive.

6.7 Putting System Out of Action

To put system out of action for a longer time contact your local service centre.

7 Error Messages

7.1 General Error Messages

If the **ELISYS QUATTRO** does not work, this is often due to minor problems which you can deal with by yourself.

This chapter describes error messages and gives instruction on error recovery.

'%1' and '%2' are placeholders for a system module or the designation of a plate, a reagent, or an error number.

System messages appear in the status bar of the **Phoenix** software, error messages are displayed in a separate window, which has to be confirmed.

Error:	Cause:	Action:
ABORT button pressed	Message: The Stop button has been pushed during a run.	The run has been interrupted and may be continued or aborted completely.
Aborting plate %1	The run of the plate has been aborted. Reasons: The Stop button has been pushed.	The run has been interrupted and may be continued or aborted completely.
Bar code IC error	The bar code cannot be read.	Verify the readability of the bar codes. Check the bar code parameters in the Setup menu. Try reading the bar-codes once more. If these attempts fail, call service.
Clot detected in reagent %1	Clots were detected in reagent %1.	Abort the run, if necessary, and replace reagent.
Colorimeter %1 not homed	The X-motor of the photometer is not in the home position.	Select the menu item Utilities | Selftest to initialise the system again. If the problem recurs, call service. If this error message comes up during a run, this run has to be aborted.
Colorimeter A/D error	Error of the analog/digital converter of the photometer.	Call service.
Colorimeter A/D over range error	Upper limit of photometer A/D has been exceeded due to the signal height of the preselected resolution.	The filter has not been installed properly. Call service.
Colorimeter A/D under range error	Signal detection too low. Defect of power supply unit of the photometer, or something similar.	The halogen lamp of the colorimeter 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.
Colorimeter background light level error	Typically occurs when light entered the measurement chamber.	Avoid direct exposure to sunlight, close all housing doors and covers. Select the menu item Utilities | Selftest. to initialise the system again.

Error:	Cause:	Action:
Colorimeter EEPROM error	Error during EEPROM reading or writing.	Call service.
Colorimeter filter %1 error	Error at filter no. %1. The gain factor for the respective filter cannot be identified. Filter is faulty or wrong filter has been installed.	Call service to check the installed filter and to replace it, if necessary.
Colorimeter filter motor home error	The system does not recognise the current position of the filter motor. Move to the home position.	Select the menu item Utilities | Selftest to initialise the system again.
Colorimeter filter motor movement error	The system does not recognise the current position of the filter motor. Move to the home position.	Select the menu item Utilities | Selftest to initialise the system again.
Colorimeter lamp error	Halogen lamp of photometer is faulty.	Replace the halogen lamp.
Colorimeter optic channel %1 error	Error in one of the 9 optical channels. Upper or lower optic block is dirty or faulty.	The optical blocks have to be cleaned by service personnel. Call service.
Colorimeter plate motor home error	The system does not recognise the current position of the plate motor in the measuring area. The plate motor has to be moved to the home position.	Select the menu item Utilities | Selftest to initialise the system again.
Colorimeter plate motor movement error	Error of motor when moving the plate to the measurement area.	Select the menu item Utilities | Selftest to initialise the system again. If the error persists, call service.
Colorimeter voltage reference error	Error in reference voltage of the photometer.	Call service.
COMGEN error '%1'	RS232 connection faulty.	Check correct connection between PC and analyzer. Start PC and analyzer again.
COMGEN target overflow error	-	Call service.
COP serial port test error	The components are connected via serial interfaces to the control board. Error in serial interfaces.	Call service.
ERROR: Argument error in '%1'	Component cannot be actuated. Error in component %1.	Call service.
Error scheduling plate '...'	Error in assay or missing resources. This error message is displayed in the worklist for the respective plate, after the active worklist has been verified.	The worklist or the assay has to be changed accordingly.
Incubator heater %1 error	Defect in heater foil no. %1.	Call service.
Incubator sensor %1 error	Defect of incubator sensor no. %1.	Call service.

Error:	Cause:	Action:
No disposable tips left	Pipettor tips used up or not found.	Reload required tips at the position indicated on the monitor.
No fluid detected for %1	Insufficient volume for sample %1 or reagent %1.	The status is documented in the active event log. Confirm message with retry or ignore. No further action is possible.
No respond to command '%1'	General software error. Communication between PC and analyzer is interrupted.	Push the Retry button. If the message comes up again, push the Ignore button, turn the PC off and start it again. Answer the questions "....worklist ...?" and "is the analyzer still running" accordingly. The system starts again and continues with the worklist in process.
Plate ID verification error	Plate bar code cannot be read.	Missing or faulty bar code, incorrectly selected bar code type (see scanner setup). Enter the plate ID manually.
Plate transport %1 motor home error	Plate transport motor cannot find home position.	Select the menu item Utilities | Selftest to initialise the system again.
Plate transport %1 motor movement error	Error in plate transport motor no. %1.	Push the Retry button. If the error recurs, push the Ignore button.
Plate transport %1 motor not homed	Plate transport motor cannot find home position.	Select the menu item Utilities | Selftest to initialise the system again. If the error persists, call service.
Plate transport carrier error	Plate holder does not move far enough into the instrument, so that the light barrier is not interrupted.	Push the Retry button. If the error recurs, push the Ignore button. If this error recurs, the plate transport has to be adjusted new. Call service.
Plate transport EEPROM error	EEPROM error in plate transport.	Call service.
Plate transport error	Error in plate transport in case of increased resistance.	Push the Retry button. If the error recurs, try to locate the cause of the resistance (blocking) and eliminate it. If no mechanical blockage is evident, call service.
Plate transport sensor error	Error in plate transport sensor.	Call service.
Rack scanner focusing error	The barcode scanner of the reagent and sample racks cannot be focused.	Manual allocation of racks or samples and reagents is possible. Call service.
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.	Manual allocation of racks or samples and reagents is possible. Call service.
Rack scanner not detected	Scanner of reagent and sample racks is not connected.	Manual allocation of racks or samples and reagents is possible. Call service.

Error:	Cause:	Action:
Reading at %1/%2	Message: measurement at wavelengths "%1"/"%2".	-
Reagent ... is undefined	The reagent has not been defined.	Reagent has to be defined in the reagent database. Enter the parameters of the reagent in the reagent database.
Resuming after a crash	PC does not respond while processing the worklist and has to be restarted.	Following restart of the PC, you may be able to save the worklist and the results. Connection to the analyzer is established and the results stored there are transferred to the PC.
RS232 write error - command: '%1'	Error in interface PC / analyzer.	Check connections.
Shaking at %1 for %2 seconds	Message indicating that shaking is performed at a frequency of %1 for the duration of %2 seconds.	-
Some required resources have not been allocated to system positions	Not all required reagents have been allocated to a position.	All reagents requested in the Load window have to be allocated to a position or have to be loaded.
Suspect tip pickup	Pipettor cannot take up pipettor tip correctly (does not move deep enough into the tip).	New teaching of pipettor required. Call service.
System cover closed	Message instrument cover is closed.	-
System cover opened	Message instrument cover is opened.	Close cover, otherweise the system can not start processing a worklist.
System fluid low	System fluid for pipettor too low.	Fill up system fluid container with deionized water.
The plate transport cannot find a route from its current position to its next destination	Plate transport has no information about its present position.	Select the menu item Utilities | Selftest to initialise the system again. If the error persists, call service.
Tip eject failure	Error in the tip eject station.	Remove tip manually from the pipettor or trigger the eject mechanism manually. If this error recurs, call service.
Unknown colorimeter error code %1	Unknown photometer error.	Call service.
Unknown incubator error code %1	Unknown incubator error.	Call service.
Unknown plate transport error code %1	Unknown plate transport error.	Call service.
Unknown washer error code %1	Unknown washer error.	Call service.

Error:	Cause:	Action:
Verification failed %1	The reader has failed the validation criteria.	Replace the photometer lamp. Repeat validation. If this error persists, call service.
Washer %1 motor not homed	Error in washer motor.	Select the menu item Utilities | Selftest to initialise the system again. If the error persists, call service.
Washer aspirate pump error	Error in washer aspirate pump.	Confirm displayed message by pushing the Retry button. If error recurs, push the Ignore button. Upon completion of the run or unlocking of the washer drawer, check if the aspirate bottles are closed correctly. If the error persists, call service.
Washer dispense pump error	Error in washer dispense pump.	Confirm displayed message by pushing the Retry button. If error recurs, push the Ignore button. Select the menu item Utilities | Selftest to initialise the system again. If the error persists, call service.
Washer EEPROM error	Error in EEPROM of the washer module.	Call service.
Washer head home movement error	Error when moving washer head to home position.	Select the menu item Utilities | Selftest to initialise the system again. If the error persists, call service.
Washer head motor movement error	Error in movement motor of the washer head.	Select the menu item Utilities | Selftest to initialise the system again. If the error persists, call service.
Washer plate home movement error	Error when moving to the home position.	Select the menu item Utilities | Selftest to initialise the system again. If the error persists, call service.
Washer plate motor movement error	Plate transport motor of washer blocked.	Select the menu item Utilities | Selftest to initialise the system again. If necessary, take out the plate that may still be in the washer. If the error persists, call service.
Washer reagent level low error	The wash buffer runs low.	Refill the wash buffer. Push the Retry button. Then you may continue.
Washer valve test error	Error in testing the pump valve. Valve does not switch.	Call service.
Washer waste full	Container for washer waste full.	Empty container.
Washer waste pump error	Error in washer waste pump.	Check connections and container caps for leaks. If the error persists, call service.

Table 7-1:   General Error Messages

7.2 Error Messages of Components

The following error codes have been assigned to the individual system modules. An error code consists of six parts: IDxx03xx4552nnnn

- ID: ID number of the module
- xx: Insignificant
- 03: Error
- xx: Insignificant
- 4552: Start of the error number
- nnnn: Error number, sometimes there are only two numbers

Example: 42xx03xx45524243 means: Module 42, error number 4243. In the following tables you find this error display under the module number and the error code.

Call service for errors, which were not specified!

Module 41   Virtual Module

Module ID:	Error number:	Cause:	Action
41	46	System fluid low.	Refill the system fluid container.
41	57	System waste container is full.	Empty the system waste container.

Table 7-2:   Module 41 - Virtual module

Module 42   Plate transport

Module ID:	Error number:	Cause:	Action
42	41	Argument error in command.	Check that the firmware is the correct version for the version of software being run.
42	42	Plate transport bar code IC error.	Replace the plate transport barcode scanner.
42	42 43	The plate bar code scanned was not what was expected.	Replace the plate with the correct one.
42	44	Plate load/unload door is open while trying to move.	Close the plate load/unload door. Check the connectors to the switch.
42	48 nn	Motor not home. nn shows the position.	None. The software will reset the plate transport and try again.

Module ID:	Error number:	Cause:	Action
42	4D nn	Motor jammed during movement. nn shows the axis.	Call service.
42	50	Plate carrier sensor failure.	Call service.
42	52	Firmware was unable to compute a safe route between the two positions.	Call service.
42	57	EEPROM error.	Call service.

Table 7-3:   Module 42 - Plate transport

Module 43   Photometer

Module ID:	Error number:	Cause:	Action
43	41	Argument error in command.	Check that the firmware is the correct version for the version of software being run. Call service.
43	42	Background light levels too high.	Check position of lamp. Check filter positions. Call service.
43	43	A/D conversion error.	Call service.
43	46 nn	Filter error. nn shows the filter position.	Call service.
43	48 nn	Motor not homed. nn shows the motor.	None. The software will reset the photometer and try again.
43	4C	Lamp has blown.	Replace the lamp.
43	4D nn	Motor is jammed. nn shows the motor.	Call service.
43	50	Plate carrier error.	Check that the plate carrier correctly breaks the sensor. Call service.
43	50 44	No scan data available.	Call service.
43	50 4F	A/D over-range error.	Call service.
43	50 55	A/D under-range error.	Call service.
43	50 57	Reading overrun error.	Call service.
43	52	A/D reference voltage error.	Call service.
43	54 nn	Faulty optic channel. nn shows the filter position.	Call service.
43	57	EEPROM error.	Call service.

Table 7-4:   Module 43 - Photometer

Module 44   Washer

Module ID:	Error number:	Cause:	Action
44	41	Argument error.	Call service.
44	45	EEPROM error.	Call service.
44	48 nn	Motor not homed. nn shows the motor.	None. The software will reset the washer and try again.
44	4D nn	Motor has become jammed during movement. nn shows the motor.	Clear the obstruction. Call service.
44	50	Plate carrier sensor error.	Call service.
44	53 41	Washer waste bottle is full.	Empty the washer waste bottle. Call service.
44	53 52	Reagent level is low.	Refill the reagent bottle. Call service.
44	52 41	Aspirate pump error.	Call service.
44	52 44	Dispense pump error.	Call service.
44	52 57	Waste pump error.	Call service.
44	56	Valve error.	Call service.
44	57	EEPROM error.	Call service.

Table 7-5:   Module 44 - Washer

Module 45   Incubator

Module ID:	Error number:	Cause:	Action
45	41	Argument error.	Call service.
45	48 nn	Heater error. nn shows the incubator group number	Call service.
45	4B 43	Shake calibration failed.	Call service.
45	4B 52	Shake position frequency out of range.	Call service.
45	4B 54	Shake position edge timeout.	Call service.
45	4B 49	Shake override.	Call service.
45	50	Plate carrier sensor error.	Call service.
45	54 nn	Temperature sensor error. nn shows the sensor number or name.	Call service.
45	57	EEPROM error.	Call service.

Table 7-6:   Module 45 - Incubator

8   Technical Data

System Overview

Number of plates	Up to 4 plates at once
Number of samples	Max. 200 tubes, ϕ 16 mm
Number of reagents	Depending on rack configuration
Controls & Standards	Depending on rack configuration
Dilution area	For up to 152 dilution tubes
Number of tips	Up to 5 tip racks for 300 μl or 1100 μl disposable tips
Loading	Continuous loading of plates, samples, reagents and tips

Photometer

Spectral range	400 - 700 nm
Dynamic range	-0.100 to 3.000 O.D.
Accuracy	+/- 0.005 or 2.5 %
Linearity	0 - 2.000 O.D. +/- 1 %
Detection	Photo diode
Reading time	< 15 seconds
Read modes	OD
Filters	Up to 8 positions

Pipetting System

Pipettor	Liquid pipettor for disposable tips
Liquid level detection	Standard (capacitive)
Min.-Max. volumes	10 μl to 300 μl with 300 μl tips or
	301 μl to 1000 μl with 1100 μl tips
Accuracy	< -15 % at 25 μl (aqua)
	< -5 % at 100 μl (aqua)
Precision	< 5 % CV at 25 μl
	< 2.5 % CV at 100 μl
Features	Tip detection, mixing, multi-dispensing

Washing

Capacity	Up to 4 buffers
Wash head	1 x 8
Dispense volume	200 - 2500 μl/well
Precision	+/- 5 % CV at 300 μl
Residual volume	< 2.5 μl in U-shaped bottom
	< 4 μl in flat bottom
Fluid alarms	Low reagent, waste full
Features	Sweeps, soak, purge, top and bottom wash, variable pump speeds

Others

Bar code	Samples and in rack system
Plate bar code reader	Optional
Interfaces	ASTM interface
Time Scheduling	Schedules 4 plates
Multiple assays per plate	Up to 12 assays per plate
Export options	ASCII export and report
Qualitative	User definable result classes
Quantitative	Linear to quadratic regression, sigmoidal, and many more
Language support	Optional; supported via use of Passolo (commercially available program)
QA analysis	Mean, SD, CV, Standard Error and Levey-Jennings (basic version)

PC requirements

PC	IBM compatible Pentium PC
RAM	At least 64 MB
Ports	2 serial ports 1 parallel port
Hard disk	Hard disk with min. 150 MB free hard disk space
CD-ROM drive	
Accessories	Colour monitor Keyboard and mouse Printer

Software features

Operating system	Microsoft Windows® 95 or Microsoft Windows® 2000

Mains voltage and fuses

Universal a.c. input	100 - 260 VAC, 47 - 63 Hz Typically max. 500 VA
Main fuses	4 A T
Computer, monitor and printer	For electrical details of the PC equipment please refer to the technical documentation of the manufacturer.

Dimensions

W x D x H	114 cm x 156 cm x 100 cm (Depth with waste bag and completely opened drawer)

Weight

Analyzer with cover	130 kg
Accessories	Approximate 84 kg For electrical details of the PC equipment please refer to the technical documentation of the OEM manufacturer.

Noise

67 dB (distance 1 m)

Environment conditions

This standard applies for equipment designed to be safe at least under the following conditions:

- indoor use
- altitude up to 2000 m
- temperature 5 °C to 40 °C
- maximum relative humidity 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C
- mains supply voltage fluctuations up to +/- 10 % of the nominal voltage
- applicable rated pollution degree

Operating conditions

15 °C to 25 °C

Conformity

The following technical tests were carried out:

- Safety regulations tests: EN 61010-1
- EMC (Test for electromagnetic compatibility): EN 61326

Values are archived under optimal conditions and can vary depending on environmental conditions, instrumental status and processing conditions!

Human