

Instructions for use

SUPER GL *easy*
SUPER GL *easy+*

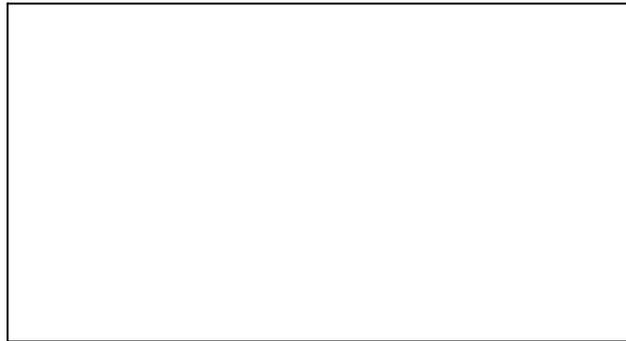
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C) List of symbols**Symbols on the equipment**

Symbol	Description
	Biohazard
	Enter - key for selecting a menu item or changing the menu area
	Menu button for selecting menu items
	Follow instructions for use
	in vitro diagnostics
	Manufacturer
	CE - conformity
SN	serial number

Symbols on consumables

Symbol	Description
	Biohazard
	in vitro diagnostics
	CE - conformity
	read accompanying documents
	Follow instructions for use
	Recyclable material
	Dispose of correctly
	Storage temperature
	Item number
	Contents of package
	Batch number
	Use by

Symbols in instruction manual

Symbol	Description
	Attention or Note
<i>Bold/italics</i>	Very important notes

* Explanation of terms: Authorized people are people who have gained expert knowledge by completing training courses offered by the manufacturer or authorized companies.

1 Preface

1.1 Introduction

Congratulations on purchasing the SUPER GL easy / easy+ analyser. We hope you will find working with your analyser satisfying and successful.

In the following chapter "The SUPER GL easy / easy+" you will find a first overview of your analyser: what parameters you can measure, what further devices and accessories belong to your analyser, and an overview of the device's functionality.

Furthermore, you will receive information on safety, on liability and warranty, and on indications or contraindications of your analyser.

For further and more detailed information, please read the corresponding chapters.

1.2 The SUPER GL easy / SUPER GL easy+

The SUPER GL easy / easy+ analyser is a device for biochemical analysis in in-vitro diagnostics. The device is an analyser for determination of glucose and / or lactate* respectively for determination of glucose and / or lactate and / or hemoglobin.✓



Fig. 1.1 General view SUPER GL easy / easy+

* depending on sensor type
✓ depending on model of equipment

1.2.1 Basic matters

The SUPER GL easy / easy+ was developed with the use of modern technical resources, associated with decades of experience in the field of clinical-chemical analyser production.

In construction and manufacture it fulfils all the legal EU regulations pertaining to equipment for use in in-vitro diagnostics. Application of the CE mark clearly documents compliance with the applicable standards and laws. The CE mark means the product complies with the law and standards and ensures safety and reliability for you and your patients.

Through the use of a sensor for high quality determination of glucose and/or lactate* and a photometer for determining hemoglobin[✓], it is possible to fulfil all the quality assurance requirements (e.g. the RiLiBÄK in Germany) prescribed for its field of use with the simplest handling and lowest maintenance and operating costs. This means that all users are able to achieve analysis results which meet the quality requirements for professional measurements.

* depending on sensor type

✓ depending on model of equipment

1.2.2 Equipment and accessories

Range:

Description	Quantity
SUPER GL easy / SUPER GL easy+	1
Mains cable	1
Power supply unit for equipment and printer	1
Instructions for use	1
<u>Optional</u>	
Printer DPU 414	1
Printer cable	1
EDP cable	1



Fig. 1.2 View of equipment

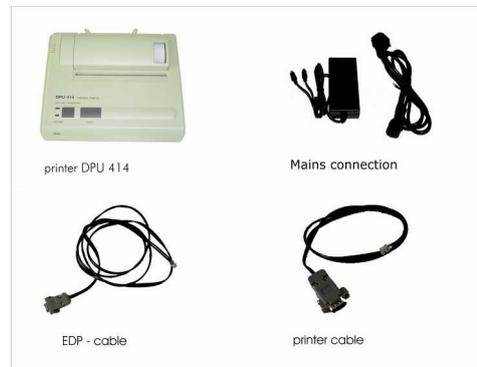


Fig. 1.3 Accessories

1.2.3 Overview of functions

The SUPER GL easy / easy+ analyser is an automatic analyser for the determination of glucose and / or lactate* and / or hemoglobin[✓] in 1+50 pre-diluted samples, e.g. in hemolysed blood samples.

The device measures by using the sample position at the sample rotor single samples or control samples. The results of measurement will be showed at the display and will be printed out and also could be sended at EDP.

You can find further information in the relevant chapters on the measuring principle and on obtaining samples.

* depending on sensor type
[✓] depending on model of equipment

1.3 Indication / Contraindication

Indication

The SUPER GL easy / easy+ analyser determines glucose and / or lactate* and / or hemoglobin[✓] in human sample material and supplies measurement values for the diagnosis and treatment of diabetes.

Possible sample material can include:

- capillary or venous or arterial blood
- serum (not for hemoglobin)
- plasma (not for hemoglobin)
- cerebro-spinal fluid (not for hemoglobin)
- for more materials ask the manufacturer

The blood taken should contain the following anticoagulants / glycolysis inhibitors: heparin, citrate, fluoride, EDTA.

Contraindication

The use of incorrect sample materials can lead to incorrect readings. Please call the manufacturer if you are in doubt.



Operating the device for home testing is expressly forbidden!

1.4 Manufacturer's liability

Legal liability and claims under the guarantee or warranty are expressly excluded in the following cases:

- Grossly negligent or wilful damage to the equipment, parts or consumable materials
- Unauthorised opening of the analyser by untrained staff (without service training)
- Force majeure (e.g. lightning strike, water damage, fire)
- Non-observance of the instructions for use and package inserts

1.5 Guarantee

Dr. Müller Gerätebau GmbH guarantees its products to the purchaser in accordance with Directive 1999/44/EC for a period of two years from the purchase date. Consumable materials (because of their short shelf-life) and wear and tear of parts are expressly excepted from this as these should be changed annually during servicing. Please find further details of replacement parts and consumables in the relevant chapter.

* depending on sensor type

✓ depending on model of equipment

2 Safety

2.1 Introduction

The following chapters deal with the safety of people working on the equipment.

Please read these chapters carefully **BEFORE** operating the equipment as they contain the general safety instructions and information on the personal protection of people working on the equipment and also on the protection of the equipment.



The installation of the following safety instructions does not release the equipment user from the duty to observe other relevant safety measures which apply to all equipment.

2.2 Responsibility / Training of user

- The SUPER GL easy / easy+ provides measured values for the diagnosis and treatment of diabetes.
- Use for personal use is expressly forbidden.
- An introduction to the correct use of the equipment can be given by a member of staff from the manufacturer or authorised sales partner in agreement with the persons working on the equipment.
- Each user is responsible for observing the safety, health and legal regulations and for using the equipment in the proper manner only.
- Evaluation of the results and the diagnostic and therapeutic measures derived from them must be carried out only by specialist staff authorised to do so.

2.3 General safety instructions

- Before use of the equipment, please read all the instructions for use – carefully, especially the regulations on taking samples –.The manufacturer’s staff or the authorised sales company are available to answer any questions.
- All persons working on the equipment must be made aware of the relevant safety regulations before use and these must be kept ready to hand at all times.
- Please note all the general safety regulations for your area of application, such as the wearing of protective gloves and the relevant disinfection and hygiene regulations.
- If there is any accidental skin contact with potentially infectious substances, e.g. human samples, disinfect the affected parts of the body with a suitable disinfectant solution.
- The haemolysis system solution is not corrosive, poisonous or seriously harmful to skin. If there is any skin contact with the haemolysis system solution or the calibration solution, rinsing with water is sufficient. You can find more information on this in the safety data sheet for each solution.

- To avoid the risk of electric shock, do not place either the equipment or the power supply unit in water or other liquids. If the cable or power supply unit are damaged in any way, the power supply unit should no longer be used. Never touch the power supply unit plug with wet hands. The power supply unit should only be used in closed, dry spaces and must be protected from damp.

2.4 Product-specific safety instructions

- The equipment should only be used in accordance with the described indication and the defined bans and restrictions on use must be adhered to (contact the manufacturer if necessary).
- The equipment should only be operated when standing on a level, horizontal surface. Wide temperature fluctuations and draughts, direct sunlight or vibrations should be avoided as they can lead to faulty readings.
- We expressly point out that if the equipment is incorrectly used the intended protection measures for the analyser may be ineffective.
- Stop working immediately if there is a fault! Before further use of the equipment, note the instructions on cleaning and on reporting and remedying faults. After consultation with the manufacturer or the relevant authorised sales company, it may be necessary to send the equipment to the manufacturer or authorised sales company for repair.
- Use only original accessories and replacement parts to avoid damage to equipment and persons. Repair work should only be carried out by the manufacturer or companies authorised by the manufacturer.
- The use of reagents and consumables not expressly recommended by the manufacturer may lead to serious reading and functional faults and is therefore not approved.
- If the equipment is opened by the user without authorisation, liability for the equipment and any damage caused by this is excluded.

2.5 Maintenance intervals

The SUPER GL easy / easy+ needs servicing once a year by assigned specialist staff. A warning will appear on the screen once the service interval has elapsed.

If the service is not carried out, this can lead to incorrect readings which are not the responsibility of the manufacturer.

You can find further instructions in the chapter on servicing and remedying faults.

3 Description of the analyser

3.1 Introduction

This chapter describes the measuring principle, the construction and accessories and the consumable materials for the analyser.

This chapter provides preliminary information – but you can find more details on the operation and function of the equipment in the chapters “Operation – Part 1” and “Operation – Part 2”.

3.2 Purpose

The SUPER GL easy / easy+ analyser is an automatic analyser for the determination glucose and / or lactate* and / or hemoglobin[✓] in 1+50 diluted samples, e.g. in hemolysed blood samples.

Possible sample material:

- capillary or venous or arterial blood
- serum (not for hemoglobin)
- plasma (not for hemoglobin)
- cerebro-spinal fluid (not for hemoglobin)
- for more materials ask the manufacturer

The blood taken may contain the following anticoagulants / glycolysis inhibitors: heparin, citrate, fluoride, EDTA.



When using non-flouride-stabilized sample material, the 15-minute period from taking the sample until stabilising with haemolysis system solution should not be exceeded.

The diluted sample material identified with haemolysis system solution is removed from closed reaction cups.

In detail, the equipment features the following performance characteristics:

- Determination of glucose and / or lactate* using the enzymatic-
amperometric measuring principle
- Determination of hemoglobin using photometric measuring principle
- Automatic individual sample measurement
- Automatic calibration
- Serial printer interface
- Serial RS 232 electronic data processing interface
- Interface for PS/2 keyboard or bar code reader

* depending on sensor type

✓ depending on model of equipment

3.3 Measuring principle

3.3.1 Measuring principle glucose and lactate determination

Determination of glucose and lactate with the SUPER GL easy / easy+ is based on an electro-chemical measuring principle with a biosensor. System solution, calibration, control or patient material is extracted with the aid of a piston pump. The electrodes in the sensor are separated from the flow of liquid by barrier layers in which the immobilised enzyme is found. The following illustrations show the flow diagram of the equipment and the reactions running in the sensor:

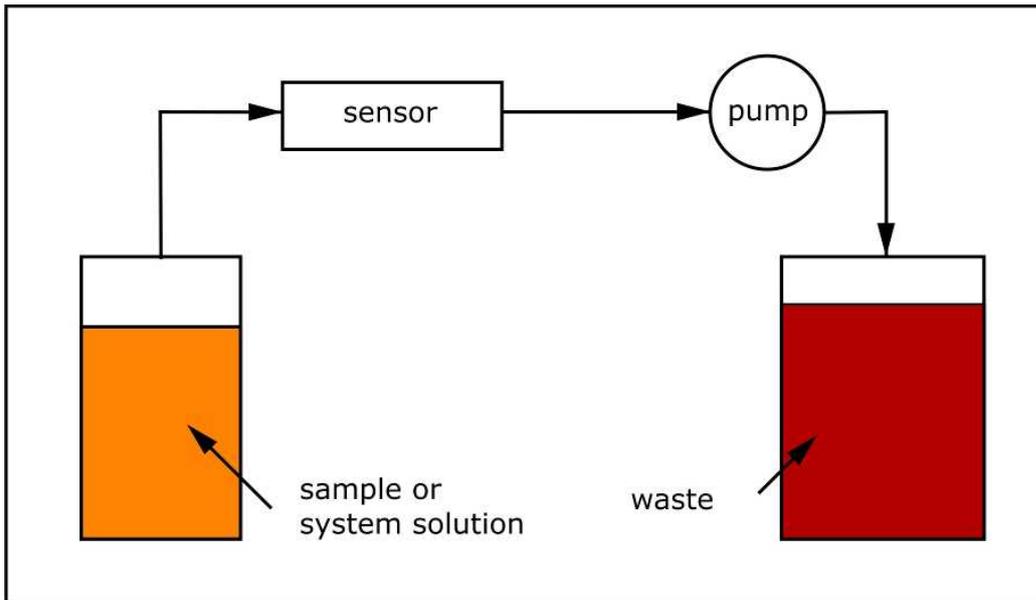


Fig. 3.1 Flow chart Type SUPER GL easy

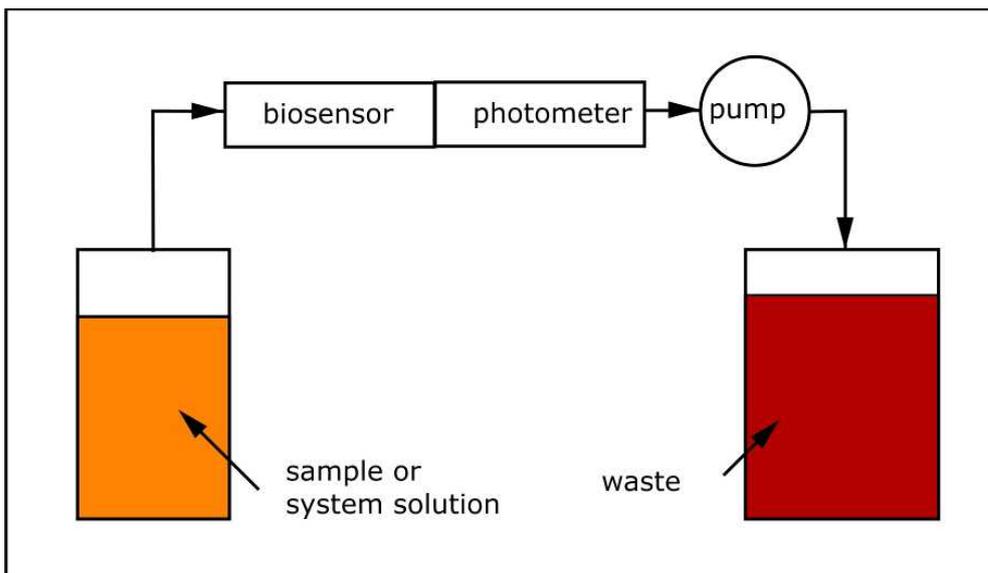


Fig. 3.2 Flow chart Type SUPER GL easy+

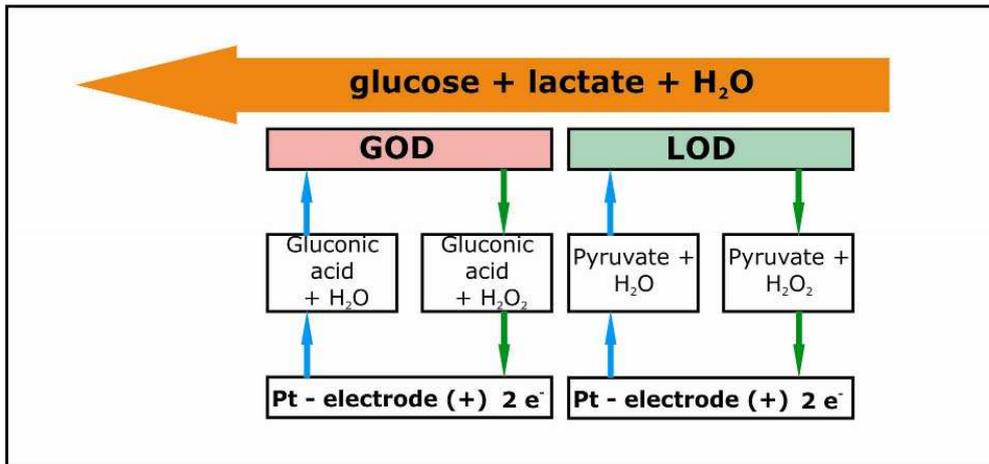


Fig. 3.3 Diagram of measuring principle

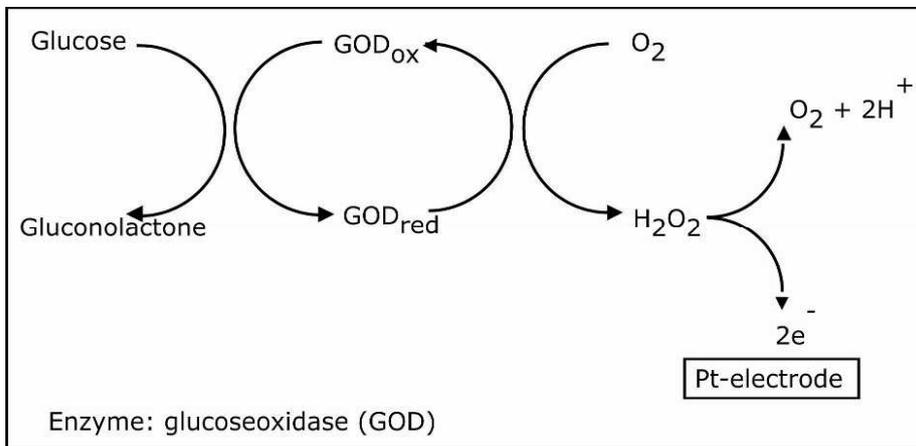


Fig. 3.4 Reactions in glucose sensor

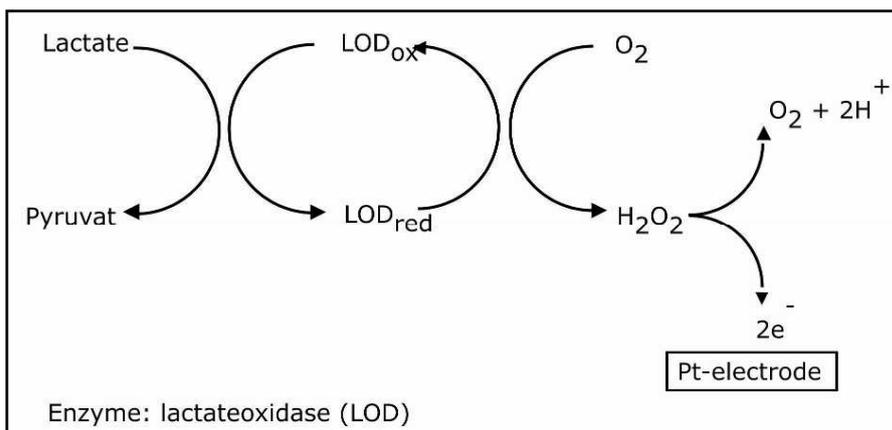


Fig. 3.5 Reactions in lactate sensor

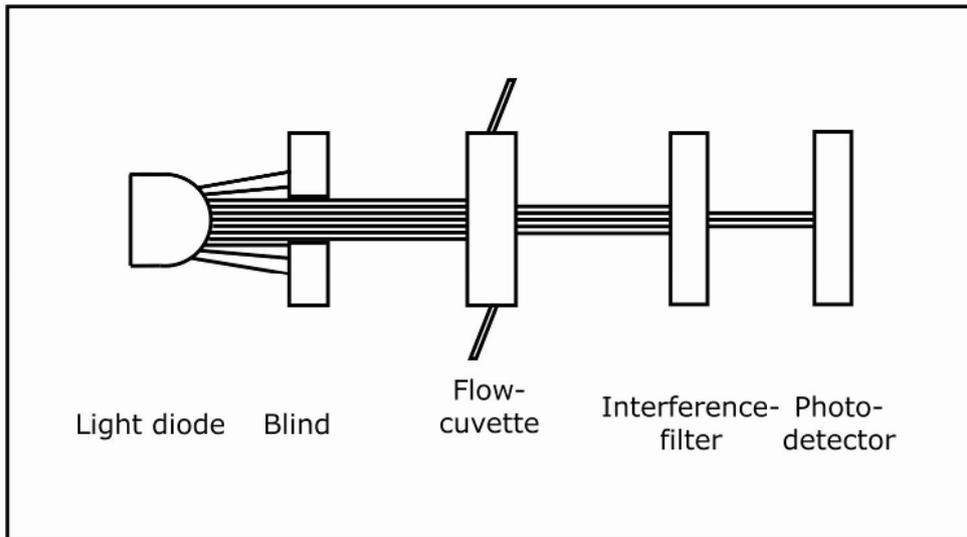


Fig. 3.6 Flow chart photometer

3.3.2 Measuring principle for hemoglobin determination

The hemoglobin in the blood is photometrically determined. To avoid serious environmental load, the sodium dodecyl sulfate method is used instead of the hemoglobin cyanide method.

The photometer unit, consisting of LED, flow cuvette, interference filter, photo detector and electronic evaluation unit, is arranged in front of the biosensor and the pump. These are used to determine an extinction equivalent value for the sample solution. The dependence of the extinction on the concentration is described by the Lambert-Beer-Bouguer law. Under the constraints defined there, the size of the extinction is proportional to the material concentration.

Determining hemoglobin

The hemoglobin is released from the erythrocytes by the haemolysis which takes place in the reaction cup after addition of the sample. This reacts with the sodium dodecyl sulfate contained in the solution in the cup to produce a stable colour complex.

The pump is used to add the resulting sample solution to the flow cuvette and the extinction equivalent quantity is produced with a wave length of 530 nm. With the aid of a mathematical function, the hemoglobin concentration of the sample is calculated and produced from this quantity. The parameters for the mathematical function have been produced by measuring samples with known hemoglobin content and securely stored in the equipment.

3.3.3 Plasma-related glucose values

If this function is switched on (explanation of function in the relevant chapter), this means that the haematocrit value is also determined in addition to the glucose. Both values are calculated and a plasma-related value is also produced if full blood samples are used.

If this function is switched off (explanation of function in the relevant chapter), this means that the glucose value is produced from full blood samples.

3.4 Structure and appearance

Appearance:



Fig. 3.7 View of equipment

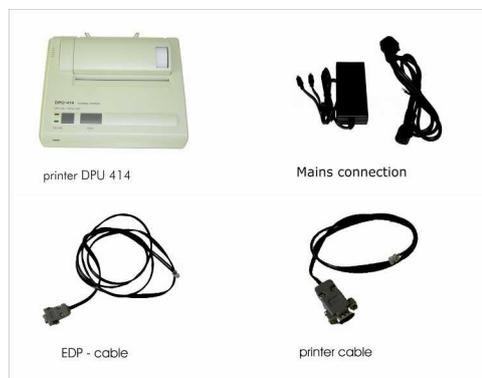


Fig. 3.8 Accessories

Deliverables

Description	Quantity
SUPER GL easy / SUPER GL easy+	1
Mains cable	1
Power supply unit for device and printer	1
Instruction manual	1
<u>Optional</u>	
Printer DPU 414	1
Printer cable	1
EDP cable	1

3.5 Accessories

As described and illustrated above, the SUPER GL easy / easy+ is supplied with standard accessories. Additional optional accessories can be ordered. The manufacturer or the authorised sales company will be happy to provide information on the relevant options.

3.6 Consumables

The following consumable materials are required for operating the analyser.

- Prefilled reaction cups without capillary tubes or with end-to-end capillary tubes or with open-end capillary tubes for taking samples
- Calibration solution
- Containerkit for haemolysis system solution and waste
- Glucose sensor or glucose/lactate sensor
- Control materials

Please find the details for using these consumable materials in the operating chapter of these instructions for use or in the relevant packaging inserts.

4 Operation – Part 1

4.1 Introduction

This part of the instructions for use summarises all the information needed for daily operation of the equipment.

In Part 2 there is a summary of all the additional information important for understanding the functions, additional functions and certain sources of error.

The operating staff must inform themselves about both parts and should also be able to interpret technically the readings obtained.

Evaluation of the results and the diagnostic and therapeutic measures derived from them must be carried out only by specialist staff authorised to do so.

4.2 Safety instructions

As already mentioned, some safety instructions must be observed when operating the equipment in order to ensure correct and error-free work:

- The equipment must be operated for the described indication only. Before using the equipment, please read all the instructions for use – carefully, especially the regulations on sampling –.
- Each user is responsible for keeping to the safety, health and legal regulations and for using the equipment in the proper manner only.
- Evaluation of the results and the diagnostic and therapeutic measures derived from them must be carried out only by specialist staff authorised to do so.
- Use for personal use is expressly forbidden.
- During daily work, regular quality control of the readings obtained should be noted and additional control readings carried out if necessary.
- The equipment should not be switched off or disconnected from the power supply when it is still operating. If this should happen, it can lead to faults in function when it is next switched on. If faulty functioning or incorrect readings are suspected, please inform those responsible for the equipment. They may then need to discuss the matter with the manufacturer or the sales partner in order to solve the problem.
- If there is any accidental skin contact with potentially infectious substances, e.g. human samples, disinfect the affected parts of the body with a suitable disinfectant solution.
- The haemolysis system solution is not corrosive, poisonous or seriously harmful to skin. If there is any skin contact with the haemolysis system solution, rinsing with water is sufficient. You can find more information on this in the safety data sheet for each solution.
- We expressly point out that if the equipment and consumable materials are not used correctly the protective measures provided for the equipment may be ineffective.

4.3 Installation of the equipment

Before first using the equipment please check that the equipment and accessories are complete by using the list in 3.4. If the accessories are not complete, please contact your sales partner immediately.

All parts delivered should also be checked to see that they are intact. Proper operation can only be ensured if original parts and accessories are used. Other parts or damaged parts must NEVER be used.

Stand the equipment on a horizontal, level and dry work surface. Please choose a position so that the equipment is protected from direct sunlight and extreme temperature variations, as this can impair the reading results.

Conditions at the set-up site:

- No direct influence of moisture
- No direct sunlight
- No strong electromagnetic fields or ionising radiation
- No rapid temperature change caused by windows, doors, air conditioning, etc.
- Level, waterproof surface
- The whole placement surface must be completely free of the floor

Connecting the equipment to the electricity supply (see Fig. 4.1):

Make sure that the voltage given on the power supply unit matches your mains supply.

Mains connection of the equipment is carried out via the supplied power supply unit. Connect the mains connection lead to the power supply unit. Insert the plug into the power supply unit connection on the right side of the housing (marked with "DC 12V") and insert the mains connection lead plug into the socket.

Connecting the printer (see Fig. 4.1):

If the SUPER GL easy / easy+ is used with the DPU 414 printer, the printer's voltage supply comes via the second power supply unit connection. The voltage adapter must be switched between the printer and the power supply unit. The printer cable plug is inserted into the printer connection on the right side of the equipment housing ("Printer") and connected to the appropriate socket on the back of the printer.

EDP – connection (see Fig. 4.1):

Insert the EDP connection cable into the EDP connection socket on the right side of the housing and connect the other end to the EDP. Make sure you follow the information in the interface description and from your EDP – company.

The following illustration shows the connections on the right side of the housing of the SUPER GL easy / easy+:

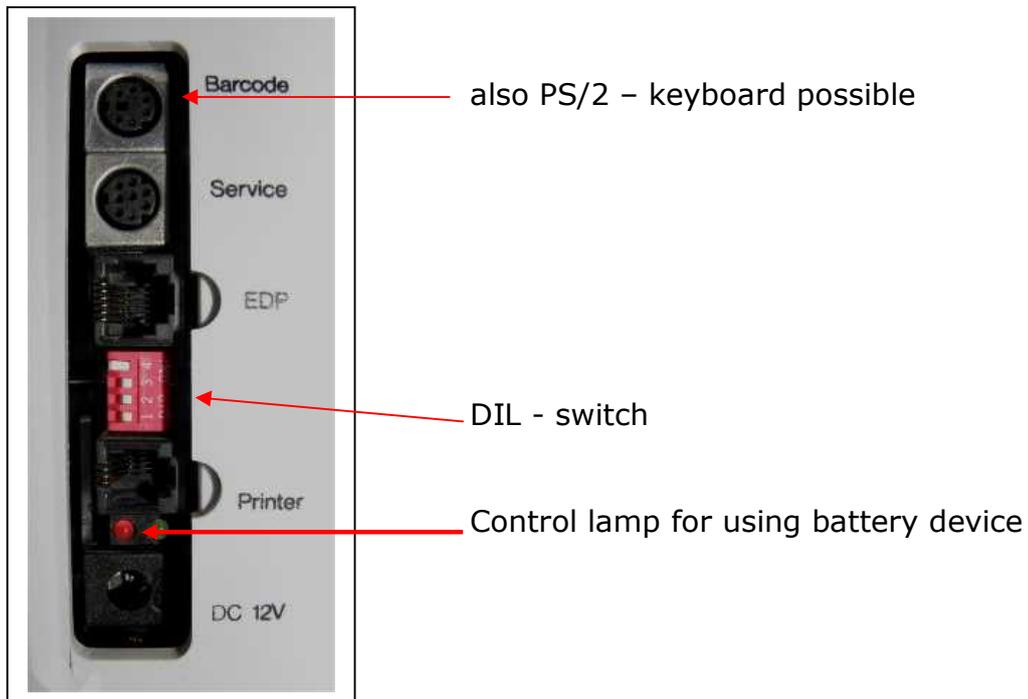


Fig. 4.1 View of connector panel

4.4 Setting up the equipment

If the equipment has been installed as described above, the following steps must be carried out so that the equipment can begin working:

1. install the sensor (chapter 6.3.2)
2. install the containerkit (chapter 6.3.3)
3. put on pump head (chapter 6.3.4)
4. insert operation card or a special card
5. select determination method and measuring unit using the DIP switch

This procedure completes the installation of the device.



Warning! To avoid loss of data, the device must not be switched off unless in "STAND BY" mode or if required by a corresponding error message.

Turn on the device by a short press at the MENUE key (sound "beep" will show that device turns on).

After switching on the device, it will enter "Stand By" mode after the necessary warm-up period.

This time depends on parameters which should be measured:

- Measuring of hemoglobin only 2 min

- Measuring of glucose and / or lactate
 - New sensor 15 min
 - Used sensor 10 min

You can terminate the start-up period when small stars on the left and right of the lower part of the display. Please note that in this case there is a higher risk of the drift of measuring values.

SUPER GL easy / easy+ is operated by using MENU or ENTER key. There are two main program menus, the „Measurement menu" and the „Function Menu". The „Measurement menu" contains all functions that are directly needed for measuring. The „Function Menu" contains additional functions. Switching between the two main menus is done only in "Stand by" mode by pressing the Enter key. The type of menu you are in is shown in the second row of the display.

We recommend staying in "Stand by" all the time, also during night.

Switch off the device by pressing menu key long (sound "peep" will show that device will be switched off).

Following page shows menu structures of SUPER GL easy / easy+.

Fig. 4.2 Menu structure

4.5 Preparation of measuring process

4.5.1 General

The SUPER GL easy / easy+ works with pre-diluted reagents. A prefilled reaction cup with appropriate capillary tube is required for each analysis.

For measurements on the SUPER GL easy / easy+ you also need the appropriate biosensor, calibrator cups and appropriate control material.

The analyser measures blood samples in haemolysed form or other material (see chapter 3.2). The sample must be diluted in the ratio 1 part sample + 50 parts of the solution supplied in the pre-diluted cups.



Note particularly that to determine hemoglobin, a separate system of consumable materials consisting of "system glucose/lactate/hemoglobin system solution" and "system glucose/lactate/hemoglobin calibrator" must be used. Incorrectly used consumable material will lead to incorrect readings.

The cups are placed on the appropriately labelled spots on the sample plate or in the cartridge and after insertion of the reaction cup with the patient samples either individual sample measurement or series measurement is started. Measuring starts automatically if a sample cup is placed in the sample position (red segment) on the sample plate. Calibration is carried out if necessary before measurement.



Cartridges must not be positioned in the analyser.

Series measurement starts automatically if the cartridge is positioned in the analyser. Only the occupied positions will be processed.

A control reading must be indicated on the touch screen. On instruction, the plate is turned to the loading position for the control samples. After that, the positions must be loaded within 15 seconds and the measurement started with another instruction using the touch screen. If this does not happen, the analyser reverts to the initial state.

4.5.2 Sample preparation

Please follow the instructions in the packaging inserts for the reaction cups and calibrator for sample preparation.

Please follow the following instructions additional to the above instructions:



When taking samples of capillary blood, the tissue must not be squeezed under any circumstances. This process leads to thinning of the blood sample with cell fluid and, particularly with the measurement of hemoglobin, leads to false results. Suitable lancets should be used for taking capillary blood and if necessary measures to increase perfusion (such as massage of the appropriate area of the skin) should be carried out to achieve a sufficiently large sample.

When using non fluoride-stabilised sample material, a 15-minutes period from taking the sample until stabilisation with haemolysis system solution must not be exceeded.

Taking capillary blood using an open-end capillary tube is described and shown on the following page. Proceed in the same way with an end-to-end capillary tube (the end-to-end capillary tube is NOT broken during this).

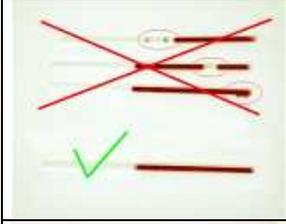
	<p>Taking capillary blood from an earlobe or finger pad and filling the capillary tube to above both markings</p>
	<p>Make sure you fill the tube correctly (sufficient quantity of blood, no air bubbles, no drops of blood on the end of the capillary tube, etc.)</p>
	<p>Carefully wipe the outside of the capillary tube</p>
	<p>Break the capillary tube at the correct spot (the correct spot is in the middle between the two markings)</p>
	<p>Insert the completely filled part of the capillary tube into the prefilled reaction cup</p>
	<p>Shake the reaction cup thoroughly until the blood from the capillary tube has completely dissolved</p>

Fig. 4.3 Sample preparation with open-end capillary

4.6 Measuring operation

4.6.1 Calibration

The SUPER GL easy / easy+ requires valid calibration to ensure correct readings. The SUPER GL easy / easy+ automatically performs required calibrations. Every time you leave "Stand by" without a valid, the device asks you to insert a cup filled with calibration solution and then performs a calibration. With a valid calibration, the operator can decide whether an additional calibration is carried out or not.

If you want to carry out a calibration, switch into the "Function Menu" and select "Calibration" by pressing the menu button. If you press the enter button (=OK), you switch back to the "Measuring menu" and the sample rotor is turned into the calibration position (blue). If there is a sample cup in the calibration position, you will be asked to remove it so that the fill level can be checked. To start calibration, insert a sample cup filled with calibration solution.

After successful calibration, the device is ready for measuring. As long as the device is not switched back to **Stand by**, the device automatically checks calibration periodically.

In Stand by, calibration is retained within the given time frame and becomes invalid afterwards without a new calibration.



Even if the calibrator in a cup is not used up during a working day, you should insert a new cup on a daily basis to guarantee the correctness of the measuring results.

Note that the calibration cups are not fully emptied and that a small residue remains in them. When the SUPER GL easy / easy+ requests a new calibration cup, a new one must be inserted, even though there is still some residue in the old one.

4.6.2 Patient samples

To measure a patient sample, proceed as follows:

1. Select the menu item Measuring sample by pressing the MENU button; the sample plate is turned into the sample position (red). If there is a sample cup in the sample position, you will be asked to remove it.
2. To start measurement, insert a sample cup filled with the hemolyzed sample.
3. After about 40 seconds the measured value is displayed and printed out if a printer is connected.
4. You can remove the sample cup as soon as the display shows "Remove cup"!
5. To view the result again, press ENTER. The result of the most recently measured sample is displayed for about 2 seconds.
6. After removing the sample, the display shows "Insert cup".

Now another sample can be measured. Proceed as described in steps 2 to 4.

4.6.3 Patient samples with bar code

This menu item is only available if a bar code reader (or a PS/2 keyboard) is connected. The SUPER GL easy / easy+ automatically recognizes a supported bar code reader. Please ask the manufacturer or your supplier for supported bar code readers.

Instead of a bar code reader, a PS/2 computer keyboard can be connected. In this case, digits and letters can be entered manually to identify a sample (16 characters maximum). Confirm your input by pressing enter on the keyboard. Now you will be asked to insert the sample cup. The sample identification entered will be shown on the display, at the printer or will be sent to EDP, as well as stored in the result memory. To view it repeatedly, press "Display result memory".

4.6.4 Active Controls

This menu item is only active when controls are active. Activating controls is described under chapter 5.3 (Functions when switching on). If no controls are active, quality control can be done manually, e.g. the control material is measured as a sample and the results are documented on appropriate evaluation sheets.

Non-active controls are saved in the result memory just like patients samples. In addition, active controls are saved in control memory (see Quality control). For active controls, names and limit values can be entered. These values are entered using a special card that has to be coded before. Coding is done for selected controls by manufacturer. It is also possible for the user to code the card using a PC and separately additional accessories and software.

4.7 Method

The following parameter variations can be measured with the SUPER GL easy / easy+:

- glucose
- lactate
- glucose and lactate

SUPER GL easy+ is able to measure additional to the parameters mentioned above the value hemoglobin.



For the measurement of hemoglobin and special calibration cups (green) and reaction cups (yellow) must be used.

4.8 Printer settings

The DPU 414 printer provided for use with the equipment has several connection options.

To set/program the printer for use with the SUPER GL easy / easy+ the following steps are needed:

1. When switching on the printer keep the "on line" button pressed. You will then receive a printout of the current settings.
2. Press "on line" again and you can reprogram the printer.
3. Press "on line" for "ON", press "Feed" for "OFF"
4. Press "Feed" to confirm at the end of the programming process

The following settings are needed for the SUPER GL easy / easy+:

Position	SW1	SW2	SW3
1	OFF	ON	ON
2	ON	ON	ON
3	ON	OFF	ON
4	OFF	ON	ON
5	ON	ON	OFF
6	OFF	ON	ON
7	ON	ON	ON
8	ON	OFF	ON

4.7 Switch off equipment

The equipment should not be switched off until it is no longer performing any functions. The equipment should NEVER be switched off in the middle of a measurement process, during calibration or rinsing, as this can lead to faulty functioning.

If the equipment is to remain switched off for a long period (e.g. during holidays), it should be rinsed and emptied before switching off in order to prevent the liquid in the tubing system from drying. The consumable material (especially the sensor and calibrator) must also be suitably stored (see Ch. 6.3.6).

Please contact the service department if you have any further questions.

5 Operation – Part 2

5.1 Introduction

This part of the instructions for use describes special functions and settings relevant to the user. You can also get additional information here on quality control and on some equipment faults which can be remedied by the user.

5.2 Menu functions

As – already described in chapter 4 – there are two types of analyser function: functions which may be needed for daily work and functions which only authorised staff should use.

There are two main program menus, the “Measurement menu” and the „Function Menu“. The “Measurement Menu” contains all functions that are directly needed for measuring. The “Function Menu” contains all setup functions. Switching between the two main menus is done only in “Stand by” mode by pressing the “Enter” key.

The „Measurement Menu“ is available after a valid calibration took place. It can be browsed by pressing the Menu button repeatedly.

Apart from specialist knowledge, you also need precise knowledge of the menu construction of the SUPER GL easy / easy+ for the following functions. You can find an overview of the menu guide in Fig. 4.3.

5.2.1 Stand by / Measurement Menu

In this mode, the device only carries out certain functions to condition the biosensor. A valid calibration remains valid for a certain amount of time; after that it becomes invalid. If no valid calibration exists, the „Measurement Menu“ is restricted to the item “Calibration” if the measuring method glucose or lactate is active. If you only want to determine hemoglobin[✓], “Calibration” is skipped.

The functions of the various menu items were already described in chapter 4.

5.2.2 Stand by / “Function Menu”

In this mode, the device only carries out certain functions to condition the biosensor. A valid calibration remains valid for a certain amount of time; after that it becomes invalid.

[✓] depending on model of equipment

5.2.2.1 Calibration

By pressing the Menue key you reach the menu item "Calibration" if the measuring method for glucose or lactate is active. In the second row of the display, you can choose between "yes" or "no" assigned to the two device buttons. If you select "no", the next item "Display result memory" appears; if you press "yes", you switch to the „Measurement Menue" and the sample plate is turned into the calibration position (blue). If there is a sample cup in the calibration position, you will be asked to remove it so that the fill level can be checked. To start calibration, insert a sample cup filled with calibration solution. After successful calibration, the device is ready for measuring. As long as the device is not switched back to Stand by, the device automatically checks calibration periodically.

5.2.2.2 Display results

Here you can view the results of about the last 100 measurements. The value measured last is displayed first; by pressing "Menue key" repeatedly the value before that is displayed and so on. If glucose and hemoglobin[✓] are measured simultaneously, both results of a sample are displayed one after the other. First the method is displayed, after a second the display changes and the result appears in the second row. The first row displays either date and time of the measurement or the sample identification entered. By pressing ENTER again, the display disappears and you return to the menu item "Display result memory".

5.2.2.3 Delete results

If the result memory is deleted, all results are lost and cannot be recovered. Therefore, after selecting this item, you'll be asked for confirmation "Delete yes/no".

5.2.2.4 Copy results

This function copies the result memory to a special data transfer card. This allows transferring the results to a PC for further processing using a card reader. Processing on a PC is currently under development.

5.2.2.5 Output results

Selecting this menu item and pressing ENTER outputs the measured values stored in memory to the printer and electronic data processing system. The results are not deleted. Results that have been output already can be read out again by selecting "yes" after the prompt "Print all?".

[✓] depending on model of equipment

5.2.2.6 Washing

The display shows "Washing" in the first row; "YES / NO" in the second row, matched to the keys. After confirmation with "YES" the tube system is washed for 100 seconds.

5.2.2.7 Set time

After pressing ENTER, the first row of the display shows the current time in the device. The second row displays "OK" beneath ENTER and "Set" beneath MENU. By pressing Menu briefly, you can count up the minutes in single steps; holding the button counts up the minutes more quickly. Setting the time can only be done in this direction. After reaching the desired time, press ENTER to confirm.

5.2.2.8 Plasma reference glucose

As described in chapter 3.3.3, the SUPER GL easy+ could display the measured whole blood samples as plasma reference values. So it is necessary to adjust this function. This happens in this menu item.

For switching on you have to do following steps:

Plasma ref YES / NO → **YES** → Plasma ref ON / OFF → **ON** → Plasma ref YES / NO → **NO** → Stand by "Function Menue"

For switching off the plasma reference you have to do the same steps (but: Plasma ref ON / OFF → **OFF**).

Because of the red colour of whole blood samples the device is able to difference between samples of whole blood and other sample materials (i.e. serum, plasma, fluid).

Please take notice if this function is activated or not, if you have not plausible values.

5.3 Functions when switching on

After switching on the device, some tests of internal systems and the inserted card are carried out (see also function of cards and troubleshooting). Among other things, information about the available supply on the card and the remaining lifetime of the sensor are displayed.

If you press ENTER until you hear a beep while switching on the device, you reach the menu for activating and deactivating controls. This function allows you to activate a maximum of three controls per method for quality control statistics purposes. To activate press ENTER, to deactivate press MENU. The position of the star displays the current state.

If a control is activated, a sub-menu for this control is stepped through consisting of three items:



The number in the middle of the second row of the display is for internal purposes only and is of no importance for the set-up.

- **New name:**

If the current control name is to be changed, confirm by pressing "YES". The current name is then shown in the upper row of the display. The letter to be changed is underlined. Pressing the Menu key changes the letter is confirmed by pressing Enter. For corrections press Enter until the position to be corrected is again underlined.

Please note that to shorten a control name, the surplus positions have to be filled with blanks.

- **New lower limit:**

If the lower warning limit (smallest valid value for this control) has to be changed, confirm it by pressing "YES".

The currently valid value is then shown in the upper row of the display. The value could be changed using the Menu key, the Enter key changes the direction (up arrow = direction towards larger values and vice versa). The correct value is confirmed by pressing the Enter key for a longer time.

- **New upper limit:**

If the upper warning limit (largest valid value for this control) has to be changed, confirm by pressing "YES".

The currently valid value is then shown in the upper row of the display. The value could be changed using the Menu key, the Enter key changes the direction (up arrow = direction towards larger values and vice versa). The correct value is confirmed by pressing the Enter key for a longer time.



No plausibility control takes place (entries where upper limit < lower limit are possible but make no sense). Settings are done in mmol/l, independently of the selected measuring unit.

The menu must be stepped through completely. If you cancel this process, e.g. by pulling the plug, all changes that were just entered are lost.

For each method, deleting the result memory is offered after this setting. Since only activated controls are saved, it is recommended to delete the result memory when making changes in this area.

For more detailed information about the controls' function see Quality Control

If both buttons are pressed while switching on the device, all saved limit values for the controls are printed if a printer is connected.

5.4 DIL switch settings

At the SUPER GL easy / easy+ could be chosen which parameter could be measured and in which unit the values of several parameters should be displayed. This happens by using the DIL switches, but note that the selected parameter depends on the sensor in the device. The DIL switch is situated at right side of casing (fig. 4.1)



Fig. 5.1 DIL switch

Basic rule for adjustments is that DIL switches 1 and 2 are for adjusting the unit and DIL switches 3 and 4 are for adjusting the method. Following variants are possible:

Sensor glucose / lactate

The following adjustments are valid:

- DIL 1: Adjustment for unit glucose (ON = mg/dl and OFF = mmol/l)
- DIL 2: Adjustment for unit lactate (ON = mg/dl and OFF = mmol/l)
- DIL 3: Switching on / off measuring glucose (ON = determination of glucose; OFF = no determination of glucose)
- DIL 4: Switching on / off measuring lactate (ON = determination of lactate; OFF = no determination of lactate)

The inquiry of measuring hemoglobin[✓] (YES / NO and unit) will happen while switching on the device.

Sensor glucose:

The following adjustments are valid:

- DIL 1: Adjustment for unit glucose (ON = mg/dl and OFF = mmol/l)
- DIL 2: Adjustment for unit hemoglobin[✓] (ON = g/dl and OFF = mmol/l)
- DIL 3: Switching on / off measuring glucose (ON = determination of glucose; OFF = no determination of glucose)
- DIL 4: Switching on / off measuring hemoglobin[✓] (ON = determination of hemoglobin; OFF = no determination of hemoglobin)

[✓] depending on model of equipment

Sensor lactate:

The following adjustments are valid:

- DIL 1: Adjustment for unit lactate (ON = mg/dl and OFF = mmol/l)
- DIL 2: Adjustment for unit hemoglobin[✓] (ON = g/dl and OFF = mmol/l)
- DIL 3: Switching on / off measuring lactate (ON = determination of lactate; OFF = no determination of lactate)
- DIL 4: Switching on / off measuring hemoglobin[✓] (ON = determination of hemoglobin; OFF = no determination of hemoglobin)

Sensor hemoglobin:

The following adjustments are valid:

- DIL 1: Adjustment for unit hemoglobin (ON = g/dl and OFF = mmol/l)
- DIL 2: irrelevant
- DIL 3: Switching on / off measuring hemoglobin[✓] (ON = determination of hemoglobin; OFF = no determination of hemoglobin[✓])
- DIL 4: irrelevant



Please note while measuring with sensor hemoglobin that DIL switch 3 is turned to ON, otherwise the device will not display any value.

5.5 Functions of the cards

The Super GL easy / easy+ is equipped with a card reader allowing various functions to be made more user friendly. Various cards with the following designations and functions are available:

Operation Card:

Necessary for measuring operation and supplier identification

Device Setting Card:

Enables the user to change specific device internal parameters. This setting changes the measuring value; the cards are only made available upon request.

Language Cards:

Change the language of the menu

It is important to insert the appropriate card before the device is switched on. If not, an error message is displayed and the device cannot be used. When using the special card (not operation card), the device switches itself off after carrying out the instructions on the special card.

Before taking a measurement, the device checks how many samples can be measured using the card and how long the sensor will remain active.

If the supply on the operation card is less than samples, a warning is displayed both on the printer and the display. The same happens when the remaining life time of the sensor is less than 10 days.

[✓] depending on model of equipment

5.6. Quality Control

In general there are national instructions for quality control of clinical analyses. These instructions are obligatory for all medical users.

In Germany there are the "Guidelines of the Federal General Medical Council for Quality Assurance in Medical Laboratories (RiliBÄK)" in their valid version. The responsible person for the device has to catch up the valid rules.

Self contained the software of the SUPER GL easy / easy+ affords following support of quality control:

- The Super GL easy stores the measuring values of active controls in separate control memories. From there they can be transferred to a data card and processed further with a PC.
- If controls are activated, all results up to the first correct measuring of this control are marked with an "!". This shows that there is no correct result for one control.



Possibly a simplified quality control at so called POCT – analysis is allowed (point-of-care-testing). Not every control material is usable non-restrictive for using our device. If there are any problems, contact your distributor.

6 Maintenance and troubleshooting

6.1 Introduction

This chapter tells you what you need to know about maintenance of the SUPER GL easy / easy+ and about faults which can occur and whether and how you can remedy these yourself.

If you are unsure about some of the items or options, DO NOT UNDER ANY CIRCUMSTANCES try any options you think might help without technical aid. DO NOT UNDER ANY CIRCUMSTANCES open the analyser without an authorised service technician. Our service hotline is available by telephone free of charge.

6.2 Maintenance

The SUPER GL easy / easy+ needs servicing once a year by specialist staff assigned and authorised by the manufacturer. A warning will appear on the display once the service interval has elapsed.

If the service is not carried out, this can lead to incorrect readings which are not the responsibility of the manufacturer.

Please contact the manufacturer or your sales partner to have this service carried out.

6.3 Servicing

The following operations can and should be carried out by the user. These operations help with the careful treatment and care of the analyser and to ensure its longest possible lifespan. This is NOT servicing and repair work, for which only authorised servicing engineers are responsible.

6.3.1 Cleaning and disinfection

Please note the valid regulations in your laboratory for cleaning and disinfection of the analyser. For disinfection, all the accessible surfaces of the analyser should be wiped with a cloth moistened with disinfectant. Use a disinfectant for surface disinfection. Note the manufacturer's instructions on disinfectant.

6.3.2. Change the sensor

Removal of sensor

1. Open the sensor housing by turning the fastener upwards

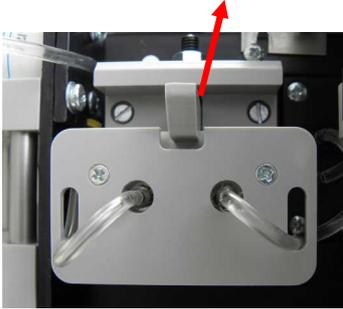


Fig. 6.1 Sensor opening closed

2. Removal of sensor



Fig. 6.2 sensor opening open

Inserting the sensor

1. Open the packaging and remove the sensor
2. Open the sensor housing by turning the fastener upwards
3. Insert the sensor
4. Close the sensor opening

6.3.3 Changing the containerkit

The SUPER GL easy / easy+ is operated with what is known as a containerkit. This is a system solution/waste bottle combination specially produced for this type of analyser. It is hung on the back of the analyser and connected by the tubes to the analyser tubing. The volume is designed so that the waste bottle is full when the reservoir bottle is used up.

The analyser monitors the availability of the solution but not the waste container.

To avoid disruption in the work process of the analyser and soiling, we recommend changing the containerkit only when the operating status is "Stand by" and when there is an inbuilt rinse vessel and sample canula. Changing the containerkit should be carried out quickly, as liquid is expelled during the rinse processes carried out from time to time.

Never refill the containerkit!!



Fig. 6.3 Containerkit



The majority of germs which occur in human samples are killed by the composition of the system solution and the high dilution of human samples. Nevertheless, the waste must be regarded as potentially infectious so follow the relevant regulations for disposal.

6.3.4 Exchange of pump head

In some situations it is necessary to exchange the pump head, e.g. if device should get service.

For changing the pump head proceed as following steps:



Abb. 6.4 View of pump head

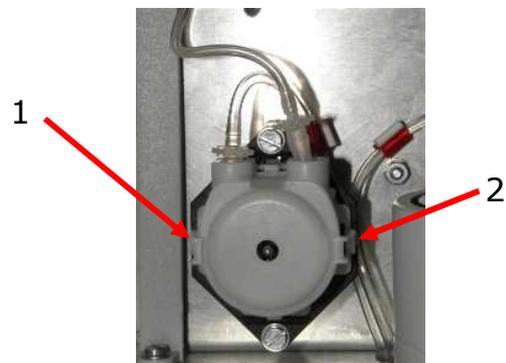


Abb. 6.5 Pump head

Please note for installing the pump head (is situated under the sensor – fig. 6.4) that rounded side of the pump head is shown to the door and the flat side is shown to the black panel. If you install the pump head you have to hear a Click and after installing you should not remove it from the axle.

If you remove the pump head you have to press gently the springs at the sides (fig. 6.5). If you have done this you could remove the pump head pulling it to the front side of the instrument.

If there are any questions, please call our service for help.

6.3.5 Taking equipment out of operation

To take the analyser out of operation for a long period or to prepare it for transport, proceed as follows:

1. Rinse the analyser with distilled water (menu item "Emptying")
2. Empty the system by taking the tube out of the containerkit and selecting again "Empty"
3. Switch the analyser off and remove all connections

The consumable material (especially the sensor and calibrator) must also be suitably stored.

Please contact the service department if you have any further questions.

Taking the analyser permanently out of operation:

For disposal of equipment please ask your sales partner.

6.3.7 Prepare equipment for transport

To prepare the analyser for transport, proceed as follows:

- Rinse and empty system (see Ch. 6/3/6)
- Switch off analyser
- Remove containerkit from analyser and remove all reaction cups from the analyser
- Remove plug from power supply unit and printer and/or EDP
- Disinfect outside of analyser
- Pack and transport the equipment in the original cardboard box with foam insert only as this is the only way to avoid damage during transport as far as possible.
 - Place analyser in one half of the foam, making sure that the analyser is placed correctly in the mould
 - 2. Place the other half of the foam on top and close the carton
 - NB. If force is needed to close the transport crate, the analyser is not correctly seated in the mould.

Please contact your sales partner or the manufacturer if you have any further questions.

6.4 Reporting and repairing faults

6.4.1 Warnings

Before reading out the results, the analyser checks whether the set warning limits have been exceeded.

The following warnings are given on the display and the printer:

Warning	Meaning
++++	Measurement range exceeded
----	Measurement range below limits
!!	Sample or control warning limits exceeded or not reached
*!	Previous control measurement outside the control limits and below or above the sample warning

6.4.2 Measurement errors

Error message	Meaning	Action
Error pump	Pump / flow system jammed	Check pump head (chapter 6.3.4). Call service
Exchange reagent kit!	System solution in containerkit is used up	Exchange containerkit according to section 6.3.3
Insert operation card	No operation card	Insert a correct operation card and confirm by pressing Enter-key
Wrong operation card	Operation card is not properly inserted	
Operation card *empty*	Operation card not properly inserted or operation card empty	
Operation card typing error	Operation card defective	
"no sensor" or "sensor defective"	Sensor is not properly recognized	Use other sensor; if this happens repeatedly, call service
Sensor "run out" or sensor "used up"	Sensor is used longer than its lifetime	
Error photometer	Photometer measuring unsuccessful	if this happens repeatedly, call service
Photometer unstable Zero line unstable	Photometer signal variation is too strong	Solution polluted or air in cell (wrong solution), photometer defective; call service
Sample rotor defective	The sample rotor cannot turn its position	Turn device off, check for mechanical block. Call service
Sample taker defective	The sample taker cannot turn its position	Turn device off. Call service

Fig. 6.7 Table of measurement errors

6.4.3 Equipment errors

There is the possibility that you can't read anything at the display; in this case switch off the device and switch it on again. If you to see the last measuring values follow the steps described in chapter "display measuring results".

If the display is everlasting unreadable you have to call the service.

6.4.4 Measuring errors

Glucose and/or lactate* readout happens after the enzymatic-amperometric read process. The signal occurs after a chemical reaction with the immobilised enzyme as a change in current on an electrode.

As with all flow systems, the tightness and patency of the channel between the sample cannula and piston pump is very important for the function of the analyser.

Escaping fluid just like air segments running irregularly through the system is always an indicator of lack of tightness, e.g. worn out seals in the rinse cup, loose tubes or incorrectly inserted sample cannula.

Please call the service, if you see these problems at your equipment.

Scattered readings:

May also be due to a sample that is not exact. Check therefore with a few calibration solution cups where the precision has been incorrect on several occasions. Can also be due to a defective sensor

Calibration unstable, frequent errors, scattering too great:

Can also be due to extreme temperature variations (e.g. direct sunlight)

Calibration not possible, value too small:

Can also be due to a defective (insensitive) sensor, frequent occurrence of the error "maximum margin"

* depending on sensor type

7 Technical data

Measuring time per sample Glucose and/or lactate* Additional hemoglobin	40 sec 90 sec
Measurement range Glucose Lactate Hb	0.8 – 50 mmol/l (11 - 910 mg/dl) 0.5 – 30 mmol/l (4.5 - 270 mg/dl) 1.86 – 15,52 mmol/l (3.0g/dl - 25 mg/dl)
Sample quantity	10 / 20 µl sample diluted with 500 / 1000 µl haemolysis solution
Precision (24 samples) Glucose (216 mg/dl) Lactate (90 mg/dl) Hb	< 2.0 % with 12.0 mmol/l < 2.5 % with 10.0 mmol/l < 1.0 % with 7.6 mmol/l
Sensor storage time	12 months
Sensor storage temperature	+ 2°C to + 8°C
Duration of sensor operation	Glucose 6 months Lactate, glucose/lactate 3 months
Interfaces Printer EDP	Parallel, centronics V 24, RS 232
Work temperature	+ 15°C up to + 35°C
Storage temperature (without sensor)	- 10°C up to + 50°C
Operating voltage	12 V DC
Power consumption	Approximately 10 W
Classification according to MPG [German Medical Devices Act]	In vitro diagnosis
Dimensions (W x H x D)	200mm x 150mm x 170mm
Weight	approximately 2.0 kg
Manufacturer	Dr. Müller Gerätebau GmbH Burgker Str. 133 D-01705 Freital

Fig. 7.1 Table Technical data

* depending on sensor type