# *Instructions for use*

## SUPER GL *compact*

Valid from version: 2.0

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**Manufacturer/Copyright:**

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## B) List of illustrations

## C) List of symbols

### Symbols on the equipment

| Symbol | Description |
|---|---|
|  | Biohazard |
|  | Follow instructions for use |
| IVD | In vitro diagnostics |
|  | Manufacturer |
| CE | CE – conformity |
| **SN** | Serial number |

### Symbols on consumables

| Symbol | Description |
|---|---|
|  | Biohazard |
| IVD | In vitro diagnostics |
| CE | CE conformity |
|  | read accompanying documents |
|  | Follow instructions for use |
|  | Recyclable material |
|  | Dispose of correctly |
|  | Storage temperature |
| REF | Item number |
| Cont. | Contents of package |
| LOT | Batch description |
|  | Use by |
|  | Manufacturer |

## Symbols on the display

| Symbol | Description |
|---|---|
|  | Waiting period |
|  | Blue reaction cup – calibrator system glucose/lactate (if hemoglobin deactivated) |
|  | White reaction cup – reaction cup for blood sample, system glucose/lactate (if hemoglobin deactivated) |
|  | Green reaction cup – calibrator system glucose/lactate/hemoglobin (only if hemoglobin activated) |
|  | Yellow reaction cup – reaction cup for blood sample, system glucose/lactate/hemoglobin (only if hemoglobin activated) |
|  | Arrows upwards – remove reaction cup |
|  | Arrows downwards – insert reaction cup |
|  | Sample cartridge |
|  | Arrows to the right – remove sample cartridge |
|  | Arrows to the left – introduce sample cartridge |
|  | Analysis time (calibration and sample scan) |
|  | Send to printer |
|  | Send to EDP |
|  | Equipment locked because of incorrect follow-up measurement |
|  | Barcode reader connected |
|  | Scan individual sample with barcode reader |
|  | Scan cartridge with barcode reader |

## Symbols in the instructions for use

| Symbol | Description |
|---|---|
|  | Warning or instruction |
| ***Bold/italics*** | Text for special attention |

Explanation of term: Authorised persons are people who have acquired appropriate specialist knowledge through training with the manufacturer or authorised company.

# 1 Introduction

## 1.1 Introduction

Congratulations on acquiring your SUPER GL compact analyser. We hope you enjoy working with this equipment.

The next chapter "The SUPER GL compact" presents an initial overview of your analyser, showing which parameters can be measured, which other equipment and parts are available for your analyser and an overview of the way the equipment functions.

There is also information on safety instructions, liability and claims under the warranty or guarantee, as well as indications or contraindications for your analyser.

Please read the other chapters for further, more detailed information.

## 1.2 The SUPER GL compact

The SUPER GL compact analyser is an analyser for biochemical or photometric analyses in in-vitro diagnostics. The SUPER GL compact was designed for determining glucose and/or lactate* and/or hemoglobin.


Fig. 1.1 General view of SUPER GL compact

* depending on sensor type

### 1.2.1 Basic matters

The SUPER GL compact 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

### 1.2.2 Equipment and accessories

**Range:**

| Description | Number |
|---|---|
| SUPER GL compact | 1 |
| Sample cartridge | 1 |
| Mains cable | 1 |
| Power supply unit (PSU) for equipment and printer | 1 |
| Instructions for use | 1 |
| | |
| Optional | |
| Printer DPU 414 | 1 |
| Printer cable | 1 |
| EDP – cable | 1 |
| Other sample cartridges | |


Fig. 1.3 View of equipment

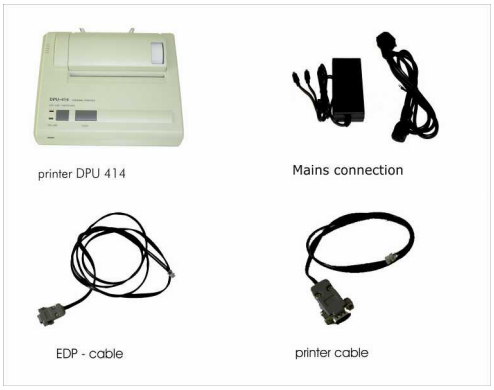



Fig. 1.4 Accessories

### 1.2.3 Overview of functions

The SUPER GL compact is an automatic analyser for determining glucose and/or lactate* and/or hemoglobin in 1 + 50 pre-diluted samples, e.g. in haemolysed blood samples.
The equipment can scan individual samples and small series of up to 6 patient samples. The measurement results are displayed on the integrated touch screen and a connected printer and can also be transferred to the EDP.

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

* depending on sensor type

## 1.3 Indications/Contraindications

**Indication**

The SUPER GL compact 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)
- Other materials after enquiring with the manufacturer

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

**Contraindications**

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

# 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 compact 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 compact needs servicing once a year by assigned specialist staff. A warning will appear on the touch 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 compact is an automatic analyser for determining glucose and/or lactate* and/or hemoglobin in in 1 + 50 diluted samples, e.g. in haemolysed 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
- Other materials after enquiring with the manufacturer

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

***When using non-fluoride stabilised 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 which may be arranged on a sample plate or sample cartridge. The cups for the rinsing and waste solution are – in a containerkit connected – to a unit at the back of the equipment.
In detail, the equipment features the following performance characteristics:

- Measurement of glucose and/or lactate* using the enzymatic-amperometric measuring principle.
- Measurement of hemoglobin using a photometer
- Autocal operation
- Programmable EDP connection
- Serial printer connection
- PS2 – barcode reader or keyboard connection

* depending on sensor type

## 3.3 Measuring principle
### 3.3.1 Measuring principle glucose and lactate determination

Determination of glucose and/or lactate* with the SUPER GL compact is based on an electrochemical 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:

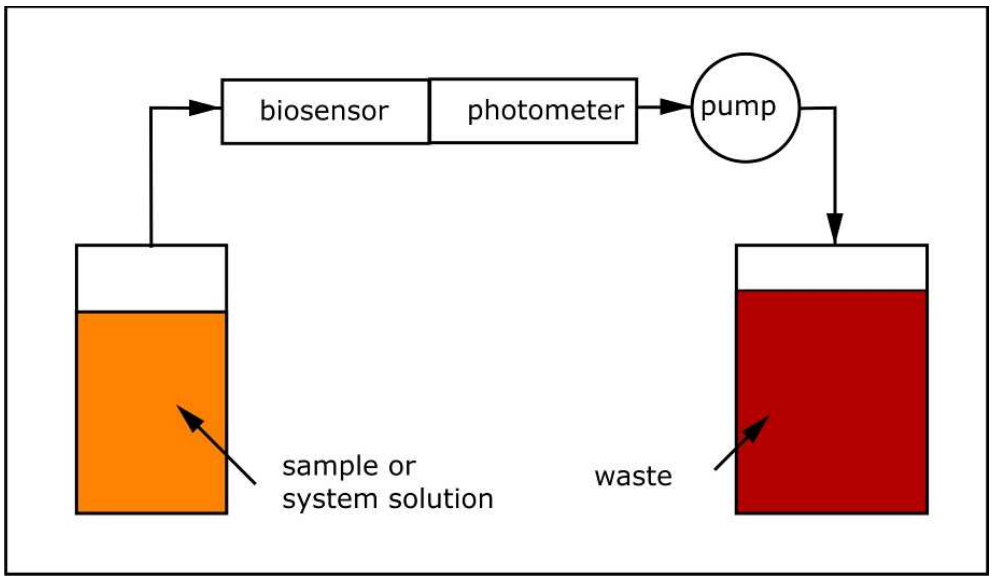



Fig. 3.1 Flow diagram

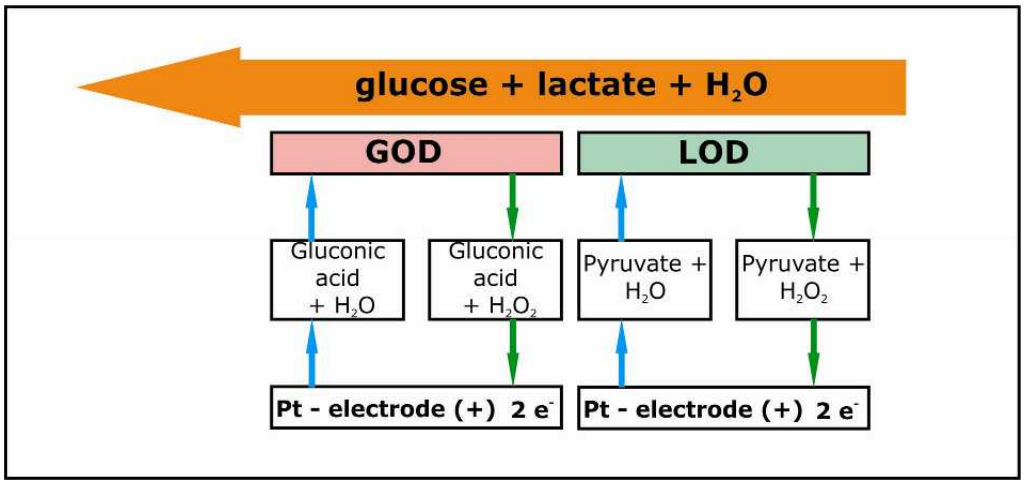



Fig. 3.2 Diagram showing the principle of action

* depending on sensor type

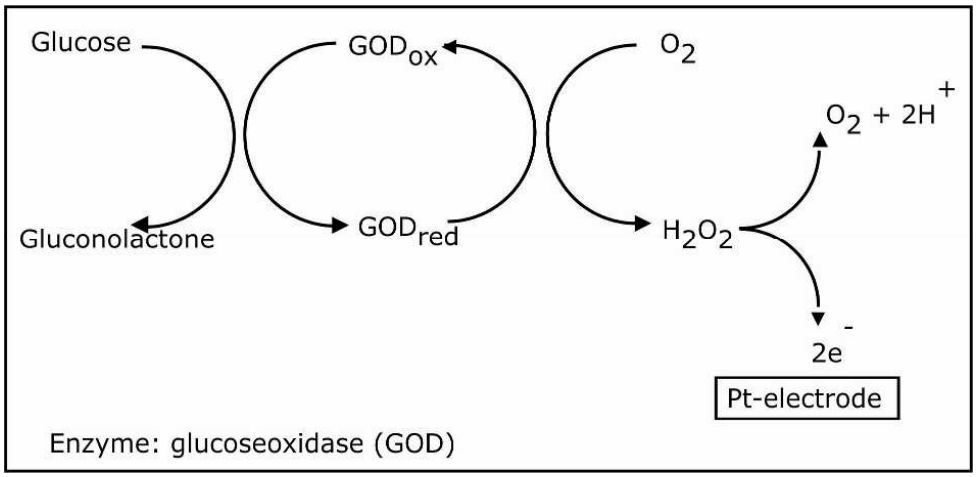



Fig. 3.3 Reactions in the glucose sensor

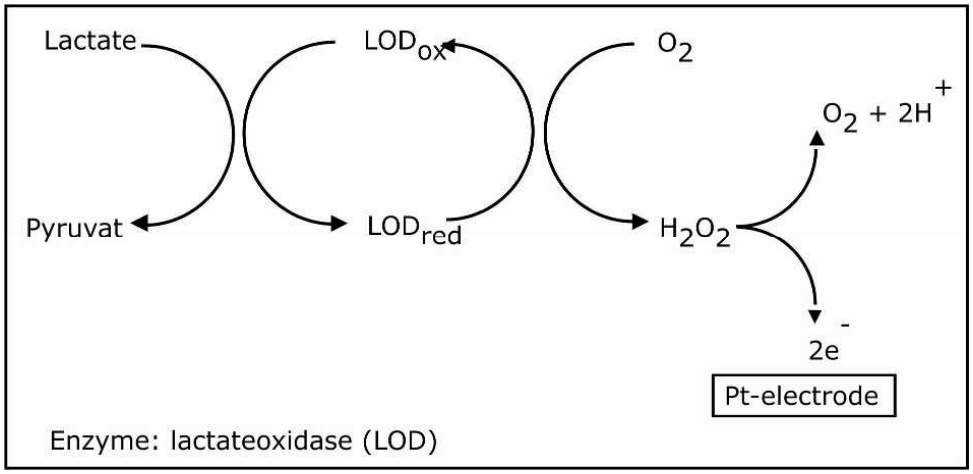



Fig. 3.4 Reactions in the lactate sensor

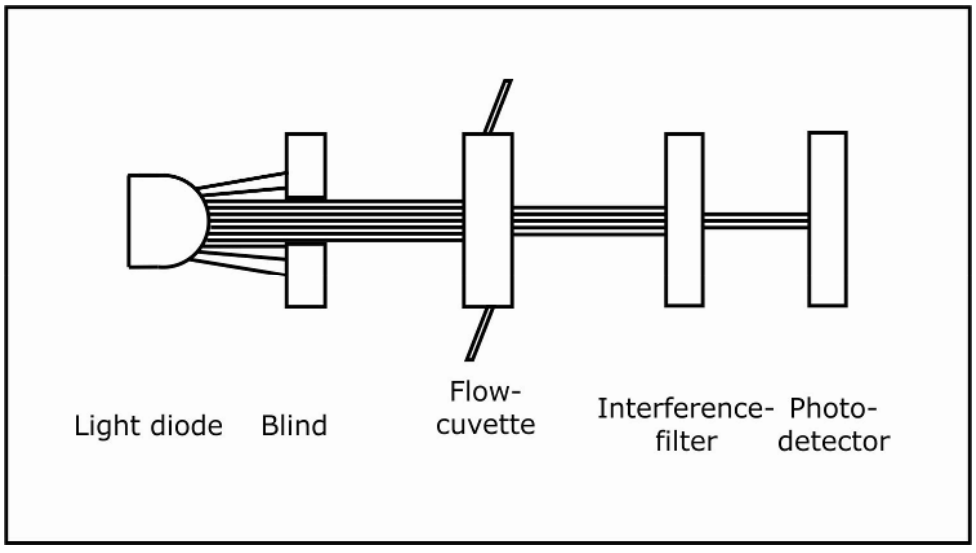



Fig. 3.5 Flow diagram: photometer

### 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 extinctionequivalent 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. 3.6 View of equipment

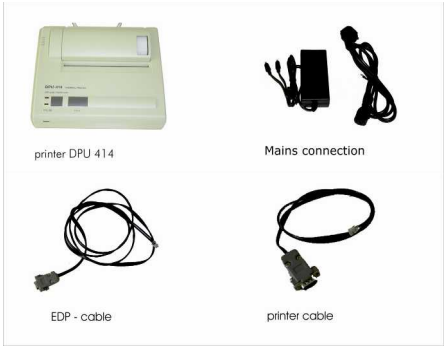



Fig. 3.7 Accessories

**Range:**

| Description | Number |
|---|---|
| SUPER GL compact | 1 |
| Sample cartridge | 1 |
| Mains cable | 1 |
| Power supply unit (PSU) for equipment and printer | 1 |
| Instructions for use | 1 |
| | |
| Optional | |
| Printer DPU 414 | 1 |
| Printer cable | 1 |
| EDP – cable | 1 |
| Other sample cartridges | |

## 3.5 Accessories

As described and illustrated above, the SUPER GL compact 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 compact 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 compact:

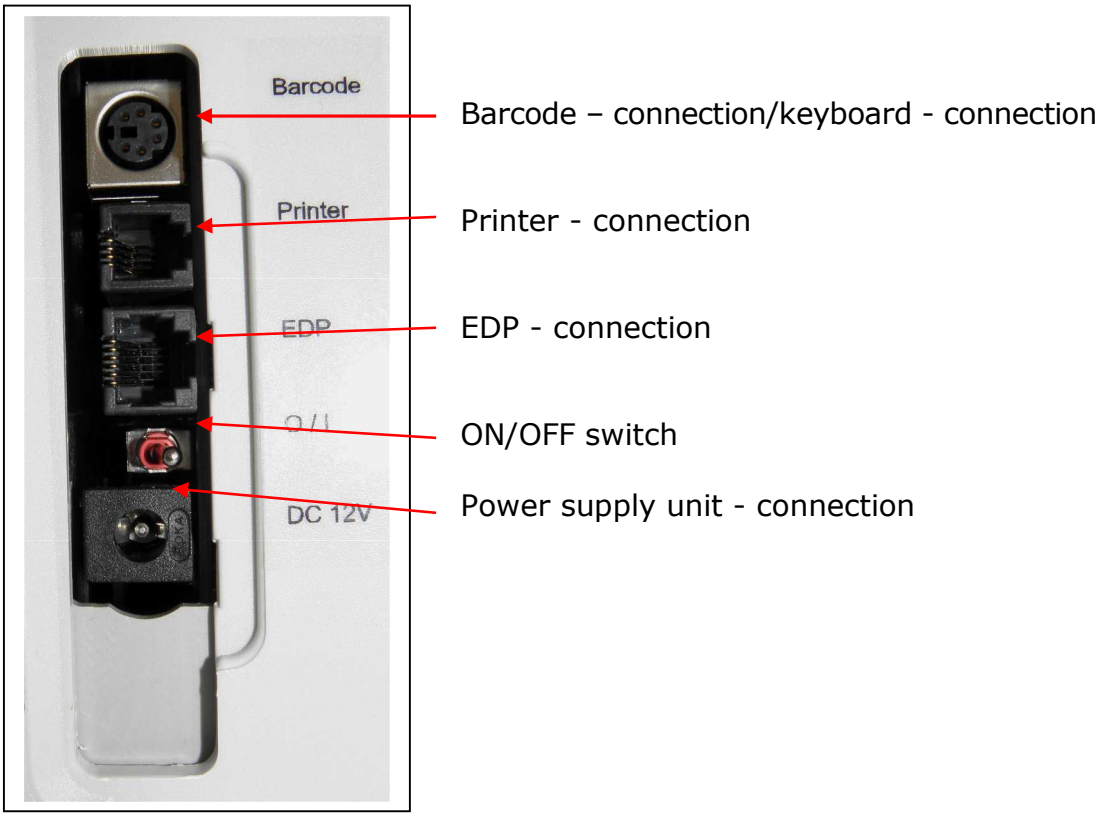



Fig. 4.1 View of connection wall

## 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. Installation of sensor (Section 6.3.4)
2. Connection of containerkit (Section 6.3.5)

Once these tasks have been completed the installation of the equipment is finished. The equipment is switched on by activating the switch.

After the equipment has been switched on, it will run in for the necessary time and will then be ready for work.

Subsequent operation of the SUPER GL compact is carried out by using the touch screen only (see picture below).

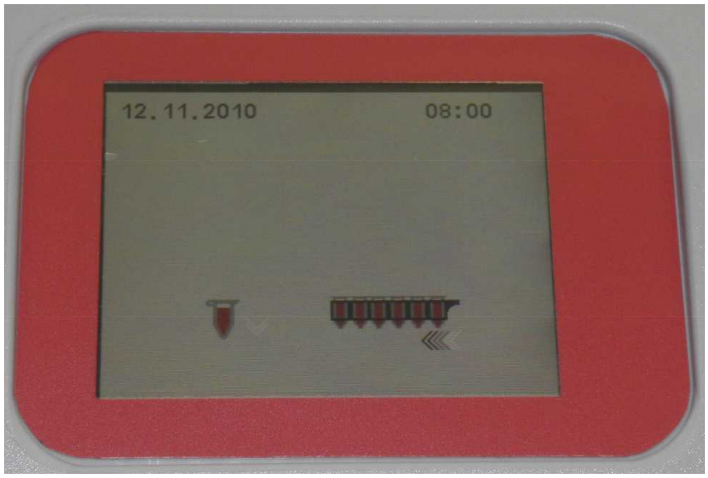



Fig. 4.2 View of touch screen

When using the touch screen, please note:

- Only a light touch is required on the screen
- Do not use any pointed or sharp objects
- Do not use any solvents for cleaning, apart from the planned solutions for disinfection

Leafing through the menu or adjusting the numbers is carried out by touching the relevant buttons. Note that dark underlined buttons describe the "off" or "inactive" state, while light underlined or blinking buttons show the "on" state.

When operating the SUPER GL compact note that there are menu points/functions which may be needed for daily work and those which are only used for servicing.

Functions which are needed on a daily basis can be called up without special passwords and can also be changed. However, the service functions are protected with a password known only to authorised staff who are the only ones entitled to use them.
Functions which are not available in the current configuration of the equipment are also not shown as buttons.

***NB: With unauthorised entry to protected fields the manufacturer cannot accept any liability for incorrect readings or defective equipment.***

The menu structure for the SUPER GL compact is shown on the next page. The manufacturer or your sales partner is available if you have any further questions.

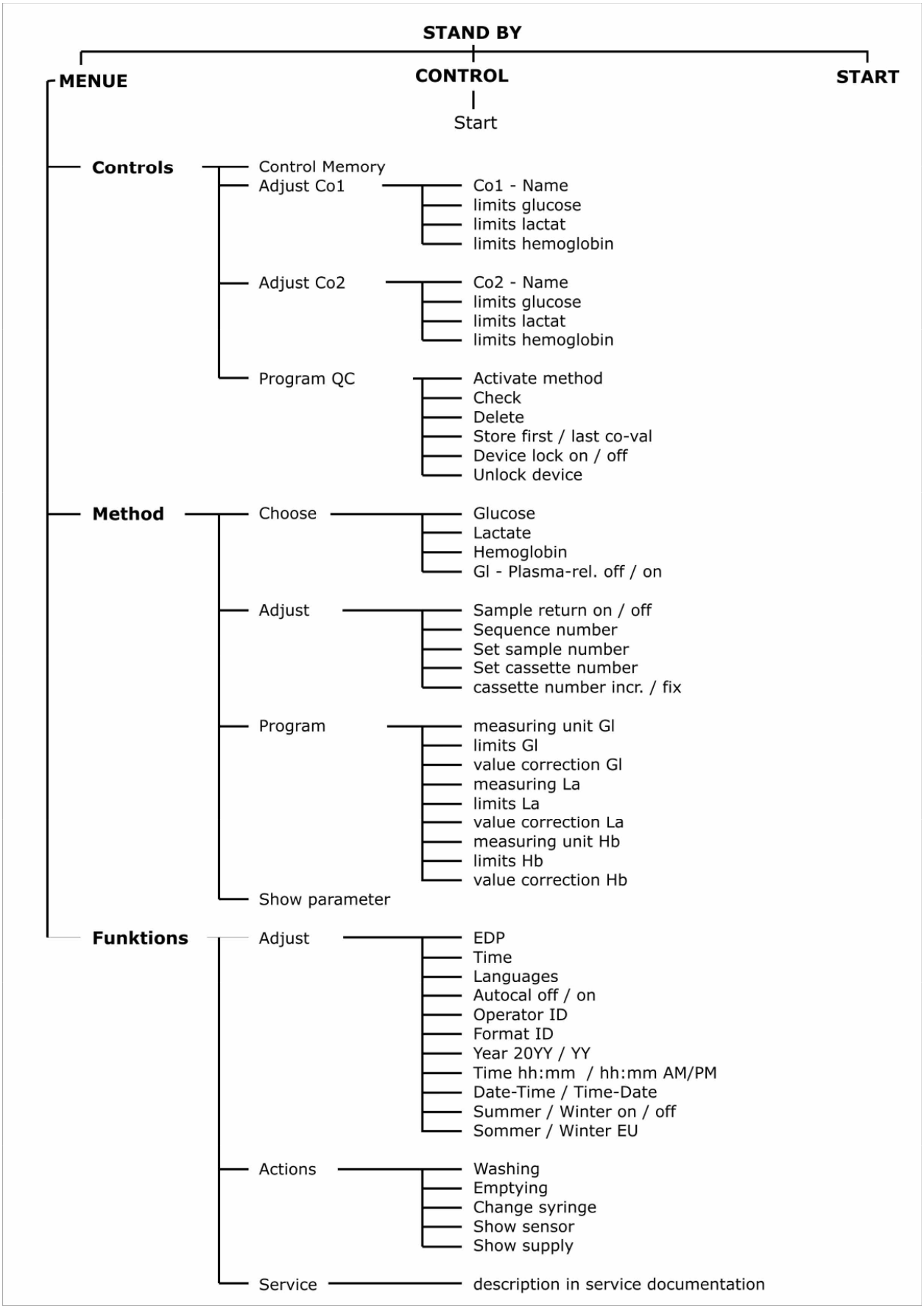



Fig. 4.3 Menu structure

## 4.5 Preparation of measuring process

### 4.5.1 General

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

For measurements on the SUPER GL compact 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 12the 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).

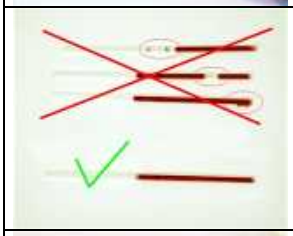
| | |
|---|---|
|  | Taking capillary blood from an earlobe or finger pad and filling the capillary tube to above both markings |
|  | Make sure you fill the tube correctly (sufficient quantity of blood, no air bubbles, no drops of blood on the end of the capillary tube, etc.) |
|  | Carefully wipe the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

Fig. 4.4 Sample preparation with open-end capillary

## 4.6 Measuring operation
### 4.6.1 Calibration

The SUPER GL compact requires valid calibration to ensure correct readings. An automatic calibration is therefore carried out before measurement for each variant of the measuring operation. After the first calibration, the calibration is checked and adjusted according to a prescribed schedule.
A choice can thus be made between "autocal in", i.e. calibration is performed in the prescribed schedule, and "autocal out", i.e. calibration is left out according to the prescribed schedule and calibrated automatically before the next measurement.

Before the first calibration or if the calibration cup is empty, the equipment requests the use of a new calibration cup.

***Even if the calibrator in a cup is not used up in a day's work, in the interests of the accuracy of the readings a new calibration cup should be used each day.***

Note that the calibration cups are not fully emptied and that a small residue remains in them. When the SUPER GL compact 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

With the SUPER GL compact it is possible to carry out measurements in two types of operation.

- Determination of individual or control samples
- Determination of a sample series

To start a sample series, proceed as follows:

- If a valid calibration is not available, a blue or green reaction cup is displayed on the touch screen with an arrow (empty position: downward arrow; loaded position: upward arrow). After insertion of a calibration cup the analyser carries out a calibration.
- After calibration has been carried out or if a valid calibration is available, a reaction cup for a blood sample and a cartridge symbol with appropriately positioned arrows and the last measured result are displayed on the touch screen.
- Load the cartridge with reaction cups. It is not necessary to begin with position 1 and positions can be left empty, as the analyser has automatic reaction cup recognition.
- Place the cartridge in the analyser. Measuring begins automatically. During series measuring it is not possible to scan individual samples or control samples.

To determine an individual sample, proceed as follows:

- If a valid calibration is not available, a blue or green reaction cup is displayed on the touch screen with an arrow (empty position: downward arrow; loaded position: upward arrow). After insertion of a calibration cup the analyser carries out a calibration.
- After calibration has been carried out or if a valid calibration is available, a reaction cup for a blood sample and a cartridge symbol with appropriately positioned arrows and the last measured result are displayed on the touch screen. Cartridges must not be positioned in the analyser.
- Place a sample in the sample position (red segment) on the plate. Measuring begins automatically.

To start a control sample series, proceed as follows:

- If a valid calibration is not available, a blue or green reaction cup is displayed on the touch screen with an arrow (empty position: downward arrow; loaded position: upward arrow). After insertion of a calibration cup the analyser carries out a calibration.
- After calibration has been carried out or if a valid calibration is available, a reaction cup for a blood sample and a cartridge symbol with appropriately positioned arrows and the last measured result are displayed on the touch screen. Cartridges must not be positioned in the analyser.
- For a control sample series only the occupied control positions are measured and no samples.
- The control measurement 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 measurement is started with another instruction using the touch screen. If this does not happen, the analyser reverts to the initial state.

**Explanations about the data memory:**

The data memory is designed as a ring memory. It stores the results of the last 100 readings. If it is full, the oldest value is deleted. The data memory can also be manually deleted.

The stored values can be

- looked at
- repeatedly sent to the EDP
- repeatedly printed
- deleted

The data memory is permanently available even though no reading is being carried out. The last result measured is displayed. There is an arrow on the right which indicates upwards. By clicking on this arrow the next oldest result is displayed. Two arrows are now displayed, up and down. By clicking on the printer symbol displayed below on the right, all results are printed out again from the sample displayed to the last measured value.

### 4.6.3 Controls

The SUPER GL compact has two control positions to meet quality assurance requirements.

To ensure effective quality assurance, the two control positions can be individually programmed. Control 1 is the position with the orange-coloured ring and control 2 is the position with the red ring. The following input options are programmable for the individual positions:

- Lower warning limit for glucose
- Upper warning limit for glucose
- Lower warning limit for lactate
- Upper warning limit for lactate
- Lower warning limit for hemoglobin
- Upper warning limit for hemoglobin
- Name of control

The stored values can be displayed for the control positions.
You can find further information on control administration in chapter 5.4.

### 4.6.4 Method

The following parameter variations can be measured with the SUPER GL compact (selectable buttons)

- Glucose
- Lactate*
- Hemoglobin
- Plasma glucose

When more than one method is selected the SUPER GL compact carries out the parameter combination automatically.

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

### 4.6.5 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 compact 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

* depending on sensor type

**The following settings are needed for the SUPER GL compact:**

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

## 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.

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

## 5.3 Programming

### 5.3.1 General

Programming the controls, calibration regime and printer settings has already been described in Chapter 4.
The following points mesh with the readings and their output and should therefore be performed by specialist staff only (where necessary after discussion with the servicing department).

### 5.3.2 Method

#### 5.3.2.1 Select

All three parameters (glucose/lactate/hemoglobin) are displayed as buttons. Each method can be switched on (i.e. the parameter is measured) or off (i.e. the parameter is not measured) by pressing the buttons. Please note: light button means "on", dark button means "off".
For glucose measurement you can also select whether the readings should be given as full blood values ("GL plasma" button off) or as plasma values ("GL plasma" button on).

#### 5.3.2.2 Adjust

The following settings can be made under this point:

- Repeat sample on/off
- Sequence number (1-999) or day sample number (begins with 1 each day)
- Reset sample number, sets the sample number to 1

#### 5.3.2.3 Programming

The following parameters can be programmed for each method under this point:

- Unit of measurement
- Sample warning limits (values found outside these limits are labelled or repeated)
- Reading correction (for adjusting the reading on a control station which measures using another method)
- Display parameters, the parameter list can also be printed out here

### 5.3.3 Functions

#### 5.3.3.1 Adjust

**EDP – interface parameters**

Allows configuration of the EDP interface. This should be done in accordance with specialist advice only.

**Time**

Time is given in the form HH:MM

**Dialogue language**

The currently planned dialogue languages are German, English, Czech and Russian. Other languages are possible on request.

**Autocal on/off**

Selects the calibration regime.
"Autocal on" means that after a set time regime calibrations or checks on calibrations are carried out independently of whether samples are to be measured or not. This regime is sensible if urgent samples are measured and time is critical. This regime has also proved reliable in doctors' practices.
"Autocal off" means that after the above time regime, calibrations lapse. In this case, a calibration is then repeated only if a sample or sample series is to be measured. If no measurements are performed for more than 6 hours, a calibration must be displayed by positioning a calibration cup. Make sure that calibration cups which have started are not used longer than 12 hours.

**Operator ID**

The operator number must be a maximum of 13 alphanumerical strokes. Options for this are as follows:
- ID active/ID inactive (activates operator ID administration)
- ID control/ID sample (ID query time: either only during control measurement or before each sample or series)
- ID scanner/ID keyboard (if a barcode scanner is connected, the entry is directly requested via the scanner, otherwise entry is performed via the touch keyboard)

**Date format**

Allows entry of different date formats, e.g. European, American, etc.

**Year format**

Allows a choice of year as two or four keystrokes.

**Time format**

Allows a choice of 24-hour or 12-hour format (am; pm).

**Date-time**

Allows choice of date and time sequence.

**Summer/Winter**

Allows switching on or off of automatic summer or winter time setting.

#### 5.3.3.2 Actions

**Rinsing the system**

Liquid is pumped through the system for a defined time with the aid of a pump and this is sucked in via the suction tube for the system solution. This may be system solution or even other solutions such as for disinfection. The latter ruins the sensor however.

**Emptying**

The system is emptied using the pump. It is a combination of rinsing and emptying. Follow the instructions on the display.

**Change dosing agent (see maintenance)**

Moves the dosing agent piston into a position where the change is possible.

**Indicate sensor**

Indicates the data currently programmed in the sensor. The display shows the maximum following data:

| | |
|---|---|
| Method | Method display (GLUC/LAC/HB) |
| Sensor number | XXXXXX |
| Lifespan | X (months) |
| Month of expiry | XX |
| Year of expiry | XX |
| Days remaining | XXX |

**Indicate reservoir**

The display shows the maximum following data:

| | |
|---|---|
| Stocks Super GL OK | |
| Beakers | xxxx |
| Samples | xxxxxx |
| Maintenance | xx.xx.xx |

#### 5.3.3.3 Function of operation card

Stocks of reaction cups are electronically stored on the operation card. The operation card therefore guarantees the use of the full system (device and consumable material) to ensure analysis quality.
The relevant operation card is enclosed with each package of pre-diluted reaction cups. During operation, the operation card must be inserted into the machine.

#### 5.3.3.4 Operation with barcode

An external barcode reader can be connected to the Super GL compact. The machine recognises when a barcode reader is connected and waits for a read process for each sample before measurement. The barcodes are assigned to the relevant sample positions during measurement.

If you want to use the barcode reader for sample identification, note the following instructions: The maximum length of a barcode is 12 keystrokes.

When operating the machine the symbols (reaction cup and sample cartridge) are appropriately labelled on the screen. Note that a red margin around the appropriate symbol indicates that a barcode has not yet been read and the machine can therefore not measure the sample. Conversely, a green margin around the relevant symbol means that at least one barcode has been measured and the machine is ready to measure the relevant sample or sample cartridge.

## 5.4. Controls

### 5.4.1. General

The SUPER GL compact has two control positions to meet quality assurance requirements.
To ensure effective quality assurance, the two control positions can be individually programmed. Control 1 is the position with the orange-coloured ring and control 2 is the position with the red ring.
The following input options are programmable for the individual positions:

- Lower warning limit for glucose
- Upper warning limit for glucose
- Lower warning limit for lactate
- Upper warning limit for lactate
- Lower warning limit for hemoglobin
- Upper warning limit for hemoglobin
- Name of control

The stored values can be displayed for the control positions.

### 5.4.2. Administration of control measurements according to RiliBÄK (only Germany)

#### 5.4.2.1 RiliBÄK requirements (only Germany)

The current version of RiliBÄK (Federal Medical Council guidelines on quality assurance of medical laboratory tests) can be found and downloaded at www.bundesaerztekammer.de.

#### 5.4.2.2 Programming QC

This point is reached via:

Stand by -> Menu -> Controls -> Programming QC

To access this menu point you need to enter a code. This code retrieval ensures against unauthorised use. If you do not know this code, please ask your sales partner or the manufacturer.

There are several menu items under this menu item to perform the following functions:

- Activate method
  - The quality control function for each of the three methods can be activated or deactivated here. This is done by pressing the relevant fields on the touch screen
- Check
  - This point displays how many values are already in the memory for all three methods and for controls 1 and 2. By pressing the relevant field the values for the selected controls are deleted.
- Delete
- Save first/last control
  Here you can choose whether the first or last control measured on the day in question is recorded in the statistics (retrospective evaluation of a control cycle).
- Machine lock off/on
  In accordance with RiliBÄK, it is prohibited to measure patient samples if there is no valid correctly calculated control reading available. When the machine lock is switched on, the machine automatically blocks patient readings. Whether this function is used is the decision of the person responsible, i.e. e.g. the physician, the laboratory manager or a member of staff specially authorised for this.
- Unlock device
  If there is a measured control value just outside the allowable area, the person responsible can still decide to measure more patients. It is a condition that this must not lead to erroneous diagnoses and that this value is entered into the statistics. This function was implemented in order to accomplish this. Whether to use this function is the decision of the person responsible, i.e. e.g. the physician, the laboratory manager or a member of staff specially authorised for this.

#### 5.4.2.3 Print the control evaluation

The sub-item control memory is in the control menu item. If this is selected, it can be displayed or deleted. On display there is a printer symbol on the touch screen which gives out the measured values (only the valid ones) and the mean value, rel. QMM and VK when activated.

The "Graphics" button for displaying the control values measured as a diagram and the "Co1/Co2" button for selecting the control are also on this screen and should be displayed.

# 6 Maintenance and troubleshooting

## 6.1 Introduction

This chapter tells you what you need to know about maintenance of the SUPER GL compact 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 compact needs servicing once a year by specialist staff assigned and authorised by the manufacturer. A warning will appear on the touch 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.

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 piston/cylinder system

To change the piston-cylinder system the following work should be carried out in the given order:

Select on the touch screen:
Menu -> Functions -> Actions -> Change dosage

Moves the dosing agent piston into a position where the change is possible.

- Switch off the analyser
- Open the machine door
- Switch off the piston-cylinder system from the valve block
- Take the piston-cylinder system out through the flaps and pull out
- Insert the piston-cylinder system in the reverse order
- Close the analyser door

### 6.3.3 Change the sample cannula and the rinse vessel

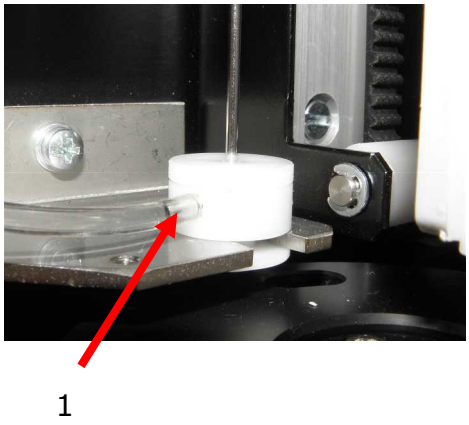



Fig. 6.1 View of rinsing cup

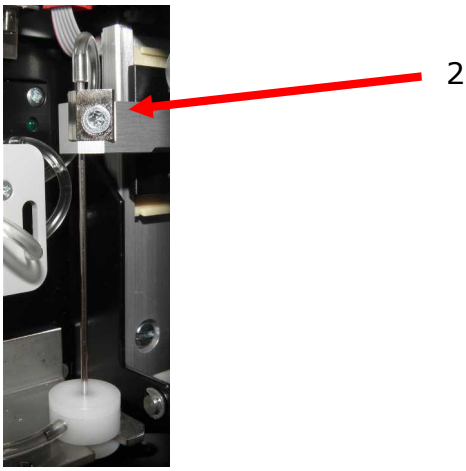



Fig. 6.2 View of sample canula

**Extension**

1. Switch off the analyser
2. Take the suction tube from the containerkit
3. Place the suction end at the level of the table in a small cup or on a little cellulose wadding (a little fluid will run out).
4. Pull off the tube (1)
5. Release the screw (2)
6. Remove the needle
7. Take the rinse vessel out of the holder

**Fitting**

1. Place the rinse cup into the holder
2. Insert the sample cannula
3. Attach the tube to the rinse cup
4. Place the suction tube in the containerkit

### 6.3.4. Change the sensor

**Removal of sensor**

1. Open the sensor housing by turning the fastener upwards

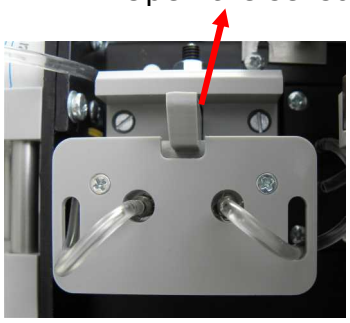


Fig. 6.3 Sensor opening closed

2. Removal of sensor

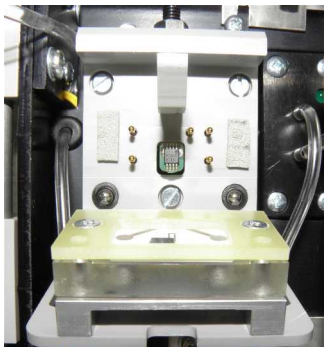


Fig. 6.4 sensor opening open

**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

### 6.3.5 Changing the containerkit

The SUPER GL compact 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.

***Never refill the containerkit!!***

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.

Fig. 6.5 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.***

### 6.3.6 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 – Functions – Actions – Rinsing.
2. Empty the system by taking the tube out of the containerkit and selecting "Empty" (Menu – Functions – Actions – Emptying).
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 is 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. When assessing patient samples, the set sample warning limits (see section 5) are decisive. For control samples, however, the set control limits are decisive (see section 5).
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

| | |
|---|---|
| Zero line unstable | - Chance occurrence -> repeat process<br>- Reagent changed -> select "Washing"<br>- Blockage in system -> rinse by hand<br>- Sensor defect -> change sensor<br>- Electronic error -> call service engineer |
| Calibration value too low | - Incorrect reaction cup used<br>- Sensor defect -> change sensor<br>- Electronic error -> call service engineer |
| Calibration drift too high | - Chance occurrence -> Recalibrate<br>- Big temperature change (draught) -> recalibrate<br>- Blockage in system -> rinse by hand<br>- Sensor defect -> change sensor<br>- Electronic error -> call service engineer |
| Sample error | - Blockage in system -> rinse by hand<br>- Connection tube sample needle – sensor very discoloured<br>- Sample canula out of adjustment (defective) |
| Sample cup empty | - The residual quantity left in the reaction cup was insufficient for a reading |

Fig. 6.6 Table of measurement errors

### 6.4.3 Equipment error

If the following errors occur, the user cannot intervene without the help of the service engineer. The announcements serve only to better describe the error for the service engineer.

**Type of fault**

**Communication error**

| | |
|---|---|
| ERROR (Name of assembly unit) | No action (no command receipt) |

**Handler does not send a command receipt**

| | |
|---|---|
| ERROR (Name of assembly unit) | Timeout |

**Analyser/photoelectric beam error**

| | |
|---|---|
| ERROR (Name of assembly unit) | Photoelectric beam does not open |

**Handler does not reach final position**

| | |
|---|---|
| ERROR (Name of assembly unit) | 3 attempts |
| ERROR (Name of assembly unit) | 3 attempts reference run |

**Communication problem between control computers**

| | |
|---|---|
| ERROR (Name of assembly unit) | Device not available |

**Erroneous parameters in the memory**

| | |
|---|---|
| ERROR (Name of assembly unit) | Parameter-Flash |

**Hardware and software are not compatible**

| | |
|---|---|
| ERROR (Name of assembly unit) | Hardware version |

**Plunger does not reach instructed final position**

| | |
|---|---|
| ERROR Plunger | Types of error in plain language |

**Error lifter**

| | |
|---|---|
| ERROR lifter | Cannot prick |

**Internal memory error**

| | |
|---|---|
| ERROR Fe-RAM 1 | (Error name) |

Other similarly stored error reports can occur which may be displayed according to the same pattern.

### 6.4.4 Measurement 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.
A special procedure was applied to the SUPER GL compact, which comes out with a minimum sample quantity. The tubes between cannula and sensor are crucial for the functioning of this regime. These tubes must therefore be replaced by original replacement parts only.
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.

**Testing for patency and tightness:**
Switch the analyser off and on again after about 2 seconds. This ensures that the piston pump is switched on. The sound of it will tell you whether the piston pump is working. Take the lid off the waste bottle and observe whether fluid escapes from time to time. If that is the case, there is no error in the flow system.
If no fluid drips off, the system is either leaking or blocked. In this case, proceed as follows:

Pull off the connection tube between the right sensor connection and the housing of the housing connection and place a suitable injection spray on the tube. Suck fluid out of the reservoir bottle with the syringe. Observe the fluid in the tube between the sample cannula and the sensor. The following phenomena may occur:

- The syringe is easily moved and there are a number of air bubbles or only air in the tube. In this case, the system is leaking. The best way to find the site of the leak is by noting the site where the air bubbles occur. Check all the connection sites and change the tubes and rinsing cup one after another if necessary.
- The syringe is very difficult to move and the liquid in the tube hardly moves at all. In this case, the system is blocked. Take the tube out of the reservoir bottle, loosen the fixing screw on the sample cannula and pull it out of the rinsing cup. Place the sample cannula in a glass beaker. Fill the syringe with distilled water or system solution and squeeze it out of the tube in the direction of the sample cannula. The liquid must flow out of the cannula. If this does not happen, clean the cannula with a cleaning wire and/or replace the sensor. The syringe can be moved against resistance but can still be moved evenly, so the fluid flows back and forth in the tube. In this case the error is inside the housing and must be repaired by the service engineer.

These simple measures allow most errors in the flow system to be eliminated. These errors can produce the following phenomena:

* depending on sensor type

**Scattered readings:**
May also be due to a sample that is not exaxt. 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"

# 7 Technical data

| | |
|---|---|
| Measuring time per sample | 45 sec. |
| | |
| Measurement range<br>Glucose<br>Lactate<br>Hb | <br>0.6 – 50 mmol/l (11 - 910 mg/dl)<br>0.5 – 30 mmol/l (4.5 - 270 mg/dl)<br>1.9 – 19 mmol/l (3.0g/dl - 30 mg/dl) |
| | |
| Sample quantity | 10 / 20 µl sample diluted with 500 / 1000 µl haemolysis solution |
| | |
| Precision (20 samples)<br>Glucose (216 mg/dl)<br>Lactate (90 mg/dl)<br>Hb | <br>< 1.5 % with 12.0 mmol/l<br>< 2.0 % with 10.0 mmol/l<br>< 1.5 % 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<br>Lactate, glucose/lactate 3 months |
| | |
| Interfaces<br>Printer<br>EDP<br>Barcode reader | <br>V 24, RS 232<br>V 24, RS 232<br>PS/2 |
| | |
| Work temperature | + 15°C to + 35°C |
| Storage temperature (without sensor) | - 10°C to + 50°C |
| | |
| Operating voltage | 12 V DC |
| | |
| Power consumption | Approximately 12 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 2.5 kg |
| | |
| Manufacturer | Dr. Müller Gerätebau GmbH<br>Burgker Str. 133<br>D-01705 Freital |

Fig. 7.1 Table Technical data