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Instruction Manual

SUPER ID clinchem

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Manufacturer / Copyright:

Dr. Müller Gerätebau GmbH Burgker Str. 133 D – 01705 Freital

Distributor:



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A) Table of contents:

2		Page	Rev.
Α	Table of contents	2	03
В	Table of figures	4	03
С	Table of symbols	5	03
1	Preface	6	02
1.1	Introduction	6	02
1.2	The SUPERID <i>clinchem</i>	6	02
1.2.1	Basics	7	03
1.2.2	Declaration of compliance	8	03
1.2.3	Device and accessories		04
1.2.4	Overview of functionality		03
1.3	Indication / Contraindication	10	03
1.4	Manufacturer's liability	10	03
1.5	Warranty		03
2	Safety	11	03
2.1	Introduction	11	02
2.2	Responsibility / Training the operator	11	02
2.3	General safety instructions	11	02
2.4	Product-specific safety instructions	12	03
2.5	Maintenance interval		04
3	Description of analyser	13	03
3.1	Introduction	13	03
3.2	Intended use	13	03
3.3	Measuring principle	13	02
3.4	Layout and view	15	03
3.5	Accessories	15	02
3.6	Consumption material	16	04
4	Operation - Part 1	17	02
4.1	Introduction	17	02
4.2	Safety instructions	17	02
4.3	Installing the device	18	02
4.4	Initial operation	19	02
4.5	Preparing the measuring process	21	03
4.5.1	ParamCard	21	04
4.5.2	Sample preparation	22	03
4.6	Measuring operation	24	03
4.7	Printer settings	25	03
4.8	Switching off the device		03

		Page	Rev.
5	Operation - Part 2	26	<u></u> 03
5.1	Introduction	26	03
5.2	Menu functions	26	03
5.3	Menu items	27	03
5.3.1	StandBy Measuring menu	27	<u></u> 03
5.3.1.1	Measure sample	27	03
5.3.1.2	Measure sample with bar code	27	<u></u> 03
5.3.2	StandBy function menu	27	<u>03</u>
5.3.2.1	Data of results will be showed	28	<u></u> 03
5.3.2.2	Data of results will be sended	28	<u></u> 03
5.3.2.3 <u>.</u>	Data of results erase	28	03
5.3.2.4	Read method	28	03
5.3.2.5	Delete method	28	<u></u> 03
5.3.2.6	Calibration	29	<u></u> 03
5.3.2.7	Washing	30	03
5.3.2.8	_Set time		<u></u> 03
5.4	Quality control	30	02
~			
6	Maintenance and troubleshooting	31	03
6.1	Introduction	31	03
6.2	Maintenance	31	03
6.3	Servicing	31	03
6.3.1	Cleaning and disinfection	31	03
6.3.2	Changing the washing solution	32	02
6.3.3	Switching off device	32	02
6.4	Troubleshooting	33	04
7	Technical data	35	02

B) Table of figures

		Page	Rev.
Overall view SUPER ID clinchom	Fig. 1.1	6	02
Declaration of compliance	Fig. 1.2	8	03
View device	Fig. 1.3	9	
Accessories	Fig. 1.4	9	03
Diagram device layout	Fig. 3.1	14	
Diagram photometer	Fig. 3.2	14	
View device	Fig. 3.3	15	<u></u> 03
Accessories	Fig. 3.4		04
Connections SUPER ID clinchom	Fig. 4.1	19	03
Program branches, overview	Fig. 4.2	20	<u></u> 03
Ready cassette	Fig. 4.3	21	<u></u> 03
Sample preparation using open-end capillary	Fig. 4.4	23	
Ready Rack for measuring	Fig. 4.5	24	03
Diagram menu areas	Fig. 5.1	26	03
List of error messages	Fig. 6.1	33	03
List of technical data	Fig. 7.1		

C) Table of symbols <u>Symbols on device</u>

Symbol	Description
	ENTER - key for selecting a menu item or changing the
	menu area
	MENU button for selecting menu items
 ↓	Follow instruction manual
IVD	In-vitro-Diagnostica
	Manufacturer
CE	CE Compliance
SN	serial number

Symbols on consumptions materials

Symbol	Description
IVD	Diagnostic use in vitro
CE	CE Compliance
\triangle	Note attached documents
Ĩ	Follow instruction manual
	Recyclable material
	Dispose according to regulations
X	Storage temperature
REF	Item number
Cont.	Contents of package
LOT	Batch number
\geq	Use before

Symbols in instruction manual

Symbol	Description
\triangle	Attention or Note
Bold/italics	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 ID** *elinchem* analyser. We hope you will find working with your analyser satisfying and successful.

In the following chapter "The SUPER ID clinchem" 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 ID clinchem

The **SUPER ID** *elinchem* analyser is a device for biochemical analysis in invitro diagnostics. Turbidimetric and color reactions can be measured.



Fig. 1.1 Overall view **SUPER ID** elinchem

1.2.1 Basics

The **SUPER ID** *elimehem* was designed using the latest technology along with decades of experience in the area of production of clinical-chemical analysers.

It fulfils all legal specifications with regard to design and production that are required of all devices used in clinical chemical laboratories. The compliance with the valid norms and statutes is documented through the visibly attached CE-Label. The CE-Label signifies compliance with all pertaining laws and regulations and consequently safety and confidence.

By employing an altogether newly developed technology for the determination of various blood parameters, it is possible to fulfill all requirements of quality assurance (e.g. RiliBäk (Guidelines of the Federal General Medical Council for Quality Assurance in Medical Laboratories)) in medical laboratories while maintaining easy handling and minimum operating effort. All users are thus able to achieve analysis results that meet the quality demands.

1.2.2 Declaration of compliance

EU - Declaration of Conformity



Dr. Müller Gerätebau GmbH Burgker Str. 133 D-01705 Freital



The device fulfils the requirements of the following EU-norms and guidelines. We do not guarantee the fulfilment of these norms and guidlines after unauthorized modification of the device.

name:

Analyzer
SUPER ID clinchem

following standards and guidlines

DIN EN 61326	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1 : general requirements.	2002-03
DIN EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	2002-08
DIN EN 61010-2- 081	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2- 081: Particular requirements for automatic and semi- automatic laboratory equipment and other purposes	2004-07
DIN EN 61010-2- 101	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2- 101: Particular requirements for in vitro diagnostics	2003-09
	(IVD)-medical equipment In-vitro-diagnostics	1998-10

The CE - mark was fixed to the device. Valid from SUPER ID clinchem Sn0041 Freital, 02.01.2008

Kalf Unithe

Company Manager Ralf Günther

Company Manager

Company Manager Martin Schäfer

Fig. 1.2 Declaration of compliance

1.2.3 Device and accessories

Deliverables:

Designation	<u>Quantity</u>
SUPER ID elinchem	1
Power connection cable	1
Power supply adapter for device and printer	1
Sample cartridge	1
Instruction manual	1
Optional	
Printer DPU 414	1
Printer cable	1
EDP cable	1
Bar code reader	1





Fig. 1.3 View device

Fig. 1.4 Accessories

1.2.4 Overview of functionality

The **SUPER ID** *clinchem* analyser was designed for measuring various parameters of human sample material. Because of its ability to determine the glucose and HbA1c value simultaneously, the analyser is especially suited for use in healthcare institutions with emphasis on diabetes. The device shows the measuring results on the built-in display and a connected printer and EDP.

The analyser also allows you to provide patient samples with a bar code and thus link it to the patient in the EDP.

For further information on measuring principle and sample taking, please refer to the appropriate chapters.

1.3 Indication / Contraindication

Indication:

The **SUPER ID** *clinchem* analyser is used for measuring various parameters of human sample material. Because of the ongoing advancement of reagents, it is not possible to give a complete list here. For further information contact the manufacturer or authorized distributor. Current information is always available at <u>www.glukose.de</u>.

For the selection of sample material, please refer to the packaging of the package inserts of the reagents. Use only these sample materials, else faulty measuring results may occur.

The **SUPER ID** *clincham* analyser must only be used and operated by trained personnel.

Contraindication:

Using unsuitable sample material can result in faulty measuring results. If in doubt, call the manufacturer!

Operating the device for home testing is expressly forbidden!

1.4 Manufacturer's liability

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

- gross negligence or willful damage of the device, parts thereof or consumption material
- unauthorized opening of the device by untrained personnel (without proper service training)
- force majeure (e.g. stroke of lightning, water damage, fire)
- nonobservance of user manual and package inserts

1.5 Warranty

For their products Dr. Müller Gerätebau GmbH gives a two-year warranty according to EU Directive 1999/44/EG starting with the day of purchase. Consumption material (because of shorter shelf-life) and parts subject to wear (they should be replaced on a biyearly basis) are expressly excluded from this warranty.

For further information on spare parts and consumption material, please refer to the appropriate chapter.

2 Safety 2.1 Introduction

The following chapters concern the safety of the person operating the device.

Read these chapters carefully **PRIOR** to starting up the device because they contain general safety warnings, warnings concerning the personal safety of the person operating the device, and warnings for the protection of the device.



Displaying the following safety warnings does not release the person operating the device from adhering to the safety measures of the facility.

2.2 **Responsibility / Training of the operator**

- The **SUPER ID** *clincham* analyser must only be used and operated by trained personnel. An employee of the manufacturer or of an authorized distributor will introduce the operation of the device.
- Every user is responsible for adhering to safety, health and legal regulations, and operating the device only according to its intended use.
- Interpreting the results and diagnosing on that basis must be left to a medical specialist. Operating the device for home testing is expressly forbidden.

2.3 General safety instructions

- Prior to operating the device, read the entire instruction manual especially the instructions for sample taking. If you have any questions, please contact the manufacturer or authorized distributor.
- Every person working with the device must be acquainted with the relevant safety rules prior to operating the device and these rules should be kept at hand all the time.
- Please pay attention to all general safety rules for laboratories such as wearing protective gloves, and the applicable disinfection and hygiene regulations.

- To avoid risk of electric shock, do not place the device or power supply in water or other liquids! If the cable or the power supply adapter is damaged in any way, you must not continue using the power supply. Never touch the plug of the power supply adapter with wet hands. The power supply adapter must only be used indoors and must be protected from humidity.

2.4 **Product-specific safety instructions**

- The device may only be used for the intended use with special attention to the defined usage restrictions and constraints that have to be strictly adhered to (if need be, contact the manufacturer).
- Operate the device only on smooth, horizontal surfaces. Avoid variations in temperature, drafts, direct sun light, and vibrations. These can result in faulty measuring values.
- In case of malfunctions, stop operating the device immediately! Prior to continuing to operate the device, read the notes concerning cleaning, error messages and troubleshooting. After consulting the manufacturer or authorized distributor you may ship the device for repairs to the manufacturer or authorized distributor.
- Use only original accessories and spare parts to avoid damage to device and people. Repairs must only be conducted by the manufacturer or by companies authorized by the manufacturer!
- The use of reagents and consumption materials that are not expressly recommended by the manufacturer can cause severe measuring errors and malfunctions and is therefore not permissible.
- If the user opens the device without authorization, the user shall not be entitled to any rights concerning the liability for the device and damages caused thereby.

2.5 Maintenance intervals

The **SUPER ID** *clincham* needs maintenance every two years by trained personnel.

Without regular maintenance, false measuring results can occur that are not the responsibility of the manufacturer.

For further information, please refer to the chapter Maintenance / Troubleshooting.

3 Description of analyser 3.1 Introduction

This chapter describes the analyser's measuring principle, layout, accessories and the consumption material.

This chapter will provide you with forward information. For detailed instructions and descriptions of the device, please refer to chapter Operation.

3.2 Intended use

The **SUPER ID** *elineham* analyser is a device for biochemical analysis in invitro diagnostics. The device must only be used and operated by trained personnel. Operating the device for home testing is expressly forbidden.

The sample material is taken out of a closed sample cup that is aligned in a sample cassette. The containers for the washing and waste solution – located on the back side of the device – are capped with marked stoppers including hose. Both containers must be replaced at the same time since they are adjusted to each other.

The device has the following features:

- Measurement of various parameters of human sample material (for an overview of the parameters, please contact the manufacturer or authorized distributor).
- Automatic recognition of parameters using a bar code
- Options:
 - Serial printer interface for thermal printer DPU 414
 - Serial RS 232 electronic data processing interface
 - Interface for PS2 keyboard or bar code reader

3.3 Measuring principle

The **SUPER ID** *elinchem* analyser uses a spectrophotometer with a wavelength range of 450 nm to 700 nm to collect data.

The photometer unit consists of a halogen lamp, an iris, the flow cell, and the detection unit. The whole photometer unit is tempered at 37°C and contains a flow thermostat to incubate the substance to be measured.

The change in absorption – caused by a chemical reaction of the sample with the reagents – detected by the detector corresponds to the change in concentration of the analyte.



Fig. 3.1 Diagram device layout

Using the pipette unit consisting of dispenser unit and sampler, the device is able to dispense and mix exact amounts of sample and reagent.



Fig. 3.2 Diagram photometer

All information the device requires for analysis are stored on the ParamCard. This card is included with every package of reagent cartridge. For further information, please refer to the chapter Operation.

3.4 Layout and view

<u>View</u>



Fig. 3.3 Overall view SUPERID clinchem

Fig. 3.4 Accessories

Deliverables:

Description	<u>Quantity</u>
SUPER ID elinchem	1
Power connection cable	1
Power supply adapter for device and printe	er 1
Sample cassette	1
Instruction manual	1
Optional accessories	
Printer DPU 414	1
Printer cable	1
EDP cable	1
Bar code reader (upon request)	1

3.5 Accessories

The **SUPER ID** *clincham* will be delivered with standard accessories as described and shown above. In addition, further optional accessories can be ordered. Both the manufacturer and the authorized distributors will gladly supply you with information about connecting interfaces.

3.6 Consumption material

To operate the analyser following consumption material is needed:

- Pre-filled sample cups with capillaries for taking blood
- Cartridge of used parameter with Paramcard and Cleaner (if necessary for parameter)
- Containerkit with washing solution

For detailed instructions on the use of these consumption materials, please refer to the chapter Operation of this manual.

4 Operation - Part 1

4.1 Introduction

In this part of the instruction manual, all information is included that is useful for the day-to-day operation of the device.

In part 2, all additional information is included that is important for understanding the functions, complementary functions and certain sources of possible problems.

The qualified personnel for the device must be familiar with both parts and must also have the medical knowledge to be able to interpret the acquired values correctly. Conclusions for a therapy may only be drawn by a medical specialist.

4.2 Safety instructions

As mentioned before, certain safety warnings must be heeded when operating the device to guarantee correct and faultless operation:

- The device must only be used for the described indication and must only be used and operated by trained personnel.
- Every user is responsible for adhering to safety, health and legal regulations, and operating the device only according to its intended use.
- Interpreting the results and diagnosing on that basis must be left to a medical practitioner. Operating the device for home testing is expressly forbidden.
- In daily operation, regular checks of the results should be made; if needed, an additional control measurement should be carried out.
- Do not switch off the device or disconnect it from the power supply while it is running. If this happens, malfunctions can occur the next time the device is switched on.
- If you suspect a malfunction or faulty measuring results, please inform the person responsible for the device immediately. If necessary, this person will contact the manufacturer or distributer to solve the problem.

4.3 Installing the device

Before start-up, check the supplied device and accessories for completeness referring to the list at 3.4. If anything is missing, please contact your supplier immediately.

Furthermore, please check all parts for intactness. Proper and safe operation is only guaranteed when using original parts and accessories. NEVER use damaged parts or parts from other manufacturers!

Place the device on a horizontal, smooth and dry surface. Please choose a location where the device is protected from direct sunlight and extreme variations in temperature since these can impair measuring results.

Connecting the device to the power supply:

Please make sure that the voltage noted on the power adapter is the same as the voltage of your power grid.

The device is connected to the power supply via the included power supply adapter. Connect the power supply cable to the power supply adapter. Plug one end of the power supply adapter into the power connector at the right side of the device and the other end into the socket.

Connecting the printer:

If you use the **SUPER ID** *clinehem* together with the printer DPU 414, the printer is supplied with power via the second connection of the line cord. The jack of the printer cable is inserted into the printer interface on the printer based of the printer deviced and the second connected based on the printer based of the printer cable is inserted into the printer interface on the printer based on the prin

right hand panel of the device's casing and connected to the corresponding interface on the back panel of the printer.

Connecting EDP (s. fig. 4.1):

Plug the EDP cable into the EDP-port at the right side of the device and connect the other end with your EDP. Please pay attention to the notes in the manual for interfaces and also to the notes from your EDP partner.

The following image shows the interfaces on the right hand panel of the casing of the **SUPERID** clinchem.



Fig. 4.1 Connections SUPERID elinehom

4.4 Initial operation

When the device was installed as described above, the Containerkit with washing solution must be connected to the device.

Proceed as follows:

- Hook the combined supply/waste bottle to the device's back panel.
 Please make sure that waste and supply hoses are connected correctly!
- Unscrew the purple lid of the container with the washing solution.
- Screw the caps on the hoses onto the washing solution's container (purple lid: supply, rubber stopper: waste)

After finishing these steps the installation of the device is completed. Switch on the device by switching the "ON/OFF" switch backwards.

After switching the device on, rinsing takes place and the thermostat heats up. When the thermostat has reached the proper temperature, the device carries out a self test and is then ready for use. <u>NOTE</u>: This can take up to 15 minutes! The **SUPER ID** *elineham* is operated using the MENU and ENTER buttons. This takes you through to the two main program branches: the Function menu and the Measuring menu (cf. Fig. 4.1)

The Measuring menu contains all functions that are directly needed for measuring. In the Function menu you'll find all functions that are not needed in daily operation. Switch between the two program branches by pressing ENTER, in StandBy mode only. The bottom line of the display shows the current menu.



Fig. 4.1 Main program branches

4.5 Preparing the measuring process4.5.1 ParamCard

The **SUPER ID** *clincham* uses predosed reagents. For each analysis a reagent cartridge bearing a bar code is needed. With this bar code, the device can recognize the reagent cartridge and assign it to the appropriate application and calibration data. The bar code also communicates the LOT information of the used reagents to the device.



Fig. 4.2 Reagent cartridge with bar code

The application, calibration and LOT data are stored on a parameter card, named "ParamCard", which is included with every reagent cartridge. With every LOT change, this included ParamCard must be read. If there is no LOT change, then the ParamCard must not be read.

Reading the ParamCard:

- 1. If the Measuring menu is active, insert ParamCard in slot in upper casing panel. If the Function menu is active, select menu item "Read method" by pressing the MENU button before you insert the card.
- 2. Confirm by pressing ENTER.
- 3. If the device reads the parameter first time, the device checks the measuring unit with you.
- 4. To change the measuring unit of one of the methods you have to erase all stored lots of this parameter in the memory of the methods, as described in 5.3.2.5 and then put the ParamCard of this mehod into the instrument again.
- 5. After the data from the ParamCard has been read, you can remove the card and return to the Measuring menu.

4.5.2 Sample preparation

Please observe the instructions on the package insert of the reagent cartridge concerning sample preparation!

The following notes complement the above notes and they are only valid if capillary blood is used as sample material:



When drawing a capillary blood sample, do not compress the tissue. Compressing the tissue leads to a dilution of the blood sample with intracellular fluid and can thus lead to faulty results. For taking a capillary blood sample use suitable lancets and, if necessary, circulation-enhancing measures (such as massaging the spot) to yield a sufficient sample amount.

On the following page, taking capillary blood using open-end capillaries is described and shown. Proceed likewise with an end-to-end capillary (this capillary hasn't to be broken).

	Taking capillary blood from the earlobe or the finger pad and filling the capillary over both markings.
	Make sure, it is properly filled (sufficient amount of blood, no air bubbles, no drops of blood at the end of the capillary etc.).
	Carefully wipe off the outer surface of the capillary.
	Break the capillary at the predetermined breaking point (predetermined breaking point is located in the middle between two markings).
	Insert the completely filled capillary into the pre- filled sample cup.
1 2 3 4 5 8 Clukosenesses non-the-the-the-the-the-the-the-the-the-the	Shake sample cup until the blood has completely left the capillary.

Fig. 4.4	Sample	preparation	using	open-end	capillary
5			J		

4.6 Measuring

The following steps require complete preparation of the device. This also implies that the appropriate ParamCards have been read. If this hasn't happened, yet, they must be read now.

To measure a patient sample, proceed as follows:

- 1. If necessary, select menu item "Measure sample" by pressing the MENU button in the Measuring menu.
- 2. Prepare sample according to chapter 4.5.2.
- 3. Insert the prepared sample into the first slot of the sample cassette.
- 4. Insert the reagent cartridge and the possibly necessary cleaner for the parameters to be measured into the sample cassette.



Fig. 4.5 Ready cassette

- 5. Insert the loaded sample cassette into the device.
- 6. The device reads the bar code on the reagent cartridge.
- 7. Now the selected parameters of the patient sample will be determined. The results are displayed and/or printed out on the printer and/or transferred to EDP. The sequence of output/transfer depends on the sequence of the reagent cartridges on the sample cassette.

Now another patient sample can be measured. Proceed as described in steps 2 to 6.

Note:

For some parameters the flow cell may require special cleaning. This is done with a cleaner that is supplied with the consumption material for each parameter. For further information, please refer to the package insert.

4.7 **Printer settings**

The intended printer DPU 414 has several interface options.

Follow these steps for setting / programming the printer for use with **SUPERID** *elineham*:

- 1. Keep the "on Line" button pressed whole switching on the printer. You will receive a print out of the current settings.
- 2. Press "On Line" again to reprogram the printer.
- 3. Press "On Line" for "ON" and "Feed" for "OFF"
- 4. Press "Feed" at the end of the programming to confirm.

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

The following settings are required for **SUPER ID** *elinchem*:

4.8 Switching off the device

The device may only be switched off when no more functions are being carried out. NEVER switch off the device while measuring or rinsing since then malfunctions can occur the next time the device is switched on.

If the device is switched off for a longer time period (e.g. during vacation), rinse and empty the device before switching it off. For further information, please contact Service.

5 Operation - Part 2

5.1 Introduction

This part of the instruction manual describes special functions and settings relevant to the user. Furthermore, it gives additional information about quality control, problems that can be solved by the user.

5.2 Menu functions

As described in chapter 4, there are two main program branches: the Measuring menu and the Function menu.

The Measuring menu contains all functions that are directly needed for measuring. The Function menu contains all data management and setup functions. Switch between the two main program branches by pressing ENTER, in StandBy mode only.

The Measuring menu is immediately ready for use after the start-up period. It can be browsed by pressing the Menu button repeatedly. If you need the Function menu, switch to StandBy mode and select the Function menu.



The menu branches show the following menu items:

Fig. 5.1 Diagram menu areas

5.3 Menu items

5.3.1 StandBy Measuring menu

In this operating mode the device does not carry out any functions. However, it is possible to switch into the Function menu.

5.3.1.1 Measure sample

The device is ready for measuring. As soon as a sample cassette is inserted, the measuring process begins as described in chapter 4.

After the sample has been measured, the results are displayed and optionally output to a connected printer and/or to an electronic data processing system.

The results of the last sample can be displayed repeatedly by pressing ENTER.

5.3.1.2 Measure sample with bar code

This menu item is only available if a bar code reader or a PS2 keyboard is connected. The **SUPER ID** comechant automatically recognizes a supported bar code reader. For further information, please contact the manufacturer or distributor.

Instead of a bar code reader, a PS2 keyboard can be connected. In this case, digits and/or letters can be entered manually to identify a sample (up to 16 characters).

For measuring a sample with bar code identification use following steps:

- 1. Choose menu "Bar code ID" by pressing the menu-key in the measurement menu.
- 2. By pressing the enter-key the device reads the bar code. If you are using a PS2 keyboard you have to quit your input by pressing the enter-key at the keyboard. You can abort the input of the bar code by pressing the enter-key at the device.
- 3. Now you could measure the sample as written in 4.6.

The read sample identification will be printed out at display, printer and EDP.

5.3.2 StandBy function menu

In this operating mode the device does not carry out any functions. However, it is possible to switch into the Measuring menu.

5.3.2.1 Data of results will be showed

Here you can view the results of the last 50 measurements. The value measured last is displayed first; by pressing "Menu" repeatedly the value before that is displayed and so on. The first row displays either date and time of the measurement or the sample identification entered and the second row shows the measured result.

By pressing ENTER again, the display disappears and you return to the menu item "Display result memory".

5.3.2.2 Data of results will be sended

Selecting this menu item and pressing ENTER output 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?".

5.3.2.3 Data of results erase

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".

5.3.2.4 Read method

The ParamCard's functionality and handling were described in chapter 4.5.1.

5.3.2.5 Delete method

In this menu item the whole memory of methods could be clear for each parameter. This could be necessary if the memory is full or single parameters won't be needed anymore.

To clear parameter use following steps:

- 1. Choose menu bar "Delete method" by pressing menu key in function menue.
- 2. If you want to delete the whole memory, please answer the prompt "Delete all" with "YES". Function ends now.
- 3. If you chose "NO" in step 2 all parameters in memory will be shown one after the other. By choosing "YES" the shown parameter will be deleted. By pressing "NO" the next parameter will be shown.

5.3.2.6 Calibration

Although the ParamCard stored calibration data, possibly it is necessary to recalibrate the device.

Possibly reasons for a recalibration could be:

- expiry of calibration at the ParamCard
- changing of quantity of reagents during working time

For recalibration of the device the device needs up to five codes which has 8 figures. Please ask your distributor.

For recalibrate the device use following steps:

- 1. Choose menu "Calibration" by pressing the menu-key in the function menu.
- 2. Confirm the menu item by pressing the enter-key.
- 3. Choose the parameter which should be recalibrated by pressing the menu-key and the enter-key.
- 4. Enter the recalibration code digit by digit. By pressing the menu-key you enter the number, by pressing the enter-key you switch to the next figure.
- 5. If you entered all 8 figures the device checks this code.
- 6. A wrong code will not processed.
- 7. The device asks, if you have finished entering recalibration codes. If you have to enter more codes, choose NO by pressing the menue key and enter the next code (see 4.). If you entered all codes, choose YES by pressing the enter key.
- 8. Enter the security code (3 figures) you get with the recalibration codes.
- 9. After you entered the security code you can check them again. If the security code is ok, choose YES by pressing the enter key, otherwise choose NO by pressing the menue key for entering the security code again (see step 8).
- 10. If the security code was entered correct, the recalibration was now successful. If the security code was wrong or you entered not all recalibration codes, the calibration is blocked. The measurement of this LOT is possible not before you entered the codes again on the right way or you read the ParamCard again.

By inserting the ParamCard again the recalibration will be reased.

5.3.2.7 Washing

The top line of the display shows "Washing"; the bottom line shows yes/no next to the buttons. After pressing "YES" the system will be washed. If you want to empty the whole system remove the hose from the supply of the containerkit and chose the menue item by pressing ENTER.

5.3.2.8 Set time

After pressing ENTER, the first row of the display shows the current time of the device. The second row displays "OK" below the ENTER button and "SET" below the MENU button. 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.

5.4 Quality Control

For the required quality control observe the national laws and regulations.

In Germany these regulations can be found in the guidelines of the German Medical Association. For further information, please refer to <u>www.bundesaerztekammer.de</u>.

6 Maintenance and troubleshooting6.1 Introduction

This chapter gives information on maintenance of the **SUPER ID** *clinchem* and about problems that may occur and how you might be able to solve them yourself.

If you are unsure about certain aspects, DO NOT try anything you might think appropriate without qualified technical help. DO NOT open the device without an authorized service technician*! Please contact our service hotline free of charge!

6.2 Maintenance

Biyearly the **SUPER ID** *elinchem* must be serviced by manufacturer-authorized and trained personnel*. Please contact the manufacturer or distributor immediately to make an appointment for service.

6.3 Servicing

The following operations can and should be carried out by the operator. These actions are part of diligent care and serve to enhance the device's life span. They are NOT maintenance or service work, these may only be carried out by authorized service personnel^{*}!

6.3.1 Cleaning and disinfection

Please adhere to the regulations valid in your laboratory with regard to cleaning and disinfecting the device. For disinfection wipe the entire accessible surface of the device with a cloth containing disinfectant. Use a disinfectant for surface disinfection! Also note the instructions of the manufacturer of the disinfectant.

6.3.2 Changing the Containerkit

A combination of system solution / waste container made specifically for the **Super ID** comehon can be attached to the device's back side. The sizes are such that the waste container is full when the system solution is used up. The device monitors the system solution but not the waste container.

<u>Note:</u> Do not use other than the prescribed bottles since this can result in malfunctions.

6.3.3 Switching off device

To switch off the device for a longer period of time or for transport, proceed as follows:

- 1. Rinse the device according to 5.3.1.7.
- 2. Empty the system by removing the hose from the supply bottle and repeating the rinsing (see chapter 5.3.1.7).
- 3. Switch off the device and disconnect.

Disposing of the device:

For the disposal of devices please ask your distributor.

6.4 Troubleshooting

Error message	Meaning	Action
Containerkit has to change	The system solution in the supply bottle is empty.	Replace the bottle and empty the waste bottle. Confirm by pressing ENTER.
Cleaner has to change	Not enough Cleaner in the cup for next measuring.	Insert a new cup with cleaner into the rack and insert the rack into the device again.
Result "———"	The result is lower than lower limit of the measurement range!	Check, if the result can be plausible! If it isn't plausible, rerun the sample! The sample was putted on the right position of the slider? The right sample cup is used? (Check, if the color of the sample cup corresponds with the packaging insert!) The right container kit is used? (Check the color of the closure cap!)
Result "++++"	The result is higher than upper limit of the measurement range!	Check, if the result can be plausible! If it isnt plausible, rerun the sample!
Failure reagent	The measurement is disturbed	Check, if the reagent cartridge was used for a second time.Rerun the sample!

Expiry XXX XX/XX	The storage time for the used reagent cartridge will be over in a few days.	Order reagents with a younger LOT. Please Note: Although this error message the device measures the sample.
XXX XX/XX expired!	The storage time of used reagent cartridge is over.	Use a reagent cartridge of a younger LOT.
Calibration XXX XX/XX expired!	Calibration data at ParamCard are expired.	Recalibrate the device!
Expiry calibration XXX XX/XX	Calibration data at ParamCard will be expired in a few days.	Recalibrate the device. Please Note: Although this error message the device measures the sample.
Calibration invalid!	The recalibration wasn't successful!.	Repeat the recalibration or read the ParamCard!
Method XXX LOT XX isn't stored	There is no application stored for the bar code read on this reagent cartridge.	Read ParamCard of this reagent cartridge.

Card error VX	The version of the ParamCard isn't compatible with the Softwareversion of the device.	Contact your distributor!
Card error XX	The device can't read the card!	Check if the card is inserted correctly! (The chip has to show to the backside of the device!) Call service!
Error dilutor	The dispenser unit cannot reach its position.	Switch off the device. Call service!
Error Spectro	The spectrometer unit doesn't deliver data.	Switch off the device. Call Service!
Photometer instable!	No stable measurement possible!	Switch off the device and turn it on again! If the error occurs again call service!
Failure Cassette	The sample cassette cannot reach its position.	Switch off the device. If the sample cassette is blocked mechanically, call Service!
Failure lifter	The sampler cannot move to its position.	Switch off the device. Call Service!
Failure T-Sens	The thermostat doesn't get the set temperature of 37°C or the temperature tops 37°C.	Switch off the device. Call Service!

Fig. 6.1 List of error messages



If in doubt or if you have any questions, please call our service hotline! Our technicians are at your disposal to help you solve your issues to your satisfaction! Unauthorized opening of the device automatically forfeits your warranty claim!

7 Technical data

Measuring time per sample	Depending on selected parameter Information on package insert
Measuring range	0-2 absorption units
Amount of sample material	Depending on selected parameter Information on package insert
Interfaces	
Printer	V24, RS 232
EDP	V24, RS 232
Operating temperature (during measuring no great variations in temperature allowed!)	+15°C to +30°C
	1000 10 15000
system)	-10°C to +50°C
Voltage	12 V DC
Power consumption	12 W maximum
Classification according to MPG	In vitro diagnostic (according to guideline 98/79/EC)
Dimensions	
Width	200 mm
Height	150 mm
Depth	170 mm
Woight	
weight	арргох. 4 кд
Manufacturer	Dr. Müller Gerätebau GmbH Burgker Str. 133 01705 Freital

Fig. 7.1 List of Technical data

The technical data for the various determination methods can be found on the corresponding package inserts.