Information and Operating Instructions

for the

CORNEOMETER CM 825®

CK

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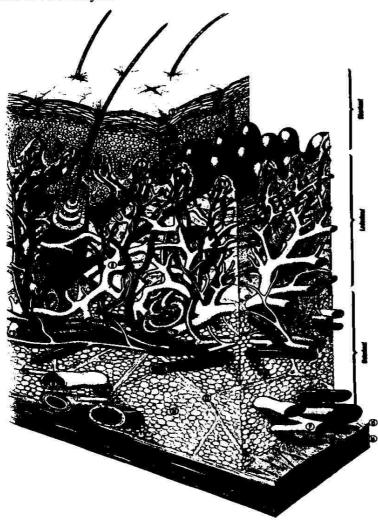
PART I - INFORMATION

1. Information on the Skin

Our skin is more than just a living coat, it is a real multi talent. The skin is responsible for many vital functions. It shields the organism from the environment and is in direct contact with it at the same time. The skin receives warmth and cold as well as the feeling of well-being and pain. Like a chemical plant it processes drugs and poisons and produces enzymes and hormones. It offers protection against bumps, pressure and friction. Its natural acidic barrier prevents germs from intruding. In a word, our skin performs extraordinary work around the clock. Therefore it deserves special attention, in particular if some of its functions are disturbed.

1.1 The Structure of the Skin

Human skin consists of three layers. Each layer has particular tasks, but works in harmony with the next layer.



- 1. Epidermis
- 2. Dermal rete ridge
- 3. Hair bulb
- 4. Sebaceous gland
- 5. Dermal papillae
- 6. Artery
- 7. Vein
- 8. Lymphatic vessel
- 9. Nerve
- 10. Pacinian corpuscle
- 11. Meissner's corpuscle
- 12. Pore of a sweat gland
- 13. Collagen fibers
- 14. Subcutaneous fatty tissue
- 15. Muscular membrane
- 16. Muscle

Geo, 1/1988

• The Epidermis

The Epidermis is the outer layer of our body and therefore in close contact with the environment. It is relatively thin and meshes with the next layer, the Dermis, by its indented profile.

The Epidermis itself consists of different layers. The Stratum germinativum steadily renews the skin and is responsible for the production of melanin (tanning). Cells continuously generate in this layer dividing and multiplying themselves. These newly formed cells move to the outside where they form the Stratum corneum as horny disks. This process takes 4 weeks in healthy skin. Due to this process cells are transformed into keratin, become flatter and flatter and eventually die. They are then released from the surface singly or as small scales to make room for new cells.

• The Dermis

The Dermis is responsible for the elastic properties of the skin. Collagen and elastic fibers stabilize the skin and prevent it from being torn. The sensory cells are also located in this layer. All sensations (pain, itching, temperature etc.) are transferred from the receptors via nerves to the brain as electric impulses. The high content of chondoitin and hyaluronic acid provides a liquid depot which nourishes the epidermal cells.

• The Subcutis

This is the bottom layer of the skin. It contains fat cells as well as nutrients, blood-vessels, sebaceous glands, sweat glands and arrector pili muscles for the hairs. It therefore serves as a depot and as protection against bumps. Normally the fat cells are the main component. Their volume, the thickness of the layer and the arrangement of the cells is constitutionally and hormonally regulated. The subcutaneous fat cells are very rare on the nose, the eyelids and the outer ear only.

1.2 The Moisture Content of the Stratum Corneum

An important parameter of the skin is the hydrolipidic film, which consists of sebum excreted by the sebaceous glands and moisture components excreted with the sweat. This emulsion protects the skin from drying out, keeps it supple and due to the natural acid protection barrier it prevents the penetration of harmful external substances (e. g. germs).

Any disorder of the hydrolipidic film causes problems from skin irritations to skin diseases. Even cleansing of the skin disturbs the balance of the hydrolipidic film. In healthy skin this is not alarming as the sebaceous glands begin to work instantly. Within two hours the hydrolipidic film is restored completely.

The composition of the hydrolipidic film varies and is depending on different parameters. Most important for the moisture balance of the skin is the horny layer (stratum corneum). The beneath lying living layers are almost constantly hydrated.

1.3 Field of Application of Moisture Measurements

The moisture content of the skin surface is one of the most important parameters to evaluate the barrier function of the skin.

The more balanced the hydrolipidic film the higher the water content. Only a sufficiently hydrated skin can function fully.

Therefore dermatology is very interested in balancing the hydrolipidic film.

Typical fields of application are allergy tests, occupational medicine (bakers, hairdressers, etc. - contact dermatitis), control of healing processes of skin damage and burns.

Skin barrier function damage can be detected at an early stage by the use of moisture

measurements.

In efficacy testing of cosmetic and pharmaceutical products and raw material moisture measurements also play an established role, especially in regard the 6th Amendment to the EU Cosmetic Directive on claim supports.

In food and packaging industry measurements of moisture are used for quality control purposes.

1.4 Influences on the Moisture Content

Many studies exist about the effects on moisture of the skin. Please note especially Rogiers et al.: "Standardized Conditions needed for Skin Surface Hydration Measurements" in Cosmetics & Toiletries 105, 1990, p. 73-82 and Courage: "Hardware and Measuring Principle: Corneometer" in Bioengineering of the Skin: Water and the Stratum Corneum, edited by Elsner et al. 1994.

1.4.1 Skin's Physiological Influences

The temperature regulation mechanism of the body influences the moisture content. The temperature of the human body is higher than the environment's temperature. The body balances this difference by evaporating water. Under normal climatic conditions (20° C, 40 - 60 % air humidity) the temperature regulation is mainly done by evaporation.

Water is the main substance of the body. A newborn's water content is approx. 75 %, that of an adult approx. 50 - 60 % of their weight. The water balance of the body therefore plays an important role.

The daily average water need of an adult is approx. 2.4 l. The water is mainly excreted through urethras, by breathing out vapor and through the skin. The water balance is indispensable for the barrier coat of the epidermis.

The measured **body site** also influences the moisture value, especially due to the thickness of the skin and the activity of the sweat glands. On the forehead and on the palms of the hands the moisture content is very high. On the arm only a few centimeters away from the hands, the skin is mostly very dry.

The moisture content also depends on the age. A child's skin moisture is very low, that of an adult (between the age of 20-40 years) reaches its maximum, while a senior's skin's moisture content becomes lower again due to the decreasing storage capacity of the stratum corneum.

Allow your test persons to rest for at least 10-20 min., so that their blood circulation can regain a normal level after possible **physical exercise**. **Emotional stress** may also lead to increased transpiration.

1.4.2 Environmental Effects

Direct light can warm up the skin and may cause higher transpiration. Therefore try to prevent measuring under direct light.

The higher the air humidity and the room temperature are, the higher is the skin's moisture level. Ideal measuring conditions are approx. 20° C and approx. 50 % air humidity. Therefore

also season and climate influence the moisture measurement. Because of the low air humidity in winter time, the water content of the hydrolipidic film is also low. Additional strain by often washing the skin, may lead to extreme dehydration of the skin. In summer time transpiration is higher, but due to the increased air humidity less water can evaporate from the skin and the stratum corneum is more hydrated.

The life style of a person, the food, the regular consumption of nicotine and alcohol, and the use of pharmaceutical and cosmetic products influence the moisture content of the skin. For cosmetic products, e. g. for testing purpose also the type of emulsion plays a role. W/o emulsions provide more moisture to the skin than o/w emulsions. Please wait at least 30 min. after the application of a product before starting the moisture measurements in order to prevent the measurement of the evaporation of the product.

2. The Moisture Measurement

2.1 Survey of the Most Important Measuring Principles

Infrared Spectrography

The dermal absorption of infrared waves, which depends on the water content of the skin, is measured and thus the moisture content is determined.

Resonance Frequency Measurements

This measuring principle measures moisture by the transmission of waves. The measurement depends on the elasticity of the skin.

Nuclear Magnetic Resonance Measurement (NMR)

This measuring method determines the proton density and their volume concentration, which indirectly determines also the moisture content.

Very similar to this principle is the Magnetic Resonance Imaging (MRI).

Desquamation

The dead cells of the horny layer leave the stratum corneum in single parts or in scales to provide space for the new cells. The dryer the horny layer is the more scales can be found. Measurements of the desquamation therefore tell about the moisture content of the stratum corneum.

Impedance Measurements

An indirect measurement of the skin hydration is done by measuring its electrical resistance.

2.2 Measuring Principle of the CORNEOMETER CM 825®

With the CORNEOMETER CM 825[®] the most modern scientific analyzing instrument for skin moisture is at your disposal.

It not only works quickly and precisely but due to the latest electronic technique it is also very reproducible.

The measurement of the skin moisture is based on the worldwide acknowledged CORNEOMETER® -method, a capacitance method.

This measurement is based on the completely different dielectric constant of water (81) and other substances (mostly < 7). The measuring capacitor shows changes of capacitance according to the moisture content of the samples. A glass lamina separates the metallic tracks (gold) in the probe head from the skin in order to prevent current conduction in the sample. An electric scatter field penetrates the skin during the measurement and the dielectricity is determined. One track builds up a surplus of electrons (minus charge) the other a lack of electrons (plus charge). An electric field between the tracks with alternating attraction

develops. During the measurement the scatterfield penetrates the very first layer of the skin and determines the dielectricity.

On the contrary to the impedance measurement no galvanic relation between the device and the measuring object or polarization effects exist.

2.3 Advantages of the CORNEOMETER CM 825®

- 1. On the contrary to the impedance measurement with the capacitance measurement there is no influence of chemical substances or salts of products which are applied to the skin.
- 2. The penetration depth of the electric scatter field is demonstrably very small, so that only the moisture on the skin surface is measured. Measurements before and after covering a measuring area with a special foil (15 μ thickness) show that on the foil only 20 % of the original value are measured.
- 3. The latest new probe electronics provide temperature stability of the probe.
- 4. The very short measuring time (1 sec. with single measurements) prevents occlusion effects which influence the result.
- 5. Influences of the ground capacity on the measurement have been excluded.
- 6. Changes in power supply do not influence the measurement.
- 7. Constant but low pressure of the probe head provides exact, reproducible measurements, which do not influence the skin.
- 8. With the CORNEOMETER CM 825® it is possible for the first time to check the calibration values of the device as well as the penetration depth of the scatter field.

Additional advantages of the CORNEOMETER CM 825®

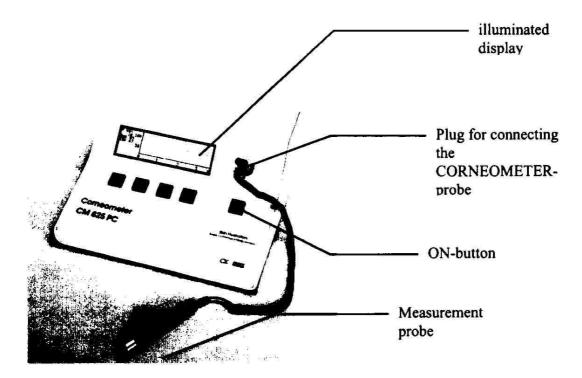
- Four different measurement modes are at your disposal: (single measurement, continuous measurement with and without direct contact to the skin). The continuous measurement with direct contact to the skin measures the occlusion of the skin. The continuous measurement without direct contact to the skin (chamber) does not determine the moisture content of the stratum corneum but the transpiration of the skin. This is not identical to the measurement of the transepidermal waterloss because of the uncontrolled environmental temperature and because the measurement takes place in a closed chamber. An important application for this kind of measurement is, for example, to find out if test persons sweat before a panel study, because sweat has great influence on the moisture measurement and will lead to undesired results.
- The keys on the device allow quick and easy handling.
- The curves and measuring values are shown on a big illuminated display.
- In contrast to the previous instrument, the CORNEOMETER CM 820[®], the probe of the CORNEOMETER CM 825[®] can be plugged out. In its plug all calibration data of the probe are stored. This makes changing of the probe for service purpose easily possible.
- The low weight of the probe allows easy handling.
- With the small measuring head even measurements on very small body sites (e. g. lips, ears, etc.) can be realized.
- The new software for Windows® helps in all fields of application and shows you all different curves at once on request. All data can be stored, printed out and exported for statistical use (e. g. Microsoft Excel®).
- Our special service takes care that, in case of repair, your device will be sent back as soon
 as possible. If this is not possible you will receive an exchange unit.

PART II - OPERATING INSTRUCTIONS

1. Delivery Content

The following accessories are delivered with the CORNEOMETER CM 825[®]:

- CORNEOMETER CM 825®-probe
- Chamber
- · Power cable
- Check Calibration Set
- Software for Windows® + PC connection cable and adapter
- Instruction Manual



2. Set Up and Special Advice

2.1 Set Up

The CORNEOMETER CM 825® is very easy to operate.

Plug the power cable into the socket at the back of the machine. Now, the instrument can be mains-operated (230V). Before, please check if the rated voltage marked at the back of the housing corresponds to your mains voltage.

Plug the probe plug tightly into the socket on the front of the instrument. Remove the black protection cap from the probe head.

Switch on the machine by pressing the ON-button. The machine is ready for operation.

Should the display on the screen be illegible, turn the contrast button at the back of the machine until the display is sharp.

Pressing the ON-button during operation of the machine, the CORNEOMETER CM 825® switches off.

Exception: Should the machine be in the calibration mode, go back to any other function (button 1, 2, 3 or 4) before switching off the machine.

In case the machine is not operated for a longer period of time (several weeks), it is recommended to plug out the power cable.

2.2 Symbols



Please see operating instructions



Attention: Dangerous electrical voltage



Protective earth

(Protection class I device with earth connection)

2.3 Safety Advice

To work with the device, please see also the advice in the chapter "maintenance of the device".

3. Operation Advice

3.1 Proper Application

The probe is meant for measurements on undamaged skin.

3.2 Operation of the Probe

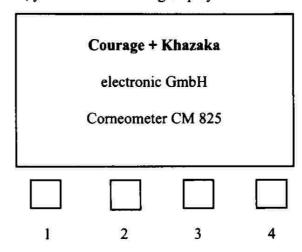
The CORNEOMETER CM 825[®] is a highly sensitive measurement instrument. For exact and reproducible measurement values it is important to follow the following instructions:

- Never hit the probe against any hard material. The glass cover of the probe head could be damaged. Do not strain and bend the cable too much.
- For all measurements of skin parameters it is important to keep constant ambient conditions. Temperature and relative humidity should be constant. This is indispensable for comparison of long-term measurements. The optimum room conditions are 20 C° and 40 - 60% relative humidity (s. page 8).
- Do not measure under direct lamp light or direct sunlight. Heat radiation might cause
 measurement inaccuracies. In case of series tests, always measure at the same time of the
 day and with the same light conditions.
- Allow your test persons to rest for at least 10-20 min., so that their blood circulation can regain a normal level after possible physical exercise. Emotional stress may also lead to increased transpiration.
- Put the probe vertically onto the area to be measured and do not move it during the measurement. A spring inside the probe head provides constant pressure on the skin.

- Repeated measurements on the same skin area lead to a moisture increase due to occlusion.
 In case of several measurements carried out at the same skin area, wait about 5 seconds between each measurement.
- Clean the probe head thoroughly. Any dirt, water or alcohol on the probe head might influence the measurement values.
- If possible measure on hairless skin areas. Should you wish to measure on hairy skin areas, it is recommended to shave the respective area some time before the measurement.
- Do not put the probe in the probe holder during transportation of the device. Always use the protection cap.

4. Operation

After switching on the machine, you see the following display:



The CORNEOMETER CM 825® offers four different measurement modes: single measurement (1), constant measurement with direct skin contact (2), constant measurement without direct skin contact (by means of a chamber) over 70 seconds (3) and over 7 minutes (4). For choosing one of the four measurement modes, press the respective button.

Please, also note the operation advice (chapter 3).

5. The Measurement Process

5.1 Single Measurement

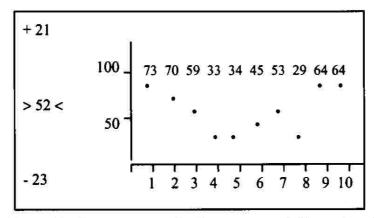
5.1.1 Procedure

With the single measurement mode you can carry out up to 10 single measurements. The measurement time of each measurement is 1 second. The measurement starts by putting the probe onto the skin area to be measured. Put the probe vertically on the measurement area according to the pressure of the spring inside the probe head.





The measurement values are displayed immediately as spots with numeric value in a system of co-ordinates.



On the left side next to the measurement values, you see further values. The second one gives the average of all measurements carried out. The first value shows the deviation between average and highest measurement value. The third value shows the deviation between the average and the lowest value.

Should you carry out more than 10 measurements, the display automatically switches over to the new measurements. In case you carry out less than 10 measurements and you wish to make further single measurements, press button 1 again. Should you wish to carry out constant measurements, press button 2, 3, or 4.

5.1.2 Experience Results

The following values are valid for healthy skin and normal room conditions (20° C and 40-60 % air humidity) and will help you to determine the skin type: in arbitrary units between 0 and 130

	forehead, t-zone, scalp, cheek, eyelid, temple, corner of the mouth, upper body parts, back, neck	arms, hand, legs, elbows
very dry	< 50	< 35
dry	50 - 60	35-50
sufficiently moistured	> 60	> 50

The table is only an approach for the interpretation of the results.

Attention:

The interpretation of the moisture values "very dry", "dry" and "sufficiently "moistured" was chosen according to the manufacturer's experience and is only a rough scale. The values will vary from the above scale due to environmental influences (temperature and relative humidity, geographical location and season). Please also see the chapter "Influences on the Measurement". It is recommended that each user works out his/her own interpretation scale.

Attention: Never compare values received with the previous instrument CORNEOMETER CM 820° with the ones you receive with the CORNEOMETER CM 825°, because due to technical changes and a new calibration procedure they are not comparable, only tendencially identical. Never switch from the previous to the successor instrument within one study.

Note:

If you obtain different results while repeating the measurement exactly on the same skin area within a very short time, this can be explained as follows:

Putting the probe on the same skin area successively causes occlusion, as water is accumulated under the probe head and cannot evaporate. This water influences the measurement and the measuring values become higher even though the water content in the stratum corneum has not changed.

Repeat the measurement not on exactly the same spot but use a neighbored skin area.

5.2 Constant Measurement With Direct Skin Contact

Choose button 2 for constant measurements with direct skin contact. With this measurement mode, the probe is kept on the skin area. The measurement starts automatically by putting the probe on the skin. Put the probe vertically on the measurement area according to the pressure of the spring inside the probe head. A beep sound announces the start of the measurement. Do not move the probe during the measurement.

The measurement curve is displayed. The first four seconds of the measurement are displayed with a zoom as this measurement period is the most important one. The initial value of the measurement strongly depends on the method of applying the probe onto the skin. The more the probe is pressed, the higher is the initial measurement value. For this reason, try to put the probe always with the same pressure onto the skin. After a few attempts and measurements, you will find out the optimum pressure.

After the first 4 seconds, the display switches over and 70 seconds measurement time are displayed. The curve showing the measurement values of the first 4 seconds is a spotted line. Further measurement values are displayed as full line.

On the left side of the screen next to the system of co-ordinates, the following values are displayed (starting from above): the actual measurement value, the measurement time, the initial measurement value (1 sec.), the measurement value after 1 second (this value corresponds to the value of a single measurement and thus is called CM-value). Furthermore the measurement values after 4, 10, 20, and 40 seconds are displayed.

The measurement stops after 70 seconds. Should you wish to carry out another constant measurement with direct skin contact, press button 2. Should you wish to carry out single measurements or constant measurements with chamber, press button 1, 3 or 4.

5.3 Constant Measurement With Chamber Over Max. 70 Seconds

With the constant measurement with chamber, there is no direct contact between probe head and skin surface. Therefore, it is not the hydration content of the outer horny layer which is measured, but the skin transpiration. This measurement is not identical with the measurement of the transepidermal waterloss as ambient temperature is not considered and as the measurement takes place in a closed chamber.

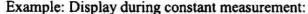
One of the various fields of application of the constant measurement with chamber is, for example, to check, in case of panel tests, if a test person sweats. Sweat influences the hydration and the transepidermal waterloss and leads to undesired measurement effects.

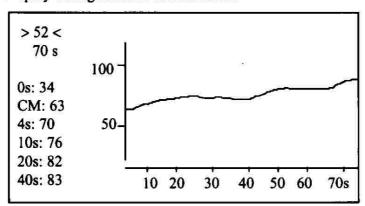
Put the black chamber on the probe head. You will hear a beep sound. To start the measurement, press button 3 again. The display counts back 3 seconds. During this time, you can put the probe onto the skin area to be measured. After three seconds, the measurements starts automatically. Do not remove the probe during the measurement. The display shows the measurement curve.

On the left, next to the system of co-ordinates, the following values are displayed (starting from above): the actual measurement value, the measurement time, the initial value (0 sec.), the measurement value after 4, 10, 20, and 40 seconds.

The measurement stops after 70 seconds. Should you wish to carry out another constant measurement with chamber over max. 70 seconds, press button 3. Should you wish to carry out single measurements or constant measurements with direct skin contact or with chamber over max. 7 minutes, press button 1, 2, or 4.

To stop the measurement before 70 seconds are over, press button 3.





5.4 Constant Measurement With Chamber Over Max. 7 Minutes

To choose constant measurement with chamber over max. 7 minutes (long term measurement), press button 4.

Put the black chamber on top of the probe head. You will hear a beep sound. To start the measurement, press button 4 again. The display counts back 3 seconds. During this time, you can put the probe onto the skin area to be measured. After three seconds, the measurements starts automatically. Do not move the probe during the measurement.

On the left side of the screen next to the system of co-ordinates, you will see the following values (starting from above): the actual value, the measurement time, the initial value (0 sec.), the measurement value after 1, 2, 4 and 7 minutes.

The measurement stops after 7 minutes. Should you wish to carry out another constant measurement with chamber over max. 7 minutes, press button 4. Should you wish to carry out single measurements, constant measurements with direct skin contact or with chamber over max. 70 seconds, press button 1, 2 or 3.

To stop the measurement before 7 minutes are over, press button 4.

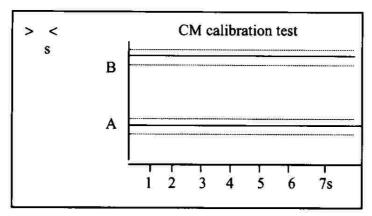
6. Maintenance of the CORNEOMETER CM 825®

6.1 The "Check Calibration"-Function

For the first time, the CORNEOMETER CM 825® offers the possibility to check at any time and easily the accuracy of the probe as well as the penetration depth of the electrical scatter field. Please check your CORNEOMETER CM 825® at least once a month.

Please, use the set of accessories consisting of a small plastic box, a special liquid, filter paper, a special foil and a pair of tweezers.

- 1. Clean the probe thoroughly with alcohol and if necessary, let the probe head dry.
- 2. Take the tweezers and put the filter paper into the small plastic box. Moisten the filter paper with the special liquid. Surplus liquid can be poured carefully. Take care that the tweezers and the plastic box are clean.
- 3. To choose the 'Check Calibration'-function, the screen has to show the initial display. If the machine does not show this display, switch the machine off and on again.
- 4. Press the ON-button and keep it pressed until you see the 'Calibration test' display (after about 5 seconds).
- 5. Now, you have to carry out two constant measurements over 7 seconds. For the **first** measurement, cut out a marked piece of the special foil and cover the moistened filter paper smoothly with it. Use the pair of tweezers. Take care that the probe does not get in contact with any liquid.
 - Measure on this foil for 7 seconds. Put the probe vertically onto the foil and do not move it during the measurement.
 - The curve displayed must be between the two lower spotted lines marked on the display (B). Repeat the measurement once or twice. After 3 4 measurements the foil might get porous due to mechanical treatment. For this reason, always use a new piece of foil.
- 6. For the **second measurement** remove the foil and measure directly on the moistened filter paper. Put the probe vertically on the paper and do not move the probe during the measurement. Carry out a measurement of 7 seconds. The displayed curve must be between the two spotted lines above the first ones (B). Repeat the measurement once or twice.



The thickness of the special foil is 15 μ . The difference between measurement curve A and B proves that the scatter field of the CORNEOMETER CM 825® probe has a very small penetration depth.

If both curves lay between the spotted lines, the CORNEOMETER CM 825® works correctly. Should the curve exceed the defined areas, a re-calibration of the probe is necessary. The probe can be disconnected from the machine with its plug. The probe contains all calibration data. Please, return only the probe to the manufacturer.

If you want to repeat the calibration check, press the ON-button again. The display will be ready for new measurements.

After finishing the calibration check, clean the probe thoroughly (s. chapter 6.2.) and dry it before any further measurement. Pay special attention to the edge of the sensor head.

To switch off the machine, go back to any other function (button 1, 2, 3 or 4). Then, press the ON-button.

Should the probe be used regularly, it is recommended to return the probe of the CORNEOMETER CM 825® to the manufacturer once a year.

6.2 Maintenance

Wipe the instrument, the cable and the probe with a soft dry tissue if necessary. In case of dirt, it is recommended to use a alcohol moistened tissue. Do not wipe to roughly.

Pay attention to clean the display only with a very soft and dry tissue.

Please, take care that no liquid enters the machine.

Before each measurement, the probe should be cleaned with a soft tissue. Any liquid or remainders of salt, oil etc. cover the sensor surface and lead to inaccurate results.

The probe is a very sensitive measurement instrument. Never hit it against any hard material.

Never open the instrument.

Never clean or bring in contact device or probe with solvents.

7. Error Messages of the CORNEOMETER CM 825®

The following error messages can be displayed by the CORNEOMETER CM 825[®]:

System error:

SE 1 = RAM error

SE 2 = Eprom error

SE 4 = EEprom error

In case these error messages appear on the display, please return the machine to the manufacturer.

SE 8 = voltage error/voltage too low. In case of this error message, check the power supply to your machine.

In case several defects occur simultaneously, the display shows the sum of the single error messages.

Errors of the hydration measurement

H E-1 = The measurement value is too low.

H E-2 = The measurement value is too high.

Corneometer-Error 4 = EEprom-error

In case these error messages appear several times, return the probe to the manufacturer.

H E-3 = mathematical overrun. Please, return the complete device to the manufacturer.

8. The Software

8.1 Installation of the Software

8.1.1 Requirements

For the installation of the software supplied with the CORNEOMETER CM 825[®] your PC has to be equipped with Windows[®] 3.x or Windows[®] 95.

8.1.2 Installation

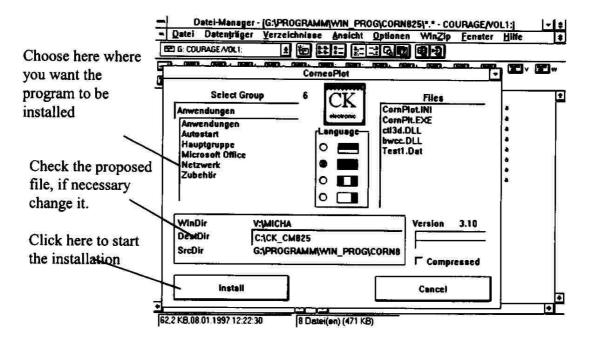
Before installing, please start the Windows® operating system with "win" and put the 3 1/2" diskette into the floppy driver.

Please call up the "file manager".

Call up the drive, where you inserted the diskette (usually it is a:).

The file-manager switches to that drive and shows on the right half the content of the diskette. The file "install.exe" installs the program on your harddisk, therefore please double click it.

Now the installation mask appears. Please choose where you want the program to be installed. Choose the language English.



Please check if the proposed file c:\ck_cm825 is the right one. If your harddisk has another name than c, please change accordingly.

Start the installation by clicking the "install" button. The installation is done automatically. The program tells when the installation is finished. Confirm the message by clicking "Ok" and quit the file manager.

Now a new icon is on the user surface. With a double click the icon of the CORNEOPLOT program appears. Another double click starts the program and you can begin with your analysis.

8.1.3 Starting the Software

Before starting, please check if the CORNEOMETER CM 825® is connected correctly to the PC and the power supply.

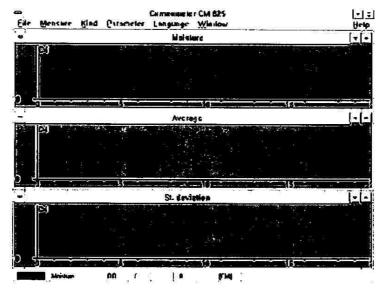
In order to connect the CORNEOMETER CM 825[®] to a PC please use only the supplied 9-pole/25-pole cable which contains special electronics. The 25-pole cable end is female. Please connect it into the male socket at you PC. If this 25-pole cable does not fit into your PC, use the attached 9-pol/25-pol adapter. The male socket at the back side of CORNEOMETER CM 825[®] is provided to use the CORNEOMETER CM 825[®] in series with other analysis instruments of Courage + Khazaka electronic GmbH. It is important to use only the original cable.

The serial interface is detected automatically by the program. Double click the icon to start. To operate the program you need a basic knowledge of Microsoft Windows[®] and a PC. You should not how to use the mouse and standard Windows[®] menus and commands. For information on basic Windows[®] features, see your Microsoft Windows[®] documentation.

8.1.4 The Main Menu

After starting the program you will see the following main menu for continuous

measurements:



8.2 The Menu ..File"

8.2.1 The Command "Save"

With this command you can store your actual measuring curves for the moisture values, the average values and the standard deviation to call them back up at a later time.

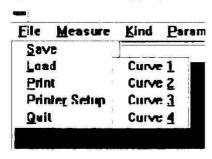


After clicking "Save" under "File" you can write the name of your curve under "filename" followed by a spot and the extension "dat" (e. g. person1.dat).

Before confirming with "Ok" please check if you chose the right drive and change it if necessary.

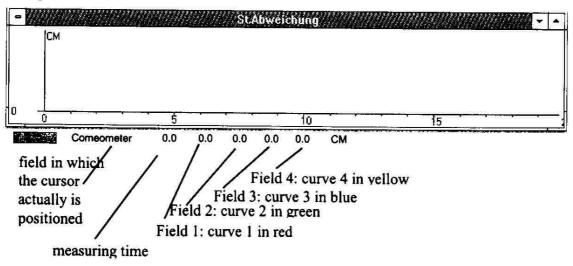
8.2.2 The Command "Load"

Up to four of the saved curves can be loaded and shown on the screen at the same time. Please call up "load" and the appropriate measurement (1,2,3 or 4).



A mask appears and you can call up the appropriate file.

To call up another curve, please proceed the same way. You can attribute a different color to each plot.



8.2.3 The Command "Print"

Clicking "print" you can print out the measuring curves, the curves of the average and the standard deviation as well as the temperature, air humidity and skin area.

A mask to choose the appropriate curves for print out appears. Confirm your choice with "Ok".

If you get no or incomplete printouts from Hewlett-Packard LaserJets and compatible printers the printout might need more memory than available in the printer. LaserJet printers first built up the whole page before printing. Solve the problem by reducing the resolution in printer dialog or install more memory for the printer.

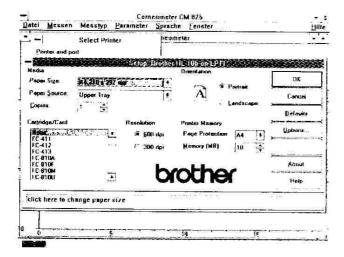
Please also pay attention to the following:

On the screen you see the Corneometer values (y-axis) on a timescale (x-axis). When printing out however, the Corneometer values are still on the y-axis but on the x-axis the number of measuring values is shown.

Ensure that your printer is set in the "landscape" mode in order to receive horizontal printouts of the screen.

8.2.4 The Command "Printer Set Up"

With this command you can adjust the program to your printer. If you can not find your printer type under the mask, please click "setup" and adjust the options according to your printer manual.



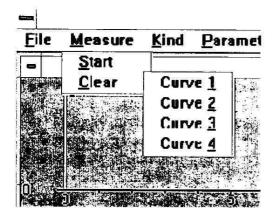
8.2.5 The Command "Quit"

With this command you can quit the program. You are asked to save the still unsaved data. With "Ok" the program is left automatically.

8.3 The Menu "Measure"

8.3.1 The Command Start/Stop

Before executing the measurement, please click "Start". The red bar on the left lower corner will switch to green and the measurement is started when the probe head gets in contact with the skin.



8.3.2 The Command "Clear"

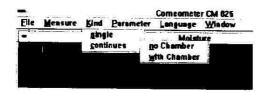
This command deletes the curves on the screen.

To delete an actual, unsaved curve click "measurement 1" and confirm with "Ok".

To delete saved and reloaded curves, first choose the appropriate curve. "measurement 1" deletes the red curves, "Measurement 2" the green, "Measurement 3" the blue and "Measurement 4" the yellow curves. Confirm each time with "Ok".

The deletion of a reloaded curve does not also delete it from the directory.

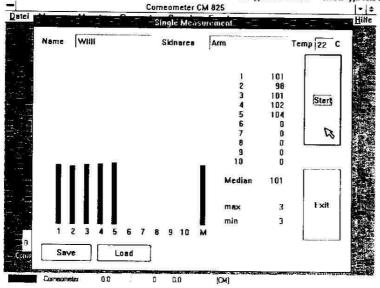
8.4 The Menu "Type of Measurement"



8.4.1 The Command "Single"

Choose "single" to do single measurements of 1 sec.

To receive the measurement mask click "measure" and "start".



Click in the field "name", "skinarea" and "temp" to enter data. To start the measurement click the "start"-button.

Also read the chapter "Single Measurements".

The bar diagram can show up to ten measuring values and calculates the average.

"Max" shows the maximum, "min" shows the minimum deviation of the values to the actual average value.

If you do more than ten measurements the actual value is displayed on the last bar, the older values are "pushed" out of the screen. The average and the "max" and "min" values are only built over the last ten (the visible) measurements. If you do less than 10 measurements, press "save" and name the measurement. Press "start" again for the next measurement.

"Save" memorizes your last measurements. Please always put the extension .c10 to the name. With "load" you can get an already saved measurement back on the screen. Do a printout of your measuring values by pressing the "print"-button.

8.4.2 The Command "Continuous"

When clicking "continuous" you can choose between measurements "with chamber" and "without chamber". Please see chapter 5.2 -5.4. In the software program there is no time limit for the continuous measurements.

8.4.2.1 Continuous Measurement without Chamber

With a continuous measurement with direct contact to the skin (without chamber) please proceed as follows:

- 1. Click "Measurement Type" "Continuous" and "Measure" "Start" to get the measurement mask.
- 2. Click "Measure" and "Start" to start the measurement.
- 3. Put the probe on the skin to start the measurement.

The measurement starts automatically by putting the probe on the skin. Put the probe vertically on the measurement area according to the pressure of the spring inside the probe head. Do not move the probe during the measurement.

The measurement curve is displayed on the screen. The initial value of the measurement strongly depends on the way of putting the probe onto the skin. The more the probe is pressed, the higher is the initial measurement value. For this reason, try to put the probe always with the same pressure onto the skin. After a few attempts and measurements, you will find out the optimum pressure.

The measurement stops according to the "Stop Event" in the Menu "Parameter" either after 7 sec., 7 minutes, 1 hour or when interrupting it by clicking "Stop" in the menu "Measure".

8.4.2.2 Continuous Measurement with Chamber

With a **measurement with chamber** the probe does not have a direct contact with the skin. Therefore, it is not the hydration content of the outer horny layer which is measured but the skin transpiration. This measurement is not identical with the measurement of the transepidermal waterloss as ambient temperature is not considered and as the measurement takes place in a closed chamber.

One of the various fields of application of the constant measurement with chamber is, for example, to check, in case of panel tests, if a test person sweats. Sweat influences the hydration and the transepidermal waterloss and leads to undesired measurement effects.

The probehead is activated by putting the chamber on top of it. To prevent starting the measurement before having put the probe on the skin, proceed as follows:

- 1. Click "Measurement Type" "Continuous" and "Measure" "Start" to get the measurement mask.
- 2. Put the probe on the skin.
- 3. Click immediately "Measure" and "Start".

Now the measurement starts automatically. Do not move the probe during the measurement. The measurement curve is displayed on the screen.

The measurement stops according to the "Stop Event" in the Menu "Parameter" either after 7 sec., 7 minutes, 1 hour or when interrupting it by clicking "Stop" in the menu "Measure".

To save and reload the curves please proceed as described under the command "save" and "load" (chapter 8.2.1).

8.4.3 The Command "Check Calibration"

For the first time, the CORNEOMETER CM 825® offers the possibility to check at any time and easily the accuracy of the probe as well as the penetration depth of the electrical scatter field. Please check your CORNEOMETER CM 825® at least once a month.

Please, use the set of accessories consisting of a small plastic box, a special liquid, filter paper, a special foil and a pair of tweezers.

- 1. Clean the probe thoroughly with alcohol and if necessary, let the probe head dry.
- 2. Take the tweezers and put the filter paper into the small plastic box. Moisten the filter paper with the special liquid. Surplus liquid can be poured carefully. Take care that the tweezers and the plastic box are clean.
- 3. To choose the 'Check Calibration' function, click "Check Calibration" and "Start".
- 4. You will see two pairs of bars in the measuring menu. The measurement curves have to be within these pairs of bars.
- 5. Now, you have to carry out two constant measurements over 7 seconds. For the **first** measurement, cut out a marked piece of the special foil and cover the moistened filter paper smoothly with it. Use the pair of tweezers. Take care that the probe does not get in contact with any liquid.
 - Measure on this foil for 7 seconds. Put the probe vertically onto the foil and do not move it during the measurement.
 - The curve displayed must be between the lower two spotted lines marked on the screen. Repeat the measurement once or twice. After 3 4 measurements the foil might get porous due to mechanical treatment. For this reason, always use a new piece of foil.
- 6. For the **second measurement** remove the foil and measure directly on the moistened filter paper. Put the probe vertically on the paper and do not move the probe during the measurement. Carry out a measurement of 7 seconds. The displayed curve must be between the two spotted lines above the first ones. Repeat the measurement once or twice.

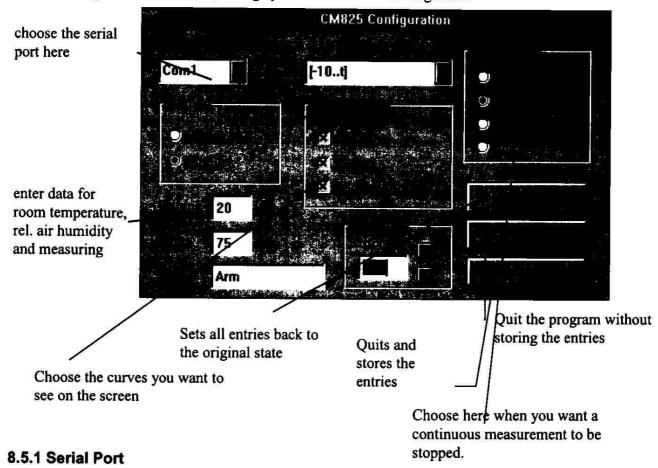
The thickness of the special foil is 15 μ . The difference between the measurement curves proves that the scatter field of the CORNEOMETER CM 825® probe has a very small penetration depth.

If both curves lay between the spotted lines, the CORNEOMETER CM 825[®] works correctly. Should the curve exceed the defined areas, a re-calibration of the probe is necessary. The probe can be disconnected from the machine with its plug. The probe contains all calibration data. Please, return only the probe to the manufacturer.

Should the probe be used regularly, it is recommended to return the probe of the CORNEOMETER CM 825® to the manufacturer once a year.

8.5 The Menu "Parameter"

When clicking "Parameter" and "Config" you will see the following mask



The serial port detected by the program is shown here. Change it, it necessary.

8.5.2 Display

This is only valid for continuous measurements.

Choose here how many curves (up to four measuring curves, curve of the average and standard deviation values) you want to see simultaneously on the screen.

"All" will show the CM-values of all curves in the bottom. "Single" shows all three values of the first curve in the bottom.

8.5.3 Temperature, Humidity and Position*

Please enter here the data of the actual room conditions and the measured skin area.

8.5.4 Default

Clicking this button will set all entries back to its original state.

8.5.5 Average

Choose here over how many measuring values you want the average to be calculated. -10 means that the average and the standard deviation are calculated for 10 measuring values.

8.5.6 Display*

On/off button for the display of the different curves on the screen.

8.5.7 Time (ms)*

This is only valid for continuous measurements and sets the time between the measurement values in ms. Ex works it is adjusted on 100 ms e. g. 10 measuring values per second.

Items marked with * are only for continuous measurements.

8.6 The Menu "Language"

Here you can choose between English and German.

8.7 The Menu "Windows"

Choose here a different display of your curves. The command is similar in all Windows® programs.

9. Technical Data

Voltage: 230 (115) V, 50-60 Hz, 8 VA

Dimensions: Housing: 10 x 26 x 25 cm

Display: 13.2 x 39 cm, illuminated

Weight: 2.3 kg

Probe: Length: app. 11 cm, weight: app. 70 g,

measurement head: 49 mm²,

Pressure approx. 0,16 N, twisted cable: max. 2 m

Frequency: 0.9-1.2 MHz

Accuracy: $\pm 3\%$

Serial Interface: together with the supplied connection cable

RS 232 C compatible

Protection Class: 1

CE

Technical changes may be effected without previous notice.

For any further information, please contact: COURAGE+KHAZAKA electronic GmbH Mathias-Brüggen-Str. 91, 50829 Köln, Germany

Telephone: ++49-221-956499-0 Fax: ++49-221-956499-1 e-mail: courage@t-online.de

10. Declaration of Conformity

EC - DECLARATION OF CONFORMITY

(according to appendix II, V, VI and VII of directive 93/42/EEC on Medical Devices)

Manufacturer's name:

Courage + Khazaka electronic GmbH

Manufacturer's address: Mathias-Brüggen-Straße 91

50829 Köln, Germany

Phone: ++ 49 221 - 956499 - 0 Fax: ++ 49 221 - 956499 - 1

We declare the conformity

of our product-group:

Devices for the determination of physiological skin-

parameters

Devices:

CORNEOMETER

Instrument for the determination of moisture content of the skin surface

CUTOMETER

Instrument for the scientifically exact determination of the skin viscoelasticity

MEXAMETER

Instrument for the determination of melanin content and erythema of the skin

SEBUMETER

instrument for the determination of sebum content of the skin surface

SKIN-pH-METER

instrument for the determination of the pH-value of the skin surface

SKIN-VISIOMETER

Instrument for the determination of the skin roughness by light transmission by

means of a silicon replica

TEWAMETER

Instrument for the scientifically exact determination of the TEWL-value

Combined Units:

SEBUMETER / CORNEOMETER / SKIN-pH-METER

SEBUMETER / CORNEOMETER

The products herewith comply with following directives:

Directive 93/42/EEC on Medical Devices

Cologne, 05.05.1998

Senior Manager / Technical Division Dipl.-Ing. Wilfried Courage

Safety officer for medical devices Dipl.-Ing.(FH) Stefan Richter

11. Instrument Passport

First operation of the instrument:

by:

CORNEOMETER CM 825® - Serial number:

Check-Calibration

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Special offer:

Annual check of your CORNEOMETER CM 825[®] for a very special price.