

gluco-comfort
Blood glucose measuring systems
BGM105/BGM 205
Operating manual

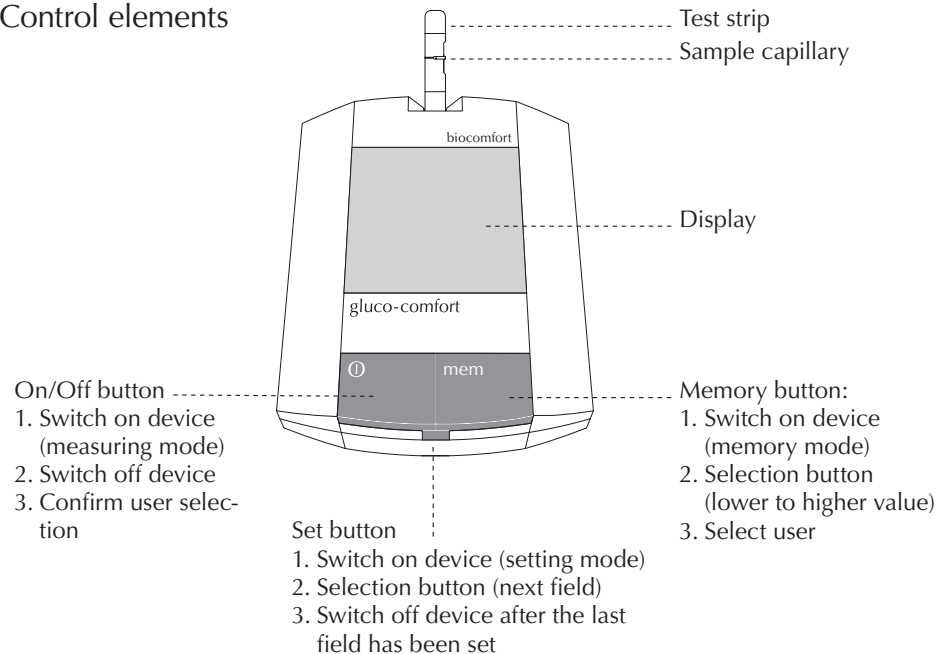
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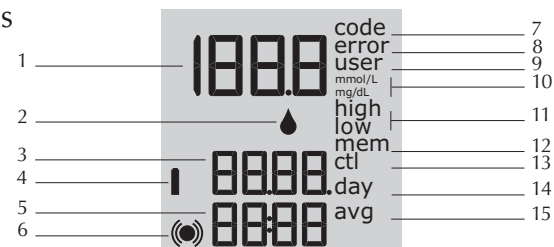
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Control elements



Display elements



1 Introduction

1.1 Intended Use

The Biocomfort blood glucose measuring system is an in-vitro diagnostic device for the quantitative measurement in capillary whole blood. It is meant for the personal use at home and therefore supports the diabetes therapy. The system is not intended for professional use and the use on neonates.

Dear User,

We are pleased that you have decided in favour of the Biocomfort blood glucose measuring system. It will be a reliable aid for you in checking your blood glucose values. The meter is easy to operate. You can transfer the results to your PC for further evaluation (model variant BGM 105).

The Biocomfort blood glucose measuring system is an in-vitro diagnostic device for the quantitative blood glucose measurement in capillary blood. It is meant for your personal use at home, and therefore support you with your diabetes therapy.

Safety information:

This operating manual contains important information for you.

It is mandatory that the safety measures mentioned in this operating manual be taken.

The Biocomfort blood glucose measurement system may only be used in the manner described in this operating manual.

Please read the operating manual carefully before using the device for the first time. It is recommended that you take a practice measurement. Keep your meter ready next to you. Carry out every step immediately after you have read it in the instructions.

All control elements and displays are exactly explained. Keep the operating manual in a safe place for future reference. We recommend that you also instruct other people in how to operate the measuring system, in case you should some day require help.

You can check your momentary blood glucose level with high precision with the Biocomfort blood glucose measuring system. Only your doctor can determine whether your blood glucose levels are an indication of a diabetic illness requiring treatment, however.

The blood glucose meter should not be used by critically ill patients (e. g. those with severe hypotension or shock, hyperglycaemic-hyperosmolar state, hypoxia, severe dehydration, diabetic ketoacidosis) because inaccurate results may occur.

The Biocomfort blood glucose measuring system includes many components, such as test strips, the test strip container, batteries, etc., which can be misplaced or can be dangerous for children. For this reason, keep your blood glucose measuring system out of the reach of children. Also, make sure the meter can't be misused while in use.

If there are signs of damage or malfunctions, the Biocomfort meter cannot be used. Please use only the *gluco-comfort* test strips BGS105 and *gluco-comfort* control solutions GCS105, GCS205 or GCS305. The *gluco-comfort* control solutions GCS205 and GCS305 are available separately as accessories.

Due to the wireless module in the *gluco-comfort* blood glucose meter BGM105, the use of this device in certain secure areas, such as intensive care stations or in airplanes, is not allowed.

The original packaging of the *gluco-comfort* blood glucose system with the wireless module contains the following main components:

1. *gluco-comfort* meter BGM105
2. *gluco-comfort* test strips BGS105
3. *gluco-comfort* control solution GCS105
4. *gluco-comfort* lancing device LDV105
5. *gluco-comfort* lancets LCE105

The original packaging of the *gluco-comfort* blood glucose system without the wireless module contains the following main components:

1. *gluco-comfort* meter BGM205
2. *gluco-comfort* test strips BGS105
3. *gluco-comfort* control solution GCS105
4. *gluco-comfort* lancing device LDV205
5. *gluco-comfort* lancets LCE105

In addition, further components are included:

- Battery
- Meter operating manual
- Package insert for test strips
- Package insert for control solution
- User instructions for the lancing device
- Meter short instructions
- Bag

Additional important information concerning the test strips:

Please observe the separate user instructions for the test strips.

- The test strips could be damaged by effects of temperature and light. For this reason, they should be used immediately after being removed from the test strip container.
- The test strips may not be used past the expiration date. The test strips can be used four months after the container has been opened. When you open the container for the first time, write down the date on the container.
- Close the container carefully after removing the test strip. Always leave the container closed and keep it in a cool, dry place.

Important information regarding the control solution:

Please observe the separate user instructions for the control solution.

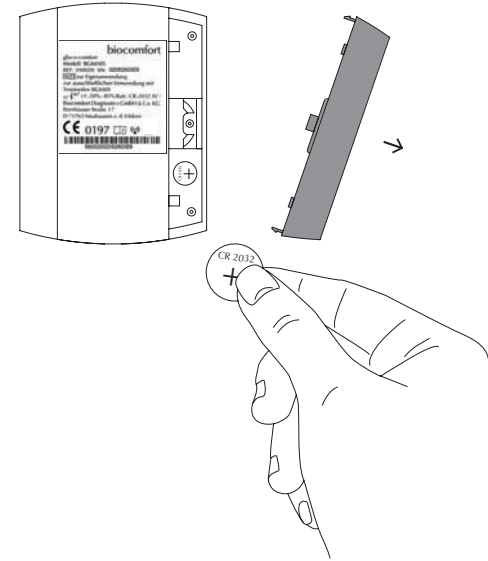
- Always shake the control solution well before use.
- The control solution can be damaged if exposed to heat. For this reason, you should immediately seal the vial immediately after use and keep it in a cool place.
- The control solution may not be used past the expiration date. Once the vial is opened, it can be used for 3 months. When you open it for the first time, write down the date on the vial.

2 How to start up your *gluco-comfort* blood glucose meter

2.1 Inserting/exchanging batteries

The Biocomfort blood glucose meter is delivered with a 3V lithium cell [type CR2032], which must be inserted before taking the first measurement.

If the battery symbol appears on the display, this is an indication that the battery is already weak and has to be exchanged soon. If the battery symbol is blinking on the display, this indicates that the battery must be exchanged. A weak battery is to be exchanged so that error-free measuring results can be guaranteed. When the battery is exchanged, all settings which have been made on the device are retained, as well as the stored measurements.



Insert battery

Please follow the following steps for inserting/exchanging the battery:

Step 1:

Please always switch off the device before exchanging the battery.

Step 2:

Pull the battery compartment cover (on the back side of the device) in the direction of the arrow and remove.

Step 3:

Remove any used battery.

Step 4:

Insert the 3V lithium cell with the writing facing up.

Step 5:

Replace the battery compartment cover and push it over the compartment until you hear the cover click into place.

Step 6:

Afterwards, check whether the battery has been correctly inserted by briefly pressing the On/Off button. In this case, all elements of the display appear for about two seconds as a function check.

Note:

- Please make sure that you always have a replacement battery on hand.
- A new battery (3V lithium cell) has a life-time of about three months (BGM105) or for around 800 measurements (BGM205).
- When the batteries are exchanged and when the meter is stored without batteries, the contents of the measured value memory are retained.
- When battery is removed, the internal clock of the measuring device doesn't continue to run, so when the device is used again after exchanging the batteries or after storing the device without batteries, the date and time may have to be reset (see Section 2.4).

Attention:

For the sake of the environment: Used batteries belong in the hazardous waste!

2.2 Switching on

Switch on your blood glucose meter by pressing the On/Off button. Every time you turn it on, all display elements appear for about two seconds as a function test. Please make sure that the display elements can really be seen completely, as shown in the figure on page 5. A defective display can show false values in later measurements.

Note:

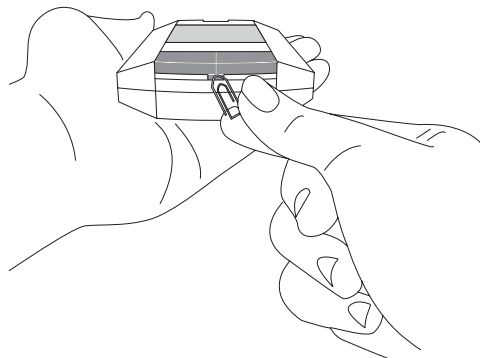
- If no test strip is inserted into the meter or if no button is pushed within 2 minutes, the blood glucose meter switches off automatically.
- If a test strip is inserted without any blood or control solution on the application field,

the meter switches off automatically after about six minutes.

2.3 Configuring the device

Before the blood glucose meter is used for the first time or when adapting the meter to your needs, you must make a few settings in the settings menu. To do this, you will press the SET, MEM and On/Off buttons, as described in the following sections.

The SET button can be found underneath the On/Off and MEM buttons. It is covered by these two buttons to avoid pressing it by mistake. It's easiest to press the SET button with a small, flat object (e.g. paperclip) (see figure on page 14).



Pressing the SET button

While you are in the settings menu, the buttons have the following functions:

SET button:

If you press the SET button with the meter switched off, you will get into the settings menu. The year of the date is the first setting which can be made. You can tell which parameter can be set at any given time by its blinking. If you press SET again, you proceed to the next settable parameter.

MEM button:

By pressing the MEM button, you can change the currently blinking parameter until it takes on a value you desire. Now you can go to the next parameter by pressing the SET button, or you can exit the settings menu by pressing the On/Off button.

Note:

If you keep the MEM button pressed, you can change the active parameter faster.

On/Off button:

By pressing the On/Off button, you exit the settings menu and the set parameters are saved.

2.4 Setting the date and time

Note:

The measured blood glucose values are stored with the date and time. The correct setting of the date and time makes it easier for you to make a correct time allocation of your measurements.

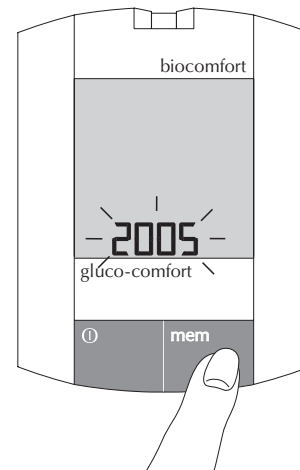
In order to set the correct date and time on your measuring device, proceed as follows:

Step 1:

With the device switched off, first press the SET button with a small, flat object (e.g. paper clip).

Step 2:

As soon as the year starts blinking on the display, keep pressing the MEM button until the correct year appears.



Step 3:
When you press the SET button again, you activate the month display.



Step 4:
Keep pressing the MEM button until the correct month is displayed.



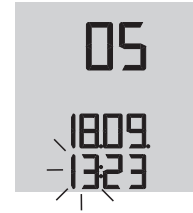
Step 5:
By pressing the SET button again, you activate the day display.

Step 6:
Keep pressing the MEM button until the correct day is displayed.



Step 7:
By pressing the SET button again, you activate the hour display.

Step 8:
Keep pressing the MEM button until the correct hour is displayed.



Step 9:
By pressing the SET button again, you activate the minute display.

Step 10:
Keep pressing the MEM button until the correct minute is displayed.



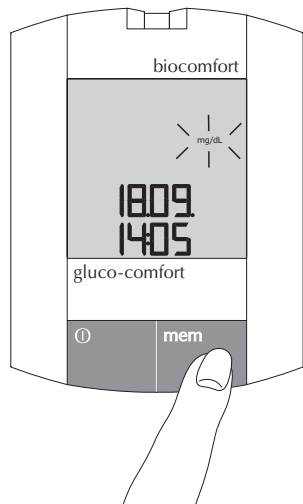
Step 11:
If you are finished making settings, you can exit the settings menu by pressing the On/Off button. Otherwise, continue making settings by pressing the SET button.

2.5 Setting the unit of measurement

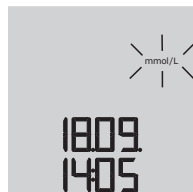
Note:

The blood glucose values can either be displayed in mg/dl or in mmol/l. The setting of the unit of measurement can be found in the settings menu sequence after the date and time.

Step 1:
To change the unit of measurement, press the SET button until the set unit of measurement starts blinking on the display (see figure on page 18, blinking unit of measurement).



Step 2:
In order to select the other unit of measurement, press the MEM button.



Step 3:
If you are finished making settings, you can exit the settings menu by pressing the On/Off button. Otherwise, continue making settings by pressing the SET button.

2.6 Configuring the measured value memory

Note:
The blood glucose meter stores the measured blood glucose values. The measured value memory can be configured so that the measurements can be allocated to eight different users.

To do this, the measured value memory must be enabled for the individual users.

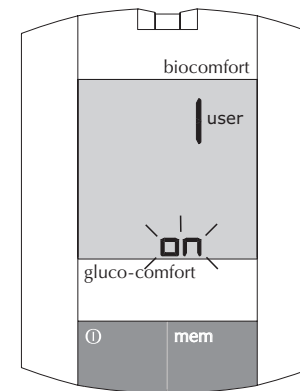
2.6.1 Configuration of the model variant BGM205

In its delivered condition, the measured value memory is only enabled for one user ("User 1").

The configuration of the measured value memory can be found after the unit of measurement setting in the settings menu sequence.

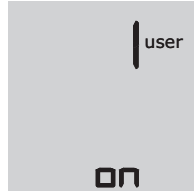
Step 1:
To enable (or block) several measured value memories, press the SET button until the word "user" appears on the display in the upper right-hand corner (see figure), and to the left of the word "user", the number "1" appears. In the lower area of the display, either the word "on" or "off" is blinking in addition.

This indicates whether the measured value memory for user 1 is enabled or blocked at this time.



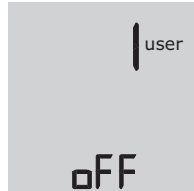
“on” means:

The measured value memory is enabled for user 1.



“off” means:

The measured value memory is blocked for user 1.



Step 2:

To change the measured value memory state for user 1 from “off” to “on” or vice versa, press the MEM button.

Step 3:

After you have set the measured value memory to the status you wish, you can set the status for user 2 by pressing the SET button.

Remark:

If, for example, you want to change the measured value memory status for user 5, press the SET button until the number “5” appears to the left of the word “user” and carry out step 2.

Step 4:

If you are finished making settings, you can exit the settings menu by pressing the On/Off button. Otherwise, continue making settings by pressing the SET button.

Note:

If measured value memories are enabled for several users, each user must know his or her own identity number. Before each measurement, it must be made sure that the correct user identity number has been selected (see Section 3.2, steps 3 to 5). The procedure for clearing the measured value memory is described in Section 2.8.

2.6.2 Configuration of the model variant BGM105

The model variant BGM105 is used together with the Health Manager software and is configured using the Health Manager on your PC or PDA.

Due to data synchronisation, at least one user must be enabled in the software on the PC or PDA before the blood glucose meter can be activated.

2.7 Resetting the wireless connection (only applies for the model variant BGM105)

Note:

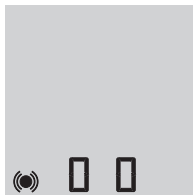
The model variant BGM105 is equipped with a wireless interface. With this, you can wirelessly transfer the measured blood glucose measurements to a PC which is equipped with a Biocomfort wireless module (USB 105) or to a PDA (equipped with wireless module CFC 105) for further processing (e.g. statistical evaluation) or archiving.

This setting should only be made when it's no longer possible to reset with the Health Manager. Details can be found in the software instructions.

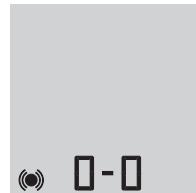
The configuration of the wireless interface can be found after the configuration of the unit of measurement setting in the settings menu sequence.

Step 1:

To reset the wireless interface, keep pressing the SET button until the radio symbol at the bottom left of the display (= fat black dot in double-parentheses) starts to blink. To the right of the radio symbol appear two “0”s. If there is no dash between the two “0”s, this means that the wireless connection is reset.



If there is a dash between the two “0”s, this means that the wireless connection is maintained.



Step 2:

To switch between maintaining and resetting the wireless connection, press the MEM button.

Step 3:

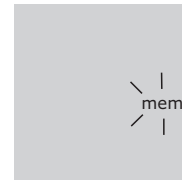
If you are finished making settings, you can exit the settings menu by pressing the On/Off button. Otherwise, continue making settings by pressing the SET button.

2.8 Clearing the measured value memory

The operation for clearing the measured value memory is the last item in the settings menu.

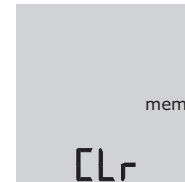
Step 1:

In order to clear the stored blood glucose values from the measured value memory, press the SET button until the word “mem” starts blinking on the right side of the display.



Step 2:

When you press the MEM button, “CLr” (clear) appears at the bottom of the display (means that the memory will be cleared).



Remark:

When the abbreviation “CLr” appears on the display and you switch off the device via the On/Off button or by pressing the SET button, the entire measured value memory is cleared. If you do not wish to clear the values, press the MEM button again to make “CLr” disappear.

3 Carrying out the blood glucose measurement

3.1 Coding your meter

Attention:

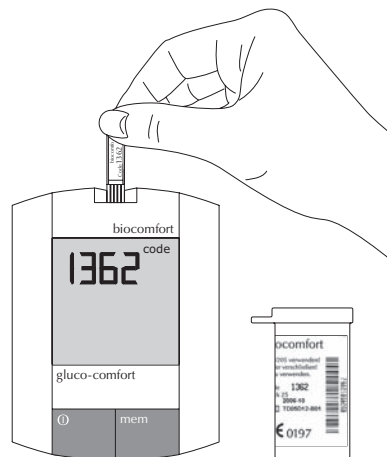
In order to get correct blood glucose measurements, the meter has to be coded for the used test strips.

Every time you make a measurement, check whether the code number on the display of the meter and the code number on the test strip package are identical.

If the code numbers on the meter display and on the label of the test strip package are not identical, the device must be (re-)coded. Coding is required before the meter is used for the first time in any case, as well as when test strips of another code number are used.

Step 1:

With the meter switched off, insert the code chip (included in the test strip package) into the test strip receptacle of the meter until it clicks into place. When doing so, the curved side of the code chip must be facing up.



The information contained on the code chip is stored together with the code number in the meter.

Step 2:

As soon as the code number of the code chip appears on the meter display, you can remove the code chip from the test strip receptacle.

Note:

Keep the code chip in the test strip package until all test strips have been used up. Afterwards, you can dispose of the code chip along with the empty test strip package in your household garbage.

3.2 Preparing the measurement

To carry out a blood glucose measurement, have the following listed utensils ready:

- The *gluco-comfort* blood glucose meter BGM105 or BGM205
- one *gluco-comfort* test strip, BGS105
- The *gluco-comfort* lancing device LDV105 or LDV205
- one *gluco-comfort* lancet LCE105
- Clean paper towel or clean paper tissue

Prepare for your blood glucose measurement as follows:

Step 1:

Wash your hands thoroughly with warm water and soap.

Step 2:
Remove one test strip from the package.
Make sure that you close the package immediately after removing the strip.

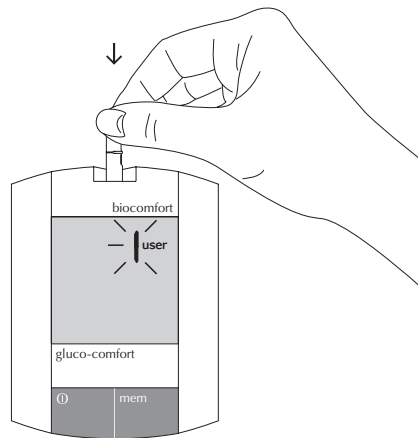
Note:
Please observe the separate user instructions for the test strips.

Step 3:
With the device switched off, guide the test strip with the darker side facing up into the test strip receptacle in the direction of the arrow until you feel it click into place.

Step 4:
If the test strip is positioned correctly, the device switches on automatically.

Step 5:
The user identity number of the measured value memory where the result of the last blood glucose measurement was stored

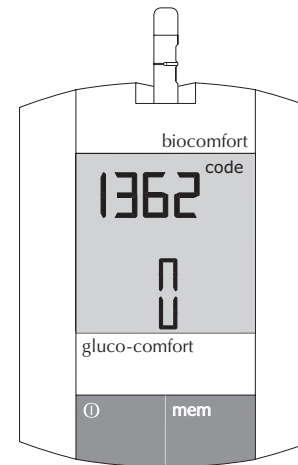
blinks on the display (see Section 3.5 “Use by multiple persons”).



Step 6:
If the user identity number doesn't agree with your measured value memory, press the MEM button until the identity number of your measured value memory appears.

Step 7:
Confirm the measured value memory selection by pressing the On/Off button. The meter acknowledges this with a beep.

Step 8:
In the top part of the display, the last stored test strip code number appears, and in the bottom part, the test strip symbol.



Note:

You can also start the meter by pressing the On/Off button without inserting a test strip in the test strip receptacle. Steps 3 - 6 are carried out the same way as described before. As opposed to the first way with the inserted test strip, the test strip symbol on the display, as described under Step 7, blinks as a prompt to the user to insert the test strip now.

Step 9:

After the test strip has been properly positioned, the meter signals that it is ready for measuring with two short beeps. In addition, a drop symbol blinks on the display.

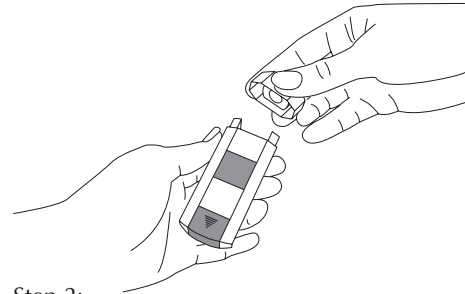
3.3 Getting a drop of blood for the blood glucose measurement

Using the *gluco-comfort* lancing device LDV 105/LDV 205 allows you to get a blood sample gently, with almost no pain, and hygienically.

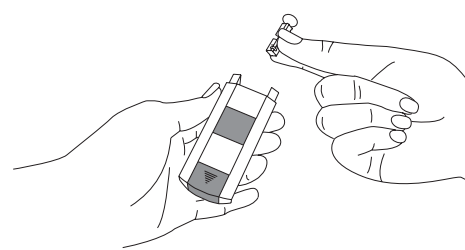
Attention:

To avoid infections, use a new lancet for every lancing. When the skin is lanced, the finely ground surface of the lancet dulls, which makes it potentially painful to use a used lancet.

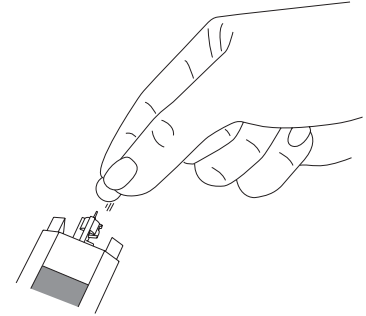
Step 1:
Remove the cap of the lancing device.



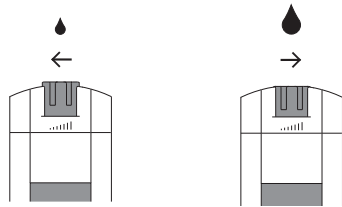
Step 2:
Insert a new lancet in the lancing device.



Step 3:
Remove the protective cap from the lance by turning and pulling it off.



Step 4:
Replace the cap of the lancing device and set it to the desired lancing depth (see figure on page 30).



lower lancing depth

higher lancing depth

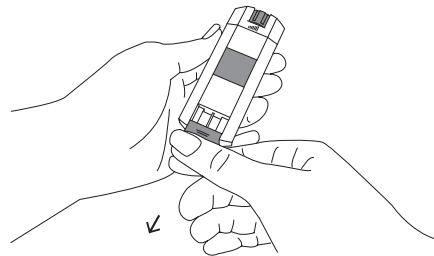
Remark:

The required lancing depth is different from person to person. In principle, it is to be assumed that you will get a larger drop of blood with a high lancing depth than you would with a low lancing depth. You can define the right lancing depth for you based on your experience.

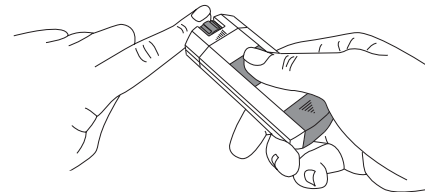
Step 5:
Allow your arm to hang down relaxed so that blood can flow into your fingertips.

Step 6:
Massage the finger from which you'd like to get your sample for about three seconds (don't squeeze) to increase the blood flow.

Step 7:
Wind up the lancing device.



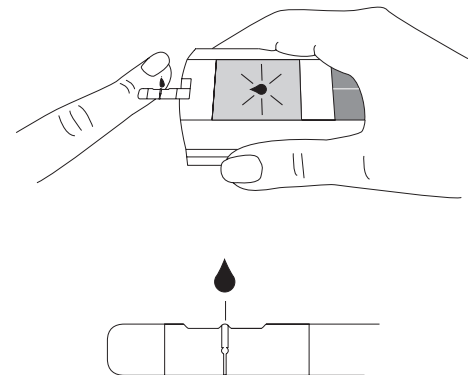
Step 8:
Hold the lancing device to the side of the finger pad and press the release button.



Step 9:
Carefully press on the finger pad until a blood drop is formed.

3.4 Carrying out the blood glucose measurement

Step 1:
Hold the drop of blood next to the right side of the test strip. As soon as the blood drop touches the "nose" in the middle of the notch, the blood is drawn in by the measuring cell.



Note:

The measuring cell of an unused test strip is transparent. After a sufficient amount of blood has been drawn in, the measuring cell is filled completely with blood. The measuring cell of the test strip can only be filled at the “nose”, mentioned above. Wetting at other places on the test strip won't lead to a correct measurement.

Step 2:

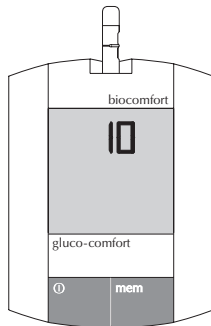
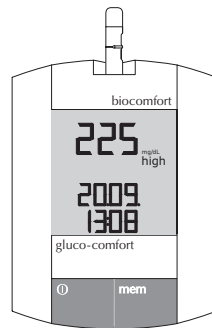
Once the measuring cell of the test strip is sufficiently filled with blood, the meter confirms this with a beep. The measurement starts automatically.

Step 3:

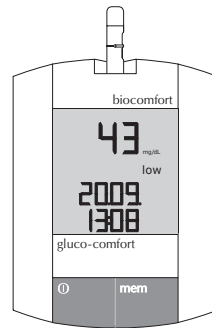
The blood glucose measurement takes ten seconds. There is a measuring time “count-down” on the display.

Step 4:

The end of measurement is confirmed with two short beeps. The measured blood glucose value is displayed with the date and time of the measurement. This data is stored in the measured value memory of the user.

**Attention:**
**Hyperglycaemia warning
(blood glucose level too high):**

If the result of your blood glucose measurement is above a level of 160 mg/dl (or 8.8 mmol/l), the word “high” appears on the right next to the blood glucose value. This is a warning that your blood glucose level is too high.


**Hypoglycaemia warning
(blood glucose level too low):**

If the result of your blood glucose measurement is below a level of 50 mg/dl (or 2.78 mmol/l), the word “low” appears on the right next to the blood glucose value. This is a warning that your blood glucose level is too low.

Attention:

- If such extreme values don't correspond with the way you feel, repeat the measurement to confirm the result.
- If the measurements don't change, see your doctor immediately!
- If you should feel symptoms which don't agree with your measured blood glucose values, never change your medicine dosage without previously consulting your physician.

The blood glucose measurement can lead to false results:

- when the haematocrit value of the patient is less than 20% or greater than 60%.
- in patients with haemolytic blood
- in patients who have icterus (jaundice)
- in patients who have lip(id)aemia
- when there is a change in the peripheral blood circulation
- when coagulated blood is measured

- when the time span from getting the blood drop to measurement is too long.
- in patients treated with specific drugs such as ...
- patients undergoing oxygen therapy
- when testing with venous, arterial blood

Your doctor can clarify whether your measurements are influenced by one of these cases.

Notes:

Take the test strip out of the meter after the measurement.

Properly dispose of used test strips and lancets immediately after measurement so that they cannot injure/infect anyone.

3.5 Use by multiple persons

When the blood glucose meter is shared by several persons, the measured value memory can be configured so that the measured blood glucose measurements can be allocated to up to eight different users based on the user identity number (1 to 8).

For the correct allocation of the respective measurements to a measured value memory, the user is prompted during the course of the measurement to confirm the user identity number displayed by the device or to select the correct user identity number (see Section 3.2, steps 5 to 7).

Attention:

To avoid infections, if the meter is used by several persons, make sure that the meter is not contaminated with blood. Contaminated blood glucose meters are to be cleaned before further use and are to be disinfected, if necessary.

To avoid infections, each user must use his or her own lancing device.

4 Measured value memory

4.1 Storing the measured values

The Biocomfort blood glucose meter automatically saves the last 122 measured blood glucose measurements together with the date and time of measurement.

If the memory is full, the oldest result is overwritten by the result of the next measurement.

The measured values are retained in the measured value memory even when the battery is removed.

4.2 Calling up the stored measured values

For every user identity number, the stored blood glucose measurements can be called up, from the last one to the oldest one. In ad-

dition, the average blood glucose values for 7, 14, 21 and 28 days can be displayed.

To display the memory contents, proceed as follows:

Step 1:
Press the MEM button to access the measured value memory. The device is now switched on.

Step 2:
The user identity number blinks on the display in whose measured value memory the result of the last blood glucose measurement was stored (see Section 3.5 “Use by multiple persons”).

Step 3:
In order to look at the contents of the measured value memory of a certain user, press the MEM button until the desired user identity number appears.

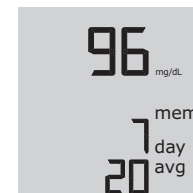
Step 4:
Confirm the selection by pressing the On/Off button.

Step 5:
The last stored measurement for the selected user appears on the display with date and time.

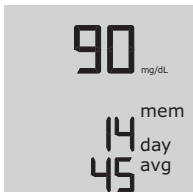


Step 6:
When you press the MEM button again, the average value the meter calculated for the last seven days is displayed. Here, the number of days selected for the average value is shown to the left of the

word “day”. To the left next to the abbreviation “avg” (average), the number of measurements appears which were taken into account in the calculation of the average value.



Step 7:
After pressing the MEM button again, the average value of the measurements of the last 14 days is displayed. Here, the number 14 is displayed to the left of the word “day” (see figure on page 38).

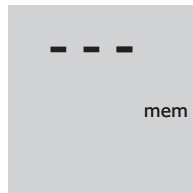


Remark:

By repeatedly pressing the MEM button, the average values of the last 21 and then 28 days are displayed. Afterwards, all stored individual values can be viewed, from the second-to-last one to the oldest available measurement.

Step 8:

To exit memory mode, switch the device off again with the On/Off button. Once the end of the measured value memory has been reached, or if there are no other measured values available, the following is displayed:



Note:

To quickly scroll through the results, press the MEM button and hold.

5 Function checks and caring for the *gluco-comfort* blood glucose meter

5.1 Function control of the display

Every time you turn on the blood glucose meter, all display elements appear for about two seconds. This allows you to see whether all display elements are working properly.

5.2 Reasons for a function check with control solution

We recommend a check be carried out with a control solution:

- at least once a week
- for practicing before your first blood glucose measurement with the Biocomfort blood glucose meter
- after opening a new package of test strips

- when you think that the meter or test strips aren't functioning properly
- when your blood glucose results don't agree with your subjective feeling of well being

5.3 Carrying out the control measurement

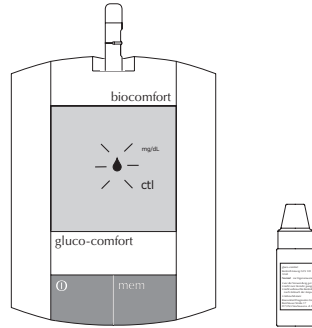
The blood glucose meter function check is carried out in the same way as a normal blood glucose measurement except the measuring cell of the test strip is filled with *gluco-comfort* control solution instead of with blood.

To do this, put a drop of control solution on one of your fingernails and then bring the drop in contact with the measuring cell of the test strip.

To carry out the blood glucose measurement, see Section 3.4.

Attention:

If the measuring cell of the test strip has direct contact with the tip of the control solution bottle, the enzyme of the measuring cell could get into the control solution, rendering it useless.



To keep the control measurement from being included in the average calculation of the blood glucose values, you must mark the control measurement as such.

To do this, press the MEM button when the meter is ready for measurement (Step 1 in Section 3.4). In the display, the abbreviation “ctl” (control) appears to the right of the drop symbol. The changeover to control mode is confirmed with a beep. The function of the individual measuring ranges can be checked with the different control solutions:

- Normal blood glucose levels are simulated with the *gluco-comfort* control solution GCS105.
- Low blood glucose levels are simulated with the *gluco-comfort* control solution GCS205.
- High blood glucose levels are simulated with the *gluco-comfort* control solution GCS305.

Notes:

- Please follow the separate user instructions for the control solutions.
- Shake the control solution before use.
- The control solution may not be used past the expiration date.
- Store the control solution at room temperature.
- The control range printed on the test strip packaging only applies for the control solution. It is not a recommended range for your blood glucose value!
- The control solution is not a cleaning solution for the meter.

5.4 Evaluating the control measurement

When the measuring system is working correctly, the measured blood glucose values must correspond with the ranges which are listed on the test strip packaging for normal, low and high.

Attention:

If the levels are not reached, please repeat your measurements. If the values are still outside the specified tolerances, please contact the manufacturer of the blood glucose measuring system. Do not use the blood glucose measuring system until it has been made sure that the displayed values are correct.

We recommend that you periodically compare this test system to another test system known to be well maintained and monitored by a healthcare provider.

Note:

Use only *gluco-comfort* control solutions (GCS105, GCS205 or GCS305), since only these are adapted to the measuring principle of the Biocomfort blood glucose meter and *gluco-comfort* test strip combination.

5.5 Maintaining and cleaning the device

Your blood glucose meter does not require any maintenance.

If needed, clean the outside of the switched-off device with a soft cloth, if necessary, with a mild cleaning solution.

If the meter is contaminated, it is to be disinfected with a suitable disinfectant in accordance with the specifications of the disinfectant manufacturer.

Attention:

Never submerge the meter in any liquid.

5.6 Storage

Make sure that no dirt, dust, blood, control solution or water can get into the inside of the blood glucose meter. Protect your device from extreme humidity.

Handle the device carefully and store it in its storage bag. The bag is for protecting and storing the supplies.

5.7 Disposing of the meter

When making blood glucose measurements, blood can get onto and into the meter. Therefore, a danger of infection is posed by used meters. After removing the battery, dispose of your used meter in accordance with the regulations which apply to you. Your local authorities can give you information about proper disposal.

The meter does not fall under the EC directive 2002/96/EC (directive about used electric and electronic devices).

6 Error messages/causes of error and measures to take

The messages on the display of your Biocomfort blood glucose meter guide you through the measuring procedure, give you information about the stored results and call your attention to occurring problems.



The following error messages may appear on the display:

Error message	Causes	Measures	Remarks
0 error	Error cannot be identified.	Switch off the device and restart.	If this error message appears repeatedly, have the device checked by the manufacturer.
1 error	Internal function test failed.	Switch off the device and restart.	If this error message appears repeatedly, have the device checked by the manufacturer.
2 error	Segmentation fault	Switch off the device and restart.	If this error message appears repeatedly, have the device checked by the manufacturer.
3 error	Information on the code chip could not be read.	Remove the code chip and insert again.	If this error message should keep appearing, try to code the device with another code chip or have the device checked by the manufacturer.

Error message	Causes	Measures	Remarks
4 error	Coding error in the device.	Remove the code chip and insert again.	If this error message should keep appearing, try to code the device with another code chip or have the device checked by the manufacturer.
5 error	Test strip isn't correctly positioned or was removed during measurement.	Remove the test strip from the device and reinsert it. Then repeat the measurement.	
6 error	Measurement is carried out with a used test strip.	Remove the used test strip from the device and repeat the measurement with a new test strip.	
7 error	Bad operating conditions: The ambient temperature is too high.	Adapt the ambient temperature to the required operating conditions (see technical data).	

Error message	Causes	Measures	Remarks
8 error	Bad operating conditions: The ambient temperature is too low.	Adapt the ambient temperature to the required operating conditions (see technical data).	
10 error	No test strip was inserted after starting the device.	Repeat measurement.	Due to a timeout error, the device interrupted the measurement.
11 error	No blood or control solution was applied to the test strip.	Repeat measurement.	Due to a timeout error, the device interrupted the measurement.
14 error	Test strip must be removed.	Remove the test strip from the device.	Due to a timeout error, the device interrupted the measurement.
15 error	After the device was restarted, the code chip was inserted in the device instead of the test strip.	Repeat measurement.	After restarting the device, insert the test strip into the device.

Error message	Causes	Measures	Remarks
16 error	Blood glucose level too high (out of measuring range of <i>gluco-comfort</i>).	If the measured value does not correspond with the way you feel, repeat measurement.	If this error message appears repeatedly, have the device checked by the manufacturer.
17 error	Blood glucose level too low (out of measuring range of <i>gluco-comfort</i>).	If the measured value does not correspond with the way you feel, repeat measurement.	If this error message appears repeatedly, have the device checked by the manufacturer.
19 error (BGM 105)	No user has yet been created with the Health Manager.	Configure the device with the Health Manager and enable at least one user.	
21 error (BGM 105)	No wireless module found.	Switch off the device and restart.	If this error message appears repeatedly, have the device checked by the manufacturer.

Error message	Causes	Measures	Remarks
23 error (BGM 105)	The wireless connection could not be cut.	Switch off the device and restart.	Measurement cannot be carried out.
24 error (BGM 105)	Communication error		Only occurs with the software, which is available as an accessory.
32 error	Function test of the system was not completed successfully.	Switch off the device and restart.	If this error message appears repeatedly, have the device checked by the manufacturer.
error and blinking battery symbol	Battery is almost completely used up.	Exchange the battery and restart the device.	When the battery symbol blinks, the blood glucose meter cannot be used.

Note: If you are not able to solve an occurring problem, contact Biocomfort Diagnostics GmbH & Co. KG.

7 Performance data summary

Diabetes experts have suggested that glucose meters should agree within 15mg/dL of a laboratory method when the glucose concentration is lower than 75 mg/dL, and within 20% of a laboratory method when the glucose concentration is 75 mg/dL or higher. The chart below displays how often the gluco-comfort meter achieves this goal. The chart is based on a study done on 100 patients to see how well the gluco-comfort compared to laboratory results.

For glucose results lower than 75 mg/dL, the percentage (and number) of meter results that match the laboratory method within 15 mg/dL is 96% (39/40).

For glucose results at 75 mg/dL or higher, the percentage (and number) of meter results that match the laboratory method within 20% is 97% (60/60).

Note: When meter results are compared to the laboratory results, results below 75 mg/dL are compared in mg/dL.

8 Technical data

Device type:	Blood glucose meter	Average values:	7-, 14-, 21-, and 28-day average	Power supply:	1 x 3V lithium cell of type CR2032	Test strips:	<i>gluco-comfort</i> test strips BGS105
Model:	<i>gluco-comfort</i> BGM105/ <i>gluco-comfort</i> BGM205	User management:	1 to 8 users	Display:	LC display		Transportation and storage conditions:
Serial no.:	Specified on the type plate (bottom of measuring device)	Size:	2.76 x 3.54 x 0.71 (W x L x H) [inch]	Battery lifetime:	BGM105: circa three months BGM205: circa 800 measurements		39.2°F to 104°F at a relative humidity of 10% to 95%
Measuring method:	Glucose is oxidised by a glucose dehydrogenase, amperometric biosensor fresh capillary blood	Weight:	circa 2.47 oz (without battery)	Wireless technology: (BGM105)	2.4 GHz IEEE 802.15.4 Wireless range max. 10 yd indoors	Control solution:	<i>gluco-comfort</i> “normal” control solution GCS105 (target value about 120 mg/dL)
Sample:		Colour:	BGM105: Housing is grey aluminium, buttons and battery compartment cover are black	Automatic function test:	yes (temperature, battery charging state, coding, functionality)		<i>gluco-comfort</i> “low” control solution GCS205 (target value about 40 mg/dL)
Sample volume:	< 2 µl		BGM205: Housing is slate grey, buttons and battery compartment are light blue	Transportation and storage conditions:	-4°F to 140°F at a relative humidity of 10% to 95%		<i>gluco-comfort</i> “high” control solution GCS305 (target value about 400 mg/dL)
Measuring range:	20 – 600 mg/dl (1.1 – 33.3 mmol/l)	Automatic switch-off function:	4 minutes when test strip is inserted; 2 minutes if no function has been activated and no test strip is inserted.	Operating conditions:	50°F to 104°F at a relative humidity of 20% to 85%. Maximum altitude:		Transportation and storage conditions: 39.2°F to 86°F at a relative humidity of 10% to 95%
Measuring period:	10 seconds						
Coding:	Code chip						
Measured value memory:	Max. 122 blood glucose measurements per user, all values are stored with the time and date.						

EMC information

The wireless module integrated in this device (BPM105 only) fulfills the regulations of EC directive 1999/5/EC (Radio and telecommunication terminal equipment, R&TTE).

The requirements of the following standards are met:

- ETSI EN 301 489-17 Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 17: Specific Conditions for 2,4 GHz Wideband Transmission Systems
- EN 300328-2 V1.2.1 Electromagnetic compatibility and radio spectrum
- FCC Class B Part 15

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the manufacturer' instructions, may cause interference harmful to radio communications. There is no guarantee, however, that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio or TV technician for help.

Not authorized changes or modifications could void authority to use this equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The BGM105/BGM205 is intended for use in the electromagnetic environment specified below. The customer or the user of the BPM105/BPM205 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 2	The BGM105/BGM205 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The BGM105/BGM205 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

For Details of essential performance: please refer to section 1.1 Intended Use

Guidance and manufacturer's declaration – electromagnetic immunity			
The BGM105/BGM205 is intended for use in the electromagnetic environment specified below. The customer or the user of the BGM105/BGM205 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, oncrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	-
Surge IEC 61000-4-5	Not applicable	Not applicable	-
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	-
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The BGM105/BGM205 is intended for use in the electromagnetic environment specified below. The customer or the user of the BGM105/BGM205 should assure that it is used in such an environment.			
Electromagnetic environment – guidance Portable and mobile RF communications equipment should be used no closer to any part of the BGM105/BGM205, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity test	IEC 60601 test level	Compliance level	Recommended separation distance:
Conducted RF IEC 61000-4-6	Not applicable	Not applicable	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b

Interference may occur in the vicinity of equipment marked with the following symbol:



NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BGM105/BGM205 is used exceeds the applicable RF compliance level above, the BGM105/BGM205 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BGM105/BGM205.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.


Recommended separation distances between portable and mobile RF communications equipment and the BPM105/BPM205			
The BPM105/BPM205 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BPM105/BPM205 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BPM105/BPM205 as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

9 Symbols and abbreviations

On the device, packaging material and in the operating manual you will find the symbols shown below with the following meanings:

 In vitro diagnostics device

 Operating temperature at 10°C to 40°C

 Please follow the operating manual.

REF Article or order number

SN Serial number


Coding: SN: 0205280008


Device type: _____

Year of production _____

Week of production _____

Production number _____

 The device BGM105 contains an HF transmitter (wireless transmitter).

 0197 The blood glucose meter, test strips and control solution are in vitro diagnostic supplies for personal use. The CE marking of this product confirms that the relevant requirements of the EC directive 98/79/EC for these products are fulfilled. The blood glucose meter BGM105 contains an HF wireless module. The CE marking on the blood glucose meter confirms that the wireless module meets the relevant requirements of EC directive 1999/5/EC.

The lancing device and lancets are medical products. The CE marking of these products confirms they meet the relevant requirements of the EC directive 93/42/EEC for these products.

The identification number 0197 behind the CE marking identifies the notified body who is responsible for monitoring the manufacturer.



0197

The blood glucose meter, test strips and control solution are in vitro diagnostic supplies for personal use.

The CE marking of this product confirms that the relevant requirements of the EC directive 98/79/EC for these products are fulfilled. The blood glucose meter BGM105 contains an HF wireless module. The CE marking on the blood glucose meter confirms that the wireless module meets the relevant requirements of EC directive 1999/5/EC.

The lancing device and lancets are medical products. The CE marking of these products confirms they meet the relevant requirements of the EC directive 93/42/EEC for these products.

The identification number 0197 behind the CE marking identifies the notified body who is responsible for monitoring the manufacturer. This device is developed and manufactured according to the regulation of the 21CFR820.

10 Limited Product Warranty Information

This product is subject to the Biocomfort One-Year Limited Warranty separately included in this box and also available from Biocomfort or any authorized Biocomfort dealer or from Biocomfort's website at

<http://www.biocomfort.com/support>.

If you do not agree with, and do not want to be bound by, the terms of the Biocomfort one-year limited warranty, return the box and its contents, including the hardware and accessories unused, to Biocomfort, or to the authorized Biocomfort dealer where you purchased the product, within fourteen (14) days of purchase, together with proof of purchase, and your full purchase price will be refunded. By using this product or letting the 14-day period lapse, you agree to the

terms of the Biocomfort one-year limited warranty.

11 Disclaimer of Warranties

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