

medisana®

MEDITOUCH 2



Meal
markers



480
Memory
slots



Test
reminder

Blood glucose monitor for self-testing MediTouch® 2

mmol/L

Art. No. 48771

CE 0483


Instruction Manual
Please read carefully!

Contents

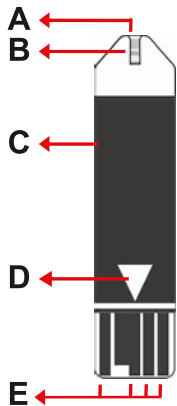
Device and controls	3	6 Memory	35
1 Explanation of symbols	6	6.1 Saving the test results	35
2 Safety information	8	6.2 Accessing and deleting test results.....	35
2.1 Always observe the following points	8	7 Miscellaneous	38
2.2 Instructions for your health	11	7.1 Display and troubleshooting	38
2.3 Instructions on how to use the blood glucose test strips.....	13	7.2 Cleaning and maintenance	42
2.4 Instructions on how to use the control solution	14	7.3 Reset the meter	43
3 Useful information	15	7.4 Technical specifications	43
3.1 Items supplied and packaging	15	7.5 medisana MediTouch® 2 accessories	44
3.2 Special features of the medisana blood glucose monitor MediTouch® 2	16	7.6 Disposal	44
4 Getting started	17	7.7 Lancets	45
4.1 Inserting the batteries	17	8 Warranty	46
4.2 Setting the time and date.....	19	8.1 Warranty and repair terms	46
5 Operating	20		
5.1 Using the control solution	20		
5.2 Preparing the blood glucose test.....	24		
5.3 Using the capAST.....	27		
5.4 Determining the blood glucose level	29		
5.5 Discarding used lancets	31		
5.6 Evaluating a test result	32		
5.7 Typical symptoms of high or low blood glucose.....	34		

Monitor



- 1 Display**
- 2 Battery compartment**
(on the back)
- 3 > - Button**
for memory access, to enter values and to look at test results
- 4  - Button**
to confirm settings, delete results or to switch on the device (press and hold for appr. 3 seconds).
- 5 Insertion slot for test strips**
- 6 Test strip**

Test strips, control solution and lancing device

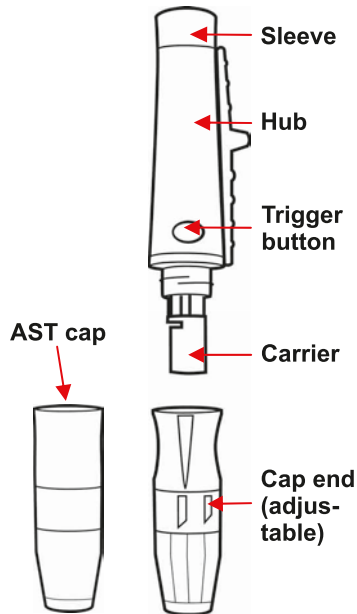


- A. Blood sample area (absorbent slot)
- B. Reaction cell
- C. Grip/holder
- D. Insert in the direction of the arrow
- E. Contact electrode

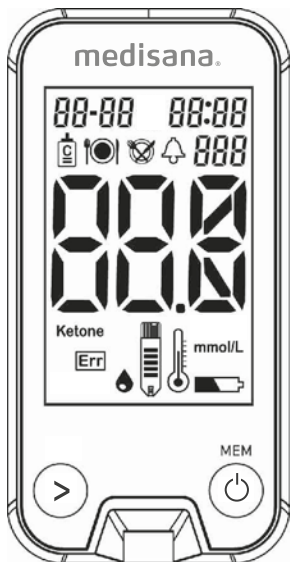


Samnia illustration

Expiration date



Display



	Date (month:day)	AM	AM (before noon)
	Time (hours:minutes)	PM	PM (after noon)
	Control solution measurement mode		Before Meals ()AC
	Alarm (before meals with automatic alarm after 2 hours to remind you to perform a test after meals)		After Meals ()PC
		Ketone	Warning regarding a possible diabetical ketoacidosis. Consult doctor!
	Blood glucose reading	Err	System error
	Insert test strip		Ambient temperature error
	Apply blood or control solution	mmol/L	Unit of measure
	Battery symbol (low battery)		

1 Explanation of symbols

The following signs and symbols on items, packaging and in the instruction manual bear important information:



This instruction manual belongs to this device. It contains important information about starting up and operation. Read the instruction manual thoroughly. Non-observance of these instructions can result in serious injury or damage to the device.



NOTE

These notes give you useful additional information on the installation or operation.



LOT number



Catalogue number



Serial number



Manufacturer



WARNING

These warning notes must be observed to prevent any injury to the user.



CAUTION

These notes must be observed to prevent any damage to the device.



Recycling symbols/codes:

These are used to provide information about the material and its proper use and recycling.





In vitro diagnostic medical device
(for external use only)



This blood glucose monitor corresponds
to the requirements of the EU
guideline 98/79 for in vitro diagnostic devices.



Do not re-use



Use by



Storage temperature range



Contains sufficient for <n> tests



Control solution



Discard 6 months after opening



Ambient
pressure
limitation



Humidity
range



Radiation sterilized



Biological risks



Medical Device



YYYY-MM-DD



YYMMDDXXXX



IMPORTANT INFORMATION! RETAIN FOR FUTURE USE!

Read the instruction manual carefully before using this device, especially the safety instructions, and keep the instruction manual for future use. Should you give this device to another person, it is vital that you also pass on these instructions for use.

2.1 Always observe the following points

Intended use

- This system is intended for taking an adult's blood glucose test from the finger tip, alternatively from the ball of the hand or lower arm. Thereby it is a matter of a fast, electro-chemical determination of the blood glucose level. The FAD-binding glucose-dehydrogenase converts the glucose in human blood to gluconolactone. The device measures the current, which is released by this reaction and which is in proportion to the blood glucose volume.
- The system is intended for external use (in vitro) and can be used for self-testing by persons with diabetes or in clinical settings by healthcare professionals as an aid to monitor the effectiveness of diabetes control.



Contraindications

- The system is not suitable for diagnosing diabetes for children younger than 12 years. For use on older children ask your doctor.
 - It is not suitable for diagnosing diabetes or for testing the blood glucose levels of newborn babies.
-
- This device measures in mmol/L.
 - The unit is only to be used for the specific purpose described in this instruction manual.
 - Any misuse will void the warranty.
 - Only use the accessories which have been recommended by the manufacturer (test strips, control solution) with this monitor.
 - This device is not designed to be used by persons (including children) with limited physical, sensory or mental abilities, or by persons with insufficient experience and/or knowledge, unless under observation by a person responsible for their safety, or unless they have been instructed in the use of the device.
 - Children must be supervised to ensure that they do not play with the device.
 - Do not operate the device in the vicinity of highfrequency transmitters, e.g. microwave and short wave transmitters.
 - Do not use the device if it is not working correctly, if it has been dropped or has fallen into water or has been damaged.
 - Protect the unit from moisture. Should moisture enter the unit, remove the batteries and stop using it immediately. Contact your authorised service centre.



- If a fault occurs, do not try to repair the unit yourself. Attempts to do so will void the warranty. Refer all servicing to authorized service personnel.
- Always keep the monitor clean and store it in a safe place. Protect the monitor from direct sunlight to prolong its service life.
- Do not store the monitor and the test strips in a vehicle, bathroom or refrigerator.
- Extremely high humidity can affect the test results. A relative humidity of more than 90% can cause incorrect readings.
- Store the monitor, the test strips and the lancing device out of reach of children and pets.
- Remove the battery if you do not intend to use the monitor for one month or longer.
- Consult your healthcare professional before making a blood glucose test with this device.



2.2 Instructions for your health

- This blood glucose monitor is intended for actively testing a person's blood glucose at home. The reading from a blood glucose home-test system does not replace a professional test performed in a laboratory.
- The monitor is intended for external use only (in vitro).
- Only use fresh, capillary whole blood from the finger tips for the test.
- You may only adapt the procedure for using products at home and self-monitoring, if you have first received the appropriate training to do so.
- Do not change any treatments as a result of your blood glucose reading without first consulting your doctor.
- The system is not suitable for testing critically ill patients.
- Your monitor only requires one small drop of blood to perform a test. You can get this from a fingertip. Use different place for each test. Repeated lancing in the same place can lead to infection and numbness.
- Test results below 60 mg/dL (3.3 mmol/L) are an indication of hypoglycemia, meaning the blood glucose level is too low. If the reading is above 240 mg/dL (13.3 mmol/L), symptoms of a high blood glucose level (hyperglycemia) can occur. Consult your doctor, if your readings are regularly above or below these levels.
- If the test results display “”, performLO” or “HI the test once again. If you obtain similar readings again, consult your doctor immediately and follow his instructions.
- If the proportion of red blood cells (haematocrit level) is very high (over 60 %) or very low (under 20 %), this could distort the test results.
- Dehydration or a lack of water (such as from sweating) can result in incorrect readings. If you think you are suffering from dehydration or a lack of water, consult your doctor immediately.
- If you have followed the instructions in this manual and symptoms persist which are not associated with your blood glucose level or your blood pressure, consult your doctor.



- For additional advice on your health, read the instruction manual for the test strips carefully.



WARNING

Risk of infection

- **Used test strips and lancets are considered to be hazardous, biological non-biodegradable waste. Carelessness when disposing of these items can lead to the spread of infection. If necessary, consult your local waste disposal company, your doctor or pharmacist.**
- **Dispose of your used test strips and used lancets carefully. If you dispose of the used parts with the household rubbish, make sure you wrap them first to avoid harming or infecting other people.**
- **Medical staff or others who use this monitor on more than one patient must be aware that all products or objects which come into contact with human blood must be dealt with as if they are capable of spreading viral diseases, even after cleaning.**
- **Never use a lancet or the lancing device on more than one person.**

- **Use a new sterile lancet and a new test strip for every test.**
- **Lancets, test strips and alcohol pads are disposable.**
- **Avoid getting hand cream, oil or dirt in or on the lancet, lancing device and test strip.**



2.3 Instructions for using the blood glucose test strips

- Only use these with the MediTouch® 2 monitor.
 - Store the test strips in their original container.
 - To avoid contamination, only touch the test strips with clean, dry hands. When removing the strips from the container and inserting them in the monitor, only touch them using the grip (holder).
 - Close the container again immediately once you have removed the test strip. This keeps the test strips dry and free of dust.
 - Use the test strip within three minutes of removing it from the container.
 - The test strip is intended to be used only once. Do not use it again.
 - Write the opening date on the label of the container when you open it for the first time. Observe the expiry date. The test strips can be used for approx. six months after opening the container or until the expiry date, whichever comes first.
- Do not use test strips which have already exceeded the expiry date, as this can distort the test result. The expiry date is printed on the container.
 - Store the test strips in a cool, dry place but not in the refrigerator.
 - Store the test strips between 2°C and 30°C (35.6°F - 86°F). Do not freeze the test strips.
 - Protect the strips from damp and direct sunlight.
 - Do not apply the blood sample or control solution to the test strip before you have inserted it in the monitor.
 - Only apply the blood sample or the control solution provided on the test strip slot. Applying any other substance will lead to an imprecise or incorrect reading.
 - The test strips can be used at altitudes of up to 3,048 m without having any impact on test results.
 - Do not bend, cut or adjust the test strips in any way.



- Keep the container with the test strips away from children. There is a risk of choking from the lid. The lid also contains desiccative substances which could be dangerous if they are inhaled or swallowed. This could also lead to skin and eye irritations.

2.4 Instructions on how to use the control solution

- Only use **medisana** MediTouch® 2 control solution.
- Only use with the MediTouch® 2 test strips.
- Write the opening date on the label of the container. The control solution can be used for approx. three months after opening the container or until the expiry date, whichever comes first.
- Do not use the control solution after the expiry date.
- The ambient temperature for using the control solution should lie between 10°C - 40°C (50°F - 104°F).
- The temperatures for storing and transporting the control solution should lie between min 2°C and max 30°C (35.6°F – 86°F). Do not store the solution in the refrigerator and do not freeze it.
- Shake the bottle with the control solution well before you open it. Wipe away the first drop and use the second one to ensure a good sample for a precise test result.
- To ensure the control solution does not get contaminated, wipe away the remaining solution on the tip of the container with a clean cloth before closing it again.
- The control solution may stain your clothing. Rinse the soiled clothing with water and detergent.
- Do not put any excess control solution back in the container.
- Close the container carefully after every use.

Thank you very much

Thank you for your confidence in us and congratulations!

The blood glucose monitor MediTouch® 2 that you have purchased is a top quality product from **medisana**. In order to achieve the desired effect with your **medisana** MediTouch® 2 blood glucose monitor in the long term, we recommend that you read the following information on its use and maintenance carefully.

3.1 Items supplied and packaging

Please check first of all that the device is complete and is not damaged in any way. In case of doubt, do not use and contact your supplier or your service centre.

The following parts are included:

- 1 MediTouch® 2 blood glucose monitor
- 1 MediTouch® 2 lancing device
- 10 MediTouch® 2 blood glucose test strips
- 10 MediTouch® 2 lancets
- 1 MediTouch® 2 control solution 4 ml
- 1 AST cap
- 2 CR2032 lithium batteries

- 1 Storage bag
- 1 Instruction manual
- 1 Teststrips manual
- 1 Control solution manual

The packaging can be reused or recycled. Please dispose properly of any packaging material no longer required. If you notice any transport damage during unpacking, please contact your supplier without delay.



WARNING

**Please ensure that the polythene packing is kept away from the reach of children!
Risk of suffocation!**

3 Useful information

3.2 Special features of the medisana blood glucose monitor MediTouch® 2

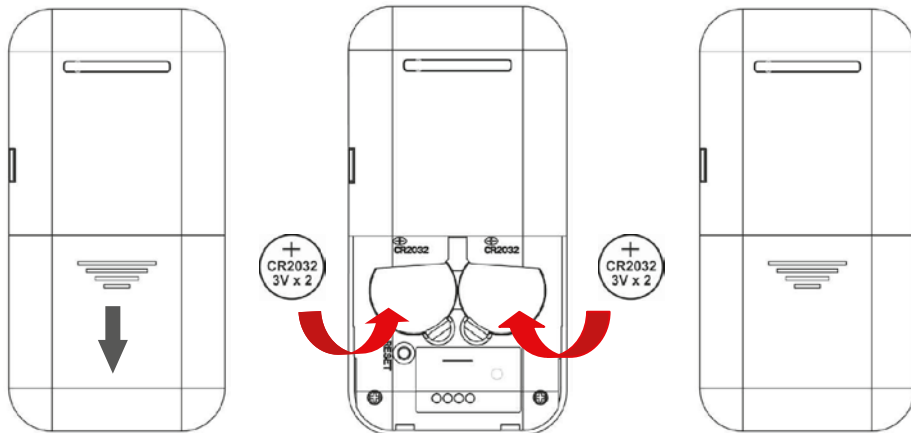
Measuring your blood glucose level regularly can be a great help when dealing with your diabetes. This blood glucose monitor is designed so that you can use it easily, regularly and anywhere you choose. The lancing device can be set to the sensitivity of your skin. The diabetic diary provided helps you to recognise and record the affect of your eating habits, sport activities or medication on the test results. Always consult your doctor about your test results and treatment. This monitor is intended for actively testing a person's blood glucose at home. It is not suitable for diagnosing diabetes or for testing the blood glucose of newborn babies.

Your **MediTouch® 2** blood glucose monitor from **medisana** consists of five main parts: the blood glucose monitor, the lancing device, the lancets, the test strips and the control solution.

These parts are specially designed to be used together and for their quality to ensure precise test results. Only use **MediTouch® 2** approved test strips, lancets and control solution for your blood glucose monitor. Precise test results can only be ensured when the monitor is used properly. Only use fresh, capillary whole blood for the test, preferably from the finger tips.

The monitor measures the blood glucose level very precisely. It has an automatic memory for 480 readings with the date and time. It also calculates the average level using the blood glucose readings from the previous 7, 14, 30 and 90 days. This allows you to monitor any changes and discuss them with your doctor.

4.1 Inserting the batteries



1. Open the battery compartment **2** on the back side of the device by sliding the lid in the direction of the arrow.
2. Insert two batteries as shown. The device will emit a short beep after correct insertion.
3. Close the lid of the battery compartment. It will "snap" into its place.



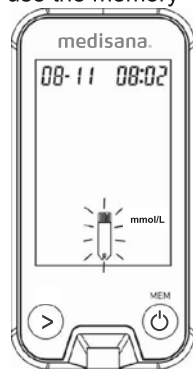
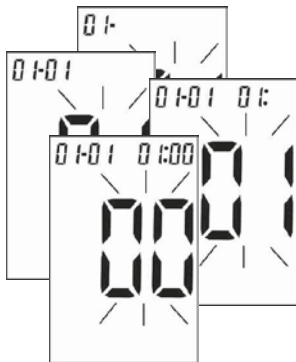
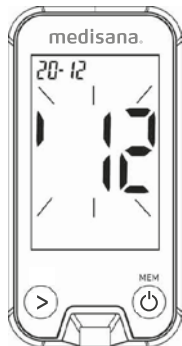
WARNING BATTERY SAFETY INFORMATION

- Do not disassemble batteries!
- Remove discharged batteries from the device immediately!
- Increased risk of leakage, avoid contact with skin, eyes and mucous membranes! If battery acid comes in contact with any of these parts, rinse the affected area with copious amounts of fresh water and seek medical attention immediately!
- If a battery has been swallowed seek medical attention immediately!
- Only replace with batteries of the same type, never use different types of batteries together or used batteries with new ones!
- Insert the batteries correctly, observing the polarity!
- Remove the batteries from the device if it is not going to be used for an extended period!
- Keep batteries out of children's reach!

- Do not attempt to recharge these batteries!
There is a danger of explosion!
- Do not short circuit!
There is a danger of explosion!
- Do not throw into a fire!
There is a danger of explosion!
- Do not throw used batteries into the household refuse; put them in a hazardous waste container or take them to a battery collection point, at the shop where they were purchased!


4.2 Setting the time and date

The correct setting of time and date is especially important, if you intend to use the memory function of the device.



1. After insertion of the batteries the monitor switches on automatically.
2. The last two digits of the year flash in the display. Press \blacktriangleright to set the correct value and press ⏻ to confirm.

3. Repeat step 2, to enter the date and time. The area flashes for the setting being made at the time.

4. The icon  appears in the display. The device is now ready for the test with control solution.



The unit of measure (mmol/L) is installed in the device. If you want to change the unit of measure, contact the customer service.

5.1 Using the control solution

Why do I need to perform a test with control solution?

When you perform a test with control solution, you will find out whether your monitor and test strips work properly and deliver exact readings. You should perform a test in the following cases:

- You are using the monitor for the first time.
- You have a new container of test strips.
- You suspect the monitor or test strips might not be working properly.
- The monitor has been dropped.
- You have repeated a test and the results are still lower or higher than you expected.
- You are practising the test procedure.

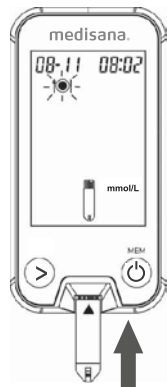
Performing a test with control solution




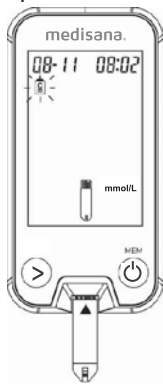
WARNING





Before you perform a test with control solution, read section 2 on Safety instructions (p. 8 - 14), carefully, especially items *2.3 Instructions on using the blood glucose test strips* and *2.4 Instructions on how to use the control solution*.

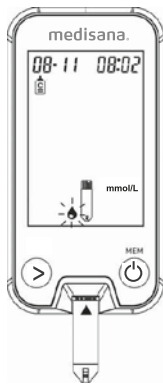
You need the device, a test strip and the control solution.



1. Insert a test strip into the monitor in the direction of the arrow. The -symbol appears automatically.



2. Press the -button, until the symbol  (control solution measurement mode) appears. The drop symbol  flashes. Press  to confirm the setting.



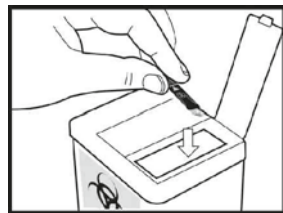
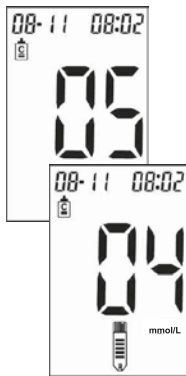
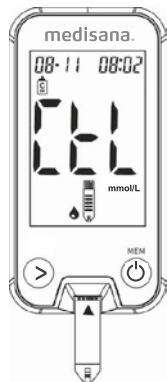
3. Place the device on a flat and even surface, e.g. like a table.
4. Remove the cap of the control solution bottle and wipe the tip of the bottle with a tissue.



The measurement results in the control solution measurement mode will not be recorded in the memory for blood glucose readings.

5 Operating


medisana.



Target range for test with control solution

Normal 5.4 - 7.2 mmol/L

Sample illustration for a target range on the test strips container

5. Press the container so that a tiny droplet forms on the tip of the container.
6. Place the drop onto the blood sample area on the end of the test strip.
7. Do not get any control solution on the top of the test strip.
8. When a sufficient amount of control solution has been absorbed by the reaction cell you will hear a beep and in the display "  " will be shown.
9. The monitor starts a countdown of approx. 5 seconds which is shown in the display.
10. In the display, a test result appears. Before you remove the test strip, check whether the result lies within the range indicated on the test strips container.
11. After that, remove the test strip and throw it away.

Evaluating the control test result

The permissible range for the control solution reading is indicated on the label of the test strip container. Your test result must lie within the range indicated. Make sure that you compare the test result with the correct range. If the control test result lies within the range indicated on the test strip container, then the monitor and the test strips are working accurately. If the control test result does not lie within the range indicated on the test strip container, then the following options will be displayed to rectify the problem:

Cause	Remedy
Has the test strip been lying around open for a long time?	Repeat the test with a test strip that has been stored correctly.
Was the test strip container properly closed?	The test strips are damp. Replace the test strip.

Cause	Remedy
Did the monitor work properly?	Repeat the test as described in section 5.1. If problems persist, get in touch with the service centre.
Is the control solution soiled or has it exceeded the expiry date?	Use new control solution to check the performance of the monitor.
Were the test strips and control solution stored in a cool, dry place?	Repeat the control test using strips and solution that have been stored correctly.
Did you follow the steps of the test procedure properly?	Repeat the test as described in section 5.1. If problems persist, get in touch with the service centre.



5.2 Preparing the blood glucose test

Using the lancing device

The lancing device enables you to hygienically and easily draw a drop of blood for the blood glucose test and it is quick and painless.

The lancing device can be set to the sensitivity of your skin. You can adjust the tip to 5 different lancing depths. Twist the cap end in the appropriate direction until the arrow is pointing to the number for the lancing depth you want.



- 1) Consult the following for the suitable lancing depth:**
1 - 2 for soft or thin skin,
3 - 4 for normal skin and
5 for thick or callous skin.
- 2) Never use a lancet or a lancing device that belongs to another person.**
Use a new sterile lancet for each test.



WARNING

Lancets are intended to be used only once. Used test strips and lancets are considered hazardous, biological non-biodegradable waste.

Dispose of them taking into account that they are capable of spreading infection. Dispose of the lancets so that there is no risk of injury or infection to other people.

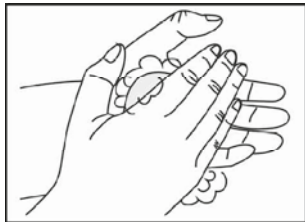
Inserting a lancet into the lancing device

Before using the lancing device you need to insert a lancet.

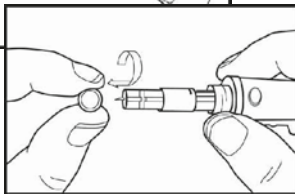
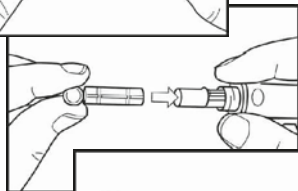
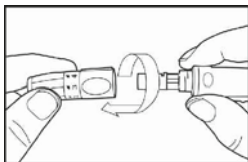


WARNING

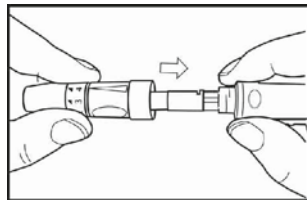
Before performing a blood glucose test and before using the lancing device, make sure you read section 2 on the safety instructions carefully, especially item 2.2 Instructions for your health and 2.3 Instructions on how to use the blood glucose test strips.



1. Wash your hands with soap and warm water. Rinse and dry thoroughly. If needed, you can also rub the area of skin you have chosen for the blood sample with a special cleansing pad.

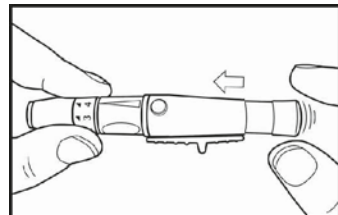
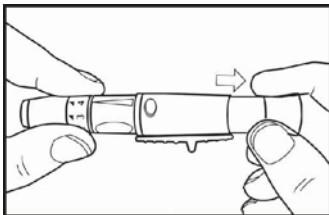
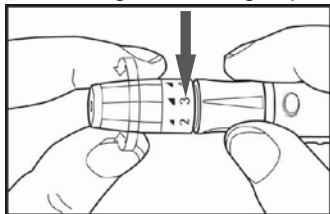


2. Open the lancing device by twisting the protective cap in a clockwise direction and then remove it. Insert the lancet all the way (without turning it) into the lancing device. Twist off the protective cap on the lancet carefully.



3. Replace the protective cap on the lancing device and tighten by turning it in an anticlockwise direction. To use the AST cap, check item 5.3 *Using the AST cap*.

Markings for lancing depths



4. Set the appropriate lancing depth, as described on the pages before.

5. Set the lancing device by extending it until it clicks into place. If it does not click, it is probably already in position from when you inserted the lancet.

6. The lancing device is ready to use. Do not lance your finger before the monitor and test strips are ready to use.



- 1) Consult the following for the suitable lancing depth: 1 - 2 for soft or thin skin, 3 - 4 for normal skin and 5 for thick or callous skin.
- 2) Never use a lancet or a lancing device that belongs to another person. Sharing lancing devices and lancets may transmit blood borne pathogens, such as viral hepatitis.

5.3 Using the AST cap

It is generally recommended that a blood sample for a blood glucose test performed at home is taken from the fingertip. If you are not able to take a blood sample from your fingertip, you can also take one from another part of the body (AST), such as the ball of the hand or lower arm using the lancing device.

In this case, exchange the protective cap on the lancing device with the AST cap. After inserting the lancet, put the transparent AST cap on the lancing device instead of the protective cap and tighten. Note that the AST cap is not intended to be used for a blood sample from the fingertip.



We recommend, only to use the alternative site testing (AST), when:

- at least 2 hours passed after the last meal
- at least 2 hours passed after the last intake of insulin and / or exercise

Discuss the readings from an AST measurement with your doctor, if:

- The glucose results are often fluctuating
- The results do not match the way you feel



WARNING

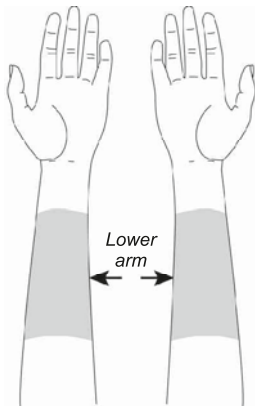
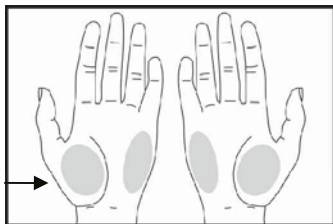
In the case of low glucose (hypoglycemia), the blood sample must be drawn from the finger tip, as any changes in the blood glucose level are quicker to detect from a blood sample from the finger than from any other part of the body.

The readings from a finger tip blood sample and from another part of the body can lead to the readings which radically differ from one another. Therefore, always consult your doctor before you perform a blood glucose test using a blood sample from another part of the body.

5 Operating

The blood sample can also be taken from:

Ball of the hand



This is how to do it:

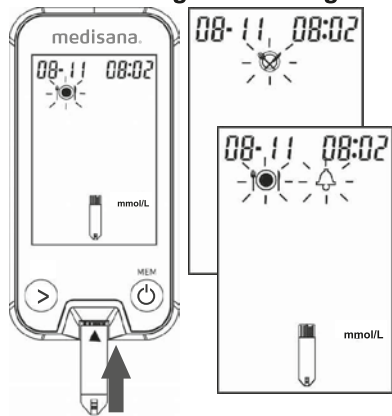
1. Select a part of the body that is soft, not too densely covered with hair and not near a bone or a vein.
2. Massage the area gently to prepare the skin and to improve the circulation.
3. Hold the lancing device against the lancing spot for a few seconds and then press the trigger button.
4. Wait until a blood drop forms under the AST cap with a diameter of approx. 1.4 mm.
5. Remove the lancing device from the skin carefully and proceed in the same way as for the normal protective cap (see 5.4 *Determining the blood glucose level*).



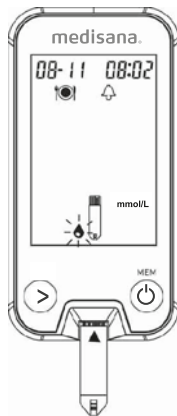
WARNING

Do NOT use the first drop of blood sample when using the AST cap.

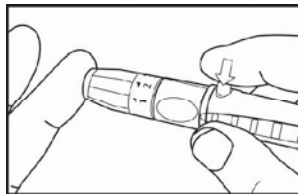
5.4 Determining the blood glucose level



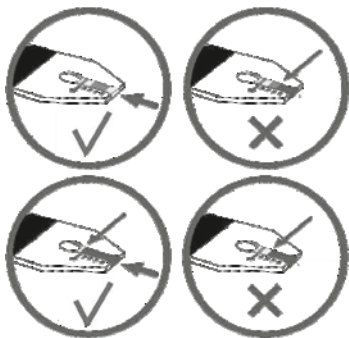
1. Insert a test strip into the monitor in the direction of the arrow. The symbol ☀️ appears automatically.
2. Press > to set ☀️ (before a meal), ☀️❌ (after a meal) or ☀️🔔 (before a meal with alarm after 2 hours) and press ⏻ to confirm.



3. When the blood drop symbol 💧 flashes in the display, take a drop of blood from your finger tip. Massage the area gently to stimulate the blood circulation.

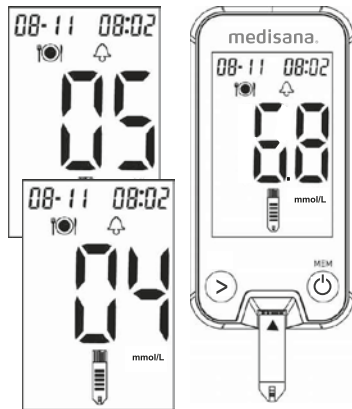


4. Place the lancing device on a finger tip (preferably at the side) and press the trigger button. Make sure, that the blood droplet does not smudge.



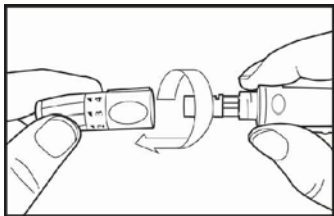
5. Place the drop onto the blood sample area on the end of the test strip. **Pay attention, that not any blood gets on the top of the test strip.**

To receive a correct test result, be sure to apply enough blood into the test strip's blood sample area - see the confirmation window as per drawing above.

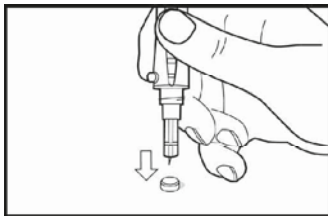


6. When a sufficient amount of blood has been absorbed by the reaction cell you will hear a beep and in the display "5.0" is shown.
7. The device will count down from 5 seconds (shown in display). After that, "OK" is shown and then the result appears in the display.

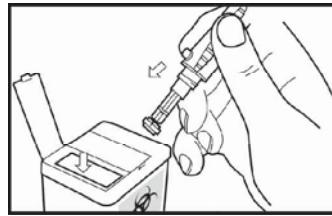
5.5 Discarding used lancets



1. Open the lancing device by twisting the protective cap in a clockwise direction and then remove it.



2. Take out the used lancet (without touching it directly) and stick it into its protective cover.



3. Move the sliding switch, located on the other side of the trigger button, which ejects the lancet. Dispose of the lancet in a container for bio-hazard material carefully to avoid harming other people.
4. After discarding, wash your hands with soap and warm water. Rinse and dry thoroughly.

5.6 Evaluating a test result



WARNING

Never change the prescribed dose of medicine or treatment on your own initiative on the basis of one test result from a blood glucose test.

The **MediTouch® 2** blood glucose test strips work based on an improved technology (-GDH FAD) for a more exact and specific glucose measurement. They are calibrated to easily compare with laboratory test results.

The normal average blood glucose reading of an adult without diabetes is between 70 and 120 mg/dL (3.9 and 6.7 mmol/L). The blood glucose level of an adult without diabetes two hours after a meal is less than 140 mg/dL (7.8 mmol/L).

For those with diabetes: consult your doctor about the range of blood glucose level valid for you.

Unusual test results

If your test result is not what you expected, proceed as follows:

1. Perform a control test, see section 5.1 *Using the control solution*
2. Repeat the blood glucose test, see section 5.4 *Determining the blood glucose level*
3. If your test result is still not what you think it should be, consult your doctor immediately.



NOTES

- **Extremely high humidity can affect the test results. A relative humidity of more than 90% can cause incorrect readings.**
- **If the proportion of red blood cells (haematocrit level) is very high (over 60%) or very low (under 20%), this could distort the test results.**



i NOTES

- **Studies have shown that electromagnetic fields can affect the test results. Do not perform a test near any devices which emit strong electromagnetic rays, such as microwaves, mobile phones etc.**

Comparing your test results with a laboratory result

The question of how you can compare the blood glucose level of the monitor with tests performed in the laboratory is frequently asked. Your blood glucose level can change quickly, especially after a meal, after taking medicine or strenuous activities.

Your blood glucose is affected by various factors and has different values at different times of the day. If you would like to compare the test result of your monitor with a laboratory result, you must do the blood glucose test on an empty stomach. Therefore, it is advisable to do this in the morning.

Take your monitor with you to the doctor's and test yourself five minutes before or after a trained nurse has taken a blood sample from you. Take into account that the technology in the laboratory is different from your monitor and that blood glucose monitors for using at home generally produce slightly different results. To ensure the accuracy and precision of such important information, read the instructions included with the blood glucose test strips.

i NOTE

Make sure that you always record your test results with the date and time in your diabetes diary and label with the appropriate symbol for:

before a meal  , **after a meal**  .

5.7 Typical symptoms of high or low blood glucose

In order to better understand your test results, you can find some typical symptoms for high and low blood glucose herewith. In each case, you should contact your doctor about the therapy if you have noticed one of these symptoms.

Result is higher than 13.3 mmol/L:

The test result is higher than reference normal range (3.9 - 7.2 mmol/L).

Possible symptoms may be:

Fatigue, increased appetite or thirst, frequent urination, blurred vision, headache, general aching, or vomiting.

What to do:

- Test your blood glucose level again
- If the result does not match how you feel, follow the steps on page 32 "Unusual test results"
- Contact your doctor

Result is lower than 3.3 mmol/L:

The test result is lower than reference normal range (3.9 - 7.2 mmol/L).

Possible symptoms may be:

Sweating, trembling, blurred vision, rapid heartbeat, tingling, or numbness around mouth or fingertips.

What to do:

- Test your blood glucose level again
- If the result does not match how you feel, follow the steps on page 32 "Unusual test results"
- Contact your doctor

6.1 Saving the test results

Your monitor can save up to 480 test results, including the time and date. You can access the readings at any time. If the memory is full and you want to add a new test result, the oldest test result will be deleted automatically.

Therefore, it is essential to enter the time and date correctly in your monitor.

NOTES

- **The content of the memory will not be deleted if you change the batteries. Just check that the time and date is still correct. You may have to reset the time and date after changing the batteries. To do this read 4.2 Setting the time and date**
- **If the memory contains 480 test results and you want to add a new test result, the oldest test result saved will be deleted.**


Average values:

Using the blood glucose readings from the previous 7, 14, 30 and 90 days, the MediTouch® 2 monitor calculates the average value taken from the latest (480) to the first (001) test result and all those results AC (before a meal) and PC (after a meal) from the past 30 days.

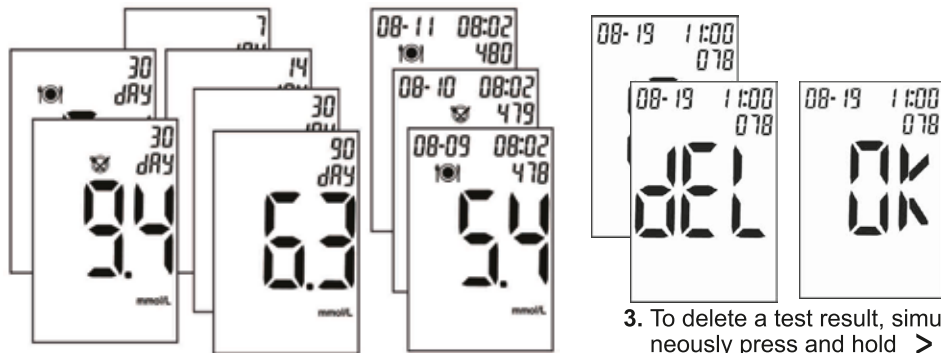
6.2 Accessing and deleting test results

You can access test results anytime without having to insert a test strip. Test results which are under certain criteria are marked with the appropriate symbol. When accessing saved test results, you can select according to these criteria by choosing the appropriate symbol:

before meals 

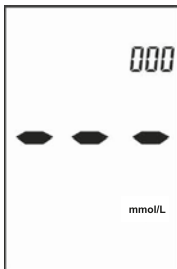
after meals 

before meals
with alarming
2 hours later 




1. Press \triangleright to display the 30-day-average of the values saved under fO . Further pressing of \triangleright displays the 30-day-average value of the saved values under X , then the total average values of the past 7/14/30/90 days. Press and hold O for 2 seconds to cancel this mode.
2. Press O to access the display mode for single values in memory. Press \triangleright to display the saved test results one after the other in sequence of 480 to 001 - in other words the latest entry will be displayed first and the oldest last.
3. To delete a test result, simultaneously press and hold \triangleright and O for 3 seconds. "dEL" appears in the display.
4. Press O to delete the result. The display shows "OK".
5. Press \triangleright to further display other saved values. Press and hold O for 2 seconds to cancel this mode. If no button is pressed, the monitor switches off automatically after approx. 1,5 minutes.

If the following display appears during memory recall process, the device has no test results in memory so far. Perform a blood glucose test first, so that the device can save a test result.



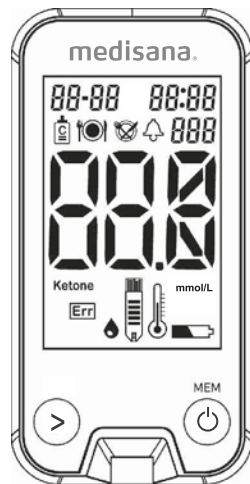
7.1 Display and troubleshooting

Display

The monitor automatically checks its own system when you switch it on and shows you any irregularities in the display. To ensure that the display is working properly, switch on the monitor. Press and hold down the  -button **4** for approx. 3 seconds so that you can see the whole display. All the display elements must be clear to see with the accompanying symbol (please compare with the drawing on this page). If this is not the case, get in touch with the service centre.

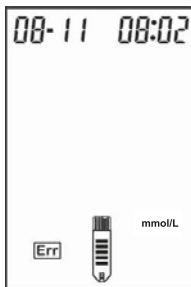
NOTES

- A description of the symbols shown can be found at the beginning of this instruction manual.
- The device may also be switched on by inserting a test strip.



Error display

On no account should you change your medication due to a measurement, which may be incorrect. If in doubt, consult your service centre or your doctor.



Cause

Damp / used test strip

Low batteries

Memory Error

System error

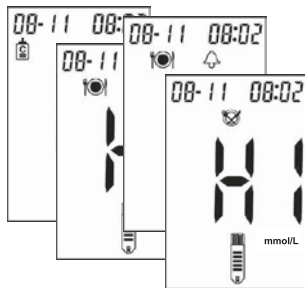
Remedy

Replace with a new test strip.

Replace with new batteries. The device will not delete earlier records when batteries are replaced.

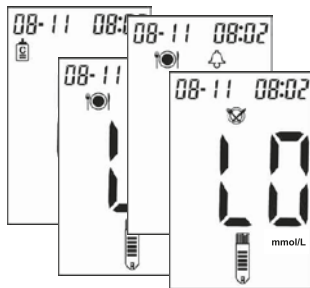
First replace the batteries. If error 005 appears again, get in touch with the service centre.

First replace the batteries. If error 001 appears again, get in touch with the service centre.



Test result is higher than 33.3 mmol/L

Repeat the test. If the result does not change, consult your doctor.



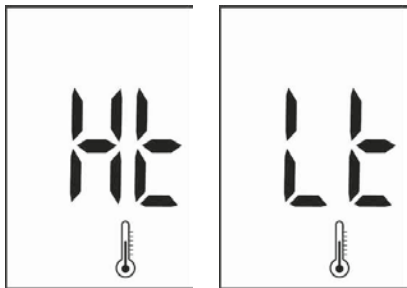
Test result is lower than 1.1 mmol/L

Repeat the test. If the result does not change, consult your doctor.



Test result is higher than 14.0 mmol/L

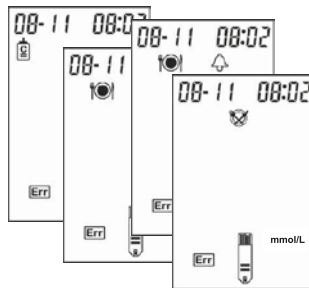
Repeat the test. If the result does not change, consult your doctor. The result may be an indication to a diabetical keto-acidosis. The wording "Ketone" appears in the display.



"Ht" / "Lt" appears. Ambient temperature is too high or too low, not within the required range of 10°C - 40°C (50°F - 104°F).

The user is warned about a potentially incorrect test result if the test proceeds.

Move your monitor to a place with a temperature between 10°C and 40°C (50°F - 104°F).



Blood sample or control solution quantity is not enough.

Repeat the test with a new test strip and sufficient sample quantity. If same problem occurs again, get in touch with the service centre.

7.2 Cleaning and maintenance

Monitor

Your MediTouch® 2 blood glucose monitor is a high-precision instrument. Handle with care to avoid damaging the electronics and prevent defects. You do not need any additional cleaning to maintain your monitor, provided it has not come into contact with blood or control solution. Keep the monitor free from dirt, dust, blood and water stains. Observe the following instructions:

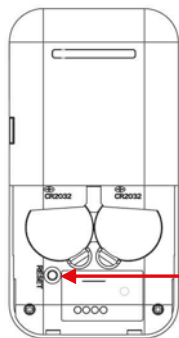
- Make sure that the monitor is switched off.
- Clean the surface of the monitor with a soft cloth slightly dampened with 70-75 % ethanol.
- Never use abrasive detergents or strong brushes.
- Never use cleaning agents on the monitor.
- Never immerse the monitor in water. Do not allow water or other liquids to penetrate the monitor. Dry the monitor with a lint-free cloth after cleaning.
- Make sure that dirt, dust, blood, control solution, water or alcohol do not penetrate the test strip slot or get onto the buttons on the inside of the monitor.

- Do not expose the monitor to extreme temperatures.
- Store the monitor in the zip bag provided after each use.
- Do not store the monitor and the test strips in a vehicle, bathroom or refrigerator.
- Remove the battery if you do not intend to use the monitor for one month or longer.

Lancing device

Clean the lancing device with a slightly damp cloth (with water and a mild detergent). Do not immerse it in water or other liquids and never allow water or other liquids to penetrate the inside of the lancing device. To disinfect the protective cap, soak it in 70 % - 75 % cleaning alcohol for 10 minutes once a week after cleaning. Leave the cap to dry thoroughly after disinfecting.

7.3 Reset the meter



Reset button

To reset the meter (Attention: All saved data will be deleted!), open the cover of the battery compartment ② on the back side of the unit. Press and hold the reset button for approx. 3 seconds to reset the device.

7.4 Technical specifications

Name and model:	MEDISANA blood glucose monitor MediTouch® 2
Measuring method:	electrochemical biosensor technology
Measuring range:	1.1 - 35.0 mmol/L
Measuring time:	approx. 5 seconds
Memory:	480 test results with time and date
Operating conditions:	Temperature 10°C – 40°C (50°F – 104°F), relative humidity up to 90 %
Storage / transport conditions:	Temperature 2°C – 30°C (35.6°F - 86°F), relative humidity up to 90 %
Blood sample volume:	0,6 µL
Sample material:	Fresh blood from finger tip, palm of the hand or arm (capillary whole blood)
Haematocrit value (Htc):	20 – 60 %
Power supply:	2 x 3V CR2032 lithium batteries
Battery operation:	over 2,000 tests
Automatic switch-off:	after approx. 1.5 minutes

Dimensions (display): approx. 37 x 56 mm

Dimensions (base unit): approx. 50 x 98 x 10 mm

Weight: approx. 30 g without batteries

Article number: 48771

EAN number: 40 15588 48771 2

C € 0483

In accordance with our policy of continual product improvement, we reserve the right to make technical and visual changes without notice.

Electromagnetic compatibility:

The device complies with the EN 60601-1-2 standard for electromagnetic compatibility.

Enquire at **medisana** for details on this measurement data.

The monitor is certified in accordance with the requirements of EU guidelines 98/79 for in vitro diagnostic devices.

7.5 medisana MediTouch® 2 accessories

Enquire at your local supplier or service centre.

- 1 MediTouch® 2 control solution Art.-Nr. 48777
- 2x25 MediTouch® 2 test strips Art.-Nr. 48773

7.6 Disposal



This product must not be disposed of together with domestic waste. All users are obliged to hand in all electrical or electronic devices, regardless of whether or not they contain toxic substances, at a municipal or commercial collection point so that they can be disposed of in an environmentally acceptable manner. Please remove the batteries before disposing of the device/unit.

Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop.

Teststrips and lancets

Always dispose of the test strips and lancets in a way that prevents injury and the spread of infection to others. Consult your local authority or your supplier for information about disposal.

8 Warranty

8.1 Warranty and repair terms

Please contact your supplier or the service centre in case of a claim under the warranty. If you have to return the device, please enclose a copy of your receipt and state what the defect is.

The following warranty terms apply:

1. The warranty period for **medisana** products is three years from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Where defects in materials or workmanship arise we will repair or replace free of charge within the warranty period.
3. Repairs under warranty do not extend the warranty period either for the unit or for the replacement parts.
4. The following is excluded under the warranty:
 - a. All damage which has arisen due to improper treatment, e.g. non observance of the user instructions.
 - b. All damage which is due to repairs or tampering by the customer or unauthorised third parties.
 - c. Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
 - d. Spare parts which are subject to normal wear and tear, such as battery, lancing device and disposable items etc.
5. Liability for direct or indirect consequential losses caused by the unit are excluded even if the damage to the unit is accepted as a warranty claim.



medisana GmbH

Carl-Schurz-Str. 2,
41460 NEUSS, GERMANY



medisana GmbH

Carl-Schurz-Str. 2,

41460 NEUSS, GERMANY