EXPLANATION OF SYMBOLS

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

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

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.

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

These test strips for blood glucose tests correspond to the requirements of the EU guideline98/79 for in vitro diagnostic devices and correspond as well to DIN EN ISO 15197:2015-12 “Requirements on blood glucose measurements systems for selftesting in diabetes mellitus” and bear the CE marking (conformance label) “CE 0483”.

IVD In vitro diagnostic medical device (for external use only)

6 M Discard 6 months after opening

Do not reuse

Storage temperature limitation

Contains sufficient for <n> tests

LOT LOT number

REF Catalogue number

Use by

Manufacturer

Keep away from sunlight

Ambient pressure limitation

Humidity range

Biological risks

Recycling symbols/codes: These are used to provide information about the material and its proper use and recycling.

IMPORTANT NOTE
Read this leaflet and the instruction manual for the MediTouch® 2 blood glucose monitor carefully before using the MediTouch® test strips. If you still have any questions or require assistance, contact the medisana service centre.

INTENDED PURPOSE

The MediTouch® 2 test strips are used with the MediTouch® 2 blood glucose monitor to determine the blood glucose level in fresh capillary blood from the finger tip, alternatively from the ball of the hand or lower arm of adults. Thereby it is a matter of a fast, electrochemical determination of the blood glucose level. The FAD-binding glucosedehydrogenase converts the glucose in human blood to gluconolactone. The device measures the current, which is released by this reaction and which is inproportion to the blood glucose volume. The system is intended for external use (in vitro) and can be used for selftesting by persons with diabetes or in clinical settings by healthcare professionals as an aid to monitor the effectiveness of diabetes control.

SAFETY INFORMATION ON STORAGE AND USE

- Do not store the test strips in the refrigerator or freezer.
- Store the test strips in a cool, dry place between 2 °C and 30 °C (35.6 °F - 86°F).
- Only store the test strips in their original container. Never put them in a new or different container.
- Keep the test strips away from direct sunlight and any other heat source
- Protect the test strips from high humidity.
- Write down the date you first opened the container on the test strip container.
- The test strips can no longer be used 6 months after opening. Dispose of the remaining test strips in the container together.
- Use each test strip directly after removing it from the container. Close the container immediately after removing a new test strip. Keep the lid sealed at all times.
- A test strip must be used within three minutes of removing it from the container.
- Only touch the test strip with dry, clean hands.
- Protect the test strip from getting contaminated.
- Never bend, cut or modify the test strips.
- Only use MediTouch® 2 test strips.

SAFETY FOR INFORMATION PATIENTS

- Only for use with in vitro diagnostics (for external use only). Do not put in the mouth or swallow.
- Never use the test strips after the expiry date.
- The test strips are only intended to be used once. Never use them twice.
- Medical staff and any others who use this system on more than one patient should be aware that all products or items that come into contact with human blood should be treated as if they are capable of spreading viral diseases, even after cleaning.
- Consult your doctor if you notice symptoms which do not correspond to your test result, despite having followed all the instructions in the manual for the monitor.
- You may only adapt the procedure for using products at home and selfmonitoring, if you have first received the appropriate training to do so.

LIMITATION

- MediTouch® 2 blood glucose test strips are for use with a fresh sample of capillary blood. Do not use serum or plasma.
- DO NOT use anticoagulant NaF or potassium oxalate for venous sample preparation.
- **Do not use the test strips for tests on newborn babies.**
- Extreme humidity can affect the test results. A relative humidity of more than 90 % can lead to incorrect readings.
- The operating temperature of the system is between 10 °C and 40 °C (50 °F - 104°F). If the temperature is not within this range, incorrect test results can occur.
- Haematocrit: the test results will not be affected by a haematocrit level of between 20% and 60%. A haematocrit level of below 20% can cause an incorrect (too high) test result, a haematocrit level of above 60% can cause an incorrect (too low) test result. If you do not know what your haematocrit level is, consult your doctor.
- Metabolites: the affect of lowering agents depends on the concentration. The following substances may affect the test result up to the test concentration they will not affect the readings:

Concentration of the interference tested			Bias glucose level 50-100 mg/dL (2.8-5.6 mmol/L)	Bias glucose level 250-350 mg/dL (13.9-19.4 mmol/L)
Acetaminophen	7 mg/dL	(0.46 mmol/L)	8.1	5.3 %
Ascorbic Acid	4 mg/dL	(0.26 mmol/L)	6.6	5.8 %
Bilirubin- unconjugated	3.3 mg/dL	(0.056 mmol/L)	0.2	5.2 %
Cholesterol	400 mg/dL	(10.32 mmol/L)	9.6	7.2 %
Creatinine	30 mg/dL	(2.7 mmol/L)	1.3	1.6 %
Dopamine	2.2 mg/dL	(0.14 mmol/L)	8.0	3.2 %
Galactose	20 mg/dL	(1.11 mmol/L)	6.2	2.5 %
Gentisic Acid	7 mg/dL	(0.45 mmol/L)	9.8	3.6 %
Glutathione	1 mg/dL	(0.03 mmol/L)	3.7	6.5 %
Haemoglobin	300 mg/dL	(0.05 mmol/L)	3.8	5.2 %
Ibuprofen	50 mg/dL	(2.43 mmol/L)	3.9	2.7 %
Icodextrin	1094 mg/dL	(0.66 mmol/L)	5.4	4.8 %
L-Dopa	2 mg/dL	(0.10 mmol/L)	10.0	8.7 %
Maltose	278 mg/dL	(7.78 mmol/L)	2.7	4.4 %
Methyldopa	4 mg/dL	(0.19 mmol/L)	9.0	3.7 %
Pralidoxime Iodide	5 mg/dL	(0.14 mmol/L)	2.8	3.3 %
Sodium Salicylate	40 mg/dL	(2.5 mmol/L)	4.3	2.2 %
Tolbutamide	100 mg/dL	(3.70 mmol/L)	1.4	2.3 %
Tolazamide	2.5 mg/dL	(0.08 mmol/L)	2.5	3.6 %
Triglycerides	800 mg/dL	(9.04 mmol/L)	9.3	5.6 %
Uric acid	16.5 mg/dL	(0.99 mmol/L)	7.2	4.0 %
Xylose	9.5 mg/dL	(0.63 mmol/L)	7.0	7.5 %

- Patients undergoing oxygen therapy treatment may receive imprecise test results.
- The test strips can be used at altitudes of up to 3,048 m without having any impact on test results.
- Incorrect test results can occur if the patient is severely dehydrated, suffers from very low blood pressure or is in a state of shock, as well as in cases of hypoglycaemia or hyperosmolarity (with or without ketosis).
- Lipaemia effects: very high levels of blood fat in the blood sample could have a negative impact on certain methodologies. To rule this out, the patient should have his basic level checked in a clinical laboratory test by his doctor before performing the home test. Thereafter, the basic blood glucose level of the patient must be regularly checked and redetermined if necessary.
- Increased cholesterol levels and triglyceride can lead to incorrect test results in certain circumstances.
- Studies have shown that electromagnetism affects the electrical performance and precision of medical equipment and could therefore lead to an incorrect diagnosis.

CONTROL TEST TO ENSURE PRECISE RESULTS

A control test should be performed to ensure precise results of the MediTouch® 2 blood glucose monitor in the following cases:

- You are using the monitor for the first time.
- You have a new container of test strips.
- You have already repeated a test, and the results are still lower or higher than you expected.
- You suspect the monitor or test strips might not be working properly.
- The monitor has been dropped.
- The test strips have been exposed to a temperature which does not lie within the specified range for the storage conditions (2°C - 30°C or 35.6°F - 86°F).
- Perform a control test at least once a week.

A control test with control solution is performed to check the precision of the monitor and test strips. Proceed as described in the instruction manual of the MediTouch® 2 blood glucose monitor. The MediTouch® control solution is only to be used with the MediTouch® 2 blood glucose monitor from **medisana**. Other control solutions may cause incorrect test results. If the result of a test with control solution lies within the range printed on the test strip container, this confirms that the monitor and the test strips are functioning perfectly. If the test result does not lie within the specified control range, repeat the control test. If the test result is still not within the permissible control range, check the standard procedure for the monitor, control solution and test strips according to the instruction manual. If incorrect results persist, contact the service centre. Test results which deviate from the control range might be caused by the following:

- The expiry date of the control solution has been exceeded or the control solution is contaminated.
- An error occurred while performing the test.
- The monitor is not working correctly.
- The expiry date of the test strips has been exceeded or the test strip is damaged.

Do not use the module to measure your blood glucose level, until you have reached a control test result within the control range.

NOTE
The control range on the test strip container can change with each new container.
Always observe the current levels on the label when comparing.

TAKING A BLOOD SAMPLE

The MediTouch® 2 blood glucose monitor is intended for use with fresh capillary blood. A blood sample must be used in the test directly after drawing it. For a blood glucose test using the MediTouch® 2 monitor, a minimum blood sample of 0.6 µL is required.
To obtain a drop of blood, proceed in the following way:
1. Wash your hands with soap and warm water. Rinse them carefully and dry them thoroughly.
2. Prepare the lancing device as described in the instruction manual for the device MediTouch® 2 (Art. 48771 / 48772).
3. Make sure that the skin is totally dry before inserting it.
4. Use the lancing device to draw a drop of blood. Avoid squeezing the area excessively.

PERFORMING A GLUCOSE BLOOD TEST

To determine your blood glucose level, proceed in the following way:
1. Inserting the test strip: Take a test strip out of the container and then close the container again immediately. Use the test strip within three minutes of opening.
   Insert the test strip in the intended slot on the device. The monitor switches on automatically. Select the setting as described in the instruction manual.
2. Applying the blood sample: Draw a drop of blood, as described in the section on TAKING A BLOOD SAMPLE. Once the drop of blood symbol appears in the display, apply the blood sample to the area (absorbent slot) on the test strip. The monitor begins analysing the blood. The blood is absorbed into the reaction cell immediately.
3. Test result: Your blood glucose test result appears in the display after approx. 5 seconds. The test results are automatically saved in the monitor memory. Remove the test strip and the monitor switches off automatically.
4. Disposal: Dispose of the used test strip and the used lancet carefully (in a sealed container in the household waste) to avoid harming and infecting others. When using the monitor in medical facilities, dispose of the test strips and lancets in compliance with the guidelines for potentially infectious material in an appropriate container.

For further information on performing a blood glucose test, read the instruction manual.

TEST RESULTS

Your blood glucose monitor shows the test results as millimol of glucose per litre (milligrams per decilitre) blood in a range of 1.1 to 35.0 mmol/L (20 - 630 mg/dL). If "LO" is shown in the display, the monitor determines a blood glucose volume of less than 1.1 mmol/L (20 mg/dL). If "HI" appears, the monitor reads a blood glucose volume of more than 35.0 mmol/L (630 mg/dL).

For your safety, observe the information in the monitor's instruction manual. If you think you have obtained questionable or unusual test results, observe the following points and repeat the test.
• Check the expiry date on the test strips.
• Check whether sufficient blood was absorbed into the reaction cell in the test strip.
• Check the performance of the monitor and test strips by performing a test with control solution.

If the test result is still questionable, consult your doctor.
Reference levels for adults without diabetes and women who are not pregnant:
Blood glucose before eating is between 3.9 and 6.7 mmol/L (70 - 110 mg/dL).
The blood glucose content should usually be below 7.8 mmol/L (120 mg/dL) two hours after a meal.

WARNING
Test results which show an unexpectedly low or high level of blood glucose might be an indication of a serious illness. If your blood glucose test produces an unusually low or high reading or you are not satisfied, repeat the test with a new test strip. If the test result still does not still match the level you anticipated or the level is below 3.3 mmol/L (60 mg/dL) or above 1 3.3 mmol/L (240 mg/dL), consult your doctor.

PERFORMANCE INDICATORS

The quality of the MediTouch® 2 blood glucose strips has been checked in laboratory and clinical tests.

PRECISION

Three lots of the MediTouch® 2 blood glucose test strips have been tested to assess the precision of blood glucose measuring system. This includes a repeat assessment using venous blood and a laboratory precision assessment using the control material. The blood glucose content of the venous blood samples ranges from 42.7 to 418.0 mg/dL and control material from three concentrations is used.
Results of the repeat precision measurements:

Sample	Venous Blood mg/dL (mmol/L)	Grand mean value mg/dL (mmol/L)	Pooled standard deviation	Pooled coefficient of variation (%)
1	43 (2.4)	36 (2.0)	2.0	5.6
2	62 (3.4)	59 (3.3)	3.5	5.9
3	121 (6.7)	127 (7.1)	4.1	3.2
4	201 (11.2)	214 (11.9)	6.7	3.1
5	317 (17.6)	330 (18.3)	10.1	3.1
6	418 (23.2)	433 (24.1)	14.5	3.3

Results of the intermediate precision measurement:

Sample	Grand mean value mg/dL (mmol/L)	Pooled standard deviation	Pooled coefficient of variation (%)
1	71 (3.9)	1.0	1.4
2	136 (7.6)	1.4	1.1
3	351 (19.5)	2.8	0.8

System Accuracy

The MediTouch® 2 blood Glucose monitor in comparison with the YSI.
Three lots of MediTouch® 2 blood glucose test strips have been tested to assess the system accuracy of the MediTouch® 2 blood glucose measuring system and to compare it with the reference method in whichcapillary whole blood concentrations of 32.4 to 511.8 mg/dL have been used.
Result of the system accuracy of glucose concentrations <100 mg/dL (<5.55 mmol/L):

within ±5 mg/dL (within ± 0.28 mmol/L)	within ±10 mg/dL (within ± 0.56 mmol/L)	within ±15 mg/dL (within ± 0.83 mmol/L)
61 / 186	117 / 186	181 / 186
32.8 %	62.9 %	98.4 %

Result of the system accuracy of glucose concentrations ≧100 mg/dL (≧5.55 mmol/L):

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
205 / 414	339 / 414	398 / 414	413 / 414
49.5 %	81.9 %	96.1 %	99.8 %

Results of the system accuracy for combined glucose concentrations between 34.4 mg/dL (1.9 mmol/L) and 442.8 mg/dL (24.6 mmol/L):

Within ± 15 mg/dL or ± 15% (within ± 0.83 mmol/L or ±15%)
579 / 600 (96.5 %)

In comparison to the YSI, the MDT2 met the EN ISO 15197:2015 standard, whereby 95% of the blood glucose values measured have to fall within the following zones: either ±0.83 mmol/L (±15 mg/dL) of the measured average value when using the reference measuring procedure for blood glucose concentrations <100 mg/dL (<5.55 mmol/L) or ±15% for blood glucose concentrations of ≧100 mg/dL (≧5.55 mmol/L).
99% of the individual measured blood glucose values must fall within zones A and B of the Consensus Error Grid (CEG) for diabetes type 1.

Performance evaluation by the user

A study to assess the glucose values of blood samples of capillary blood from the fingertips, which were obtained from 103 individuals that had no special training, produced the following results: 96.9% within ±15mg/dL (± 0.83 mmol/L) and 96.2% within ± 15% of the values obtained in the medical laboratory with glucose concentrations of at least 100 mg/dL (5.55 mmol/L).
You will find further details and information regarding blood glucose results and various technologies in generally relevant specialist medical literature.

Healthcare Professionals – Please note these additional Limitations

1. If the patient has the following conditions, the result may fails:
   - Severe dehydration
   - Severe hypotension (low blood pressure)
   - Shock
   - A state of hyperglycemichyperosmolar state (with or without ketosis)

2. Lipemic samples: Cholesterol level up to 400 mg/dL (10.32 mmol/L) and triglycerides up to 800 mg/dL (9.04 mmol/L) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with MediTouch® 2 Glucose Meter.

3. Critically ill patients should not be tested with MediTouch® 2 glucose meters.

4. DO NOT use during xylose absorption testing. Xylose in the blood will interfere Self-Monitoring Blood Glucose System.

CHEMICAL SUBSTANCES

Each test strip contains the following reagent:

6 (w/w) %	FAD glucose dehydrogenase (Aspergillus sp.; 2.0 /test strip)IU
56 (w/w) %	Potassium ferrocyanide
38 (w/w) %	Non-reactive ingredients

TECHNICAL SPECIFICATIONS

Storage temperature	2°C - 30°C (35.6°F - 86°F); rel. humidity ≤90%
Operating temperature	10°C - 40°C (50°F - 104°F)
Haematocrit value (Htc)	20 - 60%
Blood sample volume	0.6 µl
REF	48773
EANCode	4015588 48773 6
Contents	2 x 25 test strips
REF	48774
EANCode	4015588 48774 3
Contents	10 test strips
REF	48775
EANCode	4015588 48775 0
Contents	25 test strips

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