



Blood glucose
Ketones

DIATESSE
XPER



USER MANUAL

BLOOD GLUCOSE & KETONES MONITORING SYSTEM

TD-42898
Version 1.0 2018/10
DT091018-01F



Diatesse XPER Bluetooth® (TD-4289B)

Thank you for purchasing the Diatesse XPER blood glucose & ketones monitoring system, including software for measuring your ketone levels. This manual contains important information on the correct use of the meter.

Please read all the information carefully before using the device.

Regularly checking your blood sugar and ketone levels can help both you and your doctor to improve the control of your diabetes. Thanks to the small size and easy-to-use functions of the Diatesse XPER blood glucose & ketones monitoring system, you can use it to easily measure your own levels, wherever and whenever you want.

Should you have any further queries after reading this manual, please contact customer support or your distributor.

Use

This system is intended for exterior use (in vitro diagnostic use) in a non-clinical environment by persons with diabetes and in a clinical environment by healthcare professionals as an aid for assessing the effectivity of a person's diabetes treatment.

It is intended to quantitatively measure blood sugar (glucose) and β -ketones in fresh capillary whole blood drawn from a finger and venous whole blood.

This meter is not designed to diagnose and screen for diabetes mellitus. Healthcare professionals can use the meter to test both capillary and venous whole blood samples. Only capillary whole blood samples can be tested at home.



DIATESSE

Certainty in blood glucose monitoring, we care!

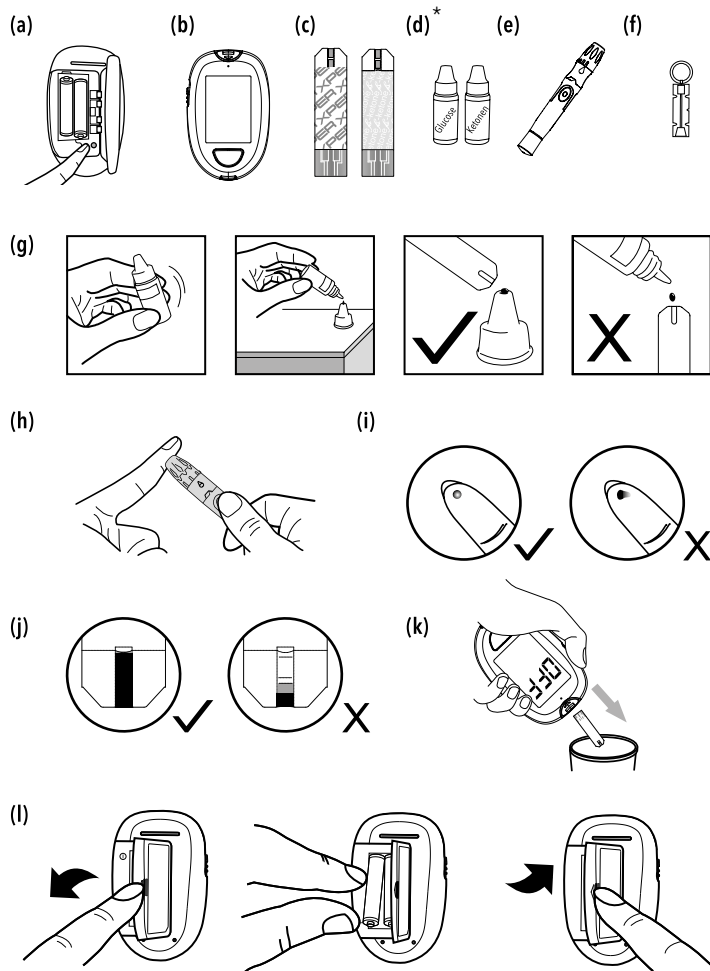
IMPORTANT SAFETY INSTRUCTIONS READ BEFORE USING

- **ONLY** use the meter for the purposes set out in this manual.
- Do not use **ANY** accessories not specified by the manufacturer.
- Do **NOT** use the meter if it is malfunctioning or damaged.
- This meter is not designed to cure given symptoms or diseases. The measured data serve solely as reference values. Always consult your diabetes physician and/or GP for the proper interpretation of the results you have measured.
- Read all the instructions carefully and practice the procedure a number of times before actually testing your blood sugar and/or ketone levels. Perform all quality checks in accordance with the instructions.
- Keep the meter and all its parts out of reach of young children. Small parts, such as the battery cover, the batteries, test strips, lancets and caps are a potential choking hazard.
- Use the meter in a dry environment, especially if synthetic materials are present (such as synthetic clothing or carpeting), which can cause a static charge that could mean incorrect results.
- Do **NOT** use the meter near sources of strong electromagnetic currents, as the accuracy of the measurement could be affected.
- Proper maintenance is essential to the operating life of your meter. If you are worried about the accuracy of your measurements, contact customer support or your distributor for support.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

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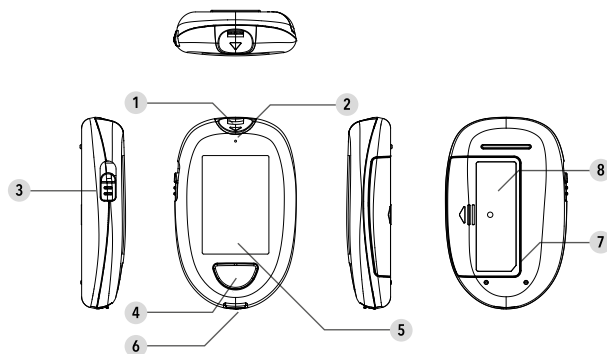
BEFORE YOU START

Important information

- Extreme dehydration and excessive moisture-loss can lead to results being measured that are below the actual values. If you suspect you are suffering from extreme hydration, contact your healthcare professional immediately.
- If your blood sugar or β -ketone levels are lower or higher than normal and you are not displaying any symptoms of being ill, then repeat the test. If you are displaying symptoms or if you continue to receive results that are lower or higher than normal, then contact your healthcare professional and follow their advice.
- Only use fresh whole blood samples for testing your blood sugar and β -ketone levels. Using any other substances will produce incorrect results.
- If you are displaying symptoms that do not match the test results and if you have followed all the instructions in this manual, then please contact your healthcare professional.
- We do not recommend that this meter be used for persons with very low blood pressure or those in a state of shock. Always consult your healthcare professional.

* control solution is not included in the starter pack.

Meter overview



1 Test strip slot and strip indicator light

Insert your test strip, the section containing the contact points, into this slot (so that it is firmly in place) in order to turn the meter on for your test.

2 Bluetooth® indicator light

(Bluetooth® can be optionally activated).

3 Ejecting the test strip

Eject the test strip by pushing this button upwards.

4 Mains button (M)

Open the memory of the meter and turn off the reminder.

5 Display

6 Data port

Download the test results to your computer using a USB cable.

7 SET button (S)

Input the selected meter settings and confirm them.

The SET button is located in the battery compartment.

8 Battery compartment

Display

1 Test result

2 Measuring mode

Gen – at any time

AC – before meals

PC – after meals

3 Automatic quality control mode

QC = Quality control test using the control solution

4 Average over a number of days

5 Memory symbol

6 Date/Time

7 Error warning

8 Alarm symbol

9 Measurement unit

10 Ketone symbol

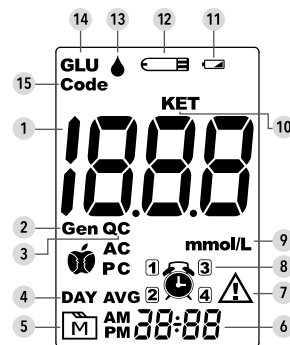
11 Low battery warning

12 Test strip symbol

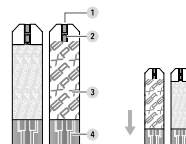
13 Blood drop symbol

14 Glucose (blood sugar) symbol

15 Code



- 1 Absorbent opening
- 2 Control window
- 3 Test strip grip
- 4 Contact points



PLEASE NOTE: The front of the test strip must be facing upwards when you insert the test strip.

The test results could be incorrect and/or inaccurate if that part of the test strip containing the contact points is not fully and correctly inserted into the test slot.

NOTE: Only Diatesse XPER test strips may be used with the Diatesse XPER meter. Using other test strips with this device could produce inaccurate results.

SETTING UP THE METER

Before using your meter for the first time or whenever replacing its batteries, check and adjust the following settings:

Open the setup mode (a)

The meter is switched off (a test strip is not inserted). Press the button marked **S** beside the batteries.

1. Setting the date

The sequence for setting the date is YEAR → MONTH → DAY. When YEAR/MONTH/DAY are flashing consecutively, press the button marked **M** to select the correct setting. Next, press **S**.

2. Setting the date format

Press the main button **M** on the front of the meter to select the required date format (12 or 24 hour). Then press **S**.


3. Setting the time

When HOUR/MINUTE are flashing consecutively, press the button marked **M** until the correct time is displayed. Then press **S**.

4. Turning sound effects on/off

For sound effects press the button marked **M** on the display to switch between "On" and "Off". Then press **S**.

5. To set a reminder

Your meter has four reminder settings. The meter displays "ON" or "OFF" and . If you do not want to set a reminder notification, then press **S** to skip this step. Otherwise press the button marked **M** to select "ON" and then press **S**.

When the hour/minute are flashing, press **M** to select the desired hour/minutes. Then press **S** and continue to the next alarm setup.

PLEASE NOTE: When the reminder notification goes off, press **M** to switch it off. The reminder will sound for 2 minutes and then switch off automatically.

6. Turning on Bluetooth

(Bluetooth® is optional)

When "bt" is visible on the display press **M** and select "ON" or "OFF". Then press **S**.

PLEASE NOTE: This means that data is transferred using Bluetooth®. If you select "ON", then the results are transmitted immediately after the test.


NOTE:

- ALL of these parameters can be changed in the setup mode.
- If the meter is not used for a period of 3 minutes while in setup mode, it switches off automatically.


Measuring methods:

for blood sugar testing

You can measure your blood sugar levels in three different ways: General, AC (before meals) and PC (after meals). You can switch between the different modes as follows:

1. Start with the meter switched off. Insert a blood sugar test strip into the slot to turn the meter on. The display shows, " flashing "▲" and "GLU".
2. Press **M** to switch between General, AC and PC.

For β-ketone testing

3. There is only one option for measuring your β-ketone levels: Gen. Start with the meter switched off. Insert a β-ketone test strip into the slot to turn the meter on. The display shows ", a flashing "▲", "Gen" and "KET".

QUALITY CONTROL TEST

When should you test the device using control solution?

You do not need to perform a test with the control solution when first using the Diateste XPER.


- When you think that either the meter or the test strips are defective.
- When your test results do not match the way you are feeling, or when you believe the results are not accurate.
- When performing a test.
- If you have dropped the meter or have reason to believe it is damaged.

Test strips (**c**), control solution (**d**), lancing device (**e**) or sterile lancets (**f**) might not be included in the kit (please check the list of contents on your product's packaging). These articles can be ordered separately. Ensure that you have a sufficient supply of all the articles you require for performing tests.

Performing a test with the control solution.

In order to perform a test with the control solution, you require (**b**), (**c**) and (**d**).

1. Insert the test strip into the slot to turn the meter on.

Wait until the meter displays "" and a flashing "▲".

2. Apply the control solution (g)

Shake the bottle of control solution well before use. Squeeze out the first droplet and wipe it off. Squeeze another droplet onto the point of the bottle's cap. Hold the meter so that the absorbent opening of the test strip comes into contact with the drop and absorbs the control solution. Once the control window contains sufficient control solution, the meter starts an automatic countdown.

NOTE:

- For blood sugar and ketone tests the meter will automatically recognise a test using control solution as a QC test.
- In order to prevent the control solution becoming contaminated, never apply it directly to the strip.

3. Read and compare the results

Once the countdown to 0 is completed, the result of the test using control solution is shown on the display. Compare the result with the range stated on the test strip packaging. The result must be within this range of values. If that is not the case, re-read the instructions and repeat the test with control solution.

NOTE:

- The range for the control solution that is stated on the test strip tube is only valid when control solution is used. It is not a recommended range for your blood sugar levels.
- See the section under **MAINTENANCE** for important information concerning the control solution.

TESTING USING BLOOD SAMPLES**WARNING:**

In order to limit the chance of an infection:

- Never share a lancet or lancing device with others.
- Always use a new sterile lancet. Lancets are single-use only.
- Ensure that you do not get any hand lotion, oil or residual dirt in or on the lancets or lancing device.

Preparing the lancing device for a blood test

Follow the instructions on the package insert of the lancing device for drawing a blood sample.

Preparing the puncture point

Stimulating blood perfusion by rubbing the puncture point before taking a sample has a major impact upon the test results. Blood extracted from a point that you did not rub beforehand will return a significantly different value than a blood sample extracted from a point you did rub in advance.

We recommend that you perform the following steps before drawing a drop of blood:

- Wash and dry your hands before starting.
- Select a puncture point.
- Rub the puncture point for around 20 seconds before inserting the lancet.
- Clean the puncture point with a cotton swab moistened with a 70% alcohol solution and allow your skin to air-dry.
- **Testing using a fingertip (h)**
Firmly press the lancing device against the underneath part of your fingertip. Press the release button to puncture your finger and the device will click when the procedure is complete.



NOTE:

- Every time you test, use a different puncture point. Repeatedly puncturing the same point can cause a sore to form and callousing.
- We recommend that you wipe away the first blood drop, as it could contain tissue fluid that will affect the test results.

Performing a blood sugar test

In order to test your blood sugar levels, you require the following: **(b), (c), (e)** and **(f)**

1. Insert a test strip into the meter's test slot to activate it

Wait until "" and "" are displayed on the meter.

2. Select the required meter mode by pressing M.**3. Taking a blood sample (i)**

Use the pre-set lancing device to puncture your skin at the selected point. We recommend that you wipe away the first blood drop with a clean tissue/cotton swab. The size of the blood drop must be at least as large as (actual size), which equals around 0.5 microliter (μl) volume for a blood sugar test and 0.8 microliter (μl) volume for a β-ketone test. Carefully squeeze the area around the puncture point to draw a further blood drop. Take care **NOT** to smear out the blood sample.

4. Apply the sample to the test strip (j)

Carefully allow the test strip to come into contact with the blood drop at an angle. The control window of the test strip will be sufficiently full once enough blood is applied. Do **NOT** take your finger away before the device beeps.

NOTE:

- Do not press the puncture point against the test strip and try not to smear the blood.
- If you do not apply a blood sample to the test strip within 3 minutes the device switches off automatically. Should this happen, remove the test strip and re-insert it in order to start a new test.
- The control window must be filled with blood before the meter automatically starts to countdown. **DO NOT** try to add more blood to the test strip once the blood drop has filled the control window. Should that happen, **dispose of the test strip, insert a new test strip and repeat the test.**
- If you struggle to fill the control window, please contact your healthcare professional or customer support for assistance.

Always follow the instructions on the lancing device's package insert for disposing of the used lancet.

WARNING:

Used test strips and lancets could pose a biological hazard. Dispose of them properly in accordance with the local regulations.

METER MEMORY

The meter stores the 1,000 most recent test results together with their dates and times.

In order to access these records, start with the device turned off.

Viewing the test results

1. **Press and release the button marked M.**
"M" will appear on the display.
Press **M** again, the first measurement displayed is the most recent one, together with the date, time and meter mode.
2. **Press M** to call up the results stored in the meter. If you keep the **M** button depressed, the meter will switch off.

Viewing the average of blood sugar results over a number of days

1. Press the button marked **M** (and keep it depressed for a few seconds) then release it to open the memory mode and to view the average results with "M" and "**DAY AVG**" on the display.
Release the **M** button and the average results over 7 days will appear on the display with the meter in General mode.
2. Press **M** to view the average results over 14, 21, 28, 60 and 90 days. These results are stored in each meter mode under Gen, AC and finally PC.
3. To shut down the meter's memory.
Press the **M** button repeatedly; the meter switches off after displaying the most recent test results.

NOTE:

- If you want to turn the memory off, keep the **M** button depressed for 3 seconds or leave the device alone for 3 minutes, after which it automatically switches off.
- The results of tests using control solution are **NOT** included in the average daily results.

DOWNLOADING YOUR RESULTS TO A COMPUTER

Transmitting data using a cable or Bluetooth®

You can attach a micro USB cable (Windows 7 and 8) to the meter or activate Bluetooth® (Windows 10 and up) to view the test results on a computer using the **Health Care Software System**. For further information on the Health Care Software System or to acquire a USB cable, please contact your local customer support or distributor for assistance.

1. Installing the software

The software can be downloaded from the website: www.diatesse.nl

2. Connecting the meter to a computer using a USB cable or (optionally) wirelessly using Bluetooth® (Windows 10 and up)

USB cable: Insert the cable in an unused USB port on your computer. Insert the other end of the cable in the meter's data port while the meter is switched off. "USB" will appear on the meter's display, indicating that the meter is now in communication mode. Under the software options, select the model: TD-4289 (B).
Bluetooth®: Turn the meter on and immediately switch it off again to activate Bluetooth® (the indicator light will flash blue). Next, follow the instructions contained in the software on your computer to connect the meter to the computer using Bluetooth®.
Under the software options, select the model: TD-4289(B).

5. Reading the test results

Your test results will appear once the meter reaches 0 in its countdown. The result is automatically stored in the meter.

6. Eject the used test strip (k)

Eject the test strip by pressing the eject button on the side of the device. Use a specially designated waste container for disposing of the used test strips. The meter switches off automatically.

1. Transmitting data

Follow the instructions contained in the software on your computer for transmitting the data. The results are transmitted together with their dates and times. When you disconnect the cable the meter will switch off automatically.
See also: diateste.nl/support


WARNING:
You cannot perform tests when the meter is connected to a computer.

CONNECTING THE METER TO A SMARTPHONE

Creating a data link using Bluetooth® (Bluetooth® can be optionally switched on or off)

Using Bluetooth®, you can create a data link between your meter and a Bluetooth®-capable smartphone (iOS or Android). Download the ProCheck app to your smartphone from the App Store (iOS) or from Google Play (Android). The ProCheck app has been created to assist you simply and intuitively in monitoring your blood sugar and ketone levels over an extended period. For further information, please contact your local customer support or distributor. You must link your meter and smartphone using Bluetooth® before you can transmit data.

Linking your meter and smartphone (using a security code)

- 1. Turn on Bluetooth® on your smartphone.
- 2. Follow the instructions in the ProCheck app on your smartphone for connecting to your meter.
- 3. Use "Search" to find your meter, which is called DIATESSE XPER xxxx (xxxx = the unique four-digit/letter combination of the Bluetooth® MAC associated with your meter).
- 4. Add your meter, press  and press "Yes" to save the settings.
- 5. Then input your unique code in order to complete the connection. Your code is the last 7 digits of the meter's serial number, excluding the final digit. Input these 6 digits then press "Connect".
- 6. Once the devices are linked, the data in your meter will be sent via Bluetooth® to the ProCheck app.

Bluetooth® indicator on your meter:

BLUETOOTH® INDICATOR	STATUS
Flashing blue light	Bluetooth® is on and searching for a connection
Solid blue light	Bluetooth® linked

For further information see www.diateste.nl

WARNING:

- If your meter and computer are connected by a USB cable then your data will be transmitted using the cable. You can use Bluetooth® to link the devices without using a cable, provided that your computer supports Bluetooth® and Windows 10 or higher is loaded.
- The meter cannot perform a test while it is transmitting data.
- Ensure that your smartphone or computer supports Bluetooth® Smart Technology and that Bluetooth® is activated before trying to transmit data. Also make sure that your meter and the computer or smartphone are sufficiently close together so that they can link. For the required parameters for your (mobile) operating system, check the App Store or Google Play before downloading and installing the app.
- Bluetooth® functionality is implemented in various ways by different manufacturers. This could mean that there are compatibility issues between your meter and the smartphone.



See, for further information:
diateste.nl/support

MAINTENANCE Battery

Your meter comes with two 1.5 V AAA alkaline batteries.

Low battery warning

The meter will warn you in one of the following ways when the power is low.

- 1. The symbol "" appears together with notifications on the display: the meter is working and the results are still accurate, but the batteries must be replaced.
- 2. The symbol "" appears together with E-b, Error and LOW: There is not enough power to perform a test. The batteries must be replaced immediately.

Replacing the batteries

The meter must be switched off when you replace the batteries.

- 1. Slide the battery cover to the left to open it.
- 2. Remove the 2 empty batteries and insert 2 new 1.5 V AAA alkaline batteries.
- 3. Close the battery cover.
If the batteries are correctly inserted, the device will beep.

NOTES

- Replacing the battery will not affect the test results stored in the device's memory.
- As with all small parts, the batteries must be kept out of reach of children. Alert the emergency services immediately if a battery is swallowed.
- Batteries can leak chemicals if they are not used for extended periods. Remove the batteries if you will not be using the device of a lengthy period (i.e. 3 months or more).
- Dispose of used batteries properly, in accordance with the local regulations.

Caring for your meter

Cleaning

1. To clean the exterior of the meter, wipe it off with a cloth that has been lightly dampened with tap water or a mild detergent. **DO NOT** rinse off with water.
2. **DO NOT** use organic solvents to clean the meter.

Storing the meter

- Storage conditions: -20 °C to 60 °C (-4 °F to 140 °F), between 10% and 93% relative humidity (non-condensing).
- Always store or transport the meter in its original case.
- Do not drop the meter or subject it to strong shocks.
- Keep it out of direct sunlight and high humidity levels.

Disposing of your meter

A used meter must be treated as contaminated waste that carries a risk of infection while performing measurements. The batteries of the meter must be removed and the meter must be disposed of in accordance with the local regulations.

The meter does not fall under European Directive 2012/19EU on waste electrical and electronic equipment (WEEE).

Caring for your test strips

- Storage conditions: 2 °C to 30 °C and between 10% and 90% relative humidity (non-condensing) for blood sugar test strips and 2 °C to 30 °C and between 10% and 85% relative humidity (non-condensing) for β -ketone test strips. **DO NOT** freeze.
- Keep the test strips in their original tube. Do not place in a different tube. For foil-wrapped test strips: do not unwrap until required.
- Store the packaging containing the test strips in a cool and dry place. Keep away from direct sunlight and heat.
- Reseal the tube immediately after removing a blood sugar test strip.
- Ensure that your hands are clean and dry before touching a test strip. Use the test strip immediately after removing it from the tube/foil packaging.
- Do not use a test strip after its expiry date, as the result may be inaccurate.
- Do not bend, cut or alter the blood sugar test strip.
- Keep tubes and foil packaging containing test strips out of reach of children. Immediately alert the emergency services if one is swallowed.


For further information, see the package insert for the test strips.

Important information on the control solution


- Only use TaiDoc (W2) control solution for your meter.
- Do not use the control solution after its expiry date or later than 3 months after opening it. Write the date you opened it on the control solution bottle and dispose of any remaining solution after 3 months.
- The recommended room temperature when performing a test with the control solution is between 20 °C and 25 °C (68 °F and 77 °F).
- Ensure that the control solution, your meter and the test strips are at the recommended temperature before conducting a test.
- Shake the control solution well before use. Discard the first droplet of control solution and wipe the dispensing tip clean in order to guarantee a pure sample and accurate result.
- Keep the control solution properly sealed at a temperature between 2 °C and 30 °C (35.6 °F and 86 °F). **DO NOT** freeze.

READING THE RESULTS

For blood sugar tests

MESSAGE	WHAT IT MEANS
Lo	< 0,56 mmol/L (10 mg/dL)
	> 13.3 mmol/L (240 mg/dL)
Hi	> 44.4 mmol/L (800 mg/dL)

Voor β -ketonentesten

MESSAGE	WHAT IT MEANS
Lo	< 0.1 mmol/L
	0.1 to 8.0 mmol/L
Hi	> 8.0 mmol/L

REFERENCE VALUES

Blood Glucose Test

The Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%. *1 The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

For blood sugar tests

Your blood sugar measurements are plasma equivalent values and are shown in millimoles of glucose per litre of blood (mmol/L).

TIME OF DAY	NORMAL PLASMA GLUCOSE RANGE FOR NONDIABETICS
Before meals on an empty stomach	< 5.6 mmol/L (100 mg/dL)
2 hours after meals	< 7.8 mmol/L (140 mg/dL)

Source: American Diabetes Association. Standards of Medical Care in Diabetes- 2018 Jan; 41(Supplement 1): S1-S2.

For β -ketone tests

Your β -ketone measurements are plasma equivalent values and are shown in millimoles of ketones per litre of blood (mmol/L).

The β -ketone test measures beta-hydroxybutyrate (BOHB), the most important of the three β -ketones in your blood. Under normal circumstances, the concentration of BOHB in your blood should be less than 0.6 mmol/L.¹

The BOHB concentration can increase if you are fasting and/or dieting, exercising intensively or suffer from diabetes and fall ill. If your β -ketone test results in a "Lo", repeat the test using a new test strip. If you receive the same result or if the result does not match how you are feeling, then contact your healthcare professional. Always follow the recommendations of your healthcare professional before making any changes to your diabetes treatment. If the levels for your β -ketone test are between 0.6 and 1.5 mmol/L, this could be due to an issue requiring professional medical attention. Carefully follow your healthcare professional's advice. If your β -ketone test levels are greater than 1.5 mmol/L, immediately contact your healthcare professional, as this means you could develop diabetic ketoacidosis (DKA).

1: Wiggam MJ, O'Kane MJ, Harper R, Atkinson AB, Hadden Dr, Trimble ER, Bell PM.

Treatment of diabetic ketoacidosis using normalization of blood 3-hydroxybutyrate concentration as the end point of emergency management.

Diabetes Care 1997; 20:1347-52.

Consult your doctor in order to determine the target range that suits you best.

TROUBLESHOOTING SYSTEM ISSUES

If you follow the recommended actions but the problem continues, please contact customer support or your distributor.

Error messages

MESSAGE	WHAT IT MEANS	WHAT TO DO
E-b	Displayed when the batteries are (nearly) drained.	Replace the batteries immediately.
E-U	Displayed when a used test strip is inserted or incorrectly used.*	Repeat the test with a new test strip.
E-2	Displayed when the code chip (ketones) has expired.	Check if the date is correctly set on the meter and check the expiry date on the packaging. If the issue continues, use a new code chip.
E-t	Displayed when the ambient temperature is greater than the operational range of the device.	The operational range of the device is between 8 °C and 45 °C (46.4 °F to 113 °F). Repeat the test when the meter and the test strip are within the above temperature range.
E-O, E-A, E-E, E-C	Meter issue.	Repeat the test with a new test strip.
E-F	Displayed when the test strip is removed during the countdown or where insufficient blood is present.	Read the instructions and repeat the test with a new test strip. If the issue continues, contact customer support for assistance.
E-8	Displayed when the code chip is not inserted prior to testing or if the meter does not support specific parameters.	Check that the code chip has been correctly inserted. Check that the code chip used supports the parameters of your meter.

*see the user instructions (video) at diatesse.nl/support or read the procedure.

Troubleshooting

1. If nothing is displayed on the meter after a test strip is inserted:

POSSIBLE CAUSE	SOLUTION
Batteries are dead.	Replace the batteries.
The test strip has been inserted upside down or not full inserted.	Insert the part of the strip containing the contact points in the meter. The part containing the control window must be pointing upwards.
Meter or test strips are defective.	Contact customer support.















2. If the test does not commence after the sample is applied:

POSSIBLE CAUSE	SOLUTION
Insufficient blood sample.	Repeat the test using a new test strip. Use more blood for the sample.
Defective test strip.	Repeat the test using a new test strip.
Sample has been applied after the device automatically switched off (3 minutes after the user performed the last action).	Repeat the test using a new test strip. Apply the blood sample when the "●" appears on the display.
Defective meter.	Contact customer support.

3. If the test using the control solution is outside of the specified range:

POSSIBLE CAUSE	SOLUTION
Test performed incorrectly.	Carefully read the instructions and repeat the test.
The control solution bottle was not shaken properly.	Shake the control solution well and repeat the test.
The control solution has expired or is contaminated.	Check the expiry date and the date your first opened the control solution.
The control solution is too hot or cold.	Control solution, meter and test strips must be at room temperature, 20 °C to 25 °C (68 °F to 77 °F) when testing.
Defective test strip.	Repeat the test using a new test strip.
Meter issue.	Contact customer support.
The meter and test strip are defective.	Contact customer support.

INFORMATION ON SYMBOLS

SYMBOL	REFERS TO	SYMBOL	VERWIJST NAAR
	In vitro diagnostic medical device		Please note, consult the accompanying documentation
	See the user manual		Humidity limit
	Temperature limits		This device may not be disposed of with domestic waste but must be surrendered to a recycling centre for electrical and electronic devices. Batteries must be disposed of at a collection point (such as at a supermarket).
	Use before		CE mark
	Batch code		Manufacturer
	Serial number		Authorised representative in the European Community
	Catalogue number		RoHS compliance

SPECIFICATIONS

Model no.: TD-4289B

Dimensions and weight: 90.3 (L) x 52.3 (W) x 18 (H) mm, 58 grams.

Power source: Two 1.5 V AAA alkaline batteries

Display: LCD backlight

Memory: 1,000 test results with associated parameters, date and time.

Export options: USB and Bluetooth®

Automatic blood sample detection

Automatic electrode placement detection

Automatic response time countdown

Automatic switch-off after 3 minutes of inactivity

Temperature warning

Operating conditions: Blood sugar: 8 °C to 45 °C (46.4 °F to 113 °F) and 10% to 90% relative humidity (non-condensing) β-ketones: 10 °C to 40 °C (50 °F to 104 °F) and 10% to 85% relative humidity (non-condensing)

Storage/transport conditions for the meter: -20 °C to 60 °C (-4 °F to 140 °F), between 10% and 93% relative humidity (non-condensing)

Storage/transport conditions for the test strips:

Blood sugar test strips: 2 °C to 30 °C (35.6 °F to 86 °F), between 10% and 90% relative humidity (non-condensing)

β-ketone test strips: 2 °C to 30 °C (35.6 °F to 86 °F), between 10% and 85% relative humidity (non-condensing)

Measuring unit:

Blood sugar tests: mmol/L or mg/dL

β-ketone tests: mmol/L or mg/dL

Range:

Blood sugar tests: 0.6 to 44.4 mmol/L (10 to 800 mg/dL)

β-ketone tests: 0.1 to 8.0 mmol/L

Anticipated lifespan: 5 years

Altitude: up to 2000 m, for use indoors

Degree of contamination: contamination rate 2

This device has been tested for compliance with the electrical and safety requirements of IEC/EN 61010-1, IEC/EN 61010-2-707, IEC/EN 6 7 326-7, IEC/EN 6 7 326-2-6, EN 300 328.

NOTES



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For self-testing



TD-4289B