TD GLUCO

Bluetooth®

BLOOD SUGAR CONTROL SYSTEM

User Manual

TD-GLUCO Bluetooth (TD-4277B)

Thank you for purchasing the TD-GLUCO Bluetooth blood sugar control system. This manual contains important information on the correct use of the system. Please read it carefully and in full before using the product.

Regularly checking your blood sugar levels can help both you and your doctor improve the control of your diabetes. Thanks to the small size and easy-to-use functions, you can use the TD-GLUCO Bluetooth blood sugar control system to easily measure your blood sugar levels, wherever and whenever you want.

Should you have any further queries after reading this manual, please contact your local 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) in fresh whole blood (drawn from a finger, palm, lower arm or upper arm).

This meter is not designed to diagnose and screen for diabetes or to test newly born babies.

Professionals can use the meter to test both capillary and venous blood samples. Only capillary whole blood samples can be tested at home.

IMPORTANT SAFETY INSTRUCTIONS
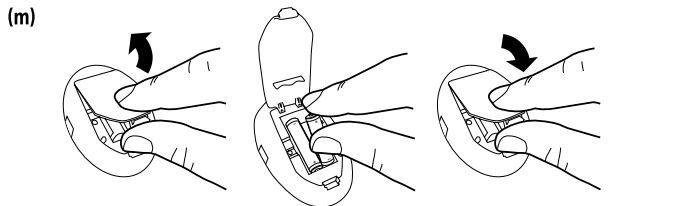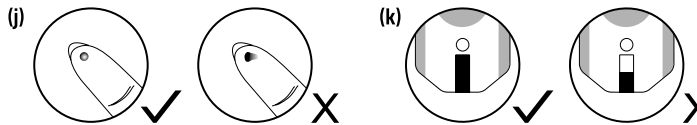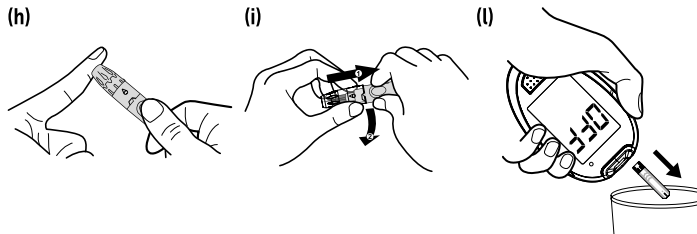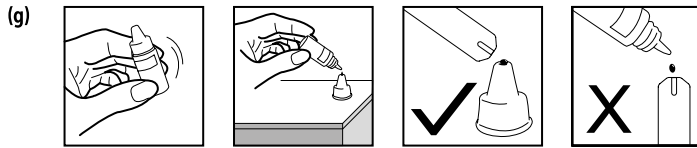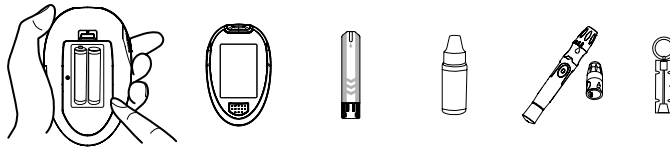## READ BEFORE USING

1. **ONLY** use the device for the purposes stated in this manual.
2. Do not use **ANY** accessories not specified by the manufacturer.
3. Do **NOT** use the device if it is malfunctioning or damaged.
4. **NEVER** use the device on newly born babies or young children.
5. This device is **NOT** designed to treat given symptoms or diseases. The measured data serve solely as reference values. Always consult your GP for the proper interpretation of the results.
6. Read all the instructions carefully and practice the procedure a number of times before actually testing your blood sugar with the device. Perform all quality checks in accordance with the instructions.
7. Keep the device and testing equipment 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.
8. 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.
9. Do **NOT** use the meter near sources of strong electromagnetic currents, as the accuracy of the measurement could be affected.
10. Proper maintenance is essential to the operating life of your device. If you are worried about the accuracy of your measurements, contact local customer support or your distributor for support.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

INHOUD

(a)   (b)   (c)   (d) *   (e)   (f)

(g)

(h)   (i)   (l)

(j)   (k)

(m)

BEFORE YOU START

Important information

- Extreme dehydration and excessive moisture-loss can lead to results being measured that are below the actual levels. If you suspect you are suffering from extreme hydration, contact your GP immediately.
- If your blood sugar 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 GP and follow their advice.
- Only use fresh whole blood samples for testing your blood sugar levels. Using any other substances will produce incorrect results.
- If you are displaying symptoms that do not match the blood sugar 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 device be used by persons with very low blood pressure or those in a state of shock. Contact your GP before use.

Control solution is not included in the starter pack.

Meter overview

Top

Left   Front   Right   Back
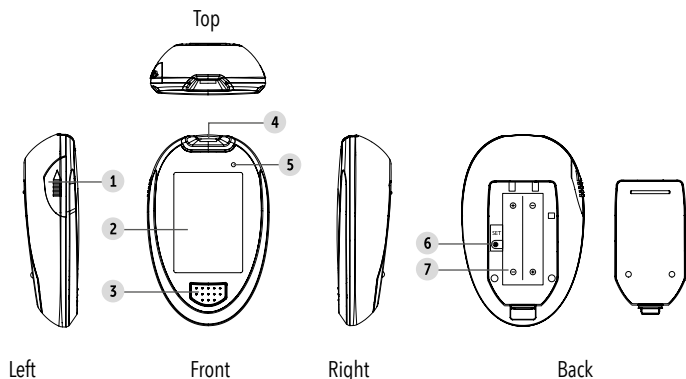
1. **Ejecting a test strip**
   Eject a test strip by pushing this button upwards.
2. **Display**
3. **Main button (M)**
   Open the meter memory and turn reminder notifications on/off.
4. **Test strip slot and strip indicator light**
   Insert the test strip into this slot to activate the meter for a test.
5. **Bluetooth indicator**
6. **SET button (S)**
   Input the meter settings and confirm them.
7. **Battery compartment**

Display

1. **Test result**
2. **Ketone warning**
3. **Error warning**
4. **Memory symbol**
5. **Control solution mode**
   QC (quality control) – testing with the control solution
6. **Measuring mode**
   AC – before meals
   PC – after meals
   Gen – at any time
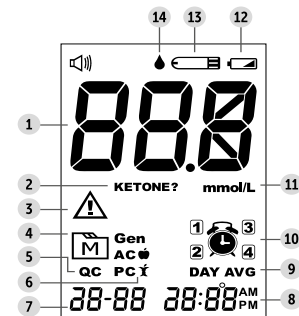7. **Date**
8. **Time**
9. **Average over a number of days**
10. **Alarm symbol**
11. **Measurement unit**
12. **Low battery warning**
13. **Test strip symbol**
14. **Blooddrop symbol**

Teststrip
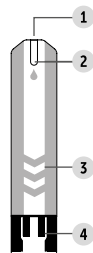
1. **Absorbent opening**
2. **Control window**
3. **Test strip grip**
4. **Contact points**

PLEASE NOTE:
The front of the test strip must be facing upwards when you insert the test strip. The test results could be incorrect if the contact point is not fully inserted into the test slot.

NOTE:
The **TD-GLUCO Bluetooth meter** may only be used with **TD-GLUCO TD-4360 test strips**. Using other test strips with this meter could produce inaccurate results.

SETTING UP THE METER

Before using your meter for the first time or whenever you replace the battery, check and adjust the following settings.

Launching the setup mode (a)
Start with the meter switched off (no test strip 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** until the correct year/month/day are displayed. Next, press **S**.

2. Setting the time format
Press the main button **M** on the front of the meter to select the required time format – 12 or 24 hours. 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
To turn sound effects on or off, press **M** to switch between "On" and "Off". Then press **S**.

5. Setting reminder notifications
Your meter has four reminder settings. The meter displays "OFF" and "①⏰". If you do not want reminders, press **S** to skip this step. Otherwise press **M** to select "On" and then press **S**.

When the hours/minutes are flashing, press **M** to select the hour/minutes. Then press **S** and continue to the next reminder setting.

PLEASE NOTE:
When the reminder notification goes off, press **M** to switch it off; hold **M** down to turn the reminder off. If you don't, the reminder will sound for 2 minutes and then switch off automatically.

Congratulations! Your device is now [properly set up!

> **NOTE:**
> * These parameters can **ONLY** be changed in the setup mode.
> * If the meter is not used for a period of 5 minutes when in setup mode, it turns off automatically

THE FOUR MEASURING MODES

There are four different ways to measure your blood sugar levels: General, AC (before meals), PC (after meals) and QC (quality control). You can switch between the different modes as follows:

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

QUALITY CONTROL TEST

This test using control solution is not required when first using the TD-GLUCO Bluetooth blood sugar control system.

Performing a test with the control solution
When should you perform a test with control solution?

- 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 practicing the test procedure.
- 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.

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

1. Insert the test strip into the meter to activate it.
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 test strip's control window contains sufficient control solution, the meter starts an automatic countdown.

3. Reading and comparing 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.

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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 obtained blood sugar levels.

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

- Wash and dry your hands before starting.
- Clean the puncture point with a cotton swab moistened with a 70% alcohol solution and allow your skin to air-dry.
- Rub the puncture point for around 20 seconds before inserting the lancet.
- Use a clean cap (included in the kit) when setting the lancing device
- 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 blooddrop, 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 in order to activate the meter**
   Wait until "⬛⬛" and "🌢" are displayed.
2. **Select the required mode by pressing M**
3. **Taking a blood sample (j)**
   Use the pre-set lancing device to puncture your skin at the selected point. We recommend that you wipe away the first blooddrop with a clean cotton swab. The size of the blooddrop must be at least as large as (actual size), which equals around **0.5** microliter (µl) volume. Carefully squeeze the area around the puncture point to draw a further blooddrop. Take care **NOT** to smear out the blood sample.
4. **Applying the sample (k)**
   Carefully allow the blooddrop to come into contact with the absorbent opening of the test strip at an angle. The test strip's control window must be completely full when enough blood is applied. Do **NOT** take your finger away before the device beeps.

5. **Reading the results**

   The blood sugar test results will be displayed once the meter has counted down to 0. The blood sugar value is automatically stored in the device's memory.

6. **Eject the used test strip (L)**

   Eject the test strip by pressing the ejector 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.

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

METER MEMORY

The meter stores the **1,000** most recent blood sugar 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 M.**

   "🅼" will appear on the display. Press **M** again, the first measurement displayed is the most recent blood sugar result, together with the date, time and meter mode.

2. **Press M** to call up the test results stored in the meter each time you press the button. **After the final result, press M and the meter switches off.**

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

1. **Press and release M.** When "🅼" appears on the display, keep the **M** button depressed for 3 seconds until the flashing "**DAY AVG**" (average over a number of days) appears. Release **M**; your averaged results over 7 days, as measured in Gen mode, appear on the display.

2. **Press M to view the average results** over 14, 21, 28, 60 and 90 days, as stored in each meter mode under Gen, AC and finally PC.

3. **Shutting down the meter's memory.** Press **M** repeatedly; the meter switches off after displaying the most recent test results.

CONNECTING 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®-enabled smartphone (iOS or Android). Download the GlucoCheck app to your smartphone from the App Store or from Google Play (iOS or Android). The GlucoCheck 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 GlucoCheck app on your smartphone for connecting to your meter.
3. Use "Search" to find your meter, which is called Ht One TD Gluco 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. Once the devices are linked, the data in your meter will be sent via Bluetooth® to the GlucoCheck app.

Bluetooth® indicator on your meter:

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

WARNING:
- The meter cannot perform a test while it is transmitting data.
- Ensure that your smartphone supports Bluetooth® smart technology and that Bluetooth® is activated before trying to transmit data. Also make sure that your meter and smartphone are sufficiently close together so that they can connect. 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 smartphone and meter.

For further information, see ht-one.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 it is low on power.
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 with E-b, Error and Low:** there is not enough power to perform a test. The batteries must be replaced immediately.

Replacing the batteries (m)
The meter must be switched off when you replace the batteries.
1. Press the rim of the battery cover and lift it out.
2. Remove the empty batteries and replace them with two new 1.5 V AAA alkaline batteries.
3. Close the battery cover. If the batteries are correctly inserted, the device will beep.

> **NOTE**
> - Replacing the battery will not affect the test results stored in the device's memory.
> - As with all small batteries, 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 for 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 the meter
- 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, then dry it using a soft and dry cloth. **DO NOT** rinse off with water.
- **DO NOT** use organic solvents to clean the meter.

Storing the meter
- Storage conditions: -20 °C to 60 °C (-4 °F to 140 °F), and under 95% relative humidity.
- 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 2002/96/EC on waste electrical and electronic equipment (WEEE).

Caring for your test strips
- Storage conditions: 20 °C to 32 °C (35.6 °F tot 89.6 °F), and under 85% relative humidity. **DO NOT** freeze.
- Keep the tests strips in their original tube. Do not place in a different tube.
- 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 test strip.
- Ensure that your hands are clean and dry before touching a test strip.

- Use a test strip immediately after removing it from the tube.
- On the label, write the date you first opened the tube. Dispose of any remaining test strips after 3 months.
- 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, as the cap and test strips could be a choking hazard. Immediately alert the emergency services if any part is swallowed.

For further information, see the test strips package insert.

Important information on the control solution
- Only use our control solution for your meter.
- Do not use the control solution after its expiry date or more 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.

TROUBLESHOOTING SYSTEM ISSUES

If you perform the recommended action but the issue continues, please call your local customer support services.

Reading the results

MESSAGE	WHAT IT MEANS
Lo or 1,6 mmol/L	≤ 1.6 mmol/L (29 mg/dL)
KETONE?	≥ 13.3 mmol/L (240 mg/dL)
Hi	> 33.3 mmol/L (600 mg/dL)

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MESSAGE	WHAT IT MEANS	ACTION
E-b	Appears when the batteries are almost drained.	Immediately replace the batteries.
E-U	Appears when a used test strip is inserted or a test strip is incorrectly used *	Repeat the test with a new test strip.
E-t	Appears when the temperature is higher or lower than the system's operating range.	The system's operating range is between 10 °C and 40 °C (50 °F and 104 °F). Repeat the test when the meter and test strip are within that range.
E-F	Appears when the test strip is removed during the countdown or when there is not enough blood present.	Read the instructions and repeat the test using a new test strip. If the issue continues, contact your local customer support for assistance.
E-0, E-A, E-C, E-E	There is a problem with the meter.	Repeat the test using a new test strip. If the meter continues to malfunction, contact your local customer support for assistance.

See the user instructions (video) at ht-one.nl/support or read the procedure to be followed

Troubleshooting other issues

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

POSSIBLE CAUSE	ACTION
Batteries are drained.	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, facing upwards.
Meter or test strips are defective.	Contact customer support.

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

POSSIBLE CAUSE	ACTION
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 (5 minutes after the user performed the last action).	Repeat the test using a new test strip. Apply the blood sample when the flashing "🌢" 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	ACTION
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 of 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 with a new test strip.
Meter malfunction.	Contact customer support.
The meter and test strip are defective.	Contact customer support.

DETAILED INFORMATION

1. The meter returns plasma-equivalent results:

Time of day	Normal plasma glucose range for **nondiabetics** (mg/dL)
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- 2016;39 (supp. 1 Diabetes Care): S16.

Consult your GP to determine a target range that suits you best.

INFORMATION ON SYMBOLS

SYMBOL	REFERS TO		SYMBOL	REFERS TO
IVD	*In-vitro* diagnostic medical device		🏭	Manufacturer
📖	See the user manual		SN	Serial number
🌡	Temperature limits		EC REP	Authorised representative in the European Community
⏳	Use before		⚠	Please note, consult the accompanying documentation
LOT	Batch code		🗑	Dispose in accordance with regulations
CE 0123	CE mark		85%	Humidity limit

SPECIFICATIONS

Model no.: TD-4277B
Dimensions and weight: 96 (L) x 61(B) x 26 (H) mm, 67,2 g
Power source: Two 1.5 V AAA alkaline batteries
Display: LCD
Memory: 1,000 test results with associated dates and times
Export options: Bluetooth

Automatic electrode placement detection
Automatic sample detection
Automatic response time countdown
Automatic switch-off after 5 minutes of inactivity
Temperature warning

Operating conditions:
10 °C to 40 °C (50 °F to 104 °F), under 85% relative humidity (non-condensing)
Meter storage/transport conditions:
-20 °C to 60 °C (-4 °F to 140 °F), under 95% relative humidity
Test strips storage/transport conditions:
2 °C to 32 °C (35.6 °F to 89.6 °F), under 85% relative humidity
Measuring unit:
mmol/L
Measuring range:
1.6 to 33.3 mmol/L (29 to 600 mg/dL)

This device has been tested for compliance with the electrical and safety requirements of:
IEC/EN 61010-1. IEC/EN 61010-2-101. EN 61326-1. IEC/EN 61326-2-6, EN 301489-17, EN 301489-1, EN 300 328.

NOTES

For self-testing

$C\epsilon$ 0123 IVD

TD-4277B