

# DEXTRA

NO CODING



**USER GUIDE**  
BLOOD GLUCOSE MONITORING SYSTEM

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**Thank you for your trust!**

You have chosen the **DEXTRA** blood glucose monitoring system, which can be used together with **DEXTRA** test strips and related accessories to easily and conveniently measure your blood glucose levels.

The measurement range of the **DEXTRA** blood glucose monitoring system is between 10 – 600 mg/dL or 0.6 – 33.3 mmol/L.

Please ask your specialist physician which unit of measurement your therapy is based upon.

In order to obtain an accurate blood glucose measurement, you must follow a few important rules.

Therefore, please read this user guide carefully before using the device for the first time.

You will be amazed at how easy it is to take measurements!

⚠ **Before taking your first measurement, please take note of the following important information.**

- The **DEXTRA** blood glucose monitoring system is an *in vitro* diagnostic tool that is suitable for self-testing. It enables people with diabetes and specialist medical staff to determine blood glucose values.
- The **DEXTRA** blood glucose monitoring system is suitable for analysing fresh capillary blood, venous blood, arterial blood or neonatal blood.
- Only use the **DEXTRA** test strips and **DEXTRA** control solutions. Using other test strips can lead to incorrect readings.
- Close the storage container immediately after removing the test strip(s).
- Check the expiry dates of the test strips and the control solution.
- Use a new lancet for each blood sample.
- Always store the measuring device or test strips according to the storage requirements, and protect both from moisture, direct sunlight and other heat sources.
- Keep the measuring device and all accessories away from small children.
- Clean your **DEXTRA** blood glucose monitoring system regularly.
- The functioning of the **DEXTRA** blood glucose monitoring system can only be guaranteed if it is used correctly and for its intended purpose.
- Blood glucose monitoring systems must not be used for diabetes diagnosis.

## USER INTERFACE



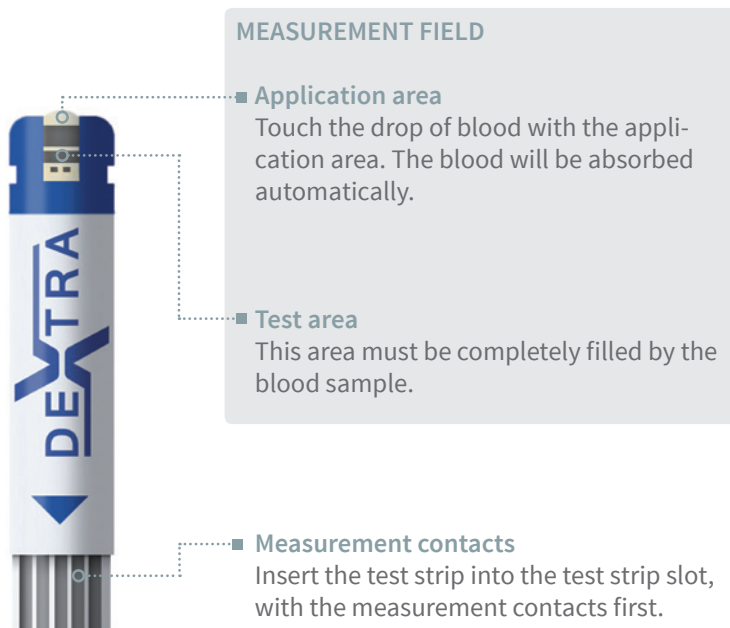
DATA PORT



BATTERY COMPARTMENT



## TEST STRIP

**NOTE** ⚠

You can touch the measurement field of the **DEXTRA** test strips freely with clean, dry hands. The test result will not be affected.

## CONFIGURATION



First remove the battery cover and check that the required 3 V lithium battery (type CR 2032) has been inserted. If this is not the case, you will need a new battery (see page 48).

Then set the current date and correct time. To do this, press the set button (using a pen, for example), and then press the main button (this changes the flashing value on the display).

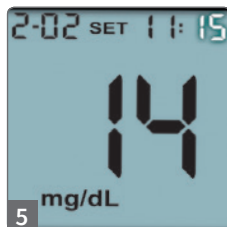
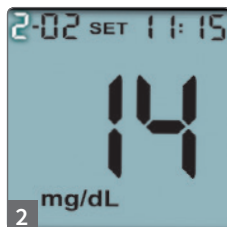
**NOTE** ⚠

Please be prepared for necessary battery changes by keeping a spare battery with you (type CR 2032).

## DATE AND TIME

**NOTE** ⚠

The figures needing adjustment flash on and off (shown in white in the illustrations).



- 1 **Set button pressed once:** The blood glucose meter switches itself on. Display of 'Year' setting
- 2 **Set button pressed second time:** 'Month' setting
- 3 **Set button pressed third time:** 'Day' setting
- 4 **Set button pressed fourth time:** 'Hour' setting
- 5 **Set button pressed fifth times:** 'Minute' setting



- 6 **Set button pressed sixth times:** The blood glucose meter switches itself off.

Finally, place the battery cover on the device.

**NOTE** ⚠

If you change settings using the set button and main button, you will need to go through all of the settings until the blood glucose meter switches itself off (after pressing the set button for the last time).

**Your changes will only be saved after this last step.**



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### ‘INSERT TEST STRIP’ NOTIFICATION

- 7 After the DEXTRA blood glucose monitoring system has been switched on with the main button, the test strip symbol will appear in the display. You should now insert the test strip into the device’s test strip slot. Correct insertion of the test strip will be confirmed by an audio signal.



8

### BLOOD SAMPLING NOTIFICATION

- 8 Once the test strip has been inserted into the test strip slot, the blood intake symbol appears in the display. You now have three minutes to perform a blood glucose measurement. If no blood sampling takes place within this time, the DEXTRA blood glucose meter will switch itself off automatically.



9

### MEASUREMENT PERIOD

- 9 Measurement begins once the test area of the test strip is sufficiently filled with blood, and lasts only 7 seconds. During the measurement, an hourglass animation is visible on the display.



**TEST RESULT**

7 seconds after the start of the measurement, the blood glucose value will be displayed and automatically saved, together with the date and time (10 and 11).



10



11

**MEASUREMENT UNIT**

This will be displayed together with the measurement reading (12 and 13).



12



13

**'HI' NOTIFICATION**

This will appear if the measured blood glucose value exceeds the 600 mg/dL or 33.3 mmol/L (14 and 15).



14



15

**'LO' NOTIFICATION**

This will appear if the measured blood glucose value is below 10 mg/dL or 0.6 mmol/L (16 and 17).



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**NOTE** ⚠

If you receive a 'HI' or 'LO' notification, repeat the measurement procedure. If the notification appears again, perform a measurement using the control solution (see page 25 onwards) or contact your specialist physician.

### MEMORY DISPLAY

The **DEXTRA** blood glucose meter can save up to 500 blood glucose measurements, along with the date and time of each. Blood glucose measurements and control solution measurements are stored separately. If the user exceeds the memory capacity, each additional measurement will automatically overwrite the oldest saved blood glucose value.

After switching on the blood glucose meter and then pressing the main button, the last blood glucose measurement taken will be displayed with its corresponding date and time (18 and 19). By pressing the main button again, other saved measurement results can be recalled.



### KETONE NOTIFICATION

If the measured blood glucose value exceeds 300 mg/dL or 16.7 mmol/L, the ketone notification will be automatically displayed, which warns you of a potential ketoacidosis (20).



For more detailed information about ketoacidosis, please consult your specialist physician.



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The following errors will be shown on the display with an 'Err' or 'EEE' notification:

#### 21 Err + battery symbol

- Not enough battery power
- » Change the battery (see page 48 onwards).

#### 22 Err + thermometer symbol

- The ambient temperature is outside the acceptable temperature range.
- » The operating temperature must be between +10 °C and +40 °C.

#### 23 EEE

- Electronic error
- » In this case, please contact **IME-DC customer service**.

**Service hotline: +49 9281 | 85 01 6-0**

#### 24 Err + test strip symbol

- Test strip malfunction
- Used test strip
- Not enough blood absorbed
- Not enough control solution absorbed
- The blood was absorbed before the blood sample symbol appeared in the display.
- » Repeat the measurement with a new test strip.

Your **DEXTRA** blood glucose meter allows you to call up and display the average values of the last 24 hours and the past 7, 14, 21, 28, 60 and 90 days.

To do this, please activate the memory display (25) (see page 18). Press and hold the main button for approximately 2 seconds. The average value of the last 24 hours is displayed (26).

Each time you press the main button again, the average values for other periods (the past 7, 14, 21, 28, 60 or 90 days) will be displayed (27 - 32).

To return to the memory display (33), press and hold the main button for 2 seconds again.



## USING THE CONTROL SOLUTION

Test measurement with the **DEXTRA** control solution is used to check that the blood glucose monitoring system is functioning correctly.

### This procedure is recommended in the following cases:

- For teaching and training purposes
- If the blood glucose meter or the blood glucose test strips have been stored at an inappropriate temperature
- Following improper handling of the blood glucose meter
- In the event of questionable blood glucose readings

### NOTES

- The control solution must not be used after the expiry date.
- When the control solution bottle is first opened, the date must be written on the label.
- The shelf life of the control solution is 90 days after it is first opened.
- Always take care that the control solution is used correctly.

## TESTING WITH THE CONTROL SOLUTION

Slide a **DEXTRA** test strip into the test strip slot. The blood glucose monitoring system will switch itself on automatically.



**34** The display will now prompt you to take a blood sample.



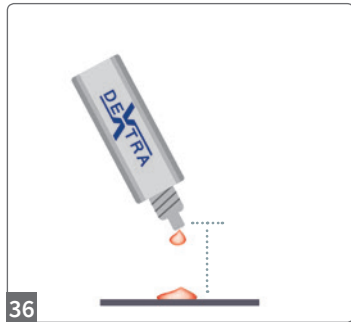
**35** Press the main button and hold for approximately 2 seconds until the control solution symbol appears in the display.

You are now in the designated control solution measurement mode. In this mode, measurement results of the control solution are saved separately.

This prevents the average values of your personal blood glucose measurements being falsified by the control solution measurements.

Next, rotate the control solution bottle 3 – 4 times.

**Please don't shake it!**



36



37

**36** After opening the bottle, put a drop of control solution on a clean, dry surface (for example, the lid of the test strip container), at a distance of approximately 2 cm. Then close the bottle. Use a new drop of control solution for each measurement.

**37** Now place the application area of the test strip on the drop of control solution, until the test area is completely filled. An audio signal will confirm the start of the measurement.



38



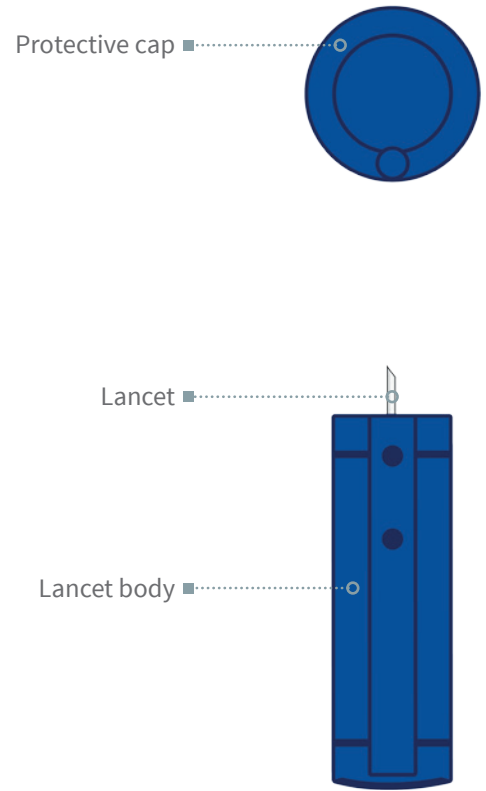
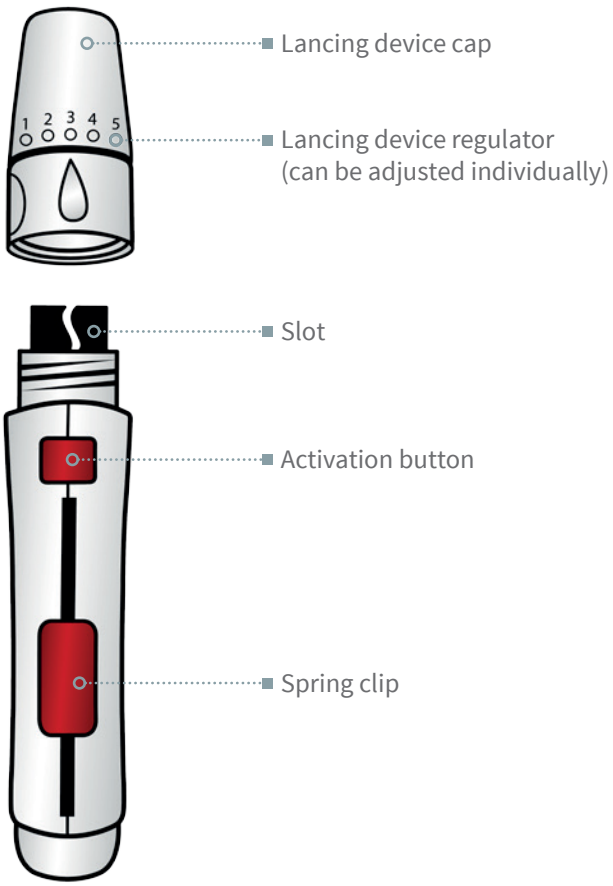
39

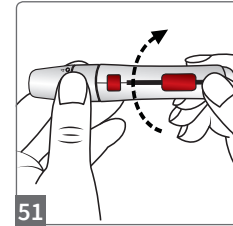
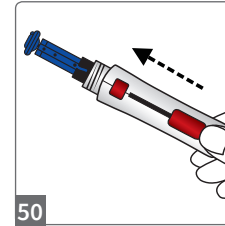
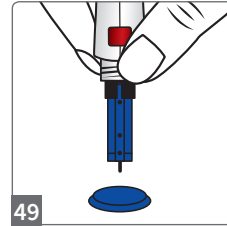
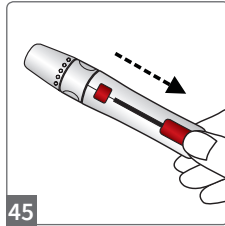
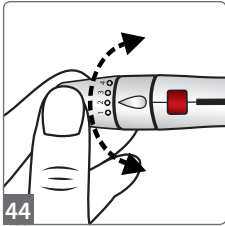
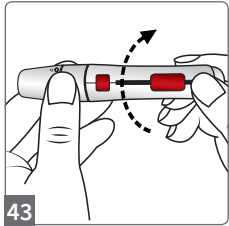
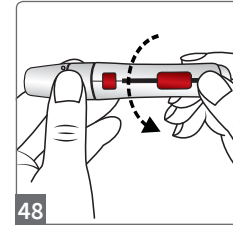
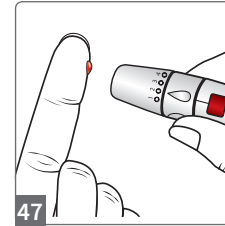
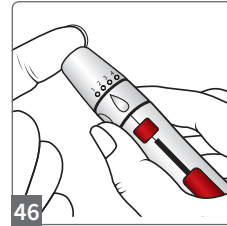
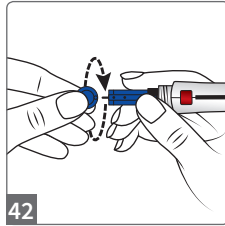
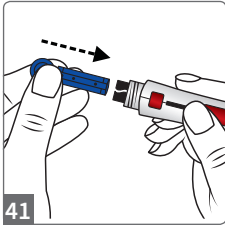
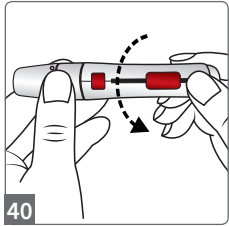
After 7 seconds, the measurement reading will be shown together with the date, time, measurement unit and bottle symbol (**38** and **39**). The measurement reading should fall within the appropriate target range (see test strip container label).

#### The test result lies outside the control range

If an error message is displayed during measurement, or if the measured value is outside the target range (as shown on the test strip container), repeat the measurement. If an error message appears again or if the measurement is again outside the target range, please contact **IME-DC customer service**.

**Service hotline: +49 9281 | 85 01 6-0**





**40** Unscrew the **lancing device cap**.

**41** Insert the lancet into the slot.

**42** Twist off the **lancet protection cap**.

**43** Screw the **lancing device cap** back on.

**44** Set your personal **puncture depth** (minimum 1, maximum 5).

**45** Load the lancing device by pulling the **spring clip** back.

**46** Press the tip of the lancing device against your finger and press the **activation button**.

**47** The blood drop obtained can be used for the measurement procedure.

**48** Unscrew the **lancing device cap**.

**49** Insert the lancet into the **protective cap**.

**50** Slide the **spring clip** forward sharply, to eject the lancet.

**51** Screw the **lancing device cap** back on.



Capillary blood for blood glucose measurements can be obtained not only from the fingertips, but also from other areas of the body (palms, forearms, upper arm, or calves). This is known as Alternative Site Testing (AST).

Talk to your specialist physician first if you would like to use blood from alternative sites for your blood glucose measurements.

#### NOTE ⚠

Measurement errors can lead to incorrect medical treatment recommendations and therefore to serious health problems. Read these instructions in full before using blood from alternative sites for your blood glucose measurements.

#### Restrictions

The following restrictions must be taken into account before taking blood measurements from alternative sites: Capillary blood in the fingertips reacts more quickly to changes in blood glucose levels than that in alternative areas of the body. For this reason, blood glucose values from alternative sites may differ from those measured from the fingertips.

#### Do NOT use blood from alternative sites on your body:

- If your last meal was less than two hours ago, as blood glucose values change rapidly during this period
- After sports activities
- If you are ill with an acute fever or if you are bedridden
- If you suspect that you have a very low blood glucose level (low blood sugar)

- If you know that sometimes you don't recognise having low blood sugar
- During the period when the effectiveness of normal insulin or rapid-acting insulin analogues is at its maximum
- If your last injection of a rapid-acting insulin analogue was less than two hours ago

#### NOTE ⚠

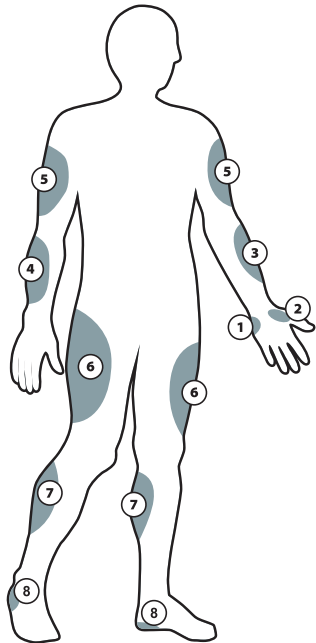
If the measurement obtained using blood from an alternative site does not correspond to your current state of health, you should perform a measurement using blood from the fingertips.

If you wish to obtain blood samples from alternative sites, you can order a special cap for the lancing device in your **DEXTRA** blood glucose monitoring system set from **IME-DC customer service**.



Unscrew the lancing device cap. After inserting the lancet, screw on the AST cap (52).

## Preferred sampling sites:



- ① Palm of the hand below the little finger
- ② Palm of the hand below the thumb
- ③ Inner side of the forearm
- ④ Outer side of the forearm
- ⑤ Upper arms
- ⑥ Thighs
- ⑦ Calves
- ⑧ Balls of the feet for newborns



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**53** Only use **DEXTRA** test strips for the **DEXTRA** blood glucose meter.

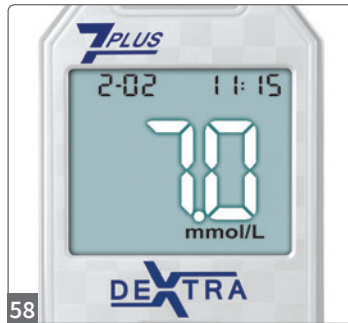
**54** Wash your hands with warm water and dry them well before taking a measurement.

**55** Insert the test strip into the test strip slot on the **DEXTRA** blood glucose monitor. The blood glucose meter will switch itself on automatically.  
If the temperature is within the permitted range, the blood glucose meter will prompt you to touch the blood drop with the application area (see page 10).

Now use the lancing device to obtain a blood drop (see **40** – **51** from page 30 onwards).



Position the application area of the **DEXTRA** test strip to the blood drop (56). The blood will be absorbed automatically. An audio signal will confirm that measurement has started.



After 7 seconds, the measurement reading will be displayed and saved automatically, together with the date, time and unit of measurement (57 and 58).

**Blood glucose values for adults<sup>1</sup>**  
(Reference sample type: venous plasma)

	without diabetes	with diabetes
Empty stomach	≤ 100 mg/dL ≤ 5.6 mmol/L	≥ 126 mg/dL ≤ 7.0 mmol/L
2 hours after a meal	≤ 140 mg/dL ≤ 7.8 mmol/L	≥ 200 mg/dL ≤ 11.1 mmol/L

<sup>1</sup> R. Landgraf et al., 2013: *Praxisempfehlungen DDG/DGIM [Recommended practice – German Diabetes Association/German Association for Internal Medicine]; Diabetologie und Stoffwechsel [Diabetology and metabolism]; Thieme Verlag*

If possible, take an immediate measurement of your blood glucose value if any of the following symptoms<sup>2</sup> occur (possible high or low blood sugar). Contact your specialist physician immediately (or have somebody contact them for you) for instructions on what actions to take.

### Symptoms of low blood sugar (hypoglycaemia):

- Sweating
- Intense hunger
- High heart rate
- Tingling lips
- Slight difficulties with concentration
- Mood swings
- Trembling (in some circumstances all over the body)
- Distorted vision (e.g. flickering)
- Disorientation, difficulty with targeted thinking or action
- Unconsciousness
- Cramps

<sup>2</sup> G.-W. Schmeisl, *Schulungsbuch für Diabetiker [Training manual for diabetics]*, Urban & Fischer Verlag/Elsevier GmbH, 5th edition, 2005

### Symptoms of high blood sugar (hyperglycaemia):

- Fatigue
- Listlessness
- Frequent urination and thirst
- Weight loss
- Weak muscles, leg cramps
- Itchiness
- Dizziness, vomiting, stomach ache
- Acetone odour (like nail polish remover) in exhaled air
- Unconsciousness

### NOTE ⚠

If your blood glucose measurement value is less than 50 mg/dL (2.8 mmol/L) or more than 250 mg/dL (14.0 mmol/L), contact your specialist physician immediately.

**Potential influences on the measurement readings**

- The blood for sampling was squeezed out of the finger using strong pressure and therefore contains tissue fluids.
- The expiry date of the blood glucose test strips has passed.
- The blood glucose test strips were stored at unsuitable temperatures (acceptable storage temperatures are between +4°C and +32°C).
- The test strips were not sufficiently protected from moisture.
- If disinfection was performed, the disinfectant was not allowed to evaporate completely.
- You did not wash your hands before taking the blood glucose measurement.
- You did not dry your hands before taking the blood glucose measurement.
- Excessively high blood pressure can result in inaccurately low measurement values.
- Severely ill patients should not be tested with blood glucose monitoring systems.

If inexplicable measurement results occur frequently, please contact your specialist physician.

**Interferences**

Endogenous substances in the human body such as bilirubin, uric acid, glutathione, triacylglycerol and cholesterol, in addition to the medical substances shown in the table, do not have a significant effect on the blood glucose monitoring results from the **DEXTRA** blood glucose meter if they do not exceed normal concentrations or therapeutic dosages. If this is not the case, it can lead to incorrect results.

Substance	Interference from
Paracetamol	> 10 mg/dL
Bilirubin	> 15 mg/dL
Pralidoxime iodide	> 50 mg/dL
Triacylglycerol	> 500 mg/dL
Cholesterol	> 200 mg/dL
Glutathione	> 1.5 mg/dL
Uric acid	> 15 mg/dL

If haematocrit values are less than 20 %, it is possible that an inaccurately high blood glucose value is displayed. If haematocrit values are more than 60 %, it is possible that an inaccurately low blood glucose value is displayed.

When measuring EDTA-treated blood samples with the **DEXTRA** blood glucose meter, the blood glucose values recorded may differ from those of an untreated blood sample. Therefore, the use of sample tubes treated with lithium-heparin is recommended.

**NOTE** ⚠

Our **IME-DC customer service department** will be happy to answer any questions you may have.

**Other information**

- Please do not make any medically significant decisions without consulting your specialist physician first.
- Clinical institutions and professional caregivers: Please dispose of used test strips according to your employer’s instructions. Please note that used test strips may represent an infectious hazard.
- Private users: Please dispose of used test strips according to local regulations.
- To check that the blood glucose monitoring system is functioning correctly, you have the option of carrying out measurements with the **DEXTRA** control solutions (available separately).

Functionality:	Amperometric biosensor system with additional alternating current measurement
Dimensions:	85 × 52 × 16 mm
Weight:	46 g
Power supply:	1 × 3 V lithium battery (CR 2032)
Device type:	<b>DEXTRA</b> blood glucose monitoring system is suitable for long-term use
Measurement range:	10 – 600 mg/dL or 0.6 – 33.3 mmol/L
Measurement period:	7 seconds
Operating environment:	+10 °C to +40 °C
Storage temperature:	-20 °C to +70 °C
Measurement memory:	500 measurement values with time and date; Blood glucose measurements and control solution measurements are stored separately
Type:	Hand-held device
Automatic shutdown:	After three minutes if test strips are inserted, otherwise after one minute of inactivity
Display:	LCD
Technology:	Patented dynamic measurement method, screen menu, automatic system check, electrode insertion sensor, temperature warning, ketone notification, average calculation of measurements, automatic startup and shutdown

Dimensions:	30 × 6 mm
Material:	PET
Measurement method:	Electrochemical/dynamic
Enzyme:	GDH-FAD
Required blood volume:	0.7 µL
Sample type:	Fresh capillary blood, venous blood, arterial blood or neonatal blood
Calibration:	Plasma equivalent
Haematocrit range:	20 – 60 %
Measurement temperature:	+10 °C to +40 °C
Storage temperature:	+4 °C to +32 °C
Relative humidity:	< 85 %
Shelf life:	18 months (from date of manufacture) After opening: 180 days

### Suitable for clinical or private use!

#### Chemical composition:

- 21.8 % Glucose dehydrogenase flavin adenine dinucleotide
- 41.6 % Potassium ferricyanide
- 36.6 % Non-reactive ingredients

All saved measurement results can be transferred to and managed on a PC using appropriate software. Only use the **IME-DC USB data cable** for this purpose.







Insert the USB data cable into the USB port on your PC. Open a compatible data transfer program on your PC. When prompted, make sure that the blood glucose meter is **switched off**, and insert the USB cable jack into the data port on the device (59). Now start transfer of the data saved on the device (60).

#### NOTE ⚠

The basic requirement for data transfer is recognition of the blood glucose meter by the data transfer program. If the **DEXTRA** blood glucose meter is not yet listed there, please contact **IME-DC customer service**. If data transfer is still not possible even when your computer does recognise your device, this could be due to missing drivers.

A list of additional drivers can be found on our homepage at [www.imedc.de](http://www.imedc.de) under 'Downloads'.

List of items	EAN code
 blood glucose monitoring system set (mg/dL)	4260155930232
 blood glucose monitoring system set (mmol/dl)	4260155930379
 blood glucose test strips	4260155930249
 control solution (level 1/level 2)	4260155930256
IME-DC lancing device	4260155930065
IME-DC UNIVERSAL blood lancets	4260155930058
IME-DC USB data cable	4260155930041
3V lithium battery (CR 2032)	4260155930072

- Use a soft cloth to clean the blood glucose monitoring system.
- Do not use any strong cleaning agents for cleaning the device.
- The outer surfaces of the blood glucose monitoring system may be disinfected using standard disinfectant wipes.
- Avoid heavy contamination.

**NOTE** ⚠

Handle your device with care.

### Quality standards

- Directive **98/79/EC** of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices
- **EN 60601-1/IEC 60601-1**: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- **EN 60601-1-2/IEC 60601-1-2**: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- **EN 61010-1/IEC 61010-1**: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- **DIN EN ISO 15197**: *In vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus





If the display shows the error message 'Err + Battery symbol', or if the device no longer switches itself on, then the battery needs to be changed (61).



62 Remove the battery cover.



63 To remove the battery, press the notch in the locking with your fingertip. The battery will be ejected automatically, and can be removed afterwards.



64 To fit a new battery, first slide it (plus icon up) underneath the plastic holder (plus sign up).



65 Now push the battery gently under the locking.



66 Close the battery cover.

#### NOTES ⚠

- After inserting the new battery, the device will switch to setup mode, and the figures indicating the year will flash on the display.
- Check the time and date settings, and refresh these if necessary (see page 12 onwards).
- If no changes are necessary, wait until the device shuts itself off automatically (after approximately 1 minute).
- Your saved measurements will not be lost after battery change.
- Please use only 3 V CR 2032 batteries.

**DEXTRA** Blood glucose meter

**5-YEAR WARRANTY**










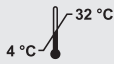






IME-DC GmbH hereby guarantees correct functioning of the **DEXTRA** blood glucose meter for a period of 5 years, starting from the date the device is activated. If any faults occur during this warranty period, you will be provided with a new device at no extra cost. This offer is contingent upon appropriate use of the blood glucose monitoring system for the intended purposes. No guarantee can be made for improper use.

**Please note:** The warranty does not take effect until the device has been activated. Therefore, after you take delivery of the blood glucose monitoring system, fill out the warranty card in full and send it to:

IME-DC GmbH, Fuhrmannstrasse 11, 95030 Hof, Germany

**NOTE** ⚠

A warranty can only be honoured if the **DEXTRA** blood glucose monitoring system has been used correctly and for its intended purpose. To make a warranty claim, contact the responsible dealer, or contact **IME-DC GmbH** directly.

	Article number
	Lot number
	Serial number
	<i>In vitro</i> diagnostic tool
	Follow user instructions
	Can be used until
	Manufacturer
	Date of manufacture
	Do not reuse
	Temperature limits
	Keep dry
	Keep away from sunlight
	Important: read product documentation
	This product meets the requirements of the IVD Directive in accordance with 98/79/EC
	Class II device in accordance with Standard 60601-1 Applied Part Type B
	Dispose of device separately according to local regulations







# IME-DC

Int. Medical Equipment Diabetes Care

**IME-DC GmbH**  
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**Diabetes Care**

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