User Manual
EasyTouch® GCHb

Blood Glucose / Cholesterol /Hemoglobin Monitoring System

Before you Begin

Before using the products, read all of the instructions carefully. It includes all the information you need to know to get accurate readings. For EU customer service, dial +49-6894-581020.

Warnings

- Do not change your medical plan without a doctor's approval. The EasyTouch® GCHb system should not be used for diagnosis.
- If using the EasyTouch® GCHb system to monitor an existing disease, only adapt treatment with proper training.
- Do not use the EasyTouch® GCHb system to test newborns.
- Be sure to follow your local regulations for proper disposal of used test strips, lancets, and batteries.
- The monitoring system will not work properly at altitudes greater than 8,000 feet (2,400 meters) above sea level.
- This system is designed for use at temperatures between 14°C and 40°C (57.2°F and 104°F) and less than 85% relative humidity. If you use the system outside of the proposed conditions, it can give false results.

Precautions

- Do not use the meter in a very dry environment, especially if synthetic materials are present.
- Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.
- Do not use this meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
- Store the device and the components in a clean, safe location.

Limitations

The following compounds (left column) in the blood at the given concentrations can cause inaccurate results on the test for:

Compound	Glucose	Cholesterol	Hemoglobin
Ascorbic Acid(Vitamin C)	>150 mg/dL	>5 mg/dL	>150 mg/dL
Amiloride	>20 mg/dL	X	X
Acetaminophen	>8 mg/dL	>15 mg/dL	X
L-Dopa	>20 mg/dL	>1.25 mg/dL	>20 mg/dL
Dopamine	>20 mg/dL	>3 mg/dL	>20 mg/dL
Methyl-Dopa	>4 mg/dL	>5 mg/dL	>4 mg/dL
Galactose	>400 mg/dL	X	X
Uric Acid	>10.5 mg/dL	X	X
Xylose	>50 mg/dL	X	X
Bilirubin	X	>20 mg/dL	X
Creatinine	X	>20 mg/dL	X
Glibenclamide	X	>10 mg/dL	X
Hematocrit	<30%, >55%	<30%, >55%	<20%, >70%

Cholesterol up to 500 mg/dL or triglycerides up to 3,000 mg/dL do not signi cantly affect the glucose results. Grossly lipaemic patient samples have not been tested and are not recommended for testing with the EasyTouch® GCHb System.

Intended Use

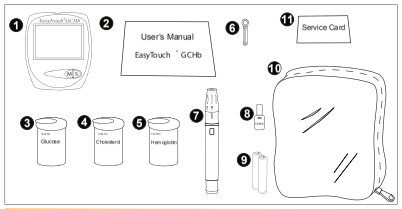
The EasyTouch® GCHb Monitoring System is designed for in vitro diagnostic use only (external use only), and is suitable for self-testing. The system is for healthcare professionals and persons with diabetes, hypercholesterolemia, or anemia to measure glucose, cholesterol, and hemoglobin. Simply add a drop of blood to the test strip, and the result is displayed on the screen in 6 seconds for glucose and hemoglobin, and 150 seconds for cholesterol.

Test Principle

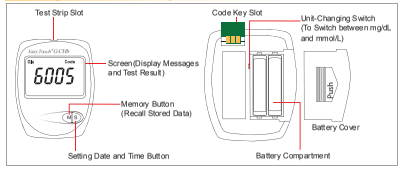
Blood glucose, cholesterol and hemoglobin measurements are based on electrical current changes caused by the reaction of glucose, hemoglobin, or cholesterol with the reagent on the electrode of the corresponding strip.

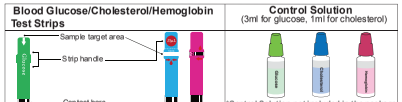
Items in the Package

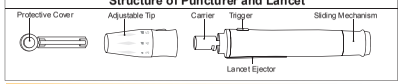
1. EasyTouch® GCHb Meter
2. EasyTouch® GCHb User Manual
3. EasyTouch® Ⅱ Blood Glucose Test Strips / Manual
4. EasyTouch® Blood Cholesterol Test Strips / Manual
5. EasyTouch® Hemoglobin Test Strips / Manual
6. Lancets
7. Puncturer
8. Check Strip
9. AAA Alkaline Batteries (2)
10. Pouch
11. Service Card



Getting to Know the System

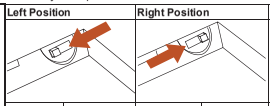






Checking the Unit of Measure

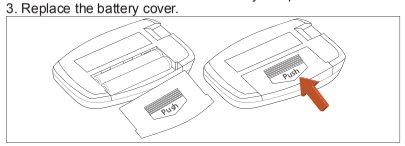
The EasyTouch® GCHb Meter can measure your blood glucose, cholesterol, and hemoglobin in mg/dL, g/dL or mmol/L. Just adjust the switch in the battery compartment:



	Unit	Decimal point	Unit	Decimal point
Glucose	mg/dL	No	mmol/L	Yes
Cholesterol	mg/dL	No	mmol/L	Yes
Hemoglobin	g/dL	Yes	mmol/L	Yes

Inserting the Batteries

1. Remove the battery cover from the back of the meter.
2. Insert two AAA batteries into the battery compartment.
3. Replace the battery cover.



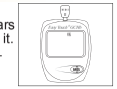
Setting the Time and Date

When you insert new batteries, the meter automatically enters date and time setting. Set the correct date before using the meter.

1. Press the "S" button to change to the current month.
2. Press the "M" button to shift to the date setting.
3. Adjust the date by pressing the "S" button until the current date appears.
4. Repeat this process to set the hour and minute.
5. Simply wait 30 seconds for the meter to turn off automatically.

Using the Check Strip

Insert the check strip into the test strip slot on the meter.The screen should display "OK". If "X" appears on the screen, remove the check strip and reinsert it. If "X" is displayed again, call our customer support. Do not test until the meter is working properly.



Use the check strip to check the meter when:
- You use the** EasyTouch® GCHb **Monitoring System for the first time.
- You drop the meter.
- You think there is something wrong with the results you got and you want to check whether the meter and test strips are working correctly or not.

Control Testing - *What control testing is*

By using control solution that has a measured amount of glucose or cholesterol, you can check if your meter and strips are accurate. If your control results fall within the range on the test strip vial, you can be sure that the system is working properly.

When to control test

Perform a control test when you think there is something wrong with your measurement and you want to check if the meter and test strips are working correctly.

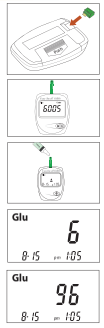
Items you need

EasyTouch® GCHb Series Meter
EasyTouch® Ⅱ Glucose Control Solution (not included)
EasyTouch® Cholesterol Control Solution (not included)
EasyTouch® Hemoglobin Control Solution (not included)
EasyTouch® Ⅱ Glucose Test Strips
EasyTouch® Cholesterol Test Strips
EasyTouch® Hemoglobin Test Strips
EasyTouch® Ⅱ Glucose Code Key
EasyTouch® Cholesterol Code Key
EasyTouch® Hemoglobin Code Key

Always write down the opening date of your glucose, cholesterol or hemoglobin control solution bottle and test strip vial. Glucose strips and solution expire three months after first opening or until the expiration date, whichever comes first. Cholesterol strips and solution expire two months after first opening or until the expiration date, whichever comes first. The meter stores control test results in its memory, where they appear just like test results. Hemoglobin strips expire two months after first opening or until the expiration date, whichever comes first. Hemoglobin control solution expires one month after first opening or until the expiration date, whichever comes first.

Control Testing Steps

1. Insert the glucose, cholesterol or hemoglobin code key into the code key slot on the back of the meter.
2. Take one glucose, cholesterol, or hemoglobin strip from the vial. Close the vial quickly.
3. Insert the test strip into the test strip slot on the meter. The meter first displays the code number, and then the blood symbol "🩸".
4. Hold the glucose, cholesterol, or hemoglobin control solution bottle upside down and slowly squeeze the bottle to form a small drop. Discard the first drop of the solution. Squeeze out a second drop and let it touch the edge of the sample target area on the test strip. The test strip draws the control solution into the targeting zone.
5. Immediately after the meter sounds a beep, close the cap of the control solution. The meter then counts down from 6 for glucose or hemoglobin, or 150 for cholesterol, and displays your result on the screen.
6. Check if the displayed value falls within the acceptable range shown on the test strip vial.
7. Remove the test strip from the meter and discard it.



Understanding Control Testing Results

You will find the acceptable range of glucose, cholesterol, and hemoglobin levels for normal and high controls on the test strip vial label. If your control results fall within the acceptable range, you can begin to test your blood glucose, cholesterol, and hemoglobin levels.
If your control results are not within the acceptable range, consider the following items:

- Are your test strips or control solutions expired?
- Have you ever forgotten to close your test strip vials or control solution bottles?
- Does the code in the meter match the code on the test strip vial?
- Did you follow all the operating instructions correctly?

Repeat the control test with a new test strip, following the steps exactly.

If you continue to receive control values that are outside of the accepted range, discontinue your blood testing and call customer service or your healthcare provider immediately.

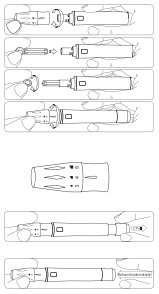
Preparing the Puncturer

Blood glucose, cholesterol, and hemoglobin monitoring devices and lancing devices can transmit bloodborne pathogens.
To avoid infection, you should:

- Never reuse the lancets.
- Never share your puncturer with others.
- Always use a new, sterile lancet each time a test is performed.
- Always use an alcohol pad to wipe blood off of the puncturer's tip after use.

For safety and to prevent cross-contamination, always place the protective cover back on before discarding the used lancets. To avoid injury, do not leave a used lancet in the puncturer. Always remove used lancets immediately after a test.

1. Unscrew the puncturer's adjustable tip.
2. Insert a lancet into the carrier.
3. Twist off the protective cover to expose the lancet tip.
4. Replace the adjustable tip tightly.
5. Choose a desired skin penetration depth by rotating the top portion of the adjustable tip until the appropriate setting number lines up with the arrow. Settings are based on skin type:
   - Depth 1~2 for soft or thin skin
   - Depth 3 for average skin
   - Depth 4~5 for thick or calloused skin
6. Hold the tip of the puncturer with one hand and pull the sliding mechanism back with the other. When you hear a click, the trigger rises up.
7. Release the sliding mechanism. The puncturer is now ready to obtain a blood sample.

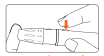


Blood Glucose Testing

1. The first time you use the EasyTouch® GCHb Meter or open a new test strip vial, insert the code key from the test strip vial. Each test strip vial contains one code key. Make sure the number on the code key matches the code number on the vial of test strips you use.
2. Take one strip from the vial of glucose test strips. Close the vial quickly.
3. Insert the test strip into the test strip slot on the meter. The meter first displays the code number, and then the blood symbol "🩸". Be sure that the code number displayed matches the code number on the test strip vial.
4. Clean your finger with an alcohol swab. Let it dry completely.

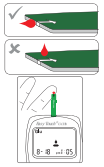
To increase blood flow to the lancing site, use warm water to wash your hands, and let your arm hang down at your side.

5. Place the puncturer on your finger.
6. Press the trigger on the puncturer.
7. Withdraw the puncturer.



It is very important that you put enough blood on your test strip so that the entire reaction zone is covered. This ensures that your meter can give accurate and reliable results

8. Wipe away the first drop of blood and allow a second drop to form.
9. Touch the drop of blood to the top of the test strip target area. The target area turns red as the strip absorbs the blood. The testing reaction starts when the meter sounds a beep. The meter then counts down from 6, shows your result on the screen, and stores your result in its memory automatically.
10. Record the your glucose value on the provided log sheet.



Fasting Blood Glucose	
Normal	70 ~ 100 mg/dL
Early Diabetes	101 ~ 125 mg/dL
Diabetic	> 126 mg/dL
The following values are expected glucose levels for non-diabetics	
Upon waking - fasting	70 ~ 99 mg/dL
After meals	70 ~ 140 mg/dL
The following values are targets for diabetics	
Before meals	70 ~ 130 mg/dL
1 ~ 2 hours after starting a meal	< 180 mg/dL

Source: American Diabetes Association

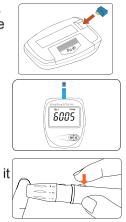
Consult your healthcare provider for the appropriate range for you.

Always consider your symptoms when interpreting your blood glucose results. If your results con ict with how you feel, perform a control test. The following are just some of the symptoms for low and high blood sugar.

Hypoglycemia	**Hyperglycemia**
• Dizziness/Headache	• Frequent urination
• Sweating	• Thirst
• Hunger	• Headache
• Pounding heartbeat	• Fatigue
• Shakiness	• Blurred vision

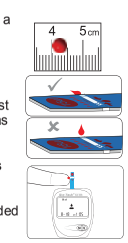
Blood Cholesterol Testing

1. The rst time you use the EasyTouch® GCHb Meter or open a new test strip vial, insert the code key from the test strip vial. Each test strip vial contains one code key. Make sure the number on the code key matches the code number on the vial of test strips you use.
2. Take one strip from the vial of cholesterol test strips. Close the vial quickly.
3. Insert the test strip into the test strip slot on the meter. The meter first displays the code number, and then the blood symbol "🩸".
4. Clean your finger with an alcohol swab. Let it dry completely.
5. Place the puncturer on your finger.
6. Press the trigger on the puncturer.
7. Withdraw the puncturer.
8. Wipe away the first drop of blood and allow a second one to form.



The blood volume needed in cholesterol test is significantly more than that in glucose test. You need to apply a 15 µl blood sample in cholesterol test and a 0.8 µl blood sample in glucose test.

9. Touch the drop of blood to the side of the test strip target area. The target area turns red as the strip absorbs the blood. Apply blood until the meter sounds a beep. The meter then counts down from 150 seconds, shows your result on the screen, and stores your result in its memory automatically.
10. Record your cholesterol value on the provided log sheet.



The following are ranges for blood cholesterol levels:	
Desirable	160 - 200 mg/dL
Borderline High	200 - 239 mg/dL
High	> 240 mg/dL

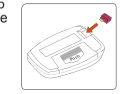
Source: American Heart Association

The above range is just for reference, and it may not apply to everyone.

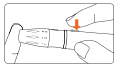
If your blood cholesterol is borderline high or high, discuss these results with your healthcare provider.
Consult your healthcare provider for the appropriate range for you.

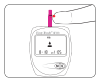
Hemoglobin Testing

1. The rst time you use the EasyTouch® GCHb Meter or open a new test strip vial, insert the code key from the test strip vial. Each test strip vial contains one code key. Make sure the number on the code key matches the code number on the vial of test strips you use.



2. Take one strip from the vial of hemoglobin test strips. Close the vial quickly.
3. Insert the test strip into the test strip slot on the meter. The meter first displays the code number, and then the blood symbol "🩸".
4. Clean your finger with an alcohol swab. Let it dry completely.
5. Place the puncturer on your finger.
6. Press the trigger on the puncturer.
7. Withdraw the puncturer.
8. Wipe away the first drop of blood and allow a second one to form.
9. Touch the drop of blood to the side of the test strip target area. The target area turns red as the strip absorbs the blood. Apply blood until the meter sounds a beep. The meter then counts down from 6, shows your result on the screen, and stores your result in its memory automatically.
10. Record your hemoglobin value on the provided log sheet.



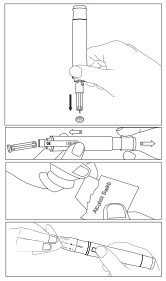



The following are ranges for hemoglobin levels:	
Male	13.5~16.5 g/dL (8.4~10.2 mmol/L)
Female	12.1~15.1 g/dL (7.5~9.4 mmol/L)

The above range is just for reference, and it may not apply to everyone. If your hemoglobin is high or low, discuss these results with your healthcare provider.
Consult your healthcare provider for the appropriate range for you.

After Blood Testing

1. Pull the test strip out of the meter. The meter turns off by itself. Unscrew the adjustable tip of the puncturer.
2. Put the protective cover back on the lancet. Place the protective cover on a flat stable surface, and stick the lancet tip in the center.
3. Pull the sliding mechanism back and slide the lancet ejector forward simultaneously. This action ejects the lancet.
4. Carefully remove an alcohol swab from its packaging.
5. Thoroughly clean the tip of the puncturer with the alcohol swab.
6. Dispose of the used alcohol swab, lancet and test strip, and store the puncturer in a clean location.

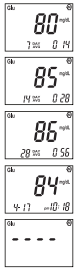


Using the Meter Memory

The EasyTouch ® GCHb Meter automatically stores the 200 most recent glucose, 50 most recent cholesterol, and 50 most recent hemoglobin test results. You can review the test results in order from the newest to the oldest. If the memory is full, the oldest result is deleted as the newest result is added. The memory is not affected by replacing or removing the batteries.

Reviewing Blood Glucose Results

1. Insert the glucose code key and press "M" to access the memory feature.
2. On each press of the "M" button, the 7-day average, 14-day average, and the 28-day average will be displayed on the screen in order.
3. On the fourth button press, after the 28-day average, the newest blood glucose test result with date will be displayed by pressing and releasing the "M" button.
4. The stored results with date are displayed in order from the most recent to the oldest with each press of the "M" button. The meter will turn off automatically in 3 seconds when the symbol "---" is displayed on the screen.



Reviewing Blood Cholesterol Results

1. Insert the cholesterol code key and press "M" to access the memory feature.
2. The most recent result will appear.
3. Each press of "M" will display in the second-most recent result.
4. Review more test results in order of the most recent to the oldest by repeatedly pressing the "M" button. After you review the oldest test result, the meter displays "---" and automatically turns off.

Reviewing Hemoglobin Results

1. Press "M" to access the memory feature.
2. The most recent result will appear.
3. Each press of "M" will display in the second-most recent result.
4. Review more test results in order of the most recent to the oldest by repeatedly pressing the "M" button. After you review the oldest test result, the meter displays "---" and automatically turns off.

Deleting Results from Memory

1. When reviewing results, simply press and hold "S" to delete the displayed result.
2. The meter then sounds a beep as the memory icon flashes once.
3. Release "S" and the meter sounds three beeps in rapid succession to con firm that the result has been deleted.
4. The meter then returns to the first result.

Maintenance - *Taking Care of Your Meter*

- Do not submit your meter to strong impact or pressure.
- Keep your meter between -10°C and 60°C (14°F and 140°F) and less than 95% relative humidity. Do not store the meter in areas such as the kitchen, bathroom, laundry room, or car.
- Keep the meter away from water.
- Do not use glass/household-cleaning solutions to clean the meter. Simply use an alcohol pad to wipe the surface of the meter, but do not wipe the test strip slot or code key slot.
- Do not disassemble the meter.
- If you have any questions, please contact customer service or your healthcare provider.

Changing the Batteries

When the symbol " [-+] " is displayed on the screen, replace the batteries immediately.

1. Slide battery cover off the back of the meter.
   - Remove the old batteries and insert 2 new AAA size batteries (1.5V) into the battery compartment.
2. Slide battery cover back in place and turn on your meter.

Cleaning the Meter

Clean the meter with a 70% isopropyl alcohol swab.

- ***DO NOT spray any cleaning solution directly onto the meter.***
- ***DO NOT dampen the code key slot or the test strip slot.***
- ***DO NOT immerse the meter in liquid.***

Specifications

Model no. ET-321	**Glucose**	**Cholesterol**	**Hemoglobin**
Measuring Range	20 – 600 mg/dL (1.1 – 33.3 mmol/L)	100 – 400 mg/dL (2.6 – 10.4 mmol/L)	7 ~ 26 g/dL (4.3 ~ 16.1 mmo/L)
Memory Capacity	200	50 results	50 results
Test Time	6 sec.	150 sec.	6 sec.
Sample Volume	≧ 0.8 µl	≧ 15 µl	≧ 2.6 µl
Sample Type	Finger capillary whole blood		
Measurement Method	Amperometric		
Operating Conditions	14 - 40 °C; 20 ~ 85% R.H.		
Storage Conditions	-10 ~ +60 °C ≤95% R.H. (for meter) 4 ~ 30 °C (for strips)		
Hematocrit Range	30 ~ 55%		
Weight	60 g without batteries		
Dimensions	90 x 66 x 22 HxWxD (mm)		
Display	LCD (35 x 45 mm)		
Battery	AAA * 2 Alkaline		
Battery Life	More than 1,000 tests		

Troubleshooting

Symbol	What it means	Action
[-+]	Low battery power.	Replace the batteries.
LO	"LO" flashes five times before the meter turns off.	Replace the batteries.
-LO-	The ambient temperature is too low.	Repeat the test in a warmer place,about 57.2°F~104°F (14°C~40°C). You may need to wait as long as 20 minutes before testing again.
-HI-	The ambient temperature is too high.	Repeat the test in a cooler place, about 57.2°F~104°F (14°C~40°C). You may need to wait as long as 20 minutes before testing again.
Glu 241 mg/dL KETONES?	Your blood glucose test result is over 240 mg/dL. Consider ketone testing.	Re-check your blood glucose level. Follow the instructions of your healthcare professional regarding ketone testing.
Glu HI mg/dL KETONES?	Your blood glucose level is higher than 600 mg/dL (33.3 mmol/L). Consider ketone testing.	Re-check your blood glucose level. If "HI" is displayed again, call your doctor immediately.
Glu LO mg/dL	Your blood glucose level is lower than 20 mg/dL (1.1mmd/L).	Re-check your blood glucose level. If "LO" is displayed again, call your doctor immediately.
Chol HI mg/dL	Your blood cholesterol level is higher than 400 mg/dL (10.4 mmol/L).	Re-check your blood cholesterol level. If "HI" is displayed again, call your doctor immediately.
Chol LO mg/dL	Your blood cholesterol level is lower than 100 mg/dL (2.6 mmol/L).	Re-check your blood cholesterol level. If "LO" is displayed again, call your doctor immediately.
Hb HI g/dL	Your hemoglobin level is higher than 26 g/dL (16.1 mmol/L).	Re-check your hemoglobin level. If "HI" is displayed again, call your doctor immediately.
Hb LO g/dL	Your blood hemoglobin level is lower than 7 g/dL (4.3 mmol/L).	Re-check your hemoglobin level. If "LO" is displayed again, call your doctor immediately.
X	Operating procedure is incorrect. The test strip has been used, or the meter is not performing correctly.	Repeat the test with a new test strip. If the symbol is displayed again, contact customer service.
- - - -	The oldest test result stored in memory appears. The meter turns off automatically after three seconds.	No action required.
E01	1. Using a wrong code key or the code key is inserted improperly. 2. Meter hasn't been coded yet.	1. Be sure the code key is inserted into the code key slot completely. 2. Insert the code key.
E02	The code key is damaged.	Contact customer service.

Warranty Information

Thank you for choosing the EasyTouch ® GCHb *Monitoring System. Bioptik Technology, Inc. is honored to present this new product to you.* Our customers are entitled to free repair and replacement of parts. However, damage resulting from improper use or accidents is excluded: strong impact or pressures, moisture intrusion, unauthorized repair, disassembly, and natural disasters. If you have problems with the product, please contact the local distributor or agent for further information. For EU customer service, dial +49-6894-581020.

Product Liability

Bioptik Technology, Inc. is not responsible for any accidents or worsening illness resulting from buyers' or users' improper use of the device without the instructions of professionals (e.g. medical personnel). Consumers may not request compensation in this regard.
Please read this manual thoroughly before using this monitoring system.

Guidance and manufacturer's declaration – electromagnetic emissions		
This device is intended for use in the electromagnetic environment speci ed below. The customer or the user of this device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissionsCISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissionsCISPR 11	Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissionsIEC 61000-3-2	Not applicable	
Voltage uctuations/ icker emissionsIEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
This device is intended for use in the electromagnetic environment speci ed below. The customer or the user of this device should assure that it is used in such an environment.			
Immunity test	IEC 60601test level	Compliance level	Electromagnetic environment –guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If oors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic eld IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic elds should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *UT* is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
This device is intended for use in the electromagnetic environment speci ed below. The customer or the user of this device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1,2 √P d = 1,2 √P 80 MHz to 800 MHz d = 1,2 √P 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from xed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and re ection from structures, objects and people.

a Field strengths from xed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to xed RF transmitters, an electromagnetic site survey should be considered. If the measured eld strength in the location in which this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this device.

b Over the frequency range 150 kHz to 80 MHz, eld strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this device			
This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitterm		
	150 kHz to 80 MHz d = 1,2 √P	80 MHz to 800 MHz d = 1,2	800 MHz to 2,5 GHz d = 2,3
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and re ection from structures, objects and people.

Labeling and Information

Item	Description	Item	Description
	Do not reuse		Consult instructions for use
	Temperature limitation		Keep away from sunlight
	Manufacturer		Use by
	Caution, consult accompanying documents	EC REP	Authorized representative in the European Community
LOT	Batch code	REF	Catalogue number
SN	Serial number	CONTROL	Control
IVD	In vitro diagnostic medical device	STERILE R	Sterilized using irradiation
	Keep dry		

* The Meter has been safety and EMC tested and approved according to the requirements of EN 61010-1/EN 61010-2-101/EN 60601-1-2/EN 61326-1/EN61326-2-6, and EN60601-1.

Lancet (Included in the package)
Speci fication: Sterile, 30G
Manufacturer: Sterilance Medical (Suzhou) Inc.
Address: No. 68 Litanghe Road, Xiangcheng, Suzhou, Jiangsu 215133, P. R. China
CE 0197 | Do not reuse | STERILE R Sterilized using irradiation
EC REP EMERGO EUROPE Molenstraat 15, 2513 BH, The Hague, The Netherlands

Lancing Device (Included in the package)
Manufacturer: Global Medical Market Corp.
Address: Room No. 1112, Ace Tower 9th Bldg., 345-30, Kasan-Dong, Kumchon-Ku, Seoul, Korea
EC REP GMMC S.L. C/Jordi de S.Jordi 13, 6-23, 46022 Valencia, Spain

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CE 0197

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