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# Instruction for Blood Glucose Meter

Please read this instruction carefully before using the blood glucose Meter. Any problems, please do not hesitate to contact with us by dialing +86-010-80123111.

## I. Application, Specification, Testing Methods and Principles

### 1. Application

Poctor 800 glucometer co-operates with Poctor 800 blood glucose testing strips produced by Lepu Medical Technology (Beijing) Co.,Ltd., applied to quantitatively detect the glucose concentration with whole blood sample from fingertip. This product is only used to supervise the effect of diabetes' blood glucose control. Do not use it to diagnose or screen diabetes, nor as the basis of therapeutic or drug adjustment.

### 2. Specification

Poctor 800

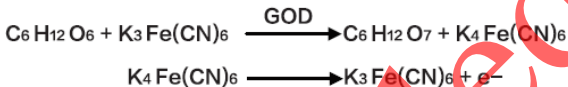
### 3. Supporting test strips

Poctor 800 blood glucose testing strip (electrochemical)

### 4. Testing principles

The blood glucose testing strips adopt a new type of biosensing technique glucose oxidase (GOD) and electron transfer mediators are fixed on the surface of the electrode. With catalysis by glucose oxidase, glucose in the blood will react with potassium ferricyanide, generating gluconic acid and potassium ferrocyanide. Redox current generates due to the electrochemistry reaction of potassium ferrocyanide. The

intensity of the redox current is proportional to the glucose concentration in the blood. The glucometer calculates glucose concentration by detecting the intensity of current.



## II. Main structure of the glucometer and illustration of composition

### 1. Main structure

The glucometer mainly consists of circuit board, functional button, LCD screen, strip slot, case, calibration chip, battery and battery cover. Accessory: lancing device (products with Registration License of Medical Instruments) and lancets.

### 2. Illustration of the glucometer composition



Figure 1 illustration of Glucometer



**Notes:** Pactor 800 glucometers produced by Lepu Medical Technology (Beijing) Co., Ltd. only cooperates with Pactor 800 blood glucose testing strips (electrochemical). Blood glucose testing strips from other manufacturer are not adaptive. Tested blood glucose testing strips might have issues in bio-safety or environmental contamination. Please use special container to collect.

### III. Requirements on Samples

1. Sample size :0.7 $\mu$ L
2. Test time : 8 s .
3. Bloodsample : fresh capillary blood samples
4. Please rub the finger to generate blood drop. Don' t squeeze vigorously. Use the second drop for test. Only 0,7 $\mu$ L blood is enough for test.
5. Please don' t press the testing strips that may hinder the syphoning.
6. Known interfering substance:  
Triglyceride more than 33.8mmol/L (>3000mg/dL) will cause a higher testing result of blood glucose. Substances like paracetamol, ascorbic acid, dopamine, ibuprofen,

levodopa, tetracycline, creatinine and trioxypurine within the evaluated concentration range recommended by National Committee for Clinical Laboratory Standards (NCCLS) will not affect the test.

7. Hematocrit: within 30%-50%, test will not be affected.

#### IV. Description of Display content

Please check the display screen after switch on analyzer (Figure 3). If the glucometer is staying in shutdown mode, short press any key (S/M), all information would display on the screen.



Figure 3 On screen display of the glucometer upon switched on  
If L.O is displayed on the meter ,you blood glucose may be below 1.1 mmol/l (19.8mg/dL) .

If H.I is displayed on the meter ,you blood glucose may be over 33.3 mmol/l (600mg/dL) .  
For detailed information on error messages , refer to the Owner' s Booklet

If your blood glucose result does not match how you feel , follow these steps :

- 1 . Using the new test paper to test .
- 2 . According to the following items for inspection

Please check whether the test Strips has expired.

Please check whether the following test steps

Please check whether the test Strips storage environment meets the requirements.

## V. Operation

### 1. Install the battery

One 3V battery is applied for Pactor 800 blood glucose.Each battery can support 1000 tests. Pactor 800 glucometer has power-save mode. Once the strip pulled out, the glucometer will shut down automatically.

- 1) Push open the battery cover at the back of device;
- 2) Install a lithium battery and pay attention to positive and negative electrodes;
- 3) Push back the battery cover to the original position.



#### **Note:**

- 1) When power indicator flashes, it indicates that the battery is dying. Tests can be carried out normally but it is recommended to replace the battery as soon as possible; when E-1 and battery symbol display on the screen, it indicates that the glucometer cannot be used continuously and the tests cannot be carried out until battery replaced;
- 2) Please take out the battery if the device will not be used for a long time;

3) After replacing the battery, it is necessary to reset the time. But it is not necessary to reset the date and other settings. History results saved in the glucometer will not be lost.

## 2. Settings of time, date

### 2.1 Time setting

Hold S button for 3 seconds, the glucometer will enter the time setting mode (Figure 4).

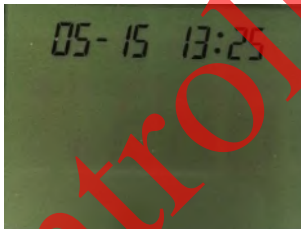


Figure 4 Time Setting of the Glucometer

Use M button to set flashing numbers and press S button to confirm.



#### Notes:

- 1) Time setting is an additional function. Tests of the glucometer will not be affected by the setting of time. But once the time is set, you will know the accurate time of the blood glucose test, which is more convenient for monitoring

and controlling the blood glucose;

- 2) Time has been preset when the product leaves the factory. If it is necessary to reset the time or replace the battery, you need set manually;
- 3) If the time has not been reset, the instrument will start timing from the preset time when leaving the factory.

## **2.2 Date setting**

After confirmation of time setting, use M button to set the flashing number of date and press S button to confirm.

## **2.3 Set Date Display Format**

Flashing m.d (month/day) displays on the screen. Use M button to set and S button to confirm.

## **3. Testing**

Prepare:

- 1) Environment temperature: 10~35℃;
- 2) Relative humidity: ≤80%;
- 3) Range of atmospheric pressure: 86 kPa~106 kPa;

If the test temperature is quite different from storage temperature, strips need to be recovered to room temperature first for about 30 minutes to assure the accuracy of test. There is a temperature sensor near to the testing strips insertion port of the glucometer, please don't hold this part when testing (Figure 5).



Temperature sensor



Figure 5 Position Diagram of Glucometer Temperature Sensor

**3.1 Wash hand with warm water. Use 75% alcohol to disinfect and wait the finger dry to sample blood.**

**Notes:**



- 1) Washing hand with warm water or rubbing finger will help increase blood volume to get enough sample.
- 2) Please do not use iodine disinfectant.

**3.2 Pull out test strip**



Note: please write down the date of open box on the label. Close the bottle immediately after taking out the strip. It may affect the test result using damped strip.

The test must be completed within 3 minutes after taking out the testing strip. If the testing strips are exposed in the air too long before the test it may affect the accuracy of test.

**3.3 Under switch-off state, insert the electrode tip into the glucometer (please insert code firstly), device will make a short 'beep' . If the symbol of blood dripping flashes (Figure 6), it indicates that blood samples can be added into the testing strip.**



Figure 6 Prompt of adding blood samples



**Note:** Only if the blood dripping is the only indicator flashing, adding sample is allowed.

**3.4 Blood sampling: sample blood from the disinfected parts with a lancing device.**



**Note:** before sampling blood, it is necessary to wait finger dry after disinfection.

**3.5 Add blood samples:** Squeeze out the blood sample to make blood drop on the finger (Figure 7.1 and 7.2). Contact blood drop with blood sampling tip to syphon blood sample into reaction chamber (Figure 7.3). With enough blood samples, a short “beep” will be made by device. Withdraw fingers, the instrument will count down 8 seconds and apply the test automatically. (Figure 7.4)



Figure 7.1 Blood sampling



Figure 7.2 Squeeze out blood



Figure 7.3 Syphoning blood sample



Figure 7.4 Apply the test



**Notes:**

- 1) It is important to complete sampling at one time. If strip does not syphon in enough blood, please change a new test strip to apply the test again.
- 2) Please do not press the finger too hard with strip that may block the bleeding spot.  
Results: 8 seconds after adding the blood sample, screen will show the test result in mmol/L (Figure 8).



Figure 8 Testing results (this value is only used for reference)

**3.6 Record testing result, pull out the testing strip. After a short “beep” device will shut down automatically.**

**3.7 Waste Disposal: dispose according to the requirements of medical wastes.**



**Note:** if “L.O” or “H.I” shown in the testing result of the blood glucose, it indicates that your testing results are lower than 1.1mmol/L or higher than 33.3mmol/L, please retest. If the testing result of your blood glucose is still displayed as “L.O” or “H.I”, please consult your doctor or professional health care workers immediately.

#### **4. Data review**

Under switch-off state, press M or S to review history data.

The device will show the average value within 7 days (Figure 9). Press M button again to

check average value within 30 days (Figure 10).



Figure 9The average value within 7 days



Figure 10The average value within 30 days

Continue to press M button to check history testing result one by one according to time. The latest result will present at first.



Figure 11 Check results one by one

Press M button to browse the stored testing results (Figure 11). If screen displaying ' End' (Figure 12), that indicates all results have been reviewed.

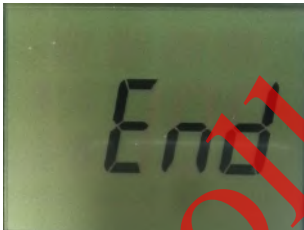


Figure 12 Complete reviewing data

Pocor 800 glucometer can store 200 tests. When the storage is full, continuing test will erase the oldest testing result. Press S button to switch off the device or it will switch off 3 minutes later.

## VI. Calibration and Maintenance

### 1. Calibration.

Quality control reagent is used to test if the glucometer and testing strip are working normally. Applying quality control examination regularly ensures accurate blood glucose testing results. Use quality control reagent produced by Lepu Medical to calibrate the glucometer.

- 1) When the system needs to be calibrated

- When using a bottle of new testing strips.
- When you suspect that the glucometer or the testing strips are not working normally.
- When your testing results of blood glucose are not consistent with that you feel by yourself.
- When the glucometer falls or might be damaged.

## 2) Steps for quality control testing

- a) Before testing, make sure that the reagent has been recovered to room temperature.
- b) Under switch-off state, insert the testing strip into the glucometer strip slot in the arrow direction. When blood drop symbol flashes, The device is ready for test.
- c) Shake the bottle of the quality control reagent properly before test. Squeeze out the first drop of quality control reagent and discard it. Contact sample tip of strip with the second drop of reagent and the reagent will be syphoned into the reaction zone. The process completes. The device will count down 8 seconds to present the test result.
- d) The testing system of the glucometer will complete the test automatically. If the testing results within the range printed on the label of reagent bottle, it indicates that the device and the testing strip work normally.
- e) Pull out the testing strip lightly, the device will shut down automatically, and the test completes.



**Note:** the quality control reagent can only be used within three months after breaking the seal. Please record the first use date on the label of the



bottle.

Please don't use quality control reagent with broken or unsealed bottle.

Please do not use expired quality control reagent or that exceeding the disposable date (3 month after the opening date)

Please pay attention to the consistency of device model and quality control reagent specification. Please read the instruction of the quality control reagent carefully before applying the test.

Please dispose the testing strips according to the method of medical wastes disposal.

## **2. Maintenance of instruments**

Poctor 800 glucometer should be stored away from the dust or high temperature and humidity environment.. Prevent it from violent shock and collision.

### **2.1 Environmental conditions for storage: -20°C-55°C**

Humidity conditions for storage: The relative humidity should not be higher than 80%.

Atmospheric pressure conditions for storage: 860 hpa~1060 hpa

### **2.2 Environmental conditions for transportation: -20°C-55°C.**

Humidity conditions for storage: The relative humidity should not be higher than 80%.

Atmospheric pressure conditions for transportation: 860 hpa ~1060 hpa

It is not necessary to maintain or clean the device after each test. Do not let dirt, dust, serum or liquid enter into strip slot. Do not clean the surface with corrosive organic solvent. The device can be wiped with soft cloth with 75% ethyl alcohol or neutral detergent.

## VII. **Warranty**

Under normal application, we promise to replace the device for free within one year.



## VIII. **Notice**

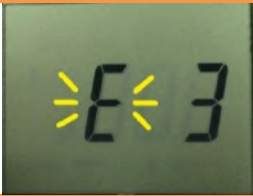

The testing results of device can only be used for monitoring the blood glucose, and cannot be used as the basis for diagnosing diabetes. Please follow opinions from doctors or experts. Donotviolate the doctor' s instructions on rehabilitation.If testing results are not consistent with symptoms, you should go to the hospital for re-examination. Please carry out laboratory examination regularly and compare the testing results. Accuracy of this test may be affected by the following factors:

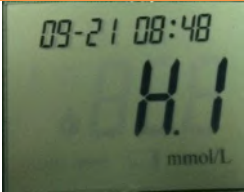

- 1) Abnormal hematocrit (exceed the range by 30%-55%)
- 2) Small molecule reducing agent, such as Vitamin C
- 3) Serum uric acid exceeds 10mg/dL
- 4) Hyperlipidemia (cholesterol higher than 300mg/dL)
- 5) Metabolic disturbance or severe dehydration.

## IX. Description of Error Codes

Table 1 Description of Error Codes

Items shown on the display screen	Issue	Solution
	Low power level	Please replace the battery as soon as possible (please see page 3)
	Too low or high temperature for the glucometer	Move the glucometer to locations within temperature range (5°C-40°C), wait for 20 minutes, let the glucometer and the blood glucose testing strips recover to the surrounding temperature, and then apply the test.

	<p>The inserted testing strips have been used</p>	<p>Discard the used testing strips and then use a new strip to apply the test. Start syphoning in blood samples when flashing “blood drop” on the display screen.</p>
<p>E5 E6 E8 E9</p> <p>E10 E12 E13</p>	<p>The glucometer's hardware or software not working well</p>	<p>Pull out the testing strips and insert a new testing strip. If the problems cannot be solved, please contact the customerservice of Lepu.</p>
	<p>The glucometer is interrupted when it is counting down; The blood glucose testing strips have been damaged after being stored outside the bottle for too long; Used testing strips have been inserted.</p>	<p>Pull out the blood glucose testing strip, and then retest with a new strip. Refer to the operation instruction and comply with the testing steps with caution. If the problems cannot be solved, please contact the</p>

		customer service of Lepu.
 <p>The display shows the date and time '09-21 08:48', a large 'HI' indicating a high glucose reading, and 'mmol/L' below it.</p>	<p>The testing results of blood glucose is higher than 33.3mmol/L</p>	<p>Clean two hands and the blood sampling spot and retest with new testing strips. If "HI" still presents, please consult your doctor or professional medical workers.</p>
 <p>The display shows the date and time '09-21 08:48', a large 'LO' indicating a low glucose reading, and 'mmol/L' below it.</p>	<p>The testing results of blood glucose is lower than 1.1mmol/L</p>	<p>Retest with a new testing strip. If "L.0" still presents, please consult your doctor or professional medical workers.</p>
<p>The display screen is blank when the glucometer switched on</p>	<p>If the glucometer has not been used, it will be turned off automatically 3 minutes for saving battery. The battery is out of power</p>	<p>Press S again to start up the glucometer. If a blank battery symbol is displayed within 3 minutes, please replace the battery.</p>

<p>Wrong units displayed for the testing results (mg/dL or mmol/L)          Note:          1mmol/L = 18mg/L</p>	<p>The accuracy of interpreting the testing results maybe affected.</p>	<p>Please contact the customer service of Lepu.</p>
<p>With the glucometer turned on, not all patterns are displayed on the display screen.</p>	<p>Machine errors might appear to the glucometer.</p>	<p>With the glucometer switched off, hold M button. Compare patterns displayed on the screen with the pattern in figure 3 on page 6. If there is any difference, please contact the customer service of Lepu.</p>

## X. Measuring performance of the testing system

### 1. Accuracy(methodology comparison)

Accuracy and repeatability of test system accord with national standard ISO15197:2013In vitro diagnostic test systems -- Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus.

Requirements on system accuracy: the deviation on measuring results  $\geq 95\%$  should meet requirements of table 1;

Requirements on repeatability of measurement of the system: SD value and CV value of results of repeated testing should meet requirements of table 2.

Table 1 System accuracy results for glucose concentration < 5.55 mmol/l (< 100 mg/dl)

within $\pm 0.28$ mmol/l (within $\pm 5$ mg/dl)	within $\pm 0.56$ mmol/l (within $\pm 10$ mg/dl)	within $\pm 0.83$ mmol/l (within $\pm 15$ mg/dl)
137/177 (77.4%)	170/177 (96.0%)	177/177 (100%)

Table 2 System accuracy results for glucose concentration  $\geq 5.55$  mmol/l ( $\geq 100$  mg/dl)

within $\pm 5\%$	within $\pm 10\%$	within $\pm 15\%$
302/486 (62.1%)	455/486 (93.6%)	486/486 (100%)

Table 3 System accuracy results for glucose concentrations between 1.10 mmol/l (11 mg/dl) and 33.3 mmol/l (333 mg/dl)

within $\pm 0.83$ mmol/l or $\pm 15\%$ (within $\pm 15$ mg/dl or $\pm 15\%$ )
663/663 (100%)

Total count of clinical testing data: N=663

## 2. Repeatability:

The precision of repeating test of the blood glucose testing strips and Pactor glucometer meets requirements on precision of ISO 15197-2013

Mean value (mmol/L)	2.3	4.6	7.3	11.2	18.3
SD value (mmol/L)	0.09	0.15			
CV value (%)			2.19	2.88	1.05

3. Accuracy of the blood glucose testing strips: 95% of the testing results with the blood glucose testing strips should be controlled within the quality control range of quality control reagent.

4. Inter assay variation: inter assay variation  $\leq 10\%$ .

5. Testtime : 8 s

6. Sample size :  $0.7\mu\text{L}$

7. Detection limit (lowest value displayed) :  $1.1\text{mmol/l}$  ( $19.8\text{mg/dL}$ )

8. System measurement range :  $1.1\text{--}33.3\text{mmol/l}$  ( $19.8\text{--}600\text{mg/dL}$ )

9. Blood Glucose Test Strips (Glucose oxidase method) performance system complies with the requirements of EN ISO 15197:2013 (In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus)

#### Notes:

1. This product is only used to monitor the level of blood glucose and cannot be used as the basis of diagnosis for diabetes.
2. Please use fresh whole blood as sample.
3. Lancet and strip are disposable. Please do not reuse. One lancing device is just for one person; please do not share with others.
4. Please do not collect strip with container other than original canister.
5. Please keep your hands clean and dry in testing; please don't contact the testing strip with wet hands.



6. Date indicated after “EXP” is expiry date; please do not use expired products.
7. Please do not bend, break or pollute test strip to assure accurate test.
8. Please do not use a strip exposed in air over 2 mins that may cause inaccuracy.
9. Please close the strip bottle immediately after taking out the test one.
10. Please follow the instruction during test.
11. Please confirm to test in proper environment
12. If the tested result does not comply with symptoms and all the operation are following the instruction, please consult doctors or professionals.
13. Please compare with test from biochemical system to make sure the monitoring system is working well.
14. Dispose the lancet and strip according to requirement of medical waste disposal.
15. Please clean the device with alcohol after test, preventing the infection due to microorganism in blood residue.
16. Please keep this product far away from children and pet.

## **XI. Safety classification**

This glucometer is a handheld device with the internal direct current of 3V. The device cannot be used in environment with mixed gas including inflammable and anesthetic gases or nitrous oxide.

## **XII. Product specification**

Samples for testing: peripheral whole blood

Sample volume: 0.7uL

Detection range: 1.1~33.3 mmol/L

Testing time: Less than 10 seconds

Storage results: Store the latest 200 test results

Battery: A button battery of 3V(DL2032 or CR2032)

Service life of the instrument: The period of validity is four years

Testing temperature: 5°C~40°C

Testing humidity: Not larger than 80%

Dimension: 80 mm × 70 mm × 19 mm

Weight: about 55 g (battery included)

### XIII. **Faults Warnings**











1. The testing values maybe inaccurate by disinfecting with iodine solution or disinfectant containing iodine, please disinfect with 75% ethyl alcohol.
2. Please wait for the hand dry to sample the blood, or the blood may not be droplike, that may make it hard to syphon.



**Note:** Children, the disabled or patients must operate the device under surveillance. Only operate Pactor 800 following the instructions.

### **Descriptions of the graphic contents of the labels and packages**

The graphic and symbol used on the labels and packages as well as their descriptions are shown in the following table.

Symbol	Reference
	In vitro diagnostic medical device
	Consult instructions for use
	CE marking
	Authorized representative in the European community
	Use by
	Caution, consult accompanying documents
	Batch code
	manufacturer
	Serial number
	Ban discarded

#### XIV. XVI. EMC DECLARATION

The Blood Glucose Meter (Poctor800) needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents;

Portable and mobile RF communications equipment can affect the Blood Glucose Meter (Poctor800).

All cables and maximum length of cables, Transducers and other accessories with which the manufacturer of the Blood Glucose Meter (*Poctor800*) claims compliance with the requirements, accessories that do not affect compliance with the requirements of these sub clauses need not be listed. Accessories, transducers and cables may be specified either *generically* or *specifically*.

#### **NOTE:**

The use of accessories, transducers and cables other than those *specified*, with the exception of transducers and cables sold by the manufacturer of the Blood Glucose Meter (*Poctor800*) as replacement parts for internal components, may result in *increased* emissions or decreased immunity of The Blood Glucose Meter (*Poctor800*).

<b>Guidance and manufacturer' s declaration – electromagnetic emissions</b>		
The Blood Glucose Meter(Poctor800)is intended for use in the electromagnetic environment specified below.The customer or the user of the Blood Glucose Meter(Poctor800)should assure that it is used in such anenvironment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
RFemissions CISPR 11	Group 1	TheBlood Glucose Meter ( <i>Poctor800</i> )uses RF energyonly for its internal function. Therefore, its RFemissions are very low and are not likely to causeany interference in nearby electronic equipment.
RFemissions CISPR 11	ClassB	The Blood Glucose Meter ( <i>Poctor800</i> )is suitable for use in all establishments, including domestic establishments and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

**Guidance and manufacturer' s declaration – electromagnetic immunity**

The Blood Glucose Meter (*Poctor800*) is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Glucose Meter (*Poctor800*) should assure that it is used in such an environment.

<b>IMMUNITY test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 6$ kV contact $\pm 8$ kV air	$\pm 6$ kV contact $\pm 8$ kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	$\pm 1$ kV line(s) to line(s) $\pm 2$ kV line(s) to earth	Not applicable	
Voltage dips	<5 % UT	Not applicable	

<p>short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p>(&gt;95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles &lt;5 % UT (&gt;95 % dip in UT) for 5 s</p>		
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>3 A/m</p>	<p>Not applicable Note: The Blood Glucose Meter (Pocor800) does not contain components susceptible to magnetic fields, such as Hall elements or magnetic field sensors. Therefore, the EUT is deemed to meet the requirement without actual testing.</p>	


**Guidance and manufacturer's declaration – electromagnetic immunity**

The Blood Glucose Meter (*Poctor800*) is intended for use in the electromagnetic environment specified below.

The customer or the user of the Blood Glucose Meter (*Poctor800*) should assure that it is used in such an electromagnetic environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	Not Applicable 3 V/m 80 MHz to 2,5 GHz	Portable and mobile RF communications equipments should be used no closer to any part of the Blood Glucose Meter ( <i>Poctor800</i> ), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance</b> $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 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 <i>separation distance in meters</i> (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> , should be less than the compliance level in each frequency range. <sup>b</sup>



			<p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p><sup>a</sup>Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and landmobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Blood Glucose Meter (<i>Poctor800</i>) is used exceeds the applicable RF compliance level above, the Blood Glucose Meter (<i>Poctor800</i>) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Blood Glucose Meter (<i>Poctor800</i>).</p> <p><sup>b</sup>Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**Recommended separation distances between portable and mobile RF communications equipment and the BLOOD GLUCOSE METER (Poctor800)**

The Blood Glucose Meter (Poctor800) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Blood Glucose Meter (Poctor800) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Blood Glucose Meter (Poctor800) 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 transmitter m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2,5 GHz $d = 1.17\sqrt{P}$
0.01	0.12	0.12	0.07
0.1	0.37	0.37	0.22
1	1.17	1.17	0.70
10	3.69	3.69	2.21
100	11.67	11.67	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (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 reflection from structures, objects and people.

## XV. **Manufacturer information**

【Product name】 Blood Glucose Monitoring System

【Specification】 Pactor 800

【Issuing Date】 15th Sept, 2015

【File Number】 CE-InJY06

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