Inspire Advance

IMC-734
Blood Pressure
Monitoring System

Owner's manual

INDEX

IMPORTANT INFORMATION
NORMAL BLOOD PRESSURE FLUCTUATION

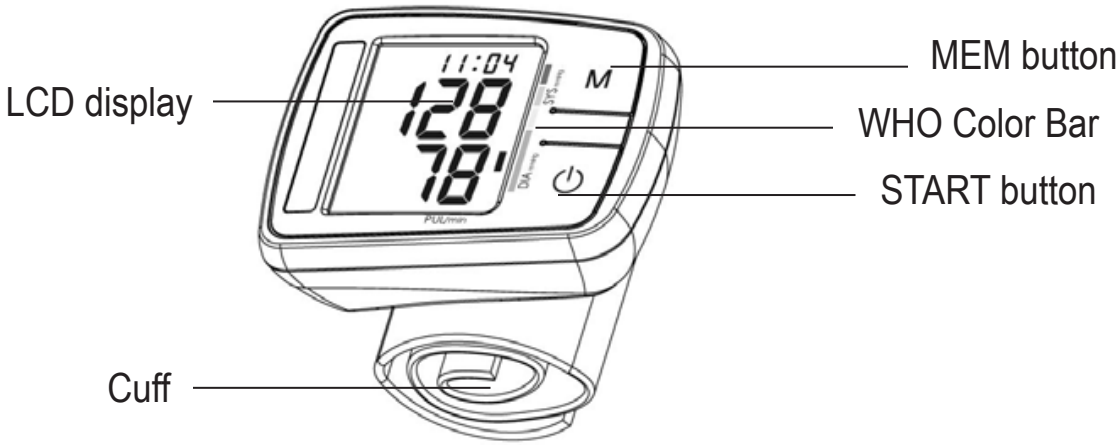
All physical activity, excitement, stress, eating, drinking, smoking, body posture and many other activities or factors (including taking a blood pressure measurement) will influence blood pressure value. Because of this, it is mostly unusual to obtain identical multiple blood pressure readings.

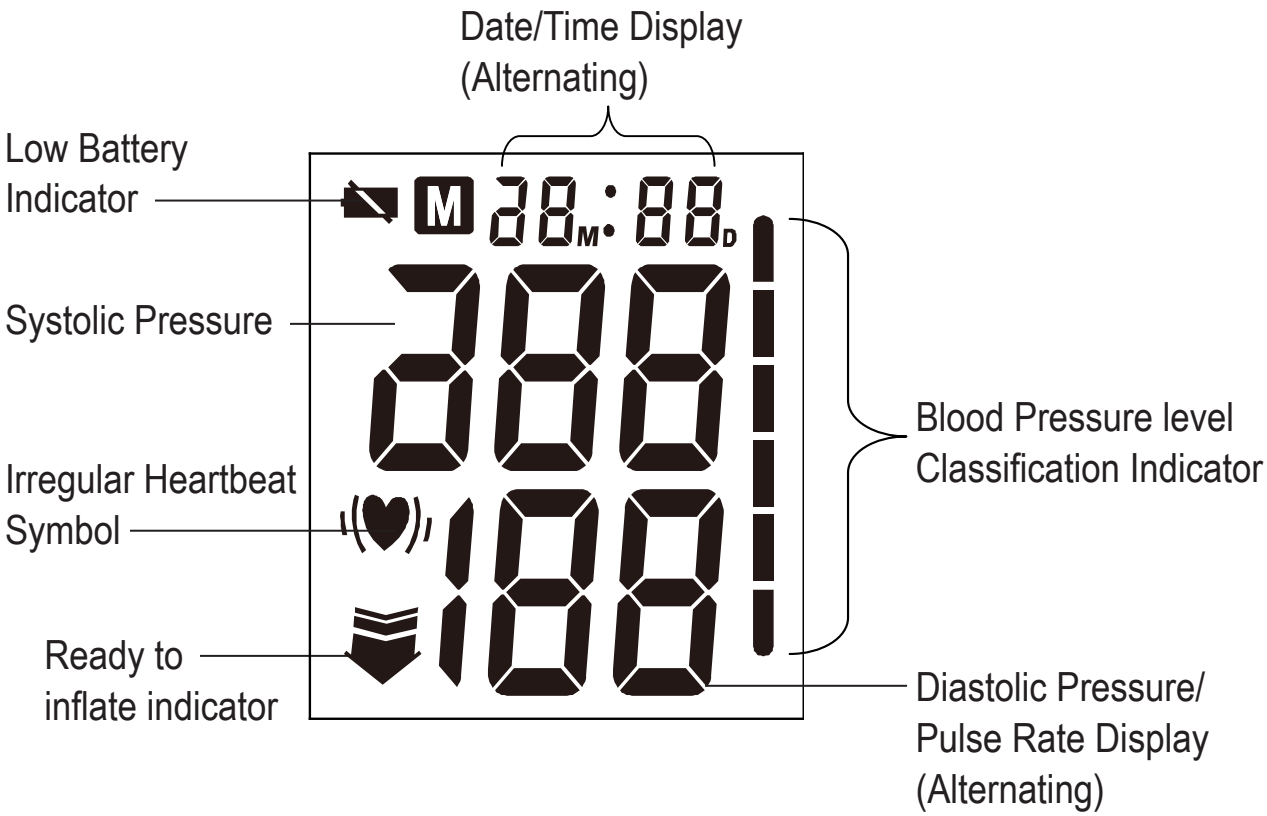
Blood pressure fluctuates continually day and night. The highest value usually appears in the daytime and lowest one usually at midnight. Typically, the value begins to increase at around 3:00AM, and reaches to highest level in the daytime while most people are awake and active.

Considering the above information, it is recommended that you measure your blood pressure at approximately the same time each day.

Please always relax a minimum moment of 1 to 1.5 minutes between measurements to allow the blood circulation in your arm to recover. It is rare that you obtain identical blood pressure readings each time.

CONTENTS AND DISPLAY INDICATORS





INTENDED USE

Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist.

CONTRAINDICATION

It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer.

PRODUCT DESCRIPTION

Based on Oscillometric methodology and silicon integrated pressure sensor, blood pressure and pulse rate can be measured automatically and non-invasively. The most recent 60 measurements can be stored in the memory with date and time stamp. The Electronic Sphygmomanometer corresponds to the below standards: EN 60601-1:1990+A1:1993+A2:1995(Medical electrical equipment-Part1:General requirements for safety) , EN 60601-1-2:2007(Medical electrical equipment-Part1:General requirements for safety; Collateral Standard-Electromagnetic compatibility-Requirements and tests) , EN 1060-1:1995+A2:2009 (Non-invasive sphygmomanometers - Part 1: General requirements), EN 1060-3:1997+A2:2009(Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems), ANSI/AAMI SP-10:2002+A1:2003+A2:2006.

SPECIFICATIONS

1.Product name: Blood Pressure Monitor
2.Model: IMC-734
3.Classification: Internally powered, Type B applied part,IPX0,No AP or APG, Continuous operation
4.Machine size: 87mm x 66.6mm x 25.3mm
5.Cuff circumference: 14cm ~ 19.5cm
6.Weight: about 115g (exclude batteries)
7.Measuring method: oscillometric method, automatic air inflation and measurement
8.Memory volume: 60 times with time and date stamp
9.Power source: 2 ×1.5V SIZE AAA batteries
10.Cuff pressure range: 0-295mmHg
11.Range of measurement: 30-280mmHg
12.Measuring accuracy: ±3mmHg
13.Heart pulse rate range: 40-180times/min, accuracy: ±5%
14.Environmental temperature for operation: 5°C~40°C
15.Environmental humidity for operation:<90%
16.Environmental temperature for storage and transport: -20°C~55°C
17.Environmental humidity for storage and transport: <95%
18.Environmental pressure: 80KPa-105KPa
19.Battery life: Approx.3 month with alkaline batteries and 3-min. usage per day.
20.a list of all components belonging to the pressure measuring system, including accessories
1)Pump: KPM14A or CJP31-C03A1 or MPDC3V-03 or KP-PUMP-01
2)Value: KSV05A3 or CJV10-A03A1 or VLDC3V-02
3)LCD: IMC-734-L01
4)Wrist Cuff: 14cm ~ 19.5cm
5)Sensor: KD-2107-006G

If you want to change these components, please contact us.

NOTICE

1.Stay quiet, calm and rest for 5 minutes before blood pressure measurement.
2.The cuff should be placed at the same level as your heart.
3.During measurement, neither speak nor move your body and arm.
4.Measuring on same wrist for each measurement.
5.Please always relax a minimum moment of 1 to 1.5 minutes between measurements to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceed 300 mmHg or maintained above15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your arm.
6.Remove the batteries if the monitor will not be used for a month or more to avoid damage of battery leakage.
7.This Electronic Sphygmomanometer is designed for adults and should never be used on infants or young children. Consult your physician or other health care professionals before use on older children.
8.Blood pressure measurements determined by this monitor are equivalent to those obtained by a trained observer using the cuff/ stethoscope auscultation method, within the limits prescribed by the American National Standard Institute, Electronic or automated sphygmomanometers.
9.Information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices together with advice regarding avoidance of such interference please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION.
10.If Irregular Heartbeat (IHB) brought by common arrhythmias is detected in the procedure of blood pressure measurement, a signal of will be displayed. Under this condition, the Electronic Sphygmomanometer can keep function, but the results may not be accurate, it's suggested that you consult with your physician for accurate assessment.

There are 2 conditions under which the signal of IHB will be displayed:
1) The coefficient of variation (CV) of pulse period >25%.
2) The difference of adjacent pulse period≥0.14s, and the number of such pulse takes more than 53 percentage of the total number of pulse.
11.Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
12.The monitor might not meet its performance specifications or cause safety hazard if stored or used outside the specified temperature and humidity ranges in specifications.
13.Please do not share the cuff with other infective person to avoid cross-infection.

SETUP AND OPERATING PROCEDURES

1. BATTERY LOADING

a.Open battery cover at the back of the monitor.
b.Load two “AAA” size batteries. Please pay attention to polarity.
c.Close the battery cover.

⚠When LCD shows battery symbol  , replace all batteries with new ones.

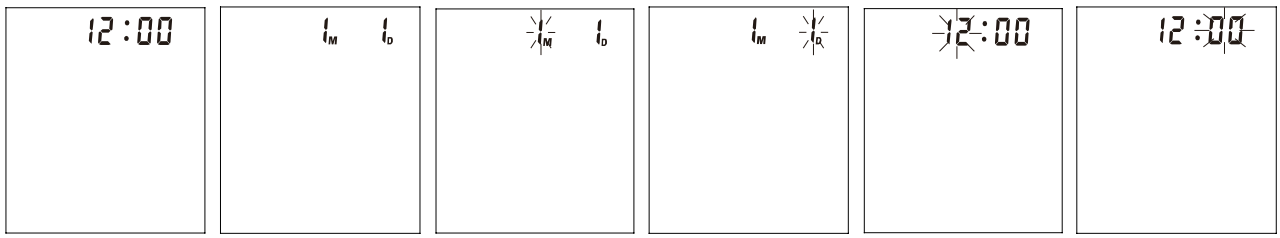
⚠Rechargeable batteries are not suitable for this monitor.

⚠Remove the batteries if the monitor will not be used for a month or more to avoid relevant damage of battery leakage

 The monitor, the batteries and the cuff, must be disposed of according to local regulations at the end of their usage.

2. CLOCK AND DATE ADJUSTMENT

a.Once you install the battery or turn off the monitor, it will enter Clock Mode, and LCD will display time and date by turns. See picture 2&2-1.



Picture 2 Picture 2-1 Picture 2-2 Picture 2-3 Picture 2-4 Picture 2-5

b.While the monitor is in Clock Mode, pressing both the “START” and “MEM” button simultaneously, a beep is heard and the month will blink at first. See picture 2-2. Press the button “START” repeatedly, the day, hour and minute will blink in turn. See picture 2-3& picture 2-4& picture 2-5. While the number is blinking, press the button “MEM” to increase the number. Keep on pressing the button "MEM", the number will increase fast.

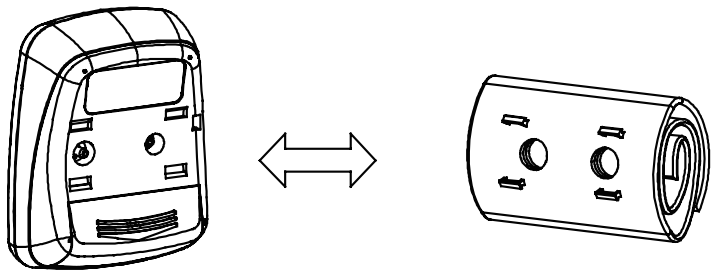
c.You can turn off the monitor by pressing “START” button when the minute is blinking, then the time and date is confirmed.

d.The monitor will turn off automatically after 1 minute of no operation, with the time and date unchanged.

e.Once you change the batteries, you should readjust the time and date.

3. CONNECTING THE CUFF TO THE MONITOR

The cuff is attached to the monitor when it is packaged. Should the cuff become unattached, align the two plugs and four brackets of the cuff with the plug sockets and bracket sockets of the monitor and press the cuff to the monitor until the plugs and brackets are securely attached.



4. APPLYING THE CUFF

a. Place the cuff around a bare wrist 1-2cm above the wrist joint on the palm side of the wrist.

b. While seated, place the arm with the cuffed wrist in front of your body on a desk or table with the palm up. If the cuff is correctly placed, you can read the LCD display.

c. The cuff must be neither too tight nor too loose.

Note:

• Please refer to the cuff circumference range in "SPECIFICATIONS" to make sure that the appropriate cuff is used.

• Measuring on same wrist each time.

• Do not move your arm, body, or the monitor during measurement.

• Stay quiet, calm for 5 minutes before blood pressure measurement.

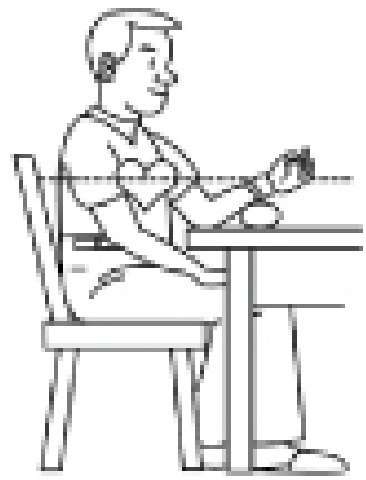
• Please keep the cuff clean. If the cuff becomes dirty, remove it from the monitor and clear it by hand in a mild detergent, then rinse it thoroughly in cold water. Never dry the cuff in clothes dryer or iron it. Clean the cuff after the usage of every 200 times is

recommended.

• Do not place the cuff around your wrist if the wrist has any inflammation, acute diseases, infections skin wounds.

5. BODY POSTURE DURING MEASUREMENT

Sitting Measurement – Recommended Position



a. Sit upright.

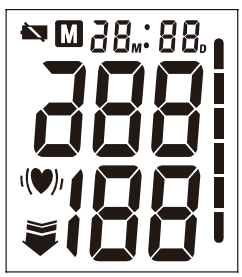
b. Place palm upside in front of you on a flat surface such as a desk or table, with your elbow resting on a chair or table

c. The cuff should be at the same level as your heart.

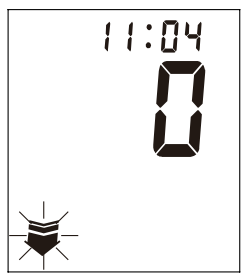
d. Placing your arm on the monitor's plastic case as shown in the picture to aid in maintaining a correct and still arm position.

6. TAKING YOUR BLOOD PRESSURE READING

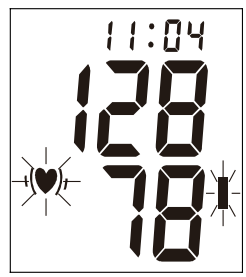
a.After applying the cuff and your body is in a comfortable position, press the "START" button. A beep is heard and all display characters are shown for self-test. See picture 6. Please contact the service center if segment is missing.



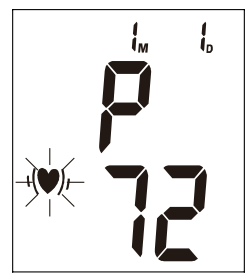
Picture 6



Picture 6-1



Picture 6-2



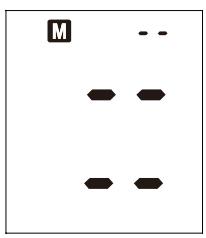
Picture 6-3

b. Then the monitor starts to seek zero pressure. See picture 6-1.
c. The monitor inflates the cuff until sufficient pressure has built up for a measurement. Then the monitor slowly releases air from the cuff and carries out the measurement. Finally the blood pressure and pulse rate will be calculated and displayed on the LCD screen separately. Irregular heartbeat symbol (if any) and blood pressure classification indicator will blink on the screen as displaying “blood pressure”, and the blood pressure classification indicator do not display as displaying “pulse rate”. See picture 6-2&6-3. The result will be automatically stored in the memory bank.
d. After measurement, the monitor will turn off automatically after 1 minute of no operation. Alternatively, you can press the “START” button to turn off the monitor manually.
e. During measurement, you can press the “START” button to turn off the monitor manually.

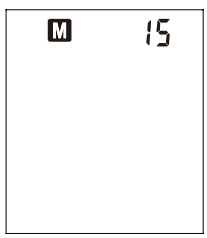
Note: Please consult a health care professional for interpretation of pressure measurements.

7. DISPLAYING STORED RESULTS

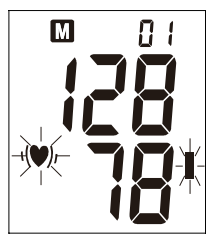
a. After measurement, you can review the results in the memory bank by pressing the “MEM” button. Alternatively, you can press “MEM” button in Clock Mode to display the stored results. If it no result stored, LCD will show dashes as picture 7, while press the button “MEM” or “START”, machine will turn off. If there are results in the memory bank, the LCD will display the amount of the results in the memory bank. See picture 7-1.



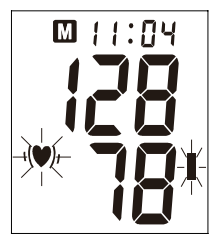
Picture 7



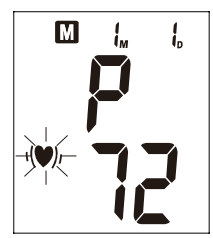
Picture 7-1



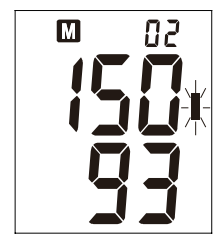
Picture 7-2



Picture 7-3



Picture 7-4



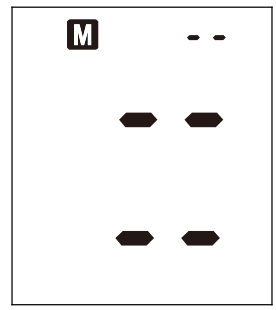
Picture 7-5

b. And then, the most recent result will be displayed with date and time stamp. See picture7-2. Followed by, the blood pressure and pulse rate will be shown separately. Irregular heartbeat symbol (if any) will blink. See picture7-3&7-4. Press “MEM” button again to review the next result. See picture7-5. In this way, repeatedly pressing the MEM button displays the respective results measured previously.

c. When displaying the stored results, the monitor will turn off automatically after 1 minute of no operation. You can also press the button “START” to turn off the monitor manually.

8. DELETING MEASUREMENTS FROM THE MEMORY

When any result is displaying, keep on pressing button “MEM” for three seconds, all results in the memory bank will be deleted after three “beep”. LCD will show dashes. See picture 8. Press the button “MEM” or “START”, the monitor will turn off.

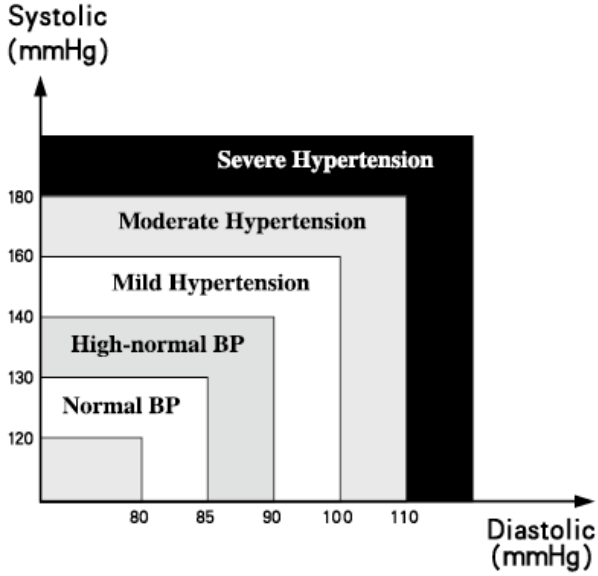


Picture 8

9. ASSESSING HIGH BLOOD PRESSURE FOR ADULTS

The following guideline for assessing high blood pressure (without regard to age or gender) has been established by the World Health Organization (WHO). Please note that other factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration. Consult with your physician for accurate assessment, and never change your treatment by yourself.

Classification of blood pressure for adults



BLOOD PRESSURE CLASSIFICATION	SBP mmHg	DBP mmHg	COLOR INDICATOR
Optimal	<120	<80	GREEN
Normal	120-129	80-84	GREEN
High-Normal	130-139	85-89	GREEN
Grade 1 Hypertension	140-159	90-99	YELLOW
Grade 2 Hypertension	160-179	100-109	ORANGE
Grade 3 Hypertension	⩾180	⩾110	RED

WHO/ISH Definitions and Classification of Blood Pressure Levels

Note: It is not intended to provide a basis of any type of rush toward emergency conditions/diagnosis based on the color scheme and that the color scheme is meant only to discriminate between the different levels of blood pressure.

11. TROUBLESHOOTING (2)

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD shows low battery symbol	Low Battery	Change the batteries
LCD shows “Er 0”	Pressure system is unstable before measurement	Don’t move and try again.
LCD shows “Er 1”	Fail to detect systolic pressure	
LCD shows “Er 2”	Fail to detect diastolic pressure	
LCD shows “Er 3”	Pneumatic system blocked or cuff is too tight during inflation	Apply the cuff correctly and try again
LCD shows “Er 4”	Pneumatic system leakage or cuff is too loose during inflation	
LCD shows “Er 5”	Cuff pressure above 300mmHg	Measure again after five minutes. If the monitor is still abnormal, please contact the local distributor or the factory.
LCD shows “Er 6”	More than 3 minutes with cuff pressure above 15 mmHg	
LCD shows “Er 7”	EEPROM accessing error	
LCD shows “Er 8”	Device parameter checking error	
LCD shows “Er A”	Pressure sensor parameter error	
No response when you press button or load battery.	Incorrect operation or strong electromagnetic interference.	Take out batteries for five minutes, and then reinstall all batteries.

MAINTENANCE

1.Do not drop this monitor or subject it to strong impact.
2.Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.
3.If this monitor is stored near freezing, allow it to acclimate to room temperature before use.
4.Do not attempt to disassemble this monitor.
5.If you do not use the monitor for a long time, please remove the batteries.
6.It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
7.If the monitor becomes dirty, please clear it with a soft dry cloth. Do not use any abrasive or volatile cleaners.
8.No component can be maintained by user in the monitor. The circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated repairably can be supplied by us.
9.The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years.

EXPLANATION OF SYMBOLS ON UNIT

 Symbol for “CONSULT INSTRUCTIONS FOR USE”

 Symbol for “TYPE B APPLIED PARTS”

 Symbol for “ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice”.

 Symbol for “MANUFACTURER”

CE 0197 Symbol for “COMPILES WITH MDD93/42/EEC REQUIREMENTS”

 Symbol for “DATE OF MANUFACTURE”

EC REP Symbol for “EUROPEAN REPRESENTATION”

WARRANTY INFORMATION

Only charge the cost of components and transport.

SERVICE CENTER

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 ANDON HEALTH CO., LTD.
No. 3 Jin Ping Street, Ya An Road, Nankai District, Tianjin 300190, China.
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EC REP Lotus Global Co., Ltd.
15 Alexandra Road, London UK, NW8 0DP
Tel: +0044-20-75868010 Fax: +0044-20-79006187

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1

For all ME EQUIPMENT and ME SYSTEMS

<table>
<tr><th colspan="3">Guidance and manufacture’s declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The [IMC-734] is intended for use in the electromagnetic environment specified below.
The customer or the user of the [IMC-734] should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td rowspan="4">The [IMC-734] 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td rowspan="2">Class B</td><td rowspan="3">The [IMC-734] is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td rowspan="2">Not applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Table 2
For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The [IMC-734] is intended for use in the electromagnetic environment specified below. The customer or the user of the [IMC-734] 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 floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity			
The [IMC-734] is intended for use in the electromagnetic environment specified below. The customer or the user of the [IMC-734] 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 the [IMC-734], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 separation distance in meters (m). Field strengths from fixed 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 reflection from structures, objects and people.

a Field strengths from fixed 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 fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [IMC-734] is used exceeds the applicable RF compliance level above, the [IMC-734] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [IMC-734].
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 4

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the [IMC-734]
The [IMC-734] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [IMC-734] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [IMC-734] 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		
	$d = 1.2\sqrt{P}$ **150 kHz to 80 MHz**	$d = 1.2\sqrt{P}$ **80 MHz to 800 MHz**	$d = 2.3\sqrt{P}$ **800 MHz to 2,5 GHz**
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 meters (m) can be determined 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.