Instruction Manual

medicare
LIFESENSE

Model **MD638**

A2 - Blood Pressure Monitor

Medical Disclaimer

This manual and product are not meant as a substitute for advice provided by your doctor.
You are not to use the information contained herein, or this product for diagnosing or treating a health problem or prescribing any medication. If you have or suspect that you have a medical problem, promptly consult your healthcare provider.

Intended Use

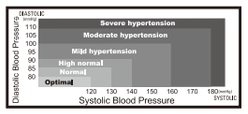
This device uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate.
The measurement position is at human being's arm.
All values can be read out in one LCD panel.
The device is designed for home use and recommended for use by adults aged 18 years and older with upper arm circumference ranging from 9 inch ~ 13 inch (approx. 23 cm ~ 33 cm).

About Blood Pressure

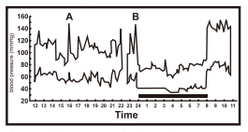
1. What is blood pressure?
Blood pressure is the measurement of the force of blood pushing against the walls of the arteries. Arterial blood pressure is constantly fluctuating during the course of the cardiac cycle. The highest pressure in the cycle is called the systolic blood pressure, and represents the pressure in the artery when the heart is beating. The lowest pressure is the diastolic blood pressure, and represents the pressure in the artery when the heart is at rest. Both the systolic and the diastolic pressure are necessary for a physician to evaluate the status of a patient's blood pressure.
Many factors such as physical activity, anxiety or the time of day, can influence your blood pressure. Blood pressure is typically low in the mornings and increases from the afternoon to the evening. It is on average lower in the summer and higher in the winter.

2. Why is it useful to measure blood pressure at home?
Having one's blood pressure measured by a doctor in a hospital or a clinic, is often associated with a phenomenon called "White Coat Hypertension" where the patient becomes nervous or anxious, thus raising his blood pressure. There are also numerous other factors that might cause your blood pressure to be raised at a specific time of day. This is why medical practitioners recommend home monitoring as it is important to get readings of blood pressure during different times of the day to really get an idea of your real blood pressure.
Medical practitioners generally recommend the "Rule of 3", where you are encouraged to take your blood pressure three times in a row (at 3 ~ 5 minute interval), three times a day for three days. After three days you can average all the results and this will give you an accurate idea of what your blood pressure really is.

A. WHO blood pressure classifications:
Standards for assessment of high or low blood pressure without regard to age, have been established by the World Health Organization (WHO), as shown in the chart. However this chart is not exact for classification of blood pressure and it's intended to be used as a guide in understanding non-invasive blood pressure measurements. Please consult with your physician for proper diagnosis.



B. Variations in blood pressure:
Individual blood pressures vary greatly both on a daily and a seasonal basis. These variations are even more pronounced in hyper tense patients. Normally the blood pressure rises while at work and is at its lowest during sleeping period. (hyper tense: means a person who has high blood pressure symptom.)
The graph below illustrated the variations in blood pressure over a whole day with measurement taken every five minutes.
The thick line represents sleep. The rise in blood pressure at 4 PM (A in the graph) and 12 PM (B in the graph) correspond to an attack of pain.



(Direct arterial pressure recording in unrestricted man. Beven, Honour & Stott: Clin. Sci. 36:329, 1969)

Precautions

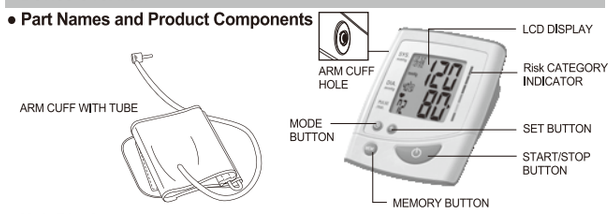
*Do not use this manual and product as a substitute for advice, diagnosing or treating a health problem or prescribing any medication by your doctor. If you have a medical problem, promptly consult your healthcare provider.
*Read the Instruction Manual thoroughly before measuring and keep it at hand for your reference at any time.
*This device uses the oscillometric method to measure systolic and diastolic blood pressure as well as your heart rate. It's recommended for use by people over the age of 18 and not to be used on infant or children.
*The device is designed for home use and not suitable for clinical use.
*This monitor is not intended for use in the MR environment.

- Do not take a measurement in a low (less than 41 °F/5 °C) and high (more than 104 °F/40 °C) temperature, nor in a place outside humidity ranges (15 % ~ 93 % R.H.), and atmospheric pressure ranges (700 ~ 1060 hPa), or you may get inaccurate readings.
- Wait 30 ~ 45 minutes before measurement if you've just consumed caffeinated beverages or smoked cigarettes.
- Rest at least 5 ~ 10 minutes before taking a measurement.
- To allow your blood vessels to return to the condition prior to taking the measurement, please wait at least 3 ~ 5 minutes in between measurements. You may need to adjust the wait time according to your personal physiological situation.
- We recommend you using the same arm (preferably the left arm) and measuring around the same time each day.
- Sit down comfortably and place your elbow on the table with your feet flat on the floor. Please do not cross your legs during measurements.
- Keep the cuff at heart level. Relax your hand with the palm facing up.
- Perform measurements in a quiet and relaxed environment at room temperature.
- Do not move or shake the device during a measurement. Please keep quiet and do not talk during measurements.
- This product is not suitable for:
  - ■ Pregnant women
  - ■ People with arrhythmias
  - ■ Undergoing intravenous injection on any limb
  - ■ Currently in a dialysis treatment
  - ■ In pre-eclampsia condition
- For those who have had mastectomy surgery (especially whose' lymph nodes removed), it's recommend take a measurement on the unaffected side.
- When used among medical electronic equipments on the same limb, pressurization of the cuff may cause temporarily malfunction to other devices.
- Keep in mind that blood pressure naturally varies from time to time throughout the day and is affected by lots of different factors such as stress, eating, smoking, alcohol consumption, medication, and physical activity, etc.
- Normally the blood pressure rises while at work and is at its lowest during sleeping period.
- Blood pressure measurements should be interpreted by a physician or a trained health professional who is familiar with your medical history. Using the unit and recording the results regularly for your physician to interpret, you will keep your physician informed of the continuing changes in your blood pressure.
- If you have one of the circulatory problems as arteriosclerosis, diabetes, liver disease, kidney disease, severe hypertension, peripheral circulation……, please consult your healthcare professional before using the device.
- Results are not intended for direct diagnosis. Please consult with a physician if you have any questions or concerns about your results.
- Blood pressure measurements taken with this device are equivalent to those obtained by a trained observer using the cuff / stethoscope auscultation method and are within the accuracy limits prescribed by the Standard of EN 1060-4.

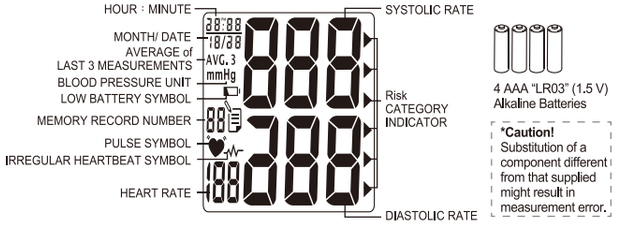
***Attention!**
1. Do not use the device on infants, children, or those who cannot express their own intention.
2. The device is equipped with sensitive electronic components. While measuring, avoid strong electrical or electromagnetic fields, e.g. mobile phones, microwave ovens, etc; or it may lead to temporary reading error or inaccuracy.
3. To avoid accidental strangulation, keep this product away from children and do not drape tube around neck.
4. Consider the electromagnetic compatibility of the device (ex. power disturbance, radio frequency interference etc.) Please use it indoor only.
5. Over high frequency measurements may result in blood flow interference, which is likely to cause uncomfortable sensations, such as partial subcutaneous hemorrhage, or temporary numbness to your arm. In general, these symptoms should not last long. However, if you do not recover in time, please seek your medical practitioners for help.

Device Overview

● Part Names and Product Components



● Unit Display



4 AAA "LR03" (1.5 V) Alkaline Batteries

***Caution!**
Substitution of a component different from that supplied might result in measurement error.

Symbol Definitions

SYMBOLS	Definitions
Low Battery Symbol	This symbol appears when the battery power is excessively low or the polarity reverses. → We suggest you replace all batteries with new ones, and make sure the +/- polarities are properly positioned.
Pulse Symbol	Once pulse is detected, the symbol flashes with each pulse beat. → Our suggestion: Please do not talk or move during measurements.
Irregular Heartbeat Detector	This symbol appears for 1 minute when the user was talking, moving, shaking, or an irregular heart beat was detected during measurements. → Our suggestion: Please do not talk or move during measurements. Repeat the measurement after resting for at least 5 minutes, and restart your measurement while sitting down comfortably and quietly.
Measurement Number Symbol	This symbol goes along with figures according to the order of reading stored in the memory.
AVG. 3 Average of Last 3 Measurements	This symbol appears when LCD displays average value of last 3 readings.
Risk Category Indicator Bar	The arrowhead points out the specific Risk Category that your measurement reading fits in.

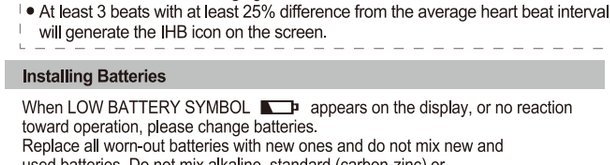
Features

● Risk Category Indicator
This device is equipped with Risk Category Indicator which classifies your blood pressure measurements into six stages (Optimal to Severe hypertension) as shown in below chart:

Stages of Blood Pressure Levels		Systolic (mmHg)	Diastolic (mmHg)	Color	Recommendations by SIGN 49: Hypertension in older people
Grade 3	Severe Hypertension	≥180	≥110	Red	Confirm immediately and repeat BP in one day and again within one week depending on clinical situation.
Grade 2	Moderate Hypertension	160~179	100~109	Red	Serial blood pressures repeated within one month.
Grade 1	Mild Hypertension	140~159	90~99	Red	Provide advice about lifestyle modification and confirm within two months.
High-Normal		130~139	85~89	Orange	Provide advice about lifestyle modification and recheck in one year.
Normal		120~129	80~84	Yellow	Recheck in 2 - 5 years.
Optimal		<120	<80	Green	(patients aged > 75 years offered annual health check)

* Source: WHO, 2003

After each measurement is completed, LCD display will show your position automatically on the six segments of the bar indicator which corresponds to Risk Category Indicator.



***Note!**
When a person's systolic and diastolic pressures fall into different categories, the higher category should apply.
e.g. systolic rate 181 & diastolic rate 99 → Red category (Severe Hypertension)
e.g. systolic rate 110 & diastolic rate 95 → Red category (Mild Hypertension)

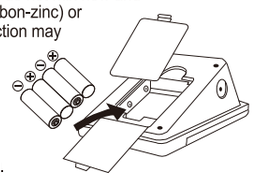
***Note!**
The above table is not exact for classification of blood pressure and it's intended to be used as a guide in understanding non-invasive blood pressure measurements.
Usually this is not a cause for concern; however we recommend you consult with your physician for proper diagnosis or seek medical advice according to our recommendation mentioned above. Please note that the device does not appropriate to diagnose hypertension, and it is only for user reference on blood pressure monitoring.

● Irregular Heartbeat Detector
The symbol ♥ will appear on screen indicating a certain heartbeat irregularity was detected during measurement.
The heartbeat rhythm that is more than or less than 25% from the average rhythm is usually defined as an irregular heartbeat rhythm.
Talking, moving, shaking or an irregular pulse during the measurement can result in the appearance of this symbol.Usually this is not a cause for concern, however if the symbol appears often, we recommend you seek medical advice.
And please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

***Note!**
- The pulse display is not suitable for checking the frequency of heart pacemakers. If a certain pulse irregularity is detected during measurement often, we recommend you seek medical advice
- As a safeguard, we recommend that if you have arrhythmias such as atrial or ventricular premature beats and atrial fibrillation or any other special conditions you should check with your physician before using your device.
- The IHB function is not designed for use by people with arrhythmias nor for diagnosing or treating an arrhythmic problem. In order to filter the unstable status of user and avoid affecting the detection of heart rate from any movement, shaking or talking in the beginning of measurement, the method of averaging heart beat intervals of subject device is calculated with the three proper heart beat pulses detected in the beginning of measurement and that is different from a strict mathematical averaging of all recorded intervals.
- At least 3 beats with at least 25% difference from the average heart beat interval will generate the IHB icon on the screen.

Installing Batteries

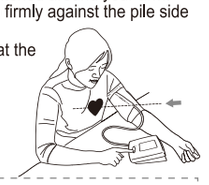
When LOW BATTERY SYMBOL appears on the display, or no reaction toward operation, please change batteries.
Replace all worn-out batteries with new ones and do not mix new and used batteries. Do not mix alkaline, standard (carbon-zinc) or rechargeable (cadmium) batteries either. Such action may shorten the battery life or cause the device to malfunction.
Slide the battery cover and insert 4 AAA (LR03) alkaline batteries into the battery compartment as shown on the figure below. Make sure the polarities "+" and "-" ends are coinciding with similar markings engraved on the battery housing.



***Attention!**
- Batteries are hazardous waste. Do not dispose of them together with the household garbage. Please discard worn-out batteries to the recycling site according to local regulations.
- Keep the battery away from children in case they choke on it.
- To prolong the battery life and prevent damage caused by leakage, remove the batteries from the device if the device is not to be used for a long period.
- After replacing the batteries, reset date and time.

Applying the Cuff

- Press your brachial artery approximately 1 inch (2 ~ 3 cm) above the elbow on the inside of your left arm to determine where your strongest pulse is.
- Slide the end of arm cuff furthest from the tube through the metal ring to a loop. The smooth cloth should be on the inside of the cuff.
- If the cuff is located correctly, the velcro will be on the outside of the cuff and metal ring will not touch your skin.
- Put left arm through the cuff loop.
  The bottom of the cuff should be approximately 1 inch (2 ~ 3 cm) above the inner elbow. The tube should lie over the brachial artery on the inner part of the arm.
- Pull the cuff so that the top and bottom edges are tightened around your arm.
- When the cuff is positioned properly, press the velcro firmly against the pile side of the cuff.
- Sit on a chair and lay your forearm on the table so that the cuff is at the same level as your heart.
- Relax your arm and turn your arm upward.
- Make sure there are no kinks in the air tube.



***Note !**
- Fit the cuff snugly, leaving enough space for 1 inch (2 ~ 3 cm) between the inner elbow and the lower edge of the cuff, or the measurement may not be accurate.
- This monitor comes with one size of arm cuff: 9" ~ 13" (23 ~ 33 cm).
- In case the cuff kept pumping up non-stop, open the cuff at once.
- Do not wrap the cuff around any body part other than your arm.
- The device is not supposed to be used when your arm is wounded or injured.

Measurement Procedure

● Switching on the monitor
Press ⏻ button to switch on the monitor.

● Setting year, date and time
A. To enter Setting Mode, press 🕒 button, then YEAR digit flashes. Use **+** button to select current year.
B. When above settings are done, press 🕒 button to adjust current MONTH. Press **+** button to select current MONTH.
C. Continue to set current DATE (varies from 1 to 31), HOUR (1, 2……12PM, 1PM……,12) and MINUTE (00,01……,59) by following Step B.
D. Users can adjust YEAR-MONTH-DATE-HOUR-MINUTE in an orderly manner. Press 🕒 button to save the settings and switches to Standby Mode.

● Taking a measurement
A. Under Standby Mode, press **+** button to select User 1, 2, or 3.

B. With the cuff wrapped around your arm, press ⏻ button to confirm the chosen user and start measurement.

***Note!**
- Do not inflate the cuff unless it is wrapped around your arm.

All display symbols appear on the screen for 1.5 seconds. After all symbols disappear, the display will show "00". The monitor is "Ready to Measure" and will automatically inflate to the level that is right for you.
C. After the initial inflation of the cuff, the pressure will slowly decrease and when a pulse is detected, PULSE SYMBOL ♥ will start flashing.

***Note!**
- This monitor will re-inflate automatically if the system detects that your body requires more pressure for measurement.
- If the cuff does not stop inflating, remove the cuff at once.
- To stop measurement, press ⏻ button to switch to Standby Mode.

After the monitor has determined your blood pressure and heart rate, the cuff automatically deflates. Your systolic rate, diastolic rate, heart rate and corresponding Risk Category Indicator and Irregular Heartbeat Detector (if any) are displayed with date and time for 1 minute and save results to memory automatically.

D. Device automatically shuts off if no operation over 1 minute.

Memory Function

● Storing data
After each measurement, the systolic and diastolic pressure, heart rate, Irregular heartbeat detector (if any) and Risk Category Indicator bar with the time and date will be automatically stored.
The monitor features 3 user memory capabilities. Each user holds the last 40 measurements, and automatically replacing the oldest data with new one.

Memory Function

- **Recalling data**

A. Press + button to select User 1, 2, or 3.
B. Press MEM button to enter Memory Mode.
If there is no data stored before, nothing (except month, date, and time) will appear on the display. If yes, the first reading will be the average of last 3 measurements.
C. Press MEM button to read the following measurements in sequence.
D. To stop reading the memories, press ⏻ button and switch to Standby Mode.

- **Erasing data**

A. Press + button to select User 1, 2, or 3.
B. Press MEM button to enter Memory Mode.
C. Press and hold ◷ and + buttons at the same time, all the data for the selected user will be erased automatically.

Note: Once deleted, your data can NOT be restored.

Storage and Maintenance

- **General Use**
  - Do not in any way twist the cuff.
  - Do not press ⏻ button if the cuff is not wrapped around your upper arm.
  - Do not drop the product and avoid any strong impacts.
- **Maintenance**
  - Use a piece of cloth with water or mild cleansing agent to wipe the device and dry it immediately with a dry cloth.
  - Do not use detergent or any strong chemicals to clean the device.
  - Disinfection - Use a piece of cloth with 75% alcohol to wipe the surface of the cuff for 10 seconds.
  - Make sure the cuff is completely dry before using.
  - Do not attempt to disassemble or change any parts of the monitor, including arm cuff, due to substitution of a component different from that supplied might result in measurement error. If any suggestion or service is requested, please consult your service station.
  - Do not implement the maintenance procedures for equipment during measurement.
  - Only trained technicians are allowed to repair and dissemble the device, including software upgrades, patches and maintenance.

***Note**
- Water quality required for cleaning: Tap water.

- **Storage**
  - If the device is not to be used for a long time, please remove the batteries from the device (leaking of battery acid can cause the device to malfunction).
  - Always store the unit in the storage case after use. It is intended to be transported or stored in a carrying case between uses.
  - Do not place the device directly under sunlight, in high temperature, or in humid or dusty places.
  - Do not store the device in extremely low (less than –13 ℉/–25 ℃) and high (more than 158 ℉/70 ℃) temperature, nor in a place its humidity exceeds 93% R.H.

Troubleshooting

SYMBOLS/SYMPTOMS	CONDITIONS/CAUSES	INDICATION/CORRECTION
Unit does not turn on when ⏻ button is pushed.	Worn-out batteries.	Replace them with 4 new AAA (1.5V, LR03) alkaline batteries.
	Battery polarities have been positioned incorrectly.	Re-insert the batteries in the correct positions.
EE Measuring Error Symbol appears when blood pressure value displayed is excessively low or high.	Cuff has been placed incorrectly.	Wrap the cuff properly so that it is positioned correctly.
	Did you talk or move during measurement?	Measure again. Keep arm steady during measurement.
	Shaking of the arm with the cuff on.	
E1 Measuring Error Symbol	Air circuit abnormality. Cuff tube may not be plugged into monitor correctly.	Check cuff connection. Measure again.
E2 Measuring Error Symbol	Inflation pressure exceeding 300 mmHg.	Switch the unit off, then measure again.
E3 Measuring Error Symbol	Can't determine blood pressure measurement data.	Wrap the cuff properly and keep steady. Measure again.
Note: If "EP" appears on the display, just return the device to your local distributor or importer.		

Limited Warranty

To ensure continued measurement precision, all digital blood pressure monitors require recalibration regularly.
After 2 years from the manufacturing date, we recommend you have your monitor recalibrated at the local distributor or importer.
Please contact your distributor/importer for the details about the recalibration service and the charge of shipping and handling.

Please also note that this service does not cover damage caused by misuse or abuse; accident; the attachment of any unauthorized accessory; alteration to the product; improper installation; unauthorized repairs or modifications; improper use of electrical/power supply; loss of power; dropped product; malfunction or damage of an operating part from failure to provide manufacturer's recommended maintenance; transportation damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of importers or distributors.

Specifications

Model Number	MD638
Measurement Method	Oscillometric
Rated Range of Cuff Pressure	0~300 mmHg
Rated Range of Determination	40~280 mmHg
Measurement Range of Heart Rate	40 ~ 199 Beats / Minute
Accuracy	Pressure: ± 3 mmHg Pulse: ± 5 % Max.
Inflation	Automatic Inflation (Air Pump)
Deflation	Automatic Air Release Control Valve
Display	Liquid Crystal Display
Memory	120 Memory Total for 3 Users
Unit Dimensions	5.31 x 4.18 x 2.09 inch (L x W x H) 135 x 105 x 53 mm (L x W x H)
Unit Weight	7.48 ± 0.35 oz (212 ± 10 g) (Excluding Batteries)
Cuff Size	9 ~ 13 inch (23 ~ 33 cm)
Storage/ Transportation Environment	Temperature: -25 °C ~ 70 °C (-13 °F ~ 158 °F) Humidity: ≤ 93 % R.H.
Operation Environment	Temperature: 5 °C ~ 40 °C (41 °F ~ 104 °F) Humidity: 15 % ~ 93 % R.H. Atmospheric pressure: 700hPa ~ 1060hPa
Power Supply	DC 6V, AAA "LR03" (1.5V) Alkaline Battery x 4
Battery Life	Approx. 300 measurements
Product Life	5 Years (4 times per day)
Sleeping Mode	Without any operation for 1 minute, device automatically shuts off.
Accessories	4 AAA (LR03) Alkaline Batteries, Arm Cuff with Tube, Instruction Manual, Pouch

*The contents of this manual and the specifications of the device covered by this manual are subject to change for improvement without notice.

Note

This blood pressure monitor complies with the EC Directive (93/42/EEC) and bears the CE mark. This blood pressure monitor also complies with mainly following standards (included but not limited):

CE 0197

Safety standard:
EN 60601-1 Medical electrical equipment part 1: General requirements for safety

EMC standard:
EN 60601-1-2 Medical electrical equipment part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility-Requirements and tests

Performance standards:
EN 1060-1 Non-invasive sphygmomanometers - General requirements
EN 1060-3 Non-invasive sphygmomanometers - Supplementary requirements for electromechanical blood pressure measuring systems.
EN 1060-4 Non-invasive sphygmomanometers - Test procedures to determine the overall system accuracy of automated non-invasive sphygmoma nometers.
EN ISO 81060-1 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type. (partially applied)
IEC 80601-2-30 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.

Note

Follow instructions for use.

SN Serial number

BF Classification:
- Internally powered equipment
- BF type applied part
- IP22-Degrees of protection provided by enclosures
- Not suitable for use in presence of flammable anesthetic mixture with air or with Oxygen or nitrous oxide
- Continuous operation with short-time loading
- The cuff is applied part

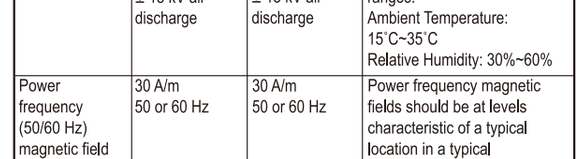
Date of Manufacture

To avoid inaccurate results caused by electromagnetic interference between electrical and electronic equipments, do not use the device near a mobile phone or microwave oven. At least keep a maximum output power of 2 W yields and a distance 3.3m away from this equipment.

Discard the used product to the recycling collection point according to local regulations.

FLEMING MEDICAL LTD
21/F, Chinachem Tower,
34-37 Connaught Road Central,
HONG KONG

EC REP **FLEMING MEDICAL LTD**
Limerick, V94 K6W4, IRELAND
1800 307777 (IRE) 0800 7314315 (UK)
WWW.FLEMINGMEDICAL.IE



Appendix

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The 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 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 device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	In the case of air discharge testing, the climatic conditions shall be within the following ranges: Ambient Temperature: 15˚C~35˚C Relative Humidity: 30%~60%
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Appendix

Recommended separation distances between portable and mobile RF communication equipment and the device.

The device is intended for use in an electromagnetic environment where radiated RF disturbances are under control. User can help prevent electromagnetic interference by keeping the device at a minimum distance from portable and mobile RF communications equipment (transmitters). Below table details the maximum output power of transmitter:

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	Not Applicable	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	Not Applicable	0.12	0.23
0.1	Not Applicable	0.38	0.73
1	Not Applicable	1.2	2.3
10	Not Applicable	3.8	7.3
100	Not Applicable	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 reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3 Proximity fields from RF wireless communications equipment IEC 61000-4-3	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz, Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz, Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	**Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 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 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Rev:20122018