

SALTER®

SINCE 1760

AUTOMATIC ARM BLOOD PRESSURE MONITOR

Instructions and Guarantee

www.salterhousewares.com.au



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 3:00 AM, 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.

Too frequent measurements may cause injury due to blood flow interference, please always relax a minimum 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.

WEEE EXPLANATION



This marking indicates that this product should not be disposed with other household wastes throughout the EU. To prevent possible harm to the environment or human health from uncontrolled waste disposal, recycle it responsibly to promote the sustainable reuse of material resources. To return your used device, please use the return and collection systems or contact the retailer where the product was purchased. They can take this product for environmental safe recycling.

BATTERY DIRECTIVE



This symbol indicates that batteries must not be disposed of in the domestic waste as they contain substances which can be damaging to the environment and health. Please dispose of batteries in designated collection points.

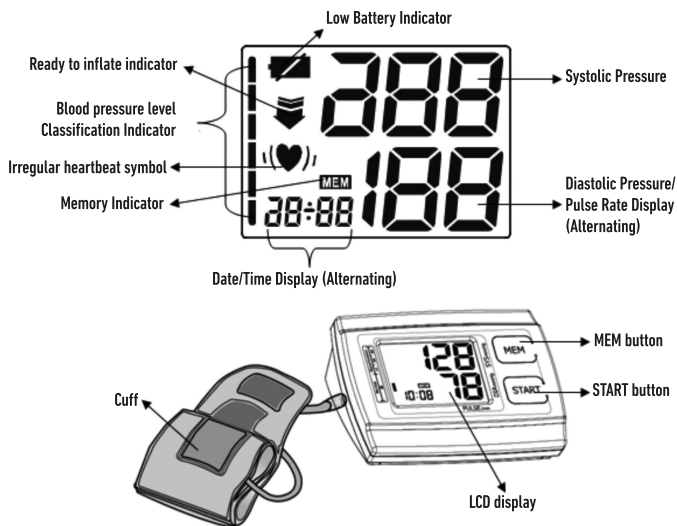
GUARANTEE

Brand Merchant Pty Ltd. Suite 8, 8A St Andrews Street, Brighton Victoria 3186, Australia

If this product does not reach you in an acceptable condition please contact our Customer Services Department at www.salterhousewares.com.au.

Please have your delivery note at hand as details from it will be required.

If you wish to return this product please return it to the retailer from where it was purchased with your receipt (subject to their terms and conditions).



INTENDED USE

Fully Automatic Electronic Sphygmomanometer 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 upper arm. The cuff circumference is limited to 22cm-48cm (approx. 8 21/32"-18 29/32").



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 LCD display will show blood pressure and pulse rate. The most recent 2 x 60 measurements can be stored in the memory with date and time stamp. The monitor can also show the average reading of the last three measurements. The Electronic Sphygmomanometers corresponds to the below standards:

IEC 60601-1 Edition 3.1 2012-08/EN 60601-1:2006/A1:2013 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC 60601-1-2:2014/EN 60601-1-2:2015 (Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests), IEC 80601-2-30:2009+AMD1: 2013/EN 80601-2-30:2010/A1: 2015 (Medical electrical equipment -Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers) 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), ISO 81060-2 : 2013 (Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type).

SPECIFICATIONS

Product name:	Blood Pressure Monitor
Model	KD-558BRMFOB
Classification	Internally powered, Type BF applied part, IP20, No AP or APG, Continuous operation
Machine size	Approx. 138 mm × 98 mm × 48 mm (5 7/16" x 3 27/32" x 1 7/8")
Cuff circumference	30 cm-42 cm (11 13/16"-16 17/32"), 22 cm-30 cm (8 21/32"-11 13/16") (Optional), 42 cm-48 cm (16 17/32"-18 29/32") (Optional)
Weight	Approx. 211 g (7 7/16 oz.) (exclude batteries and cuff)
Measuring method	Oscillometric method, automatic inflation and measurement
Memory volume	2x60 times with time and date stamp
Power source	Batteries: 4 × 1.5 V  Size AA
Measurement range	Cuff pressure: 0-300 mmHg Systolic: 60-260 mmHg Diastolic: 40-199 mmHg Pulse rate: 40-180 beats/minute
Accuracy	Pressure: ±3 mmHg Pulse rate: ±5 % precision of the displayed values: 1 mmHg
Environmental temperature for operation	10 °C-40 °C (50 °F-104 °F)
Environmental humidity for operation	≤90 %RH
Environmental temperature for storage and transport	-20 °C-55 °C (-4 °C-131 °C)
Environmental humidity for storage and transport	≤90 %RH
Environmental pressure	80 kPa-105 kPa
Battery life	Approx 500 times
All components belonging to the pressure measuring system, including accessories	Pump, Valve, LCD, Cuff, Sensor

Note: These specifications are subject to change without notice.

1. Read all of the information in the operation guide and any other literature in the box before operating the unit.
2. Stay still, calm and rest for 5 minutes before blood pressure measurement.
3. The cuff should be placed at the same level as your heart.
4. During measurement, neither speak nor move your body and arm.
5. Measuring on same arm for each measurement.
6. Please always relax at least 1 or 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 above 15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your arm.
7. Consult your physician if you have any doubt about below cases:
 - 1) The application of the cuff over a wound or inflammation diseases;
 - 2) The application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present;
 - 3) The application of the cuff on the arm on the side of a mastectomy;
 - 4) Simultaneously used with other monitoring medical equipments on the same limb;
 - 5) Need to check the blood circulation of the user.
8. ⚠ This Electronic Sphygmomanometers 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.
9. Do not use this unit in a moving vehicle. This may result in erroneous measurement.
10. 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.
11. 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. It is suggested that the blood pressure monitor be kept at least 30 cm away from other wireless devices, such as WLAN unit, microwave oven, etc. It can't be used near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magneticresonance imaging, where the intensity of EM DISTURBANCES is high.
12. 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 Sphygmomanometers 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 ≥ 0.14 s, and the number of such pulse takes more than 53 percentage of the total number of pulse.
13. Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
14. ⚠ 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.
15. ⚠ Please do not share the cuff with other infective person to avoid cross-infection.
16. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
—Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

NOTES

1. The device is not intended for use on neonates, children or pregnant women. (Clinical testing has not been conducted on neonates, children or pregnant women.)
2. Motion, trembling, shivering may affect the measurement reading.
3. The device would not apply to the patients with poor peripheral circulation, noticeably low blood pressure, or low body temperature (there will be low blood flow to the measurement position).
4. Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pre-eclampsia, renal diseases.
5. The patient can be an intended operator.
6. Swallowing batteries and/or battery fluid can be extremely dangerous. Keep the batteries and the unit out of the reach of children and disabled persons.
7. If you are allergic to plastic/rubber, please don't use this device.

NOTICE

1. The monitor requires 6 hours to warm from the minimum storage temperature between uses until the monitor is ready for its **INTENDED USE** when the ambient temperature is 20 °C.
2. The monitor requires 6 hours to cool from the maximum storage temperature between uses until the monitor is ready for its **INTENDED USE** when the ambient temperature is 20 °C.
3. No servicing/maintenance while the monitor is in use.

SETUP AND OPERATING PROCEDURES

1. BATTERY LOADING

- a. Open battery cover at the back of the monitor.
- b. Load four "AA" 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.

 Avoid the battery fluid to get in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.

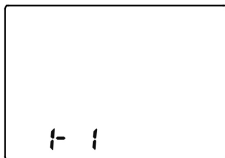
 The monitor, the batteries and the cuff, must be disposed of according to local regulations at the end of their usage.

2. CLOCK AND DATE ADJUSTMENT

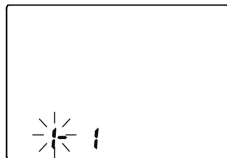
- a. Once you install the battery or turn off the monitor, it will enter Clock Mode, and LCD will display time and date by turns. See picture 2 & 2-1.



Picture 2



Picture 2-1

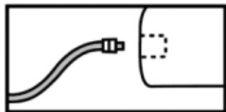


Picture 2-2

- 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. 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

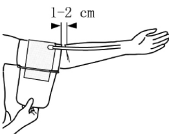
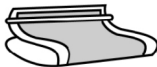
Insert the cuff tubing connector into the socket in the left side of the monitor. Make certain that the connector is completely inserted to avoid air leakage during blood pressure measurements.



⚠ Avoid compression or restriction of the connection tubing during measurement, which may cause inflation error, or harmful injury due to continuous cuff pressure.

4. APPLYING THE CUFF

- a. Pulling the cuff end through the medial loop (the cuff is packaged like this already), turn it outward (away from your body) and tighten it and close the Velcro fastener.
- b. Place the cuff around a bare arm 1-2cm above the elbow joint.
- c. While seated, place palm upside in front of you on a flat surface such as a desk or table. Position the air tube in the middle of your arm in line with your middle finger.
- d. The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger between your arm and the cuff.



Note:

1. Please refer to the cuff circumference range in "SPECIFICATIONS" to make sure that the appropriate cuff is used.
2. Measuring on same arm each time.
3. Do not move your arm, body, or the monitor and do not move the rubber tube during measurement.
4. Stay quiet, calm for 5 minutes before blood pressure measurement.
5. 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.

5. BODY POSTURE DURING MEASUREMENT

Sitting Comfortably Measurement

- a. Be seated with your feet flat on the floor, and don't cross your legs.
- b. Place palm upside in front of you on a flat surface such as a desk or table.
- c. The middle of the cuff should be at the level of the right atrium of the heart.



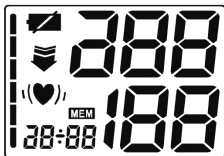
Lying Down Measurement

- a. Lie on your back.
- b. Place your arm straight along your side with your palm upside.
- c. The cuff should be placed at the same level as your heart.



6. TAKING YOUR BLOOD PRESSURE READING

- 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.
- Then the current memory bank (U1 or U2) is blinking. See picture 6-1. Press "MEM" button to change over to other bank. See picture 6-2. Confirm your selection by pressing "START" button. The current bank can also be confirmed automatically after 5 seconds with no operation.



Picture 6



Picture 6-1

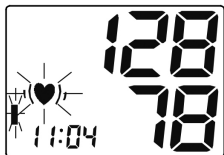


Picture 6-2

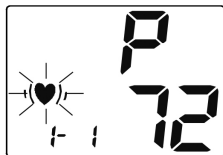
- After selecting the memory bank, the monitor starts to seek zero pressure. See picture 6-3.
- The monitor inflates the cuff until sufficient pressure has built up for a measurement. Then the monitor slowly releases air from the cuff and carries out the measurement. Finally the blood pressure and pulse rate will be calculated and displayed on the LCD screen separately. Irregular heartbeat symbol (if any) will blink. See picture 6-4 & 6-5. The result will be automatically stored in the current memory bank.



Picture 6-3



Picture 6-4



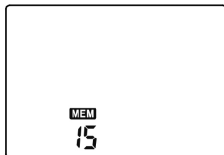
Picture 6-5

- 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.
- During measurement, you can press the "START" button to turn off the monitor manually.

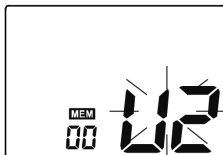
Note: Please consult a health care professional for interpretation of pressure measurements.

7. DISPLAYING STORED RESULTS

- After the measurement, you can review the measurements in the current memory bank by pressing button "MEM". Now the LCD displays the amount of the results in the current bank. See picture 7.



Picture 7



Picture 7-1



Picture 7-2

- b. Alternatively, press "MEM" button in Clock Mode to display the stored results. The current memory bank will blink and the amount of results in this bank will be displayed. See picture 7-1. Press "START" button to change over to other bank. See picture 7-2. Confirm your selection by pressing "MEM" button. The current bank can also be confirmed automatically after 5 seconds with no operation.
- c. After selecting the memory bank, the LCD will display the average value of the last three results in this bank. See picture 7-3 & 7-4. If no result stored, LCD will show dashes as picture 7-5.



Picture 7-3

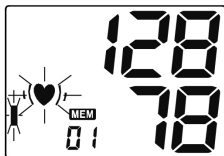


Picture 7-4

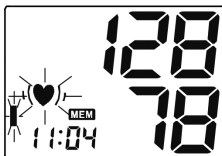


Picture 7-5

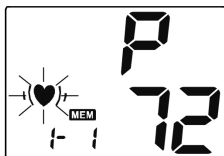
- d. When the average is displayed, press the "MEM" button, the most recent result will be displayed. See picture 7-6. Followed by, the blood pressure and pulse rate will be shown separately. Irregular heartbeat symbol (if any) will blink. See picture 7-7 & 7-8. Press "MEM" button again to review the next result. See picture 7-9. In this way, repeatedly pressing the "MEM" button displays the respective results measured previously.



Picture 7-6



Picture 7-7



Picture 7-8

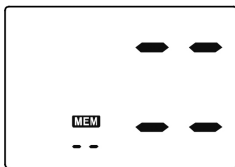


Picture 7-9

- e. 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.

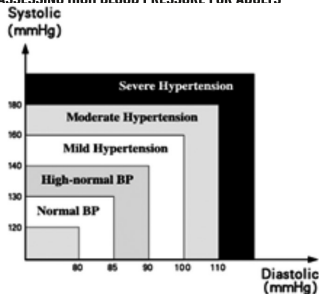
8. DELETING MEASUREMENTS FROM THE MEMORY

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



Picture 8

9. ASSESSING HIGH BLOOD PRESSURE FOR ADULTS



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

WHO/ISH Definitions and Classification of Blood Pressure Levels

10. TECHNICAL ALARM DESCRIPTION

The monitor will show 'Hi' or 'Lo' as technical alarm on LCD with no delay if the determined blood pressure (systolic or diastolic) is outside the rated range specified in part SPECIFICATIONS. In this case, you should consult a physician or check if your operation violated the instructions.

The technical alarm condition (outside the rated range) is preset in the factory and cannot be adjusted or inactivated. This alarm condition is assigned as low priority according to IEC 60601-1-8.

The technical alarm is non-latching and need no reset. The signal displayed on LCD will disappear automatically after about 8 seconds.

11. TROUBLESHOOTING (1)

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD Display shows abnormal result	The cuff position was not correct or it was not properly tightened	Apply the cuff correctly and try again
	Body posture was not correct during testing	Review the "BODY POSTURE DURING MEASUREMENT" sections of the instructions and re-test.
	Speaking, arm or body movement, angry, excited or nervous during testing	Re-test when calm and without speaking or moving during the test
	Irregular heartbeat (arrhythmia)	It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer

12. 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.

NOTICE

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. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
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.
9. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is maintained after 1,000 open-close cycles of the closure.
10. It is recommended the cuff should be disinfected 2 times every week if needed (For example, in hospital or in clinique).
Wipe the inner side (the side contacts skin) of the cuff by a soft cloth squeezed after moistened with Ethyl alcohol (75-90 %), then dry the cuff by airing.

EXPLANATION OF SYMBOLS ON UNIT

Symbol for "THE OPERATION GUIDE MUST BE READ"(The sign background colour: blue. The sign graphical symbol: white)



Symbol for "WARNING"



Symbol for "TYPE BF APPLIED PARTS" (The cuff is type BF applied part)



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"



Symbol for "DATE OF MANUFACTURE"



Symbol for "EUROPEAN REPRESENTATION"



Symbol for "KEEP DRY"

IP20 The first characteristic numeral symbol for "Degrees of protection against access to hazardous parts and against solid foreign objects". The second characteristic numeral symbol for "Degrees of protection against ingress of water".

CONTACT INFORMATION

For more information about our products, please visit www.salterhousewares.com.au

Brand Merchant Pty Ltd. Suite 8, 8A St Andrews Street, Brighton Victoria 3186, Australia

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Please have your delivery note at hand as details from it will be required.

If you wish to return this product please return it to the retailer from where it was purchased with your receipt (subject to their terms and conditions).



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36 Rue de Ponthieu, 75008, Paris, France

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1– Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions CISPR 11	CISPR 11 Group 1, Class B	Home healthcare environment
Harmonic distortion	IEC 61000-3-2 Class A	Home healthcare environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Home healthcare environment

Table 2– Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air
Radiated RF EM field	IEC 61000-4-3	10 V/m 80 MHz-2.7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3– Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18 Hz, 27 V/m
450	430-470	FM, ± 5 kHz deviation, 1 kHz sine, 28 V/m
710	704-787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800-960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700-1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217 Hz, 28 V/m
5240	5100-5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

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