UM-102

Digital Sphygmomanometer

Instruction Manual Manuel d'instructions Manual de instrucciones Manuale di Istruzioni 使用手冊

Original

Traduction

Traducción

Traduzione

翻譯



UM-102 Digital Sphygmomanometer Instruction Manual

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1. Dear Customers

Thank you for purchasing a state-of-the-art A&D sphygmomanometer. Designed for ease of use and accuracy. We recommend that you read through this manual carefully before using this device for the first time.

Intended User: This device is designed to be used by people

who can measure blood pressure by

auscultation.

Applicable Patient: The device is designed for use on adults and

children aged 3 and older.

Environment for Use: The device is designed for use in a medical

facility.

Intended purpose: The UM-102 Sphygmomanometer is used by

healthcare professionals to determine systolic and diastolic blood pressure, and to measure pulse

rate.

Clinical Benefit: Successful assessment of blood pressure reading

in accordance with the device's intended purpose.

Features

Measurement

This sphygmomanometer is designed to monitor and display cuff pressure during cuff inflation (by rubber bulb) and deflation (by exhaust bulb) while the user determines the patient's blood pressure level by listening for Korotkoff sounds with a stethoscope.

Safety

- ☐ This sphygmomanometer is designed to measure a patient's blood pressure without the use of mercury, therefore protecting your local environment.
- □ An automatic quick exhaust valve is installed in the device to prevent over pressurization of 299mmHg or higher, therefore protecting the patient.

2. Preliminary Remarks

Compliance

- □ This device conforms to the Medical Device Regulations (EU 2017/745) and UKCA Medical Device Regulations 2002 for Medical Products. This is made evident by the CE2797 and UKCA0086 mark of conformity. (2797 and 0086: The reference numbers to the involved notified body.)
- ☐ This device fulfils the following provisions.

C € 2797 Medical Device Regulation (EU 2017/745)

UK CA 0086

UKCA Medical Devices Regulations 2002

Definitions

SYS Systolic Blood Pressure
DIA Diastolic Blood Pressure

PUL Pulse

Exhaust This means "releasing the cuff air as soon as possible".

Constant exhaust This means, "releasing the cuff air at a constant

depressurization rate".

Batteries

- □ Use alkaline batteries (LR6 type, AA type) or equivalent batteries.
- □ Do not mix new and used batteries.
- □ Remove the batteries from the device and store them separately if the device will not be used for a month or more. Otherwise, the batteries may degrade.
- ☐ The battery life varies with the ambient temperature and may be shorter at low temperatures. Generally, two new LR6 batteries will last approximately for two months when used forty times for measurement each day.

A Defective Sphygmomanometer

□ Stop using the device immediately if the device does not work properly. Please attach a note with the following "Do not use this sphygmomanometer" to prevent any further use. This defective device should be stored in a safe place to avoid any misuse until it has been sent for repair.

Repair

- □ Do not attempt to open the device. Contact your nearest A&D authorized dealer and they will repair or replace the device.
- □ Do not modify the device. It may cause accidents or damage to the device.

3. Contraindications □ Do not use the device in an ambulance or air ambulance. Doing so will prevent the device from providing accurate measurements. □ Do not apply the cuff on an arm with other medical electrical equipment attached. The equipment may not function properly. □ Do not apply the cuff on an arm with an unhealed wound. Do not apply the cuff on an arm receiving an intravenous drip or blood transfusion. It may cause injury or accidents. □ Do not use the device where flammable gases such as anesthetic gases are present. It may cause an explosion. □ Do not use the device in highly concentrated oxygen environments, such as a high-pressure oxygen chamber or an oxygen tent. It may cause a fire or explosion. □ When the cuff is infected by blood or body fluid, it should be safely disposed of according to local instructions or protocol to avoid any potential spread of infectious disease. □ People who have a severe circulatory deficit in the arm must consult a doctor before using the device, to avoid medical problems. □ Do not provide any servicing and perform maintenance while the medical device is in use. □ Do not use on patients with blood flow disorders.

4. Precautions

electrical shock.

Blood Pressure Measurement

□ The user should stop using the device if there is an abnormality, such as the patient feeling excessive arm pain, and remove the cuff to protect the patient.

□ Do not touch the batteries and the patient at the same time. That may result in

Storage

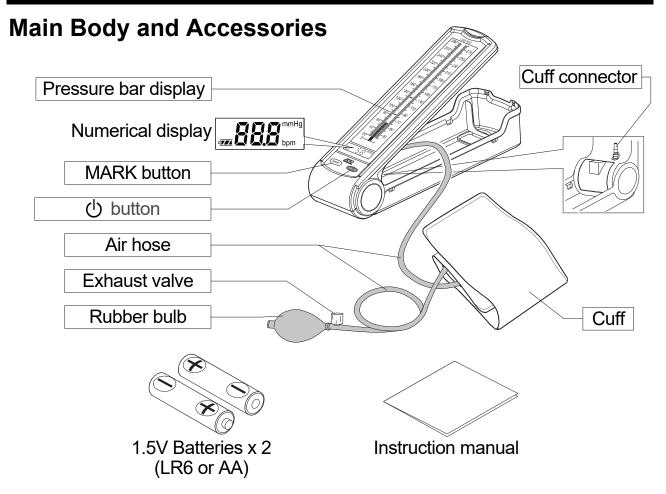
- □ Do not store the device where it could be splashed with water or other liquids. The device and cuff are not water resistant. If the device is immersed by accident, it may require servicing. (Do not use the device before it has endured a full service.) Prevent rain, sweat and water from damaging the device and cuff.
- □ Do not store the device in a high temperature or high humidity environment, or in direct sunlight.
- □ Do not store the device where it could be influenced by vibration or shock.

В	efore Use
	Make sure that the device works correctly and that measurement values
_	are accurate.
	Make sure that the cuff and air hoses are properly connected. Check and maintain the cleanliness of the parts in direct contact with the patient
	Avoid placing the device near a strong magnetic field or static electricity.
	Avoid placing the device near high frequency surgical equipment.
	When reusing the device, confirm that the device is clean.
	Allow the device to adapt to the surrounding environment before use (about one hour).
Dı	uring Use
	This device was not designed for patients' own use so care must be taken
	to ensure accurate results and to avoid possible accidents.
	Regularly confirm patient status when measurement is performed
	frequently or for a long time. Otherwise, damage may be caused due to peripheral arterial disease.
	Stop using the device if you notice any abnormalities (for example; liquid
	inside the device) and request a full service.
	To measure blood pressure, the arm must be squeezed by the cuff hard enough to temporarily stop blood flow through the artery. This may cause
	pain, numbness or a temporary red mark to the arm. This condition will
	appear especially when measurement is repeated successively.
	Any pain, numbness, or red marks will disappear with time.
	This is a device which needs to handle with care. Strong impact may result in malfunction of the device.
	Be careful not to get hurt when handling the damaged device.
	Do not replace the batteries while the device is in use.
	Should the batteries short-circuit, they may become hot and potentially
	cause malfunctions and scalding.
	Use the device so that the air hose is not bent or blocked. Using the cuff
	with the air hose kinked or bent may result in peripheral circulatory failure due to hemostasis in the arm (caused by air remaining in the cuff).
	Measurements may be distorted if the device is used close to televisions,
_	microwave ovens, cellular telephones, X-ray or other devices with strong electrical fields.

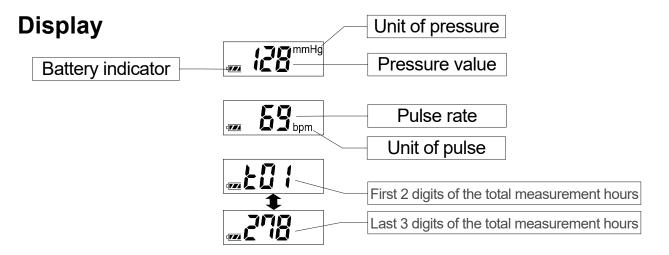
	Wireless communication devices, such as home networking devices, mobile phones, cordless phones and their base stations, and walkie-talkies can affect this digital sphygmomanometer.
A [·]	fter Use
	Clean the device, cuff and accessories with a dry, soft cloth or a wet cloth with water or a neutral detergent. Do not pull or kink the hoses. Do not use any organic solvent, (antiseptic solution or other harsh chemicals) to clean the device, cuff or accessories. Press
P	eriodic Maintenance
	This device is a precision instrument and contains electronic circuitry. Please check all functions periodically. Contact your nearest A&D authorized dealer for official calibration/check-up, according to your local regulations. Used equipment, parts and batteries are not treated as ordinary household waste, and must be disposed of according to the applicable local regulations. The user authority (the hospital, clinic, etc.) is responsible for the safe use and maintenance of this electronic medical device. Care should be taken to follow
H	the specified daily maintenance and inspection procedures for safe use. ow to Take Proper Measurements
	For the most accurate blood pressure measurement: Confirm that a patient does not cross the legs, patient's legs touch on the floor and patient's back and arms are supported. Let a patient relax for about five to ten minutes before measurement. Place the center of the cuff at the same height as a patient's heart. A patient must remain still and keep quiet during the measurement. Do not measure right after exercising or taking a bath. A patient must rest for twenty to thirty minutes before the measurement.
N	otes for Proper Measurement
	Let a patient sit down in a comfortable position. Confirm that the patient does not cross their legs, that their feet touch the floor (if possible), and that their back and the arm being measured are supported. Let a patient relax for about five to ten minutes before taking a measurement. If a patient is excited or depressed by emotional stress, the measurement will reflect this stress as a higher (or lower) than a normal blood pressure reading and the pulse reading will usually be faster than normal.

	An individual's blood pressure varies constantly, depending on what a patient is doing and what a patient has eaten. What a patient drinks can have a very strong and rapid effect on patient's blood pressure.
	Should the device detect a condition that is abnormal, it will stop the measurement and display an error symbol. Refer to page 9 for the description of symbols.
	Measurement may be affected by the position of the cuff, as well as the patient's posture (standing, sitting, supine), movement, or physiological condition.
	Measuring blood pressure too frequently may cause harm due to blood flow interference. Check that the operation of the device does not result in prolonged impairment of blood circulation, when using the device repeatedly.
	Use of accessories not detailed in this manual may compromise safety.
Fo	or the auscultation measurement
	K5 is recommended for the auscultation measurement in adults.
	K4 is recommended for the auscultation measurement in children aged 3 to 12
	years. K5 is recommended for the auscultation measurement in prognant women.
	K5 is recommended for the auscultation measurement in pregnant women, however, K4 should be used if the sounds can be heard even with the cuff
	deflated.
	During the auscultation measurement, the operator should be in a position where the pressure value is clearly visible
	Note: K5 is the point at which the Korotkoff sounds can no longer be heard. K4 is the point at which the Korotkoff sounds changed in the tones heard through a stethoscope from a clear tapping sound to a muffled sound.
O	ther
	This sphygmomanometer is intended for adults and children aged 3 and
	older. Do not use this device on newborns or infants.
	If you have had a mastectomy or lymph node clearance, please consult a doctor before using the device.
	Do not let children use the device by themselves and do not use the device in a place within the reach of infants. This may cause accidents or damage.
	Do not inflate without wrapping the cuff around the upper arm.
	When any serious incident occurs in relation to this device, report to its manufacturer and the competent authority in your country.
	Confirm for proper operation before use, if the packaging is damaged, unintentionally opened and exposed to environmental conditions outside of those specified.

5. Parts Identification



	Function	
(b) Button	Turns on the device and start / stop measurement.	
MARK	During the measurement ····· Puts a marker at a pressure value	
button	After turned off Indicates a lifetime counter	
Numerical	During the measurement ····· Indicates pressure value	
display	After exhausted air Indicates pulse rate	



6. Symbols

Symbols	Function / Meaning	Recommended Action
Ф	Press \circlearrowleft to turn on the device. Press \circlearrowleft during measurement to enter standby.	
MARK	Pressure value holding and lifetime counter	
⊕{R6(AA)]⊖	Battery installation guide	
SN	Serial Number	
UDI	Unique Device Identifier	
2023	Date of manufacture	
☀	Type BF applied part	
t //	Full Battery The battery power indicator during the measurement.	
[Low Battery The battery is low when it blinks.	Replace all batteries with new ones, when the indicator blinks.
Er 1	Pressure remains in the cuff.	Exhaust it with the
ErZ	Measurement overtime	exhaust valve.
Er3	Device is out of order.	Send for service.
Err	The pulse is not detected correctly.	Take another measurement.
mmHg	Unit of pressure	
bpm	Unit of pulse	
C € ₂₇₉₇	CE marking	
Z	WEEE label	
***	Manufacturer	
EC REP	European Authorized Representative	

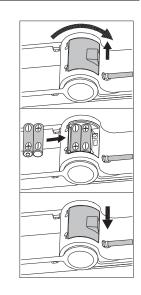
Symbols	Function / Meaning	Recommended Action
③	Refer to instruction manual/booklet *1	
UK CA 0086	UK Conformity Assessed marking	
UK REP	UK Responsible Person	
MD	Medical Device	
Ť	Keep dry	
	Temperature limitation	
	Humidity limitation	
	Atmospheric pressure limitation	
	EU Importer	
UK Importer	UK Importer	

^{*1} The symbol color: Blue

7. Using the Monitor

Inserting / Changing the Batteries

- 1. Remove the battery cover.
- Insert a new set of batteries into the battery compartment as shown. Make sure the polarities (+) and (-) are correct. Use only LR6, AA or equivalent batteries.
- 3. Putting on the battery cover.

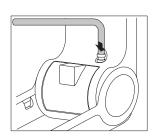


CAUTION

- ☐ Insert the batteries in the battery compartment. If not, the device will not work.
- □ When □ (LOW BATTERY mark) blinks in the LCD display, replace all batteries with new ones. Do not mix old and new batteries. It may shorten the battery life, or cause the device to malfunction.
- □ Battery life varies with the ambient temperature and may become shorter at low temperatures.
- Only the specified batteries should be used with this device. The batteries provided with the device are for testing and may have a limited life.
- □ Remove the batteries from the device and store them separately if the device will not be used for a month or more. Otherwise, the batteries may degrade.

Connecting the Air Hose

Insert the air hose into the cuff connector firmly.

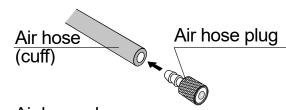


Connecting the Connector and Plug for the Cuff

(Sold separately)

1. Insert the air hose socket into the cuff connector.

2. Insert the air hose plug to the air hose of the cuff.



3. Connect the air hose plug of the cuff to the air hose socket of the main body.

Air hose plug (cuff)

Air hose socket (main body)

Securely connect by turning the air hose plug the direction of the arrow.

□ Use the specified connector. (Refer to page 19)

Selecting the Proper Cuff

Using the correct cuff size is important for accurate readings. If the cuff is not the proper size, an incorrect blood pressure value may be displayed.

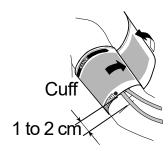
□ The INDEX and RANGE markings on the cuff will indicate that you are using the proper cuff or not. (Refer to "Attaching the Arm Cuff" in the next section)

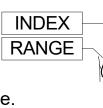
Arm Size	Cuff Size	Catalog Number
41 cm to 50 cm	LL Cuff	CUF-KW-LL
31 cm to 45 cm	Large Adult Cuff	CUF-KW-LA
22 cm to 32 cm	Adult Cuff	CUF-KW-A
16 cm to 24 cm	Small Adult Cuff	CUF-KW-SA
12 cm to 17 cm	SS Cuff	CUF-KW-SS

Arm size: The circumference of an upper arm.

Attaching the Arm Cuff

- Wrap the cuff around the upper arm, about 1 to 2 cm above the elbow as shown on the right. Apply the cuff directly against the skin, as clothing may cause a faint pulse and could result in a measurement error.
- 2. Constriction of the upper arm, caused by rolling up a shirtsleeve, may interfere with accurate readings.
- 3. Make sure that the index points are within the range.





Symbols that are printed on the cuff

Symbols	Function / Meaning
▲ INDEX RANGE	Proper fit range
ARTERY	Artery position mark
THIS SIDE TO PATIENT	Instructions to the patient
REF	Catalog number
LOT	Lot number
ADULT	Cuff size 22 cm to 32 cm
LL	Cuff size 41 cm to 50 cm
LARGE ADULT	Cuff size 31 cm to 45 cm
SMALL ADULT	Cuff size 16 cm to 24 cm
SS	Cuff size 12 cm to 17 cm
\triangle	Operation suggestions
DATEX	Latex free
CE	CE marking
③	Refer to instruction manual/booklet *1
	Cuff Wrap position

^{*1} The symbol color: Blue

8. Measurements

1.	Apply the cuff on the arm (preferably the left arm). Keep the patient still during the measurement.
2.	Press the button. When the button is pressed, all of the display symbols will appear for about one second. When starts flashing, the device is ready for measurement. If air is remaining in the cuff when the button is pressed, the display will indicate an error code fr !. Turn the device off (press the button again) and turn the exhaust valve counterclockwise once to release all the air in the cuff. Then press the button again to reactivate the device.
3.	Place the stethoscope on the brachial artery and pressurize the cuff by squeezing the rubber bulb. (Make sure the exhaust valve is completely closed.) Uhile the cuff is inflating, the pressure bar will move and in turn the LCD will display a number indicating the pressure. Inflate the cuff to 30 to 40 mmHg higher than the patient's usual systolic value.
No	te: If you want to stop inflation at anay time, press either the 🛈 button or turn the screw of the exhaust valve to release the air.
4.	 When inflation is completed. Turn the exhaust valve screw to release air slowly. Measure the systolic blood pressure and the diastolic blood pressure by stethoscope.
5.	The heart rate is shown on the numerical display when the measurement is complete or meets the following conditions. Uhen you pressurize 80mmHg or higher for the measurement. When the pressure drops to 20mmHg or lower.

- 6. Turn the exhaust valve screw counterclockwise to release all the air from the cuff.
 - □ If a measurement is taken with insufficient pressure, the ☐—— mark will be displayed. Re-pressurize the cuff to a pressure that is about 30 to 40 mmHg higher than the previous attempt.
 - □ An error message [[Frr]] will be displayed if a measurement is taken with insufficient pulses or in a very noisy environment.
- 7. Press the 🛈 button again to turn off the power.

Note: Model UM-102 has an automatic power-off function.

Allow at least three minutes between measurements on the same person.



Measurement with MARK Button

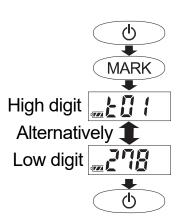
You can put a marker at a certain pressure value when the MARK button is pressed during the measurement process. Up to 5 markings can be shown over the range of 40mmHg.

5 B bpm

Lifetime Counter

When the MARK button is pressed while the device is off, the lifetime counter is displayed.

This counter function indicates the hours the device was in use and helps to determine when maintenance is necessary. High digits and Low digits are alternatively displayed. The example indicates that the device has been in use for 1,278 hours.



10. Troubleshooting

Problem	Possible Cause	Suggestion
Nothing appears	Batteries are empty.	Replace all batteries with new ones.
in the display, even when the power is turned on.	Battery polarities are not in the correct position.	Reinstall the batteries with the negative and positive ends matching those indicated in the battery compartment.
The cuff is not inflated.	The cuff is not connected properly. There is leakage of air from the cuff or rubber bulb.	Check the twist of the air hose, and connection of the cuff and air hose. Replace the cuff or rubber bulb with a new one.
Remain a display of BBB bbm.	Error symbol is displayed one minute later.	Refer to "6. Symbols".

Note: If the suggestions described above do not solve the problem, contact the authorized dealer. Do not attempt to open or repair this product, otherwise your warranty may be invalid.

11. Maintenance

Do not attempt to open the device as the delicate electrical components and intricate air unit inside could be damaged. If you cannot solve the problem using our troubleshooting guide, request assistance from your authorized dealer or from any A&D service group.

The device is designed and manufactured for a long service life. However, it is generally recommended to have the device inspected every 2 years, to ensure proper functioning and accuracy. Please contact either your authorized dealer or A&D for maintenance.

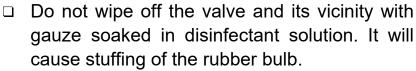
CAUTION

- ☐ The sphygmomanometer is not waterproof device. Do not splash water on it and avoid exposure to moisture.
- □ Do not use a organic solvent such as thinner or benzine.
- ☐ The sphygmomanometer cannot be sterilized by autoclave, EOG or formaldehyde etc.

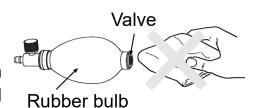
Cleaning

- □ When cleaning the device and cuff, turn off the power by pressing ⑤START/STOP button and remove the batteries.
- □ When the main body or cuff is dirty, wipe them fully by using a gauze or cloth dampened with water or warm water avoiding excess water.
- □ To prevent a risk due to infection, disinfect the main body and cuff regularly. When disinfecting them, wipe them gently by using the gauze or dampened cloth with local antiseptic solution then wipe the moisture off the surface by using a dry soft cloth.
- □ Use the following disinfectants to clean the main body and cuff.

Ethanol (70%)
Isopropanol (70%)
Chlorhexidine Gluconate Solution (0.5%)
Benzalkonium Chloride Solution (0.05%)
Sodium Hypochlorite (0.05%)



instruction specified by the user authority.



□ Clean the device about once every month, based on the policy or

Disposal

This unit and its batteries are not treated as ordinary household waste and must be disposed of according to the applicable local regulations.

Item	Parts	Material		
Package	Box	Cardboard		
	Cushion	Cardboard		
	Bag	PE		
Main unit and	Enclosure	ABS		
accessories	Internal parts	General electronic components		
	Batteries	Alkaline battery		

12. Technical Data

Model UM-102

Measurement method By applying pressure, enabling the determination

of blood pressure by the auscultatory method.

20 - 280 mmHg

Measurement range

Numerical display Pressure: 0 - 299 mmHg

Pulse: 40 - 180 beats / minute

Pressure bar display

Measurement accuracy

Numerical display Pressure: ±3 mmHg

Pulse: ±5 %

Power supply 2 x 1.5 V alkaline batteries (LR6 or AA)

Pressure:

Upper arm circumference 22 - 32 cm using the adult cuff

Number of measurements Approx. 2000 measurements, when AA

alkaline batteries are used, with pressure value

of 180 mmHg at room temperature of 23°C

Classification Internally powered ME equipment

Continuous operation mode

EMD IEC 60601-1-2: 2014+A1: 2020

Operating conditions +10°C to +40°C / 15%RH to 85 %RH

800 hPa to 1060 hPa

Transport / Storage conditions -20°C to +60°C / 10%RH to 95 %RH

700 hPa to 1060 hPa

Dimensions Approx. 98 [W] x 324 [H] x 67[D] mm Weight Approx. 520 g, excluding batteries

Applied part Cuff Type BF
Useful life Device: 5 years

Cuff: 1 year or 30,000 times Rubber bulb unit: 2 years

Contents *2 1 Sphygmomanometer

1 Instruction Manual

2 Batteries

1 Cuff

1 Rubber bulb unit1 Caution instruction

Accessories sold separately

Cuff



Catalog Number	Cuff Size	Arm Size
CUF-KW-LL	LL Cuff	41 cm to 50 cm
CUF-KW-LA	Large Adult Cuff	31 cm to 45 cm
CUF-KW-A	Adult Cuff	22 cm to 32 cm
CUF-KW-SA	Small Adult Cuff	16 cm to 24 cm
CUF-KW-SS	SS Cuff	12 cm to 17 cm

Rubber bulb unit



Catalog Number UM-102-10

Connector and Plugs for cuff replacement



Catalog Number UM-102-11

*2: Confirm that all of the parts are included to ensure that the medical device is ready to perform safely and as intended.

Note: Specifications are subject to change without prior notice.

EMD Technical Data Battery-operated Blood Pressure Monitor

Medical Electrical Equipment needs special precautions regarding EMD and needs to be installed and put into service according to the EMD information provided in the following. Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment. The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit.

Table 1 -EMISSION Limits-

Phenomenon		Compliance
Conducted and radiated RF EMISSION	CISPR 11	Group 1、Class B

Table 2 - IMMUNITY TEST LEVELS: Enclosure Port-

Phenomenon	IMMUNITY TEST LEVELS
Electrostatic discharge	±8 kV contact
IEC 61000-4-2	±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields	10 V/m
IEC 61000-4-3	80 MHz - 2.7 GHz
IEC 01000-4-3	80 % AM at 1 kHz
Proximity fields from RF wireless communications equip IEC 61000-4-3	See table 3
Rated power frequency magnetic fields	30 A/m
IEC 61000-4-8	50 Hz or 60 Hz
Proximity magnetic fields IEC 61000-4-39	See table 4

Table 3 -Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment -

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 ~ 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 ~ 470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 ~ 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
810		GSM 800/900				
870	800 ~ 960	TETRA 800 iDEN 820	Pulse modulation 18 Hz	2	0.3	28
930		CDMA 850 LTE Band 5				
1720		GSM 1800 CDMA 1900				
1845	1700~1990	GSM 1900 DECT	Pulse modulation 217 Hz	2	0.3	28
1970		LTE Band 1,3,4,25 UMTS				
2450	2400~2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240			Pulse modulation			
5500	5100~5800	WLAN 802.11 a/n	217 Hz	0.2	0.3	9
5785						

Table 4 $\,$ -Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields -

		, , ,
Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134.2kHz	Pulse modulation 2.1 kHz	65
13.56MHz	Pulse modulation 50 kHz	7.5



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