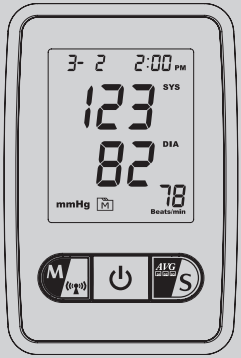
FORA® ACTIVE P30 Plus Series



Blood Pressure Monitoring System	**Owner's Manual**
Blutdrucküberwachungssystem	**Bedienungsanleitung**
Système de surveillance de la tension artérielle	**Manuel de l'utilisateur**
Sistema per il monitoraggio della pressione sanguigna	**Manuale dell'utente**
Sistema de supervisión de presión en sangre	**Manual del propietario**
Sistema de monitorização de pressão arterial	**Manual do utilizador**
Bloeddrukbewakingssysteem	**Gebruikershandleiding**
Sistem de monitorizare a tensiunii arteriale	**Manual de utilizare**
Tonometr	**Příručka vlastníka**
Tonometer	**Návod na použitie**

REF **FORA P30 Plus / FORA P30 plus BT**
For self-testing / Zur Selbstmessung / Pour l'automesure / Per l'automisurazione / Para autotest / Para auto-teste / Voor zelftest / Pentru autotestare / Pro vlastní testování / Na domáce meranie /

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CE 0123 MD

Contents

Safety Information

Read the following *Safety Information* thoroughly before using the device.

- Use this device **ONLY** for the intended use described in this manual.
- Do **NOT** use accessories which are not specified by the manufacturer.
- Do **NOT** use the device if it is not working properly or damaged.
- Do **NOT** use under any circumstances on newborns, infants, or persons who cannot communicate.
- This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your physician to have the results interpreted.
- Keep the equipment and its flexible cord away from hot surfaces.
- Do **NOT** apply the cuff to areas other than the place directed.
- Proper maintenance and periodically calibration are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact local customer service for help.

If you experience any serious incident that occurred in relation to the use of this product, please report it to the manufacturer and the competent authority of medical devices in your country.

A serious incident means any incident that directly or indirectly led, might have led, or might lead to any of the following:

(a) the death of a patient, user, or other people,
(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
(c) a serious public health threat.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

Introduction

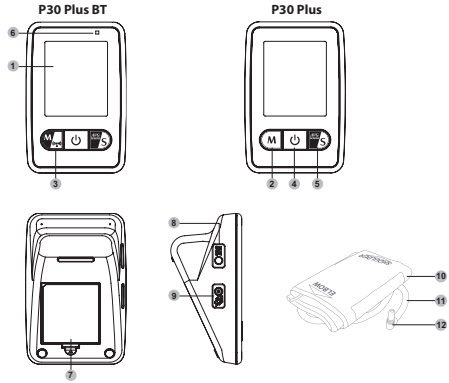
Intended Use

The FORA ACTIVE Series Multi-mode Blood Pressure Monitoring System is intended to be used to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. Do not use this system on babies, young children or persons who cannot express their consent.

Test Principle

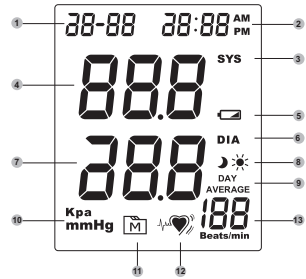
Blood pressure is measured non-invasively at the arm based on oscillometric method. For people of common arrhythmia, such as atrial or ventricular premature beats or atrial fibrillation we recommend to use auscultatory mode. The reading obtained by single and average mode which use oscillometic method is for reference only and should be discussed with the healthcare professionals.

Product Overview



1. Screen Display
2. M Button
3. M/Bluetooth Button
4. ON/OFF Button
5. AVG/S Button
6. Bluetooth LED Indicator
7. Battery Compartment
8. AC Adapter Port
9. Air Jack
10. Pressure Cuff
11. Air Tube
12. Air Plug

Screen Display



1. Date
2. Time
3. Systolic Pressure Symbol
4. Systolic Pressure Value
5. Low Battery Symbol
6. Diastolic Pressure Symbol
7. Diastolic Pressure Value
8. Day- / Night-Time Symbol
9. Day Average Symbol
10. Units for Blood Pressure
11. Memory Mode Symbol
12. IRB (Irregular Rapid Beat) Symbol
13. Pulse Rate

Getting Started

Before using the device for the first time, do the following initial setup:

Step 1: Enter the Setting Mode

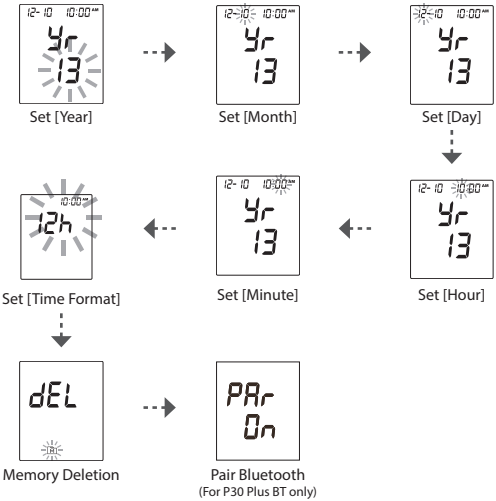
Press and hold (AVG) for 3 seconds until the device turns on.

Step 2: Configuring the Settings (Date, Time, Time Format, Memory Deletion, and Bluetooth Pairing (P30 Plus BT only))

Press (M) repeatedly to adjust the value or enable/disable the setting. Then press (AVG) / (S) to confirm the setting and switch to another field.

Note:

- During memory deletion, do the following:
  - ✓ To keep all saved results, press (AVG) / (S) to keep the saved result.
  - ✓ To delete all results, press (M) to delete all memory.
- These parameters can ONLY be changed in the setting mode.
- If the device is idle for 3 minutes during the setting mode, it will turn off automatically.
- The Bluetooth pairing process is only required when user needs to pair this device to a Bluetooth receiver for the first time, or when user needs to pair this device to another new Bluetooth receiver. The Bluetooth LED Indicator will blink during the pairing process.
- After the device has been paired with a Bluetooth receiver, press and hold (M) for 3 seconds to start the Bluetooth connection.

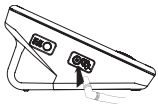


Testing Your Blood Pressure

Before Measument

- Avoid caffeine, tea, alcohol and tobacco for at least 30 minutes before measurement.
- Wait 30 minutes after exercising or bathing before measurement.
- Sit or lie down for at least 10 minutes before measurement.
- Do not measure when feeling anxious or tense.
- Take a 5-10 minute break between measurements. This break can be longer if necessary, depending on your physical conditions.
- Keep the records for your doctor as reference.
- Blood pressure varies between each arm. Always measure your blood pressure on the same arm.

Fitting the Cuff



1. Connect the air plug of the tubing to the air jack of the device.
2. Assemble the cuff.

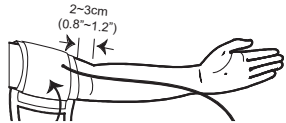
   The smooth surface should be inside the cuff loop and the metal D-ring should not touch your skin.

Note:

- Before using the cuff, be sure the cuff size fits with your upper arm circumference.

3. Stretch your left (right) arm in front of you with your palm facing up. Slide and place the cuff onto your arm with the air tube and artery mark region (in red) toward the lower arm.

   Wrap and tighten the cuff above your elbow. The red line on the edge of the cuff should be approximately 0.8 to 1.2 inches (2 to 3 cm) above your elbow. Align the tube over the main arteries on the inside.



4. Leave a little free space between the arm and the cuff. You should be able to fit 2 fingers between them.
5. Press the hook material firmly against the pile material. The top and bottom edges of the cuff should be tightened evenly around your upper arm.

Proper Measurement Position

1. Sit down for at least 10 minutes before measuring.
2. Place your elbow on a flat surface. Relax your hand with the palm facing up.
3. Make sure the cuff is about the same height as the location of your heart.

Important!

If the cuff is relatively lower (higher) than the heart, the obtained blood pressure value could be higher (lower) than the actual value. A 15 cm difference in height may result in an error around 10 mmHg.

4. Press ⏻. The device will turn on and the cuff will begin to inflate automatically. Remain still and do not talk or move during the measurement.

Measuring Blood Pressure

This device provides you different ways to measure your blood pressure.

When the device detects an irregular heart beat, the IRB symbol is shown as "♥" instead of "♥". If the problem still persists, please consult your doctor.

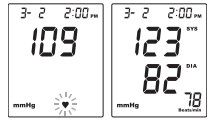
Important!
Always apply the pressure cuff before turning on the device.

A. Single Measurement

Perform an individual blood pressure measurement.

1. Press ⏻. All the LCD symbols will appear. Then the cuff will begin to inflate automatically.

2. The heart symbol "♥" will flash when a pulse is detected during the inflation. After the measurement, the monitor displays the systolic pressure, diastolic pressure and pulse rate.



3. Press ⏻ to turn the device off.

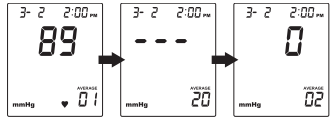
Note:
- If the device is idle for 3 minutes, it will turn off automatically.

B. Average Measurement

Automatically performs three (3) consecutive blood pressure measurements and displays the average result in the end.

1. Press AVG. The device will turn on and enter the averaging mode. Then the cuff will begin to inflate automatically.

2. After the first measurement is complete, the device will start counting down before the second measurement begins. The device will take three (3) measurements consecutively with an interval of 20 seconds.

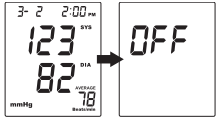


Note:

When the difference between the first and second systolic pressure

is more than 15mmHg, the time interval for third measurement will be 40 seconds.

3. After taken three measurements, the results are averaged to produce the blood pressure measurement with AVERAGE symbol display on the screen. Press ⏻ to turn the device off.

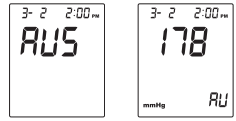


C. Auscultatory Mode

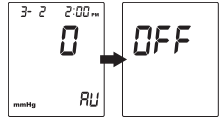
Only well trained persons may use this mode to measure blood pressure manually. This manual method involves applying a stethoscope to the arm and listening to the pulse while the air is slowly let out from the cuff (the Korotkoff method). Please ask your health-care professional to train you how to use auscultatory mode.

The systolic pressure is the maximum pressure in an artery at the moment when the heart is beating and pumping blood through the body. The diastolic pressure is the lowest pressure in an artery in the moments between beats when the heart is resting.

1. Place a stethoscope on the arm where there is a pulse. Wrap the cuff around the upper arm and hold in place with Velcro.
2. Press and hold ⏻ until "AUS" symbol appears on the display with a beep. Release the button. Then cuff begins to inflate automatically.



3. After reaching the cuff pressure, the deflation begins. You can adjust the inflation pressure by keep pressing Ⓜ to inflate if necessary. If you release Ⓜ, the inflation will stop and deflation begins.
4. The systolic pressure is measured when the operator first hears the pulse. Write down the value on the display. This value indicates the systolic pressure. You have to record the values as the result will not be stored in the memory.
5. The diastolic pressure is measured from the moment the operator is unable to hear the sound of the pulse. Write down the value on the display. This value indicates the patient's diastolic pressure. You have to record the values as the result will not be stored in the memory.
6. The device will return to 0 mmHg after the measurement is completed. To turn off the device, press and hold ⏻ or it will switch off automatically after idle for 3 minutes.



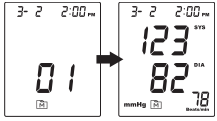
Reviewing Test Results

Your device stores the 200 (P30 Plus BT only) most recent blood pressure test results along with respective dates and times in the memory. To recall the memory, start with the device off.

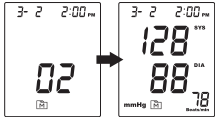
For P30 Plus

To review all test results, do the following:

1. Press and release Ⓜ. The "M" icon appears on the screen and the first reading you see is the last blood pressure result along with date and time.



2. Press Ⓜ repeatedly to review other test results stored in the device.



To review the day-average test results, do the following:

1. Press and hold Ⓜ for 3 seconds until the "DAY AVERAGE" icon appears on the screen.
2. Press Ⓜ and the Day average result appears on the display.

3. Press Ⓜ again to review the Day-time average result.

4. Press Ⓜ again to review the Night-time average result.

For P30 Plus and P30 Plus BT

Press Ⓜ to review the average and general memory recall mode.

Note:

- Day-time average (☀) is the average of the measurements taken during 4:00 A.M. to 11:59 A.M.
- Night-time average (☽) is the average of the measurements taken during 6:00 P.M. to 11:59 P.M.
- Press ⏻ to exit the memory mode or leave it without any action for 3 minutes. The device will turn off automatically.
- If using the device for the first time, the "---" icon appears when you recall the test results or review the average result. It indicates that there is no test result stored in the memory.

Classification of Blood Pressure

Human blood pressure naturally increases after reaching middle age. This symptom is a result of continuous ageing of the blood vessels. Further causes include diabetes, lack of exercise and cholesterol (LDL) adhering to the blood vessels. Rising blood pressure accelerates hardening of the arteries, and the body becomes more susceptible to apoplexy and coronary infarction.

⚠ This device does **NOT** serve as a cure for any symptoms or diseases.
The data measured is for reference only. Always consult your physician to have the results interpreted.

Definitions and Classification of blood pressure levels according to 2007 ESH-ESC Practice Guidelines for the Management of Arterial Hypertension:

Category	Systolic		Diastolic
Optimal	< 120 mmHg	and	< 80 mmHg
Normal	120 –129 mmHg	and/or	80–84 mmHg
High normal	130 –139 mmHg	and/or	85–89 mmHg
Grade 1 hypertension	140 –159 mmHg	and/or	90– 99 mmHg
Grade 2 hypertension	160 –179 mmHg	and/or	100–109 mmHg
Grade 3 hypertension	≥ 180 mmHg	and/or	≥ 110 mmHg
Isolated systolic hypertension	≥ 140 mmHg	and	< 90 mmHg

Isolated systolic hypertension should be graded (1, 2, 3) according to systolic blood pressure values in the ranges indicated, provided that diastolic values are < 90mmHg.

Source: *The European Society of Hypertension and European Society of Cardiology Task Force Members. 2007 ESH-ESC Practice Guidelines for the Management of Arterial Hypertension. J Hypertens 2007; 25: 1751-1762.*

Maintenance

Changing Battery

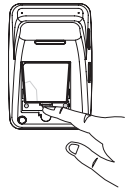
When the battery is low, one of the following screen will appear:

- the "🔋" icon appears with display messages : This indicates the device is functional and the result remains accurate, but it is time to change the batteries.

- the "▭" icon appears with E-b: This indicates the power is not enough for a measurement. You must change the batteries immediately.

To change the batteries, do the following:

1. Press the edge of the battery cover and lift it up to remove the cover.
2. Remove the old batteries and replace with four 1.5V AA size alkaline batteries.
3. Close the battery cover.



CAUTION

- **RISK OF EXPLOSION IF BATTERY IS REPLACED BY AN INCORRECT TYPE.**
- **DISPOSE OF USED BATTERIES ACCORDING TO THE INSTRUCTIONS.**

Note:

- Replacing the batteries does not affect the test results stored in memory.
- Keep away these batteries from small children. If swallowed, promptly seek medical assistance.
- Batteries may leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period.
- Properly dispose of the used batteries according to your local environmental regulations.

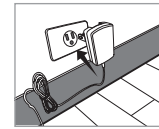
Using an AC Adapter

You can use an AC adapter to provide the power supply.

To use an AC adapter, do the following:

1. Connect one end of the AC adapter to the AC adapter jack of the device.

2. Plug the other end of the AC adapter into an electrical outlet.



Caring for Your Device

- To clean the device exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do **NOT** flush with water.
- Do **NOT** use organic solvents to clean the device.
- Do **NOT** wash or iron the pressure cuff.

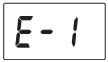
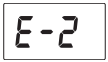
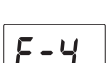
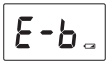
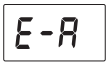
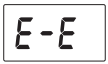
Device Storage

- Storage condition: -20°C to 60°C (-4°F to 140°F), below 95% relative humidity.
- Always store or transport the device in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Troubleshooting

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service.

Error Message

Error Message	Cause	What To Do
	Inflation or pressure error.	Please contact local customer service for help.
	Deflation error.	
	Blood Pressure measurement error.	Refit cuff tightly and correctly. Relax and repeat the measurement. If the error still remains, please contact local customer service for help.
	Battery is too low.	Replace the batteries or use the AC adapter.
	Problem with the device.	Please contact local customer service for help.
		

Blood Pressure Measurement

Symptom	Cause	What To Do
Nothing is displayed after pressing ⏻.	Batteries exhausted.	Replace the batteries.
	Batteries incorrectly installed or no battery is installed.	Check that the batteries are correctly installed.
The heart rate is higher/lower than user's average.	Movement during measurement.	Repeat measurement.
	Measurement taken just after exercise.	Rest at least 30 minutes before repeating measurement.
The result is higher/lower than user's average measurement.	May not be in correct position while measuring.	Adjust to the correct position to measure.
	Blood pressure naturally varies from time to time.	Keep in mind for next measurement.
The cuff inflates again while measuring.	Cuff is not fastened.	Fasten the cuff again.
	If user's blood pressure is higher than the pressure the device has inflated, the device will automatically increase the pressure and start to inflate again. Stay relaxed and wait for the measurement.	

Symbol Information

Symbol	Referent
	Read instructions before use
	Manufacturer
	Serial number
	Caution, consult accompanying documents
	Type BF Equipment
	Temperature limitation
	Collection for electrical and electronic equipment
	Humidity limitation
	Medical Divice
	Authorised representative in the European Union

Specifications

System performance	
Power Source	Four 1.5V AA alkaline batteries
Dimensions (w/o cuff)	150 (L) x 100 mm (W) x 70.5 mm (H)
Weight (w/o cuff)	400g with batteries
Cuff Size	24-43 cm (9.4 - 16.9 inches) with air tube 100 cm
Memory	Maximum 200 memory records (P30 Plus BT); 60 (P30 Plus)
Power Saving	Automatic power off if system is idle for 3 minutes
System Operating Conditions	10°C to 40°C (50°F to 104°F), below 85% RH
Device Storage/Transport Conditions	-20°C to 60°C (-4°F to 140°F), below 95% RH
Power Supply Input	DC +6V / 1A (max) via Power Plug
Blood pressure measurement performance	
Measurement unit	mmHg
Systolic Measurement Range	50 mmHg -255 mmHg
Diastolic Measurement Range	25 mmHg -195 mmHg
Pulse Rate Measurement Range	40 -199 beats / minute
Accuracy of Pressure	±3 mmHg or ±2% of reading
Accuracy of Pulse Rate	±4% of reading

This device has been tested to meet the electrical and safety requirements of: IEC/EN 60601-1, IEC/EN 60601-1-2.

Reference to Standards:

- EN 1060-1 /-3, NIBP-requirements
- IEC60601-1 General requirement for safety
- IEC60601-1-2 Requirements for EMC
- EN1060-4, NIBP clinical investigation
- AAMI/ANSI /IEC 80601-2-30, ANSI/AAMI/ISO 81060-2, NIBP requirements

WARRANTY TERMS AND CONDITIONS

With respect to disposable products, ForaCare Suisse warrants to the original end-user purchaser that, at time of delivery, each standard product manufactured by ForaCare Suisse shall be free of defects in material and workmanship, and the purposes and indications described on the labelling is consistent with the labelling if the product is used in accordance with the purposes and indications on the labelling. All warranties for the product, excluding the cuff, shall expire as of the product expiration date, or if none, after three (3) years from the original date of purchase, as long as it has not been modified, altered, or misused. The cuff is covered by a one (1) year limited warranty. ForaCare Suisse warranty hereunder shall not apply if:
(i) a product is not used in accordance with its instructions or if it is used for a purpose not indicated on the labeling; (ii) any repairs, alterations or other work has been performed by the buyer or others on such item, other than work performed with ForaCare Suisse's authorisation and according to its approved procedures; or (iii) the alleged defect is a result of abuse, misuse, improper maintenance, accident or the negligence of any party other than ForaCare Suisse. The warranty set forth herein is conditioned upon proper storage, installation, use and maintenance in accordance with applicable written recommendations by ForaCare Suisse. The warranty furnished hereunder does not extend to damaged items purchased hereunder resulting in whole or in part from the use of components, accessories, parts or supplies not furnished by ForaCare Suisse.

Appendix

Warning: Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided. Careful consideration of this information is essential when stac king or collocating equipment and when routing cables and accessories.

Warning: RF mobile communications equipment can affect medical electrical equipment.

Recommended separation distance between portable and mobile RF communications equipment and the FORA P30 Plus Series

The FORA P30 Plus Series is intended for use in an electromagnetic environment (for home healthcare and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the FORA P30 Plus Series can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the FORA P30 Plus Series as recommended below, depending on the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,7 GHz $d = 2{,}3\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) depending on 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 to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic emissions

The FORA P30 Plus Series is intended for use in the electromagnetic environment (for home healthcare and professional healthcare) specified below.
The customer or the user of the FORA P30 Plus Series should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance (for home healthcare and professional healthcare)
RF emissions CISPR 11	Group 1	The FORA P30 Plus Series uses RF energy only for internal use. Therefore, its RF emissions are very low and are not likely to cause any interference from nearby electronic equipment.
RF emissions CISPR 11	Class B	The FORA P30 Plus Series 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	

Manufacturer's declaration-electromagnetic immunity

The FORA P30 Plus Series is intended for use in the electromagnetic environment (for home healthcare and professional healthcare) specified below.
The customer or the user of the FORA P30 Plus Series should assure that it is used in the environment specified below.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ±8 kV Air ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	Not applicable Not applicable	Mains power quality should be that of a typical home healthcare and professional healthcare environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical home healthcare and professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *UT*; 0,5 cycle 0 % *UT*; 1 cycle 70 % *UT*; 25/30 cycles Voltage interruptions: 0 % *UT*; 250/300 cycle	Voltage dips: Not applicable Not applicable Not applicable Voltage interruptions: Not applicable	Mains power quality should be that of a typical home healthcare and professional healthcare environment. If the user of the FORA P30 Plus Series requires continued operation during power mains interruptions, it is recommended that the FORA P30 Plus Series be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The FORA P30 Plus Series power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare and professional healthcare environment.

NOTE *UT* is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration-electromagnetic immunity

The FORA P30 Plus Series is intended for use in the electromagnetic environment (for home healthcare and professional healthcare) specified below.
The customer or the user of the FORA P30 Plus Series should assure that it is used in the environment specified below.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and am-ateur radio bands between 0,15 MHz and 80 MHz	Not applicable Not applicable	**Portable and mobile RF communications equipment must not be used close to any parts of the** FORA P30 Plus Series including cables, other than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	80 % AM at 1 kHz 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** d = 1,2 $\sqrt{P}$ d = 1,2 $\sqrt{P}$ 80MHz to 800 MHz d = 2,3 $\sqrt{P}$ 800MHz 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 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 to 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 FORA P30 Plus Series is used exceeds the applicable RF compliance level above, the FORA P30 Plus Series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FORA P30 Plus Series.
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The FORA P30 Plus Series is intended for use in the electromagnetic environment (for home healthcare and professional healthcare) specified below.
The customer or the user of the FORA P30 Plus Series should assure that it is used in such an environment.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28	28
870							
930							
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28	28
1845							
1970							
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9	9
5500							
5785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.