Introduction
Congratulations on your purchase and welcome to Philips! To fully benefit from the support that Philips offers, register your product at www.philips.com/welcome.

General
The Philips upper arm blood pressure monitor with Bluetooth® enables you to perform blood pressure measurements, heart rate (pulse) measurements, transmit data via Bluetooth® to your mobile device and display your personal measurement results in the Philips HealthSuite health app. The device can also be used as a standalone device. This user manual contains important safety information and provides step-by-step instructions for using the blood pressure monitor. Read this information carefully before you use the device and save it for future reference.

Features:
- 86.5mm×24mm display with white backlight
- Measure-during-inflation technology
- Supports 2 users

Intended use
The Philips upper arm blood pressure monitor is a digital monitor intended for use in measuring blood pressure and heart rate in adult patient population with arm circumference ranging from 22cm to 42cm (about 9-17 inches). The device is intended to be used in a home environment. The warning signs and symbols are essential to ensure that you use this product safely and correctly and to protect you and others from injury. Below you find the meaning of the warning signs and symbols on the label and in the user manual.

Symbol for follow instructions for use.

This symbol means that the part of the device that comes into physical contact with the user (also known as the applied part) is of type BF (Body Floating) according to IEC 60601-1. The applied part is the cuff.

Symbol for the device complies with European Medical Device Directive 93/42/EEC requirements. 0344 refers to the notified body.

Symbol for WEEE, waste electrical and electronic equipment. Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice and see chapter ‘Battery recycling’.

The symbol means that the product contains batteries which shall not be disposed of with normal household waste (2006/66/EC).

Indicates the manufacturer, as defined in EU Directives 93/42/EEC.

Indicates manufacturing date.

Indicates the manufacturer’s batch code.

Indicates the manufacturer’s serial number so that a specific medical device can be identified.

Fuse T1A/250V @6” IEC CC.

Symbol for Class II Equipment. The adapter is double insulated (Class II) and complies with IEC 60601-1.

Symbol for indoor use only.

Symbol for including RF transmitter. This means that this device emits non-ionizing Radiation. All devices with RF transmitters or that use RF electromagnetic energy must have a label with this symbol.
Indicates caution. The user should consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

This symbol on the device means:
- Protected against access to hazardous parts with a finger and against vertically falling water drops when tilted up to 15 degrees.

This symbol on the device indicates:
- Storage and transportation temperature limits to which the medical device can be safely exposed: -20°C to 60°C.

This symbol on the device means:
- The Green Dot (Der Grüne Punkt in German) is the license symbol of a European network of industry-funded systems for recycling the packaging materials of consumer products.

This symbol on the DC charger indicates:
- TUV certified.

General description (Fig. 1)

1. Socket for DC charger plug
2. Bluetooth® symbol
3. Battery symbol
4. Systolic blood pressure
5. Diastolic blood pressure
6. Heart rate
7. Movement detector
8. Heart rate/irregular heart rate detector
9. User IDs
10. Cuff
11. On button
12. User ID button
13. Blood pressure classification

Important safety information

Read this important information carefully before you use the device and save it for future reference.

Warning

Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts can be dangerous or even fatal.

- The device is not suitable for use by children or persons with small parts.
- The device is not suitable for use by persons who have electrical implants.
- Do not do the blood pressure monitor on anyone where intravascular access or therapy (such as an intravenous drip or blood transfusion), or an arterio-venous shunt (A-V shunt) is present. The temporary interference to blood flow by the blood pressure measurement could result in injury.
- If you had a mastectomy (breast amputation) do not use this blood pressure monitor on the arm on the side of the mastectomy. The inflating cuff can lead to pain, trauma and further injury on the arm.
- Consult your doctor if you suffer from illnesses prior to using the device.
- No modifications of this equipment are allowed. This may result in increased emissions or decreased immunity of the device.
- Never use the blood pressure monitor during charging as this can cause injury.
- Do not connect the tube to other medical equipment, as this could lead to dangerous injuries.
- This device is not intended for patients outside a home environment.
- Never use any accessories or parts from other manufacturers or that Philips does not specifically recommend. Using such accessories or parts could cause a hazardous situation for the user or damage to the device.
- Only use accessories and detachable parts authorized by the manufacturer. The use of unauthorized parts or accessories may cause damage to the device or injury to the user.

Caution

- Always check the device before you use it. Do not use the device if it is damaged, as this may cause injury.
- The effectiveness of this blood pressure monitor has not been established in pregnant women (including pre-eclamptic women).
- Common arrhythmias (such as atrial or ventricular premature beats or atrial fibrillation) and periods of total heart block can affect the performance (accuracy) of this blood pressure monitor. Please consult your doctor forth to best use this blood pressure monitor or if you offer from any of these conditions.

- Only use this device for its intended purpose as described in this user manual.
- Do not confuse self-monitoring with self- diagnosis. This device is not intended for use in the diagnosis, monitoring during medical emergencies or operations.
- Do not take any therapeutic measures on the basis of self-measurement. Never change any prescribed medication without consulting your doctor. Do not consult your doctor with any questions about your blood pressure.
- If you are not sure, please consult your physician to determine the most appropriate time to measure your blood pressure.

This device is not intended for use on extremities other than the arm for functions other than obtaining a blood pressure measurement.

- Do not clean the blood pressure monitor when it is being charged. Always unplug the charger before cleaning the blood pressure monitor. (See 'Specifications').
- If the cuff pressure exceeds 40kPa (300mmHg), detach the cuff from the unit and press the ‘stop’ button to stop inflation.
- Do not attach the cuff on the same arm on which other monitoring medical electrical equipment is attached simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring medical electrical equipment.
- Never attach the cuff on injured skin, an injured arm or on an arm under medical treatment as this can cause further injury.
- Do not open, disassemble or repair the device or measurement results.
- The equipment is not AP/APG equipment and is not intended for use on limbs other than the arm.
- Do not attempt to replace your blood pressure monitor's battery. It is built-in and not changeable.
- Do not use the adapter in or near wall sockets causing injury or death.
- Do not use this device near a strong electromagnetic field, such as setting up, malfunction, maintaining or using, which other monitoring medical electrical equipment is attached simultaneously, because this could cause further injury.
- Do not, this could affect the performance, lifetime and peripheral artery disease / arteriosclerosis.
- If you are taking medication, consult your doctor how to best use this blood pressure monitor. Please consult your doctor if you suffer from any of these conditions.

- This Philips device complies with all applicable standards and regulations regarding exposure to electromagnetic fields and conforms with EN 60601-2-54.

Compliance with standards
- The device meets the relevant standards for this type of electrical medical/measuring equipment for home use.
Display

Systolic blood pressure

Maximum blood pressure, see also sections: systolic and diastolic pressure.

Diastolic blood pressure

Minimum blood pressure, see also sections: systolic and diastolic pressure.

Heart rate

Number of heartbeats per minute (pulse is typically equivalent to heart rate).

Battery status

Indicates role battery during charging.

Measurement unit

Measurement unit of blood pressure.

Irregular heart rate detector

Indicates role heart rate detection during the measurement.

User IDs

Start measurement for selected user, and transmit the measurement result.

Movement detector

Moving during the measurement will result in an inaccurate result.

Blood pressure classification

Classification of measured blood pressure following WHO system (see ‘Blood pressure classification’).

Bluetooth® symbol

The device uses Bluetooth for communication.

Battery status indications

Battery symbol

Battery status

The battery is almost empty.

The battery is empty.

When you measure 3 times a day starting with a fully charged battery, the device can be used for about 300 times. In case of normal use, the battery can be charged around 300 times.

Note: Data will be lost when the battery is completely empty.

Charging

The battery of this device is a built-in rechargeable Li-polymer battery with a capacity of 1000 mAh. Use the original DC charger supplied to charge the battery. When the battery is empty, it takes approx. 2 hours to fully charge the battery of the device.

1. Put the small plug in the socket of the device (Fig. 2).
2. Put the adapter in the wall socket.

Battery charging indications

Battery charging symbol

Battery charging indication

Battery charging: half full

Battery charging: almost full

Battery fully charged

Using the blood pressure monitor

This device uses the oscillometric method to measure systolic and diastolic blood pressure. Before every measurement, the unit establishes a “zero point” equivalent to the atmospheric pressure. Then it starts inflating the cuff. During the measurement, the device detects the pressure oscillations in the blood vessels generated by the heart pumping blood through the body. These pressure oscillations are used to determine systolic and diastolic blood pressure as well as heart rate. While measuring heart rate, the device also determines the small variations between the individual heartbeats. If these variations exceed a pre-defined threshold, the irregular heart rate detector symbol lights up.

Systolic and diastolic pressure

The heart consists of two large chambers - the ventricles - and two smaller chambers - the atria. The ventricles collect blood from the atria and expel it towards the peripheral beds of blood vessels within the body and the lungs. The atria collect blood from these peripheral beds and prime the ventricles.

When the ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure (Fig. 3).

When the ventricles relax and are filled again with blood, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure (Fig. 4).

Blood pressure classification

Consult a doctor in case of questions about your blood pressure. The doctor can inform you:

- About your normal blood pressure range.
- If your measuring result falls out of the range.
- Whether your blood pressure has reached a dangerous level.

The following table shows the classification system for the blood pressure measurements used in this device. This system follows the classification system of the World Health Organisation (WHO).
Blood pressure classification according to WHO system*

<table>
<thead>
<tr>
<th>Systolic pressure mmHg</th>
<th>Diastolic pressure mmHg</th>
<th>Blood pressure indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥180</td>
<td>≥110</td>
<td>severe hypertension</td>
</tr>
<tr>
<td>160 - 179</td>
<td>90 - 109</td>
<td>moderate hypertension</td>
</tr>
<tr>
<td>140 - 159</td>
<td>90 - 99</td>
<td>high normal blood pressure</td>
</tr>
<tr>
<td>120 - 139</td>
<td>80 - 89</td>
<td>normal blood pressure</td>
</tr>
<tr>
<td>&lt; 120</td>
<td>&lt; 80</td>
<td>optimal blood pressure</td>
</tr>
</tbody>
</table>


Irregular heart rate detector

The device is equipped with an irregular heart rate detector for monitoring heart irregularities. Whenever the heart rhythm varies above a pre-defined level, the device will display the symbol indicating an irregular heart rate was detected. If the standard deviation exceeds a predefined threshold, the irregular heart rate symbol lights up when the measurement results are displayed.

Caution: The appearance of the irregular heart rate detector symbol indicates that an irregular heart rhythm was detected during measurement. Usually this is not a cause for concern. Due to the irregularity in your heart rate the blood pressure measurement might not be accurate, i.e. it might not reflect the ‘real’ situation in your body. However, if the symbol appears often, we recommend that you seek medical advice. Please note that the device does not replace a cardiac examination.

Preparing for use

Paring the blood pressure monitor to your mobile device

Note: To switch on the device for the first time, please refer to the Quick Start Guide.

Note: Before you use the device for the first time, remove the protective foil from the display.

The blood pressure monitor is equipped with Bluetooth. You can receive your personal health data on a mobile device that is equipped with the Bluetooth function. Download the Philips HealthSuite health app from the App store or Google Play. Use the search term ‘Philips HealthSuite health app’. The app is available for iOS 8.0 and Android 4.4.

Note: You can only use the Philips HealthSuite health app to communicate with the device. It is not possible to use third party applications.

Preparing for use

1. Download the Philips HealthSuite health app on your mobile device, start the Setup wizard and follow the steps to create a user profile and add the blood pressure monitor.

2. Make sure your mobile device is able to detect and connect to your blood pressure monitor via Bluetooth (no more than 5 meters from each other, in the same room).

3. With the device turned off, press the ‘on’ button for 3 seconds, until it is in pairing mode.

4. Keep the mobile device and the blood pressure monitor within transmission range (no more than 5 meters from each other, in the same room).

5. When pairing is successful, the display shows this symbol: (Fig. 8). The app shows which user profile is assigned to you.

6. If the connection fails, the display shows this symbol: (Fig. 9).

7. The blood pressure monitor has 2 user profiles. If both user profiles are in use, choose an existing profile to overwrite. You can also delete both user profiles by pressing and holding the user ID button for approx. 10 seconds. The display of the device shows ‘del’ and all stored data is deleted and you have to follow step 1-4 to pair and add a new user.

5. The blood pressure monitor shows the Bluetooth icon on the display as soon the connection has been established and switches off automatically after a few seconds.

Measuring blood pressure

Tips for proper measurement

- Rest for 5 minutes before you measure your blood pressure.

- Wait at least 10 minutes between measurements.

- This allows your blood circulation to recover.

Measuring blood pressure

Tips for proper measurement

- Rest for 5 minutes before you measure your blood pressure.

- Wait at least 10 minutes between measurements.

- This allows your blood circulation to recover.
- For a meaningful comparison, try to measure in similar circumstances.
- For a good Bluetooth connection between the blood pressure monitor and your mobile device, make sure the two are in close distance and there are no obstacles between the two devices.
- We recommend not to have the two devices further than 5 meters apart.
- We do not advise you to take a measurement under the following circumstances, as this may cause inaccurate measurement results:
- Within 1 hour after eating or drinking
- While you are talking or moving your arm, hand or fingers
- In a cold environment
- When you need to urinate

**Attaching the cuff**

- Remove any extra cloth such as watches and bracelets from your left arm.
- Note: if your doctor has diagnosed you with poor circulation or certain medical conditions, do not wear tight clothing, bracelets from your left arm.
- Also a guest user can be selected. The guest user is for performing a measurement on other persons without a user profile in the health app. Measurements performed when using the guest user are not stored in the memory nor transmitted to the app.
- Slide the cuff onto your left upper arm (Fig. 10). Make sure your sleeve is not too tight.
- Make sure you do not wear tight clothing during measurement.
- Sit comfortably with legs uncrossed, feet flat on the floor. Make sure that you sit upright with your back straight.
- The center of the cuff should be at the same level as the heart.
- Relax your wrist and hand. Do not bend your wrist back, clench your fist, or bend your wrist forward.

**Start measurement**

1. Press the user ID button (Fig. 11) or 'on' button (Fig. 13) to switch on the device. The device automatically selects the previous user for measurement. To switch to a different user profile, press the user ID button (Fig. 11) and select a different user (Fig. 12). The device will store results of 60 blood pressure measurements for both user 1 and 2.
2. Roll or push up your sleeve to expose the artery. Make sure your sleeve is not too tight.
3. Hold your arm with your palm facing up and slide the cuff onto your upper arm (Fig. 10).
4. Position the lower edge of the cuff about 2-3 cm above the crease of the elbow.
5. Fasten the cuff around your arm, leaving no extra room between the cuff and your skin. If the cuff is too loose, the measurement will not be accurate.
- The cuff will not cause any potential sensitization or irritation of the skin. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-1:2009, ISO 10993-5:2009 and ISO 10993-10:2010.
- The movement detector will light up when movement is detected. This may result in inaccurate measurement results.
4. When the measurement is finalized, the cuff deflates and the measurement results are shown on the display. The movement detector symbol, as well as heart rate. This is shown by the heart symbol.
5. The movement detector will light up when movement is detected.

**Tips for proper measurement**

- Make sure the correct user is selected, so the measurement data is processed and stored.
- It is not possible to change a user profile after a measurement has been performed.
- When the health app is open, the app automatically selects the correct user profile in the health app. Measurements performed when using the correct user profile or by closing the app and using the user ID button - also a guest user can be selected. The guest user is for performing a measurement on other persons without a user profile in the health app. Measurements performed when using the guest user are not stored in the memory nor transmitted to the app.
- The measurements can be seen on the display (Fig. 16). To transmit the measurement results to the app, see section Transmit and store personal health data in the app.
- Press the 'on' button to start the measurement (Fig. 12). All display characters are briefly shown (Fig. 15) once, to switch on the device. The device automatically selects the previous user. To change the user profile, press the user ID button (Fig. 11) once, to switch on the device. The movement detector will light up when movement is detected. This may result in inaccurate measurement results.
- During inflation, the unit determines the systolic pressure and diastolic pressure as well as heart rate. This is shown by the heart symbol.
- The movement detector will light up when movement is detected.
- When the measurement is finalized, the cuff deflates and the measurement results are shown on the display (Fig. 14). The device is ready for the next measurement.

**Transmit and store personal health data in the app**

1. Launch the Philips HealthSuite health app and Bluetooth on your mobile device directly after a measurement.
- Keep the mobile device and the blood pressure monitor at transmission distance (no more than 5 meters from each other, in the same room).
- You can find your Philips HealthSuite health app and Bluetooth on your mobile device directly after a measurement.
- The device can store results of 60 blood pressure measurements for both user 1 and 2. However, only your current measurement will be visible on the device screen. Your previous measurements will be visible in the app after syncing.
2 Once successfully connected, the measurement results are being transmitted to the health app and the Bluetooth symbol lights up.
- If the data transmission fails, the Bluetooth symbol together with 'Err' is shown. The performance of the measurement data that is transmitted to your mobile device the next time it connects with your blood pressure monitor. You can also try to resend the data:
  - Activate the health app on your mobile device.
  - Press the user ID button or 'on' button to switch on the blood pressure monitor.
  - The measurement results will be automatically sent to your mobile device if a user profile has been connected.
- When you successfully connect via Bluetooth to the app of a user, the device will automatically select that user and measurements can only be done for that user.

Cleaning and storage

Caution: This device is not washable. Never immerse the device in water and do not rinse it under running water.

Caution: Avoid violent movements and hard contacts with objects.

1 Switch off the device and unplug the adapter from the wall socket.
2 Use a slightly damp or dry cloth to wipe the surface of the display (Fig. 17).
3 Store the device in a cool, dry, and ventilated environment. For further information please refer to the transport and storage specifications detailed in this manual.

Recycling

- This symbol means that this product shall not be disposed of with normal household waste (2012/19/EU) (Fig. 18).
- This symbol means that this product contains a built-in rechargeable battery which shall not be disposed of with normal household waste (Fig. 19) (2006/66/EC). We strongly advise you to take your product to an official collection point or a Philips service center to have a professional remove the rechargeable battery.
- Follow your country’s rules for the separate collection of electrical and electronic products and rechargeable batteries. Correct disposal helps prevent negative consequences for the environment and human health.

Removing the rechargeable battery

Warning: This procedure is irreversible. You cannot use the device anymore after this process.

Note: We strongly advise you to take your product to an official collection point or a Philips service center to have a professional remove the battery.

Caution: Observe basic safety precautions when you follow the procedure described below. Be sure to protect your eyes, hands, fingers, and the surface on which you work.

1 Make sure the rechargeable battery is empty.
2 Open the device.
3 Remove the battery with appropriate tools.

Warranty and support

If you need information or support, please visit www.shop.philips.com/service or go to your Philips dealer. You can also contact the Philips Consumer Care Center in your country (see the international warranty leaflet for contact details).

Recalibration can be carried out by an appropriate authority or authorized service center. This calibration will be charged for by said authority. If you need more information about the app, please visit www.philips.com/healthprograms.

Troubleshooting

This chapter summarizes the most common problems you could encounter with the device. If you are unable to solve the problem with the information below, visit www.philips.com/support for a list of frequently asked questions or contact the Consumer Care Center in your country.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>My blood pressure fluctuates throughout the day</td>
<td>Your measurement position, the conditions under which you measure, or the time of measurement are different for each measurement.</td>
<td>For a meaningful comparison, try to take measurements under similar conditions. For example, take daily measurements at approximately the same date, on the same arm, or as directed by a doctor.</td>
</tr>
</tbody>
</table>
Problem: Fluctuations of blood pressure during the day are normal.

Possible cause: Blood pressure fluctuates from minute to minute and normally shows a circadian rhythm over a 24-hour period, with highest readings in the afternoon and lowest readings at night. That is why, for comparable measurements, the measurements should be taken at approx. the same time of day.

Solution: You are using medication. The variations in blood pressure can be greater if you are using medication.

You performed multiple measurements directly after each other. Wait at least 3 minutes between measurements. This allows your blood circulation to recover.

My blood pressure measurement from the hospital is different from the measurement at home. Multiple variables may affect your blood pressure such as the weather, emotions, and exercise. Pay attention when you measure your blood pressure at home. Check for instance: If the cuff is attached properly. If the cuff is not too tight or too loose. If the cuff is attached on the upper arm. If you feel anxious or stressed, try to relax. Take a deep breath 2-3 times before you start a measurement.

Advice: Rest for 5 minutes before you measure your blood pressure.

The result is different when I perform measurements on my right arm. The blood pressure monitor is suitable to be used on both arms, but the measurement results on the right arm and left arm will differ. For a meaningful comparison, try to measure under similar conditions and measure on the same arm every time.

The blood pressure monitor does not work when I press the ‘on’ button. The rechargeable battery is empty. Recharge the battery (see ‘Charging’).

The light of the display dims and a battery symbol + Lo is showing. The battery is low. Charge the battery (see ‘Charging’).

The display shows Err. Communication error. Check if the app is on and try data transmission again.

The display shows E3. The cuff is not properly secured. Refasten the cuff, wait 3 minutes and then measure again.

The display shows E10 or E11. The device detects motion, noise, or the heart rate is too weak during the measurement. Wait for 3 minutes and then measure again. Do not move during measurement.

The display shows E20. The device does not detect the heart rate signal. Make sure the device is in contact with the skin. Loosen the clothing on the arm and measure again.

The display shows E21. The measurement failed. Wait for 3 minutes and then measure again.

The display shows EExx. A system error occurred. Retake the measurement. If the error persists, contact the Philips Consumer Care Center in your country.

Data transmission or pairing failed. Bluetooth is off. Turn Bluetooth on your mobile device.

The Philips HealthSuite health app is off. Press the icon on your mobile device to activate the health app.
Problem: The blood pressure monitor and mobile device are more than 5 meters away from each other.

Possible cause: You selected the wrong profile on the blood pressure monitor.

Solution: Place your mobile device closer to the blood pressure monitor.

Problem: You selected the wrong profile on the blood pressure monitor.

Possible cause: You selected the correct user profile on the blood pressure monitor before your measurement.

Solution: Select the correct user profile on the blood pressure monitor before your measurement. Otherwise the data cannot be transmitted to your app. Repeat the measurement with the correct profile selected.

Specifications

Power supply
- 3.7V 1000mAH built-in rechargeable li-polymer battery
- 6V 1A DC charger

Display
- Display with white LED backlight
- Visible area = 86.1mm (L) x 24mm (W)

Measurement method
- Oscillometric method

Measurement range
- Rated cuff pressure: 0kPa-40kPa (0mmHg-300mmHg)
- Measuring pressure: 5.3kPa-30.7kPa (40mmHg-230mmHg)
- Heart rate: 40-199 beats per minute

Accuracy
- Temperature: 5°C-40°C within ±0.4kPa (3mmHg) hear rate ±5% of measurement result on display

Specifications

Temperature conditions
- Storage and transportation conditions
- Temperature: -20°C to 60°C. Relative humidity: 10% to 93%. Atmospheric pressure: 50kPa to 106kPa

Weight
- About 220mm x 420mm

Net weight
- Approx. 205g

External dimensions
- Approx. 130.9mm x 73mm x 29.4mm

Accessories
- DC charger, user manual

Mode of operation
- Continuous operation

Protection against ingress of water
- IP22. This means: protected against access to hazardous parts with a finger and against vertically falling water drops when filled up to 15 degrees.

Device classification
- Battery Powered Mode: Internally Powered ME. DC charger charged mode: Class II ME. External DC charger charged mode: Class II ME.

Frequency band
- 2402-2480 MHz

Modulation
- GFSK

Effective radiated power
- Max. +5dBm

Caution: No modification of this equipment is allowed.

Electromagnetic emissions and immunity

The device is approved according to EMC safety standard EN 60601-1-2. It is designed to be used in typical domestic environments.

Hereby, Philips Consumer Lifestyle BV declares that the radio equipment type Bluetooth LE is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address: www.philips.com/support

EMC Guidance
- The Blood Pressure Monitor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

- Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at a distance d = 3.3 m away from the equipment.

Note: As indicated in IEC 60601-1-2:2007 for ME equipment, a typical cell phone with a maximum output power of 2W (WCDMA) 1W (DC) has an immunity level of 3V/m.
Table 1 Guidance and manufacturer’s declaration – electromagnetic emissions

- for all ME equipment and ME systems

Guidance and manufacturer’s declaration – electromagnetic emissions
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assume that it is used in such an environment.

Emissions test: - Electromagnetic - guidance

<table>
<thead>
<tr>
<th>RF emissions</th>
<th>Group</th>
<th>The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No application</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Guidance and manufacturer’s declaration – electromagnetic immunity – for all ME equipment and ME systems

Guidance and manufacturer’s declaration – electromagnetic immunity
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test: - Electromagnetic immunity

<table>
<thead>
<tr>
<th>Electromagnetic immunity test level</th>
<th>Compliance level</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 60601-1</td>
<td>Mains power quality should be at levels characteristic of a typical location in a commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 60601-4-2</td>
<td>Mains power quality should be at levels characteristic of a typical location in a commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 60601-4-3</td>
<td>Mains power quality should be at levels characteristic of a typical location in a commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 60601-4-6</td>
<td>Mains power quality should be at levels characteristic of a typical location in a commercial or hospital environment.</td>
</tr>
</tbody>
</table>

Note: UT is the AC mains voltage prior to application of the test level.

Table 4 Guidance and manufacturer’s declaration – electromagnetic immunity –for ME equipment and ME systems that are not life-supporting

Guidance and manufacturer’s declaration – electromagnetic immunity
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assume that it is used in such an environment.

Immunity test: IEC 60601-4-3

<table>
<thead>
<tr>
<th>Compliance level</th>
</tr>
</thead>
<tbody>
<tr>
<td>80 MHz</td>
</tr>
<tr>
<td>150 kHz – 40 MHz</td>
</tr>
<tr>
<td>80-100 MHz</td>
</tr>
</tbody>
</table>
the equation applicable to the frequency of the transmitter.

Recommended separation distance:

\[ d = 1.2 \sqrt{P} \]

\[ 80 \text{ MHz to } 800 \text{ MHz} \]

\[ d = 2.3 \sqrt{P} \]

\[ 800 \text{ MHz to } 2.5 \text{ GHz} \]

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, 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.

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