Dario Blood Pressure Monitoring System

Ver. 1.0
2019/05

Operation Instructions

Distributed by **DarioHealth Corp.**
142 W. 57th Street, 8th Floor
New York, NY 10019
Made in Taiwan
Toll Free:1-800-895-5921(Mon to Fri / 9am to 5pm EST)
For assistance outside of these hours, please contact your healthcare professional.

Read instructions before use.
Keep away from sunlight.
311-3128200-010

Dear Dario Blood Pressure System Owner:

Thank you for purchasing the Dario Blood Pressure Monitoring System. This manual provides important information to help you to use this system correctly. Before using this product, please read the following contents thoroughly and carefully.

With the compact size and easy operation of this Dario Blood Pressure Monitoring System, you can easily monitor your blood pressure by yourself at any time or place. In addition, this system can help you and your healthcare professionals to monitor and adjust your treatment plans, and keep your blood pressure under control.

If you have other questions regarding this product, please contact the place of purchase.

IMPORTANT SAFETY PRECAUTIONS

READ THIS BEFORE USE

1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or damaged.
4. Do **NOT** use under any circumstances on newborns or infants.
5. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured are for reference only. Always consult your doctor to have the results interpreted.
6. Keep the equipment and its flexible cord away from hot surfaces.
7. Do **NOT** apply the cuff to areas other than the place directed.
8. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
9. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
10. Proper maintenance is essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact local customer service for help.

KEEP THESE INSTRUCTIONS

BEFORE YOU BEGIN

INTENDED USE

The Dario 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. This system should only be used for the testing on people over 18 years of age and over.

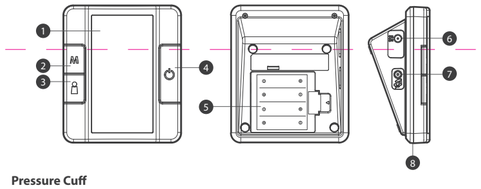
The Dario Blood Pressure Monitoring System (model no. DH-1160) provides Bluetooth transmission.

TEST PRINCIPLE

Blood pressure is measured non-invasively at the arm based on oscillometric method.

This device is **NOT** able to take measurements in the presence of common arrhythmia, such as atrial or ventricular premature beats or atrial fibrillation. It may produce reading error.

METER OVERVIEW



Pressure Cuff

1 DISPLAY SCREEN

2 M BUTTON
Enter the meter memory.

3 USER SELECTION BUTTON
Assist you with user number selection.

4 ON/OFF BUTTON

5 BATTERY COMPARTMENT

6 AC ADAPTER PORT
Connect to a power supply.

7 AIR JACK

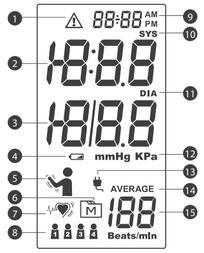
8 BT INDICATOR
Download test results with a Bluetooth connection.

9 PRESSURE CUFF

10 AIR TUBE

11 AIR PLUG
Connect to air jack.

DISPLAY SCREEN



1 Error Warning
2 Systolic Pressure Value
3 Diastolic Pressure Value
4 Low Battery Symbol
5 Movement During Measurement
6 Memory Mode Symbol
7 Pulse Rate Symbol
8 User Number
9 Time & Date
10 Systolic Pressure Symbol
11 Diastolic Pressure Symbol
12 Units of Blood Pressure
13 AC Adaptor Symbol
14 Average
15 Pulse Rate

SETTING THE METER

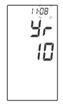
Before using your meter for the first time or if you change the meter battery, you should check and update these settings. Make sure you complete the steps below and save the desired settings.

Entering the Setting Mode

Start with the meter off. Press and firmly hold ⓘ for 3 seconds until the meter turns on.

Setting the Date and the Time

With the year flashing, press Ⓜ until the correct year appears. Press ⓘ to set.



With the month flashing, press Ⓜ until the correct month appears. Press ⓘ to set.

With the day flashing, press Ⓜ until the correct day appears. Press ⓘ to set.

With the hour flashing, press Ⓜ until the correct hour appears. Press ⓘ to set.

With the minute flashing, press Ⓜ until the correct minute appears. Press ⓘ to set.

Setting the Time Format

Press Ⓜ to select the desired time format --- 12h or 24h. Press ⓘ to set.

Setting the Unit of Measurement

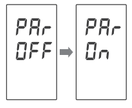
Press Ⓜ to select mmHg or KPa. Press ⓘ to set.

Delete The Memory

While "dEL" and a flashing "M1" symbol appears on the display, if you do not wish to delete the saved results, press ⓘ to skip this step.

To delete ALL the results, press Ⓜ twice. "CLr "and "M1" are displayed on the meter, which indicates that all results have been deleted.

Enter the Bluetooth Pairing



NOTE
This step is recommended when the user needs to pair this meter to a Bluetooth receiver for the first time, or when user needs to pair this meter to another new Bluetooth receiver.

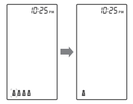
If you wish to enter the pairing mode, with "**PAr OFF**" shows on the meter, press Ⓜ once and the meter will display "**PAr On**" to enable Bluetooth pairing mode.

Congratulations! You have completed all settings!

NOTE
- These parameters can **ONLY be changed** in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will turn off automatically.

USER NUMBER SELECTION

This system stores blood pressure measurements for up to four users. Each user's test results are stored separately under each user number.



1. Press ⓘ to select the desired user number.
2. Press ⏻ to confirm. The monitor will repeat the selected user number and then turn off automatically.

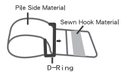
TESTING YOUR BLOOD PRESSURE

BEFORE MEASUREMENT

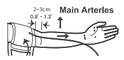
- Avoid caffeine, tea, alcohol and tobacco for at least 30 minutes before measurement.
- Wait 30 minutes after exercising or bathing before measurement.
- Sit or lie down for at least 10 minutes before measuring.
- Do not measure when feeling anxious or tense.
- Take a 5-10 minutes break between measurements.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

FITTING THE CUFF PROPERLY

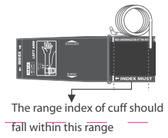
1. Connect the air plug of the tubing to the air jack of the meter.
2. Assemble the cuff as shown. The smooth surface should be inside of the cuff loop and the metal D-ring should not touch your skin.



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 toward the lower arm.
   Wrap and tighten the cuff above your elbow. The bottom edge of the cuff should be approximately 0.8" to 1.2" (2 cm 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 two fingers between them. Clothing must not restrict the arm. Remove all clothing covering or constricting the measurement arm.



The range index of cuff should fall within this range

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.

Press ⏻. Remain still and do not talk or move during the measurement.

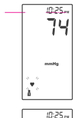
WARNING
If the cuff is relatively lower (higher) than the heart, the obtained blood pressure value could be higher (lower) than the actual value. A 15 cm difference in height may result in an error around 10 mmHg.

4. Measurement is in progress. After the meter is turned on, the cuff will begin to inflate automatically.

TAKING MEASUREMENTS

Always apply the pressure cuff before turning on the meter.

1. Press ⏻. All the LCD symbols will appear. Press ⓘ to select user "ᵃ ᵃ ᵃ ᵃ" (numbers from 1 to 4) whose test reading will be stored in its memory. Then the cuff will begin to inflate automatically.



2. The heart symbol "♥" will flash when pulse is detected during the measurement.

3. After the measurement, the meter displays the systolic pressure, diastolic pressure and pulse rate.

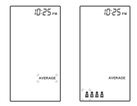
4. Press ⏻ to switch off or it will switch off automatically after being idle for 3 minutes.

5. The meter will enter Bluetooth mode automatically.

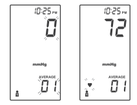
NOTE
- If you press ⏻ during measurement, the meter will be turned off.
- If the pulse rate symbol is shown as "♥" instead of "♥", this indicates that the meter has detected an irregular heart beat.

AVERAGING MEASUREMENT MODE

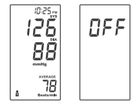
Always apply the pressure cuff before turning on the meter.



1. Press and hold ⏻ until the meter displays "AVERAGE", then press ⓘ to select user "ᵃ ᵃ ᵃ ᵃ" (numbers from 1 to 4) whose test reading will be stored in its memory. Then the cuff will begin to inflate automatically.



2. After the first measurement is completed, the meter will start counting down before the second measurement begins. The number on the right represents the remaining countdown between each measurement. The meter will take three (3) measurements consecutively with intervals of 20 seconds.



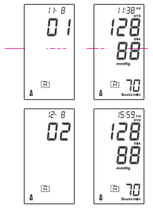
3. After taking three measurements, the results are averaged to produce the blood pressure measurement with "AVERAGE" symbol display on the meter. Press ⏻ to turn off the meter.

METER MEMORY

Your meter stores the 400 most recent blood pressure test results along with respective dates and times in the meter memory. To recall the memory, **start with the meter off.**

REVIEWING TEST RESULTS

1. Press and release Ⓜ
The user symbol ᵃ ᵃ ᵃ ᵃ (numbers from1 to 4) appears first, press ⓘ to select which one you used to store in the memory.
Press Ⓜ again, and the first reading you see is the last blood pressure result along with date and time.



2. Press Ⓜ again, and the first reading you see is the last blood pressure result along with date and time.

3. Press Ⓜ
Review all test results stored in the meter.

4. Exit the memory
Press ⏻ and the meter will turn off.

APP CONNECTION

Data Transmission via Bluetooth

You can transmit your blood pressure monitoring data from the meter to your smart mobile device via Bluetooth. Please contact your local customer service or place of purchase for assistance.

Please note that you must complete the pairing between meter and Bluetooth receiver before transmitting data.

NOTE
Only data of user number 1 is transmitted to the mobile app. Make sure the correct user number is selected during measurement to allow proper data transmission.

Pairing with your mobile device

1. Turn on the Bluetooth function on your mobile device.
2. Start with the meter off. Press and firmly hold Ⓜ for 3 seconds until the meter turns on. " PCL" will appear on the meter.
3. Open your Dario App on your mobile device. Go to MENU -> SETTINGS -> CONNECTED APPS & DEVICES. Enable the "Dario Blood Pressure Monitoring System" connection and follow the app instruction for pairing.
4. After successfully pairing the app with the device, the Bluetooth function of meter shall be on before transmitting the data to your app.

Bluetooth indicator on the blood pressure monitor:

BLUETOOTH INDICATOR	STATUS
Flashing Blue	The Bluetooth function is on and waiting for connection.
Solid Blue	The Bluetooth connection is established.

NOTE
- While the meter is in transmission mode, it will be unable to perform a blood pressure test.
- Make sure your device supports Bluetooth Smart Technology. Also make sure the Bluetooth setting on your device is turned on and the monitor is within the receiving range before transmitting the data. Please find OS version requirement on App Store or Google Play when you download the app.
- The Bluetooth functionality is implemented in different ways by the various mobile device manufacturers, the compatibility issue between your mobile device and the meter maybe occur.

MAINTENANCE

BATTERY

Your meter comes with four (4)1.5V AA size alkaline batteries.

Low Battery Signal

The meter will display either of the two messages below to alert you when the meter power is getting low.

1. The ▭ symbol appears along with display messages:
The meter is functional and the result remains accurate, but it is time to change the batteries.

2. The ▭ symbol appears with E-b:
The power is not enough to do a test. You must change the batteries immediately.

Replacing the Battery

To replace the batteries, make sure the meter is turned off.

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

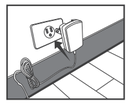
NOTE

- Replacing the batteries does not affect the test results stored in memory.
- As with all small batteries, these batteries should be kept away from small children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused for a long time. Remove the batteries if you are not going to use the device for an extended period (i.e., 3 months or more).
- Properly dispose of the batteries according to your local environmental regulations.

USING AC ADAPTER

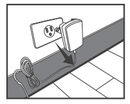
Connect AC adapter to the meter.

1. Connect **AC** adapter plug to DC adapter jack of the meter.



2. Plug **AC** adapter power plug into an electrical outlet.
Press ⏻ to start the measurement.

Remove AC adapter from the meter.



1. **When the meter is off,** remove **AC** adapter power plug from the electrical outlet.

2. Disconnect **AC** adapter plug from **DC** adapter jack of the meter.

CARING FOR YOUR METER

To avoid the meter attracting dirt, dust or other contaminants, wash and dry your hands thoroughly before use.

Cleaning

- To clean the meter 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 meter.
- Do NOT wash the pressure cuff.
- Do NOT iron the pressure cuff.

Meter Storage

- Storage condition: -25°C to 70°C (-13°F to 158°F), 10% to 95% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping or heavy impact.
- Avoid direct sunlight and high humidity.

DETAILED INFORMATION

REFERENCE VALUES

Clinical studies show that adult diabetes is often accompanied by elevated blood pressure. People with diabetes can reduce their heart risk by managing their blood pressure along with diabetes treatment*1.

Monitoring your routine blood pressure trend helps you to know your body condition. Human blood pressure naturally increases after reaching middle age. This symptom is a result of continuous ageing of the blood vessels. Further causes include obesity, 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. The recommended blood pressure range is as below:

Classification	Systolic Pressure (mmHg)	Diastolic Pressure (mmHg)
Hypotension*2	Less than 90	Less than 60
Normal*3	Less than 120	Less than 80
Pre-hypertension*3	120 – 139	80 – 89
Stage 1 Hypertension*3	140 – 159	90 – 99
Stage 2 Hypertension*3	160 or more	100 or more

*1. American Diabetes Association: The Diabetes-Heart Disease Link Surveying Attitudes, Knowledge and Risk (2002)

*2: National Heart, Lung, and Blood Institute, Diseases and Conditions

*3: The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication. 2003. No. 03-5233

SYSTEM 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. Do not attempt to repair by yourself and never try to disassemble the meter under any circumstances.

ERROR MESSAGES

MESSAGE	CAUSE	WHAT TO DO
⚠ E-1	Inflation or pressure error.	Please contact local customer service for help.
⚠ E-4	Blood pressure measurement error.	Refit cuff tightly and correctly. Relax and repeat the measurement. If error still remains, contact local customer service for help.
⚠ E-5	Appears when the cuff deflates too slow.	Please contact local customer service for help.
⚠ E-6	Appears when the cuff deflates too fast.	
⚠ E-A	Problems with the meter.	Review the instructions and repeat the test. If the meter still does not work, please contact the local customer service for help.
⚠ E-E		
⚠ E-b ▭	Batteries are too low.	Repeat with new batteries or input AC adapter.
⚠ E-A bt	Bluetooth transmission errors.	Please contact local customer service for help.

TROUBLESHOOTING

1. If no display appears after pressing ⏻.

POSSIBLE CAUSE	WHAT TO DO
Batteries exhausted.	Replace the batteries.
Batteries incorrectly installed or absent.	Check that the batteries are correctly installed.

2. If the heart rate is higher/lower than user's average:

POSSIBLE CAUSE	WHAT TO DO
Movement during measurement.	Repeat measurement.
Measurement taken just after exercise.	Rest at least 30 minutes before repeating measurement.

3. If the result is higher/lower than user's average measurement:

POSSIBLE CAUSE	WHAT TO DO
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.

4. If the cuff inflates again while measuring:

POSSIBLE CAUSE	
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.	

5. If the measurement is not transmitted to the mobile app:

POSSIBLE CAUSE	WHAT TO DO
Mobile App is not connected.	Follow the steps in the "APP CONNECTION" section to connect the monitor to the mobile App.
Measurement is not done on user number 1.	Select user 1 and measure again.
App is not open while taking a measure.	Make sure that while taking a measurement the mobile app is open and within a distance of up to 3 fit from the monitor.

SPECIFICATIONS

SYSTEM PERFORMANCE

Model no.: DH-1160

Power Source: Four 1.5V AA alkaline batteries

Size of Meter w/o Cuff: 141 (L) x 121 (W) x 72 (H)mm, 350g without batteries.

Cuff Size: M (medium): 24-35 cm (9.4-13.8 inches) with air tube 80 cm

Memory: Maximum 400 memory records

External Output: Bluetooth

Power Saving: Automatic power off if system idle for 3 minutes

Operating Conditions: 5°C to 40°C (41°F to 104°F), 15% to 93% relative humidity, 700 hPa to 1060 hPa

Storage / Transportation Conditions: -25°C to 70°C (-13°F to 158°F), 10% to 95% relative humidity

Power Supply Input: DC + 6V / 1A (max) via Power Plug

IP Classification: IP21

Expected Service Life: 3 years

BLOOD PRESSURE MEASUREMENT PERFORMANCE

Systolic Measurement Range: 60 mmHg -255 mmHg

Diastolic Measurement Range: 30 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

Measurement Unit: Either mmHg or KPa

This device has been tested to meet the electrical and safety requirements of:
IEC/EN 60601-1, IEC/EN 60601-1-2, EN 301 489-17, EN 300 328.

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

FEDERAL COMMUNICATIONS COMMISION (FCC) STATEMENT

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

Federal Communications Commission (FCC) Statement
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) This device may not cause harmful interference and B1-30 of 31.

2) This device must accept any interference received, including interference that may cause undesired operation of the device.

FCC RF Radiation Exposure Statement:

1. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator radiation source and your body.

Manufacturer's declaration-electromagnetic emissions

The DH-1160 is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the DH-1160 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance (for home healthcare environment)
RF emissions CISPR 11	Group 1	The DH-1160 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The DH-1160 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance	

Manufacturer's declaration-electromagnetic immunity

The DH-1160 is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the DH-1160 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home healthcare environment)
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	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV, ±2kV line(s) to earth	± 0.5kV, ±1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T: 0,5 cycle 0 % U_T: 1 cycle 70 % U_T: 25/30 cycles Voltage interruptions: 0 % U_T: 250/300 cycle	Voltage dips: 0 % U_T: 0,5 cycle 0 % U_T: 1 cycle 70 % U_T: 25 cycles Voltage interruptions: 0 % U_T: 250 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of the DH-1160 requires continued operation during power mains interruptions, it is recommended that the DH-1160 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	The DH-1160 power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

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

Manufacturer's declaration-electromagnetic immunity

The DH-1160 is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the DH-1160 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home healthcare environment)
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of the** DH-1160 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Interference may occur in the vicinity of equipment marked with the following symbol: ((•))
Radiated RF IEC 61000-4-3	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	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DH-1160 is used exceeds the applicable RF compliance level above, the DH-1160 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DH-1160.
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the DH-1160

The DH-1160 is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the DH-1160 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DH-1160 as recommended below, according to 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	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	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) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

The DH-1160 is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the DH-1160 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) (for home healthcare)
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
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
1 720 1 845 1 970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240 5 500 5 785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9

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.