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B.Well
Caring for everyone

Instruction for use

MED-55

Automatic Upper Arm
Blood Pressure Monitor

B.WELL SWISS CONTROLLED

1. INTRODUCTION

Thank you for purchasing the B.Well upper arm blood pressure monitor MED-55. Designed for convenient and easy operation, this device provides fast and reliable measurement of systolic and diastolic blood pressure as well as heart rate using the oscillometric measurement method.

The MED-55 is a fully automatic, digital, upper arm blood pressure measuring device. Important advantages of MED-55:

- 3check mode: intellectual analysis of three consecutive measurements.
- Colored display backlight indicates the level of blood pressure.
- Up-to-date Intellect Active technology uses oscillometric measurement during inflation for quick, precise and gentle result.
- Memory of 60 measurements for each of 2 users
- Traffic Light Indication according to European Society of Hypertension (ESH).
- The Pulse Arrhythmia Detection technology.
- Cuff check indicator: the device shows if the cuff is properly applied.
- Date and Time.
- Fan-shape anatomic cuff for arm, washable.
- The possibility to use Micro USB adapter.

2. CLASSIFICATION OF BLOOD PRESSURE VALUES

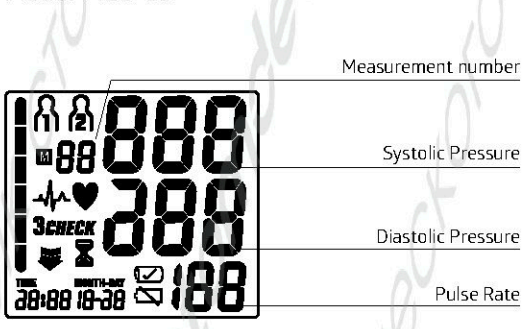
Table for classifying blood pressure values (mmHg) according to European Society of Hypertension (ESH)

Range	Systolic blood pressure	Diastolic blood pressure	Measures
Grade 3: severe hypertension	Higher or equal to 180	Higher or equal to 110	Urgently seek medical advice!
Grade 2: moderate hypertension	160-179	100-109	Consult your doctor immediately
Grade 1: mild hypertension	140-159	90-99	Consult your doctor
High normal	130-139	85-89	Consult your doctor
Normal	Lower than 130	Lower than 85	Self-check
Optimal	Lower than 120	Lower than 80	Self-check

NOTE: Show the measured values to your doctor. Never use the results of your measurements to change the doses of drugs prescribed by your doctor.

3. CONTENTS AND DISPLAY INDICATORS

Model MED-55



Memory Symbol
Indication of blood pressure level
Pulse Arrhythmia Detection symbol
Heart beat symbol
Air release symbol
User 1, 2
3CHECK 3check mode
resting time in-between measurements in 3check mode
Cuff position control symbol
Low battery symbol
TIME MONTH-DAY Date and time



4. INTENDED USE

The digital automatic blood pressure monitor is suitable for home healthcare environment and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22 cm-42 cm.

5. CONTRAINDICATION

It is inappropriate for people with skin wounds on upper arms.

6. PRECAUTIONS

1. Before use, please read this instruction manual carefully.
2. In case of questions on the use of blood pressure monitor and resulting blood pressure values, please contact a doctor.
3. Keep MED-55 out of the reach of children.
4. Do not use MED-55 near anesthetic, flammable or oxygen mixture, or with nitrous oxide.
5. Do not forget: self-measurement means control, not diagnosis or treatment. Unusual values must always be discussed with a doctor. Under no circumstances a treatment should be altered or changed without a doctor's prescription.
6. The pulse display is not suitable for checking the frequency of heart pacemakers.
7. In cases of cardiac irregularity (I.H.B.), measurements made with this device should only be evaluated after consultation with a doctor.
8. Changes to the unit by the user are not admitted.
9. We recommend consulting a doctor before using the blood pressure monitor on patients with pre-eclampsia or during pregnancy.
10. The device does not require any calibration.
11. Tubing kinking can cause continuous cuff pressure and may result in blood flow interference and patient injury.
12. Too frequent measurements can cause injury to the patient due to blood flow interference.
13. Please note that, when inflating, the functions of the limb in question may be impaired.
14. During the blood pressure measurement, the blood circulation must not be stopped for an unnecessarily long time.
15. If the device malfunctions remove the cuff from the arm.
16. The user must check that the equipment functions safely and see that all its parts are in proper conditions before use.
17. Please always relax a minimum moment of 1-1,5 minutes between measurements to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceed 300 mmHg or maintained above 15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your arm.
18. Consult your physician if you have any doubt about below cases:
    1) The application of the cuff over a wound or inflammation diseases;
    2) The application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present;
    3) The application of the cuff on the arm on the side of a mastectomy;
    4) Simultaneously used with other monitoring medical equipments on the same limb.
19. ⚠ This automatic blood pressure monitor is designed for adults and should never be used on infants or young children. Consult your physician or other health care professionals before use on older children.
20. Do not use this unit in a moving vehicle. This may result in erroneous measurement.
21. Blood pressure measurements determined by this monitor are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard Institute, Electronic or automated sphygmomanometers.
22. Information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices together with advice regarding avoidance of such interference please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION.
23. Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.

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24. ⚠ The monitor might not meet its performance specifications or cause safety hazard if stored or used outside the specified temperature and humidity ranges in specifications.
25. ⚠ Please do not share the cuff with other infective person to avoid cross-infection.
26. 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.

7. SETUP AND OPERATING PROCEDURES

7.1. Inserting the batteries

a. Remove the battery cover from the battery compartment.
b. Insert four AAA powerful batteries into the compartment and ensure each battery is in the proper direction.
c. Replace the battery cover.
⚠ After the low battery warning symbol "▭" appears, the device is blocked until the batteries have been replaced.
Please use "AAA" Long-Life 1.5 V batteries.

⚠ Rechargeable batteries are not suitable for this monitor.
⚠ Never leave any low battery in the battery compartment since they may leak and cause damage to the unit. If the blood-pressure monitor is left unused for long periods, please remove the batteries from the device.
⚠ Avoid the battery fluid to get in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.

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

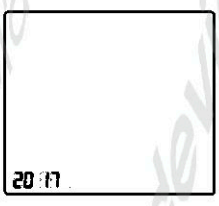
7.2. Using a mains adapter

1) Plug the mains adapter into a 110-240 V, 50/60Hz power socket.
2) Plug the Micro USB plug into the USB port at the left side of the device.
Micro USB port is for power supply only. The USB port can't be used for data downloading.

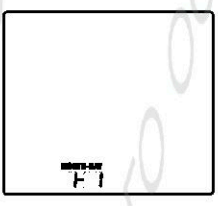
⚠ If you need an adapter, you may purchase it separately. B.Well recommends to use the B.Well Micro USB adapter for MED-55 device. Please use certified Micro USB adapters which output is 6V DC 600 mA.

7.3. Setting time and date

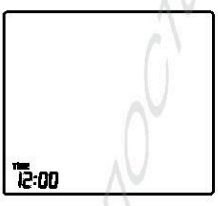
a. Once batteries are inserted and device still in OFF mode, years digit blinks on the display. See picture 3-1.
b. Press "M1" button to advance the year or "M2" button to decrease the year. If you keep the button depressed for more than 3 seconds, you can switch more quickly to the desired digit.
c. Press "Time" button to confirm and switch to the month value. See picture 3-2.
d. Press "M1" button to advance the month or "M2" button to decrease the month.
e. Repeat the above described procedure to set day, hour and minutes.
See picture 3-3.
f. At the end of the procedure, press "Time" button to confirm current setting and go in OFF mode.
The display will now show clock and date. If you need to correct the time or date press and hold "Time" for 3 seconds until years digit blinks on the display. Every time batteries are changed, time and date settings are kept.



Picture 3-1



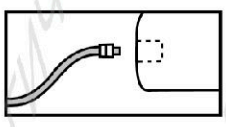
Picture 3-2



Picture 3-3

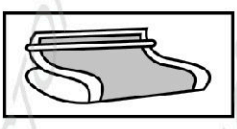
7.4. Connecting the cuff to the monitor

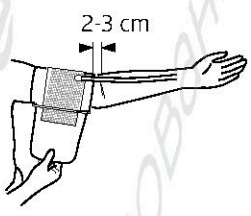
a. Insert the Air tube plug firmly into the Air tube socket on the side of the monitor. Make certain that the Plug is completely inserted in order to prevent air leakage during use.
⚠ Avoid compression or restriction of the connection tubing during measurement, which may cause inflation error, or harmful injury due to continuous cuff pressure.



7.5. Applying the cuff

a. Remove any garment that fits closely to your upper arm.
b. Pulling the cuff end through the medal loop (the cuff is packaged like this already), turn it outward (away from your body) and tighten it and close the Velcro fastener.
c. Place a cuff around a naked hand 2-3 cm higher than an elbow pole. Arrange a cuff on a hand so that the red tag (Artery mark) is over an elbow pole.
d. There must be no free space between the arm and the cuff. Clothing must not restrict the arm. Any piece of clothing which does (e.g. a pullover) must be taken off. The cuff has to cover densely a hand, otherwise the result of measurement will be the improper.





7.6. Carrying out a measurement

Before the measurement:

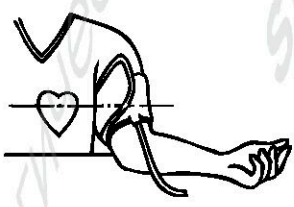
- Avoid eating, smoking as well as all forms of exertion directly before the measurement. All these factors influence the measurement result. Try and find time to relax by sitting in an armchair in a quiet atmosphere for about ten minutes before the measurement.
- Measure always on the same arm.
- Attempt to carry out the measurements regularly at the same time of day, since the blood pressure changes during the course of the day.

Sitting Comfortably Measurement:

a. Be seated with your feet flat on the floor, and don't cross your legs.
b. Place palm upside in front of you on a flat surface such as a desk or table. Make sure to be sit in a comfortably position with your arms extended and back leaning on the seatback.
c. The middle of the cuff should be at the level of the heart. To avoid errors in the measurement, it is important to remain immobile during the measurement and in silence.

Common sources of error:

- Movement during measurement
- The arm artery lies considerably lower (higher) than the heart
- The cuff does not fit you in size
- Loose cuff or a sideways protruding air-pocket



ⓘ **Warning:** Only use original cuffs!
With repeated measurements, blood accumulates in the respective arm, which can lead to false results. Correctly executed blood pressure measurements should therefore first be repeated after a 1 minute pause.

7.7. Specifying user

Press "Time" button to select the user. Press "Time" button to switch between User 1 and User 2. The pre-selected user blinks.
MED-55 is designed for two users and can store up to 60 blood pressure readings for each user.

7.8. Measurement mode selection

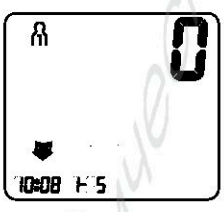
a) **"3check" mode.**
To select the "3check" mode measurement, please slide the switch to the upside toward "3check".
"3check" mode takes generally 3 measurements in succession and calculates the result.
The "3check" symbol in the display indicates that the device is set to the «3check» mode.
b) **Single mode.**
To take a single measurement, please slide the switch toward no. 1. Single mode has 1 measurement.
c) **Guest mode.**
This mode can be used to take a measure for another user.

Press and hold "Start" button for more than 3 seconds. The Time/Date information disappear on the display. Release the "Start" button and the arm cuff starts to inflate automatically. After measurement is taken, the cuff deflates and the values are shown on the display illuminated with WHO color. No values are stored in the memories.
Both single measurement mode and "3check" mode are availabe for measuring in Guest mode.

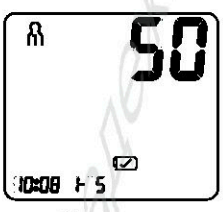
7.9. Taking your blood pressure reading

a. After the cuff has been appropriately positioned, press "Start" button to start measure. "0" appears in "DIA" field: the monitor is ready for the measurement. See Picture 7-1.
b. Cuff inflation starts and display shows increasing pressure values in "DIA" field. The "Cuff position control" symbol is displayed throughout the entire measurement. See Picture 7-2. If the cuff is applied too tightly or too loosely, then the Error symbol E3 is displayed and the "Cuff position control" symbol is blinking.
c. As the heartbeat is detected, the "Heart beat" symbol blinks and a beeping sound is generated at the same rhythm of the heartbeat. When the measurement is completed, cuff is deflated.
d. When the device is set to 3check mode, generally 3 separate measurements will take place in succession and calculates your detected blood pressure value. There will be 15 seconds resting time in-between each measurement.
A count down indicates the remaining time and a beep will sound 5 seconds before the 2nd and 3rd reading begin. In the case where a single piece of data from each cycle differs too much from each other, a fourth measurement is performed before the result will be displayed. After all the measurements are completed the display shows the result.
e. In single measurement mode after the first measurement is completed and cuff is deflated the display shows the systolic/diastolic pressure and pulse.
f. The backlight of the display is lighted according to WHO color scale and WHO segments are displayed according to the measured values.
g. The appearance of the Pulse Arrhythmia Detection symbol signifies that an irregular heartbeat was detected. See Picture 7-3.
h. The measurement value will be automatically stored. If the measurement was taken in "3check" mode the symbol "3check" will appear on the display with the measurement result.
i. After measurement, the monitor will turn off automatically after 1 minute of no operation. Alternatively, you can press the "Start" button to turn off the monitor manually.
During measurement, you can press the "Start" button to turn off the monitor manually.

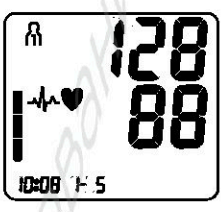
ⓘ **NOTE:** Please consult a health care professional for interpretation of pressure measurements.



Picture 7-1



Picture 7-2



Picture 7-3

7.10. Pulse Arrhythmia Detection

The appearance of the symbol signifies that a certain pulse irregularity was detected during the measurement. The result can vary from your normal blood pressure. It is better to repeat the measurement. As a rule this is not a cause for concern; however, if the symbol appears more frequently (e.g. several times per week on measurements performed daily) or if it suddenly appears more often than usual, we recommend you inform your doctor.

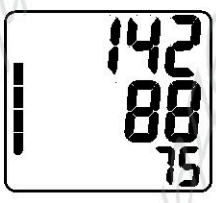
7.11. Traffic Light Indication

The colored bars on the left-hand edge of the display show you the range within which the indicated blood pressure values lies. Depending on the height of the bar, the readout value is either within the normal (green), borderline (yellow and orange) or danger (red) range. If the values of systole and diastole fall into two different categories (e.g. systole in the High normal category and diastole in the Normal category), the graphical classification on the device always shows the higher category (e.g. High).
The classification corresponds to the 6 ranges in the Table as defined by the ESH and described on the table of the point 2. The recommendations of the European Society of Hypertension (ESH) allow to diagnose and treat the hypertension more effectively and do not contradict World Health Organization recommendations.
Please note that these standard values serve only as a general guideline, as the individual blood pressure varies in different people and different age groups etc., it is important to consult your doctor regularly for advice.
Additionally, the colours on the display differ according to the readings. If, for example, the readings are in the range of 1, 2,3 the display light is green, in the range of 4,5 the light is yellow, and in the range of 6 the display light is red.

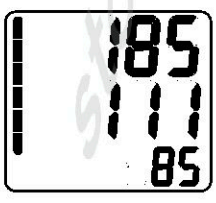
Red
Orange
Yellow
Green
Green
Green



Red
Orange
Yellow
Green
Green
Green



Red
Orange
Yellow
Green
Green
Green

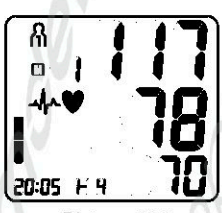


7.12. Displaying stored results

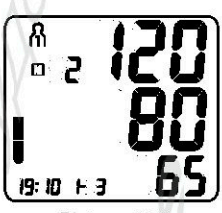
a. In mode OFF, press "M1" or "M2" button to show saved values.
b. The total number of registered measures is shown briefly on the display. See Picture 10-1.
c. Then latest values measured are displayed. See Picture 10-2.
d. By pressing "M1"/"M2" the last but one measure is shown. See Picture 10-3. Keep press the memory button for more than 3 seconds to scroll faster the recorded values.
e. The device automatically switches off after one minute or by pressing "Start" button.
When the memory for any of two users has stored 60 results, the memory is full. From this point onwards, a new measured value is stored by overwriting the oldest value.



Picture 10-1



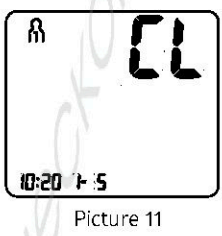
Picture 10-2



Picture 10-3

7.13. Deleting measurements from the memory

If you are sure that you want to permanently remove all stored values, press and hold down "M1" and "M2" together until "CL" appears then release the button. See Picture 11. Press again "M1" or "M2" to reconfirm the choice and clean all the memories or "Start" button to exit the procedure and turn off the device.
After confirmation, "CL" icon is blinking and beeping sounds indicate successful clearance, then device switches off automatically.
Individual values cannot be cleared.



Picture 11

7.14. Technical alarm description.

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

7.15. Troubleszhooting (1)

In case of error indication, follow the below recommended actions and press "Start" button to initiate another measurement:

PROBLEM	POSSIBLE CAUSE	RECOMMENDED ACTION
E1	Pulse was not correctly recorded	Movement can compromise the measurement. Loosen the clothes on the arm, relax for a moment and try again
E2	Inaccurate reading	
E3	The cuff is not correctly fastened	Re-apply the cuff and try again
E5	Pump pressure is too high	Relax for a moment and try again
E6	System error	Repeat the reading. If the problem persists, contact the Customer Service

7.16. Troubleshooting (2)

PROBLEM	POSSIBLE CAUSES	RECOMMENDED ACTION
The display shows the symbol "low battery"	Batteries are drained	Replace all batteries with new ones
The blood pressure values displayed are abnormally high or low	The cuff is not wrapped correctly or not at the level of the heart	Wrap the cuff correctly and raise your hand so that the cuff is at the same level of your heart
	Too much stress is applied on your shoulder or arm	Relax yourself and make measurement
	You move your arm or arm muscles during measurement	Remain still and do not move / contract the muscles during measurement
The "Pulse Arrhythmia Detection" symbol is displayed, but my heart beat rate should be normal	You move your arm or arm muscles during measurement	Remain still and do not move / contract the muscles during measurement

8. MAINTENANCE

1. ⚠ Do not drop this monitor or subject it to strong impact.
2. ⚠ Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.
3. If this monitor is stored near freezing, allow it to acclimate to room temperature before use.
4. ⚠ Do not attempt to disassemble this monitor.
5. It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
6. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent. Do not use solvents.
7. No component can be maintained by user in the monitor.
8. It is recommended the cuff should be disinfected 2 times every week if needed (For example, in hospital or in clinique). Wipe the inner side (the side contacts skin) of the cuff by a soft cloth squeezed after moistened with Ethyl alcohol (75-90%), then dry the cuff by airing.
   The cover of a cuff can be subjected to a hand wash at a temperature of 30°C.
   Not to iron!

⚠ **WARNING:** Under no circumstances washing of the internal elastic camera isn't allowed! Before washing take out the elastic bladder from a cover and afterwards accurately insert back.

9. SPECIFICATIONS

1. Product name: Upper Arm Blood Pressure Monitor
2. Model MED-55.
3. Classification: Internally powered, Type BF applied part, IP21.
4. Machine size: 85 mm x 170 mm x 48 mm.
5. Cuff circumference: 22 cm~42 cm.
6. Weight: about 275 g (exclude batteries and cuff).
7. Measuring method: oscillometric method, automatic air inflation and measurement.
8. Memory volume: 60 times for each of 2 users with time and date stamp.
9. Power source: DC 6V ⎓ 600mA, batteries: 4×1.5V ⎓ SIZE AAA.
   Mains adapter (optional).
10. Measurement range:
    Cuff pressure: 0-300 mmHg
    Systolic: 40-255 mmHg
    Diastolic: 40-255 mmHg
    Pulse rate: 40-200 beats/minute
11. Accuracy:
    Pressure: ±3mmHg,
    Pulse rate: ±5%.
12. Environmental temperature for operation: 10°C~40°C (50°F~104°F).
13. Environmental humidity for operation: ≤85% RH.
14. Environmental temperature for storage and transport: -20°C~70°C (-4°F~122°F).
15. Environmental humidity for storage and transport: 10%~95% RH.
16. Environmental pressure: от 84~106,7 kPa.
17. Battery life: Approx. 300 times.
18. Blood pressure monitor set:
    M-L size's fan shape cuff (upper arm circumferenze 22-42 cm),
    a storage bag,
    AAA batteries – 4 pieces,
    the Mains adapter (if it is included in picking),
    the instruction manual.

ⓘ **NOTE:** These specifications are subject to change without notice.

10. APPLIED STANDARDS

The device is compliant with the Council Directive 93/42/EC regarding medical devices and with the applicable European standard for non-invasive blood-pressure monitor:

EN 1060-3 Non-invasive sphygmomanometers – Supplementary requirements for electro-mechanical blood pressure measuring systems,

EN 60601-1 Electrical safety requirements,

EN 60601-1-2 Electromagnetic compatibility,

IEC 80601-2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

11. SYMBOL INFORMATION

READ INSTRUCTION BEFORE USE

WARNING

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

DO NOT DISPOSE OF WITH HOUSEHOLD WASTE

CE mark (0044)
COMPILES
WITH MDD93/42/EEC
REQUIREMENTS

MANUFACTURER'S NAME

REF NAME ARTICLE NUMBER

SN SERIAL NUMBER

IP21 HOUSING INGRESS PROTECTION RATE: IP21

10°C 40°C OPERATION CONDITION
OPERATING CONDITION, TEMPERATURE 10°C ~ 40°C

-20°C 70°C STORAGE CONDITION
STORAGE CONDITION, TEMPERATURE -20°C ~ 70°C

EC REP EC REPRESENTATIVE

MD MEDICAL DEVICE

12. WARRANTY INFORMATION

Warranty period is 3 years from the date of purchase for monitor, 1 year for cuff and adapter.
This warranty doesn't cover any damages caused by improper using, and also battery, and packaging. When a manufacturing defect is revealed during the warranty period a faulty unit would be repaired or, if repairing is impossible, replaced with another one. The warranty does not cover components and consumables subject to wear and batteries, bags, and package of the item.

Manufacturing date is in a serial number: WWYYXXXXX.

The manufacturer may change units partially or completely if necessary, without prior notice.

13. ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1
For all ME EQUIPMENT and ME SYSTEMS
Guidance and manufacturer's declaration – electromagnetic emissions

The MED-55 is intended for use in the electromagnetic environment specified below. The customer or the user of the MED-55 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The MED-55 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 MED-55 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	Complies	

Table 2
For all ME EQUIPMENT and ME SYSTEMS
Guidance and manufacturer's declaration – electromagnetic immunity

The MED-55 is intended for use in the electromagnetic environment specified below. The customer or the user of the MED-55 should assure that it is used in such an environment.

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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	Power supply ± 2 kV for power supply lines ± 1 kV for input/ output lines	Power supply ± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity

The MED-55 is intended for use in the electromagnetic environment specified below.
The customer or the user of the MED-55 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	150KHz to 80MHz 3Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the MED-55, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	**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 2,5 GHz *Where, **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, **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 eachfrequency 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 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 MED-55 is used exceeds the applicable RF compliance level above, the MED-55 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MED-55.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the MED-55

The MED-55 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MED-55 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MED-55 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 2.5 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.

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