MedTalk COMFORT

Wrist Measurement Blood Pressure Monitor
Operation Guide

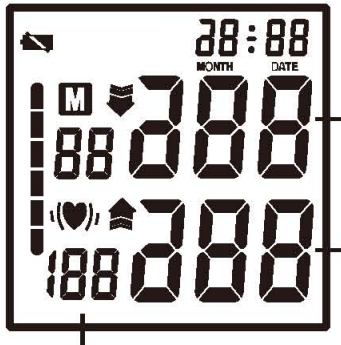
THE OPERATION GUIDE MUST BE READ

It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer.

INTENDED USE

Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home 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 wrist.

Name of Each Part

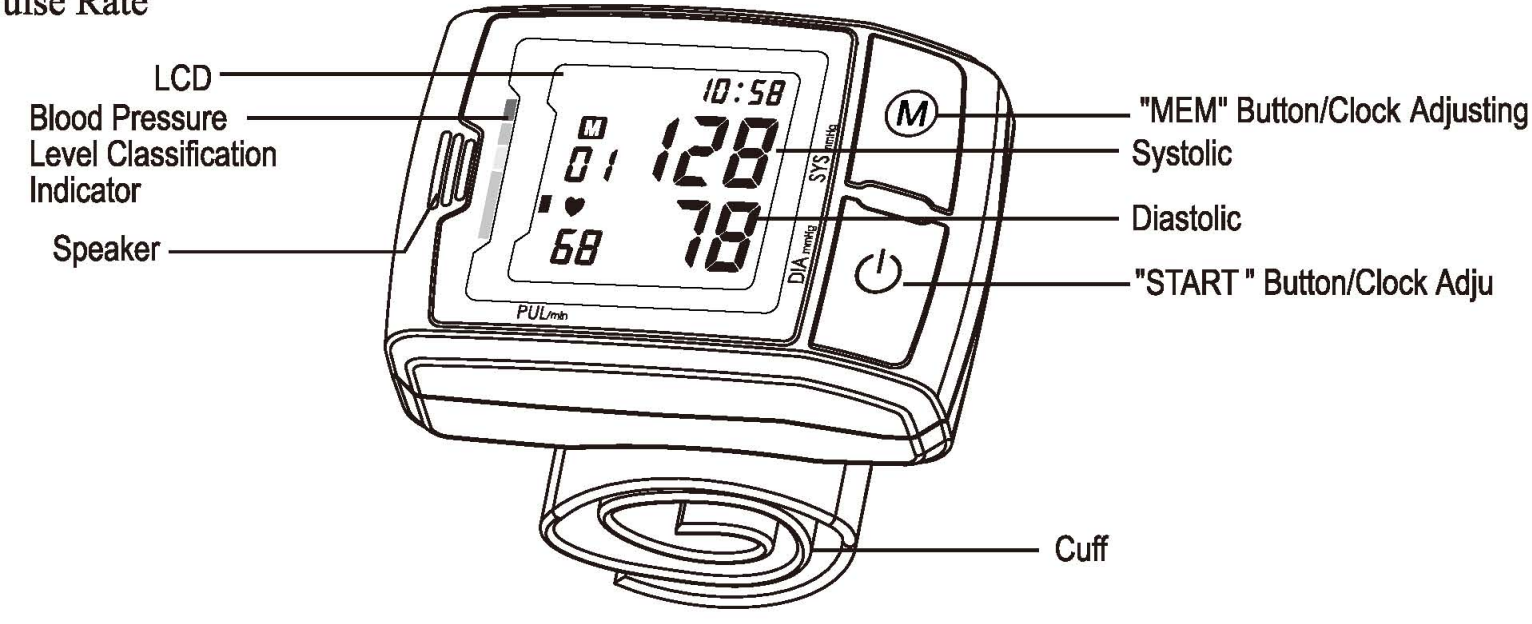


irregular heartbeat symbol

low battery

the pressure in cuff is instable, or much remnant air in cuff

find an error, please re-inflate



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Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home 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 wrist.

Contraindication

⚠ It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer.

Product Description

Based on Oscillometric methodology and silicon integrated pressure sensor, blood pressure and pulse rate can be measured automatically and non-invasively. The most recent 60 measurements can be stored in the memory with date and time stamp. The monitor can also show the average reading of the last three measurements. The voice function will ease the operation. The Electronic Sphygmomanometer corresponds to the below standards:IEC 60601-1:2005/EN 60601-1:2006/AC:2010 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC60601-1-2:2007/EN 60601-1-2:2007 /AC:2010 (Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests), EN 1060-1: 1995 + A1: 2002 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements), EN 1060-3: 1997 + A1: 2005 + A2: 2009 (Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems), ANSI/AAMI SP-10:2002+A1:2003+A2:2006.

Specifications

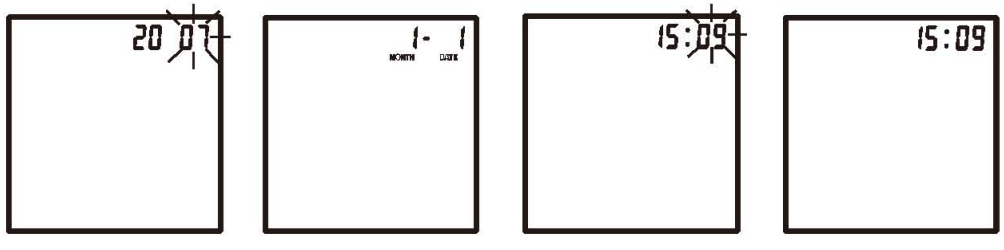
1. Product name: MedTalk Comfort
2. Classification: Internally powered, Type BF applied part,IPX0,No AP or APG, Continuous operation
3. Machine size: 87.2mm× 64mm × 30.7mm (3 7/16″ x 2 17/32″ x 1 7/32″)
4. Cuff circumference: 14cm ~ 19.5cm(5 1/2″~ 7 11/16″)
5. Weight: approx. 134g (4 23/32 oz.) (exclude batteries)
6. Measuring method: oscillometric method, automatic air inflation and measurement
7. Memory volume: 60 times with time and date stamp
8. Power source: 2 ×1.5V ⎓ SIZE AAA batteries
9. Measurement range:Cuff pressure: 0-300mmHg, Systolic: 60-260mmHg
10. Diastolic: 40-199mmHg, Pulse rate: 40-180 beats/minute,.
11. Accuracy:Pressure: ±3mmHg, Pulse rate: ±5%
12. Environmental temperature for operation: 5℃～40℃(41℉～104℉)
13. Environmental humidity for operation: ≤90% RH

Specifications

14. Environmental temperature for storage and transport: -20℃～55℃(-4℉～131℉)
15. Environmental humidity for storage and transport: ≤90% RH
16. Environmental pressure: 80KPa-105KPa
17. All components belonging to the pressure measuring system, including accessories: Pump, Valve, LCD, Cuff, Sensor

Clock and date adjustment

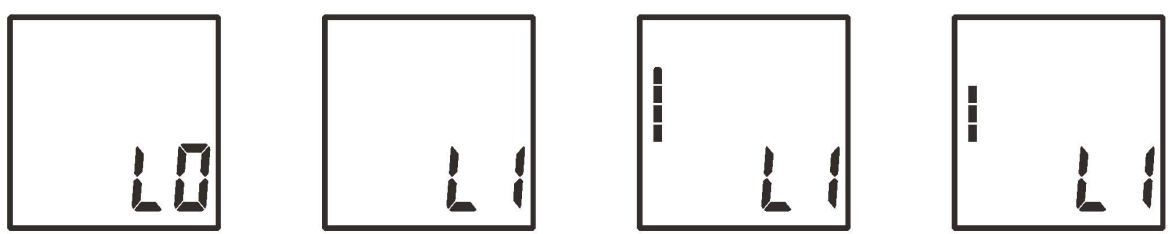
a. Once you install the battery or turn off the monitor, it will enter Clock Mode, and the LCD will display the time and date by turns. See pictures.
b. While the monitor is in Clock Mode, pressing both the “START” and “MEM” button simultaneously, the year will blink at first (See picture). Press the button “START” repeatedly, the month, day, hour and minute will blink in turn. While the number is blinking, press the button “MEM” to increase the number. Keep on pressing the button "MEM", the number will increase fast.
c. You can turn off the monitor by pressing “START” button when the minute is blinking (See picture), then the time and date is confirmed (See picture).
d. The monitor will turn off automatically after 1 minute of no operation.
e. Once you change the batteries, you should readjust the time and date.



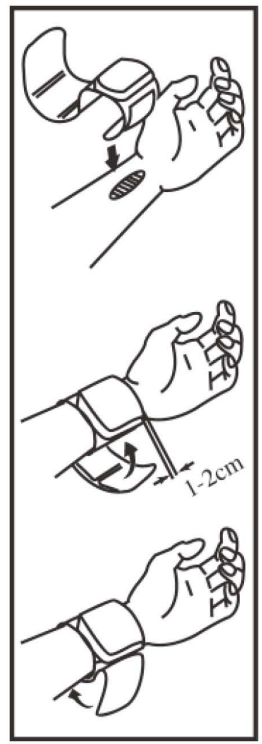
Voice setting

a. Voice language setting: In Clock Mode, you can select the voice language by keeping on pressing the button “MEM”. Now LCD blink “L0”, “L1”, “L2” … “Ln” circularly “L0” represents closing voice function, “L1” represents language 1, “L2” represents language 2,…,“Ln” represents language n, and so on. You can select the wanted language by releasing button “MEM” when display the corresponding language code.

b. Voice volume setting: Once you have selected a language, a column of bar will appear on the LCD. Keep on pressing the button “MEM” again, you can adjust the volume. The higher the bars, the louder the volume. Release button “MEM” at your desirable volume for confirmation.



Applying the cuff



a. Place the cuff around a bare wrist 1-2cm above the wrist joint on the palm side of the wrist.
b. While seated, place the arm with the cuffed wrist in front of your body on a desk or table with the palm up. If the cuff is correctly placed, you can read the LCD display.
c. The cuff must be neither too tight nor too loose.

Note:

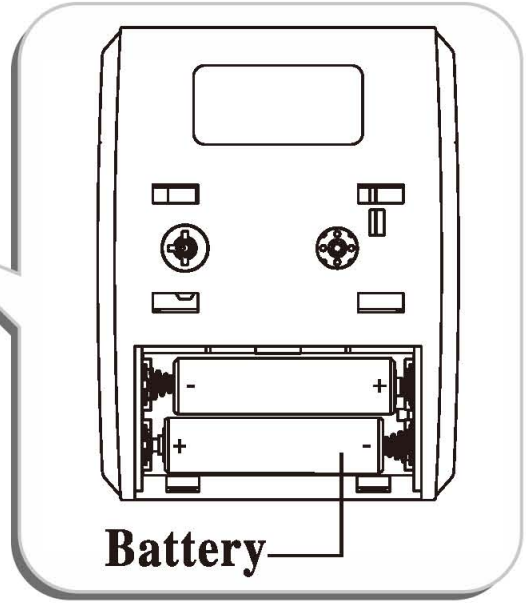
- *Please refer to the cuff circumference range in "SPECIFICATIONS" to make sure that the appropriate cuff is used.*
- *Measuring on same wrist each time.*
- *Do not move your arm, body, or the monitor during measurement.*
- *Stay still, calm for 5 minutes before blood pressure measurement.*

Please keep the cuff clean. If the cuff becomes dirty, remove it from the monitor and clear it by hand in a mild detergent, then rinse it thoroughly in cold water. Never dry the cuff in clothes dryer or iron it. Clean the cuff after the usage of every 200 times is recommended.

Measuring Procedures

Battery Loading

a. Open battery cover at the back of the monitor.
b. Load two "AAA" size batteries. Please pay attention to polarity.
c. Close the battery cover.



When LCD shows battery symbol , replac all batteries with new ones.

Rechargeable batteries are not suitable for th monitor.

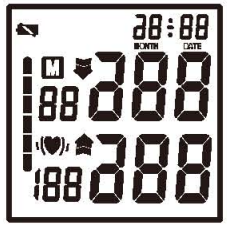
Remove the batteries if the monitor will not b used for a month or more to avoid relevai damage of battery leakage

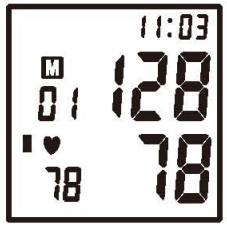
⚠Avoid the battery fluid to get in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.

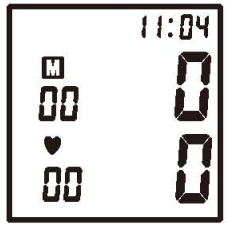
The monitor, the batteries and the cuff, must be disposed of according to local regulations at the end of their usage.

Measuring Procedures

a. After applying the cuff and your body is in a comfortable position, press the "START" button, all display characters are shown for self-test. You can check the LCD display according to picture 1 below. Please contact the service center if segment is missing.
b. The most recent result will be displayed with date and time. See below picture 2. If no memory stored in the memory bank, LCD will show picture 3.
c. If the voice function is switched on, the monitor will speak out measurement tips.







d. Then the monitor inflates the cuff until sufficient pressure has built up for a measurement. Then the monitor slowly releases air from the cuff and carries out the measurement. Finally the blood pressure and pulse rate will be calculated and displayed on the LCD. See picture 3. The irregular heartbeat symbol (if any) and blood pressure classification indicator will blink on the screen. The result will be automatically stored in the memory bank. If the voice function is on, it will announce the measurement result.

e. 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.
f. 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.

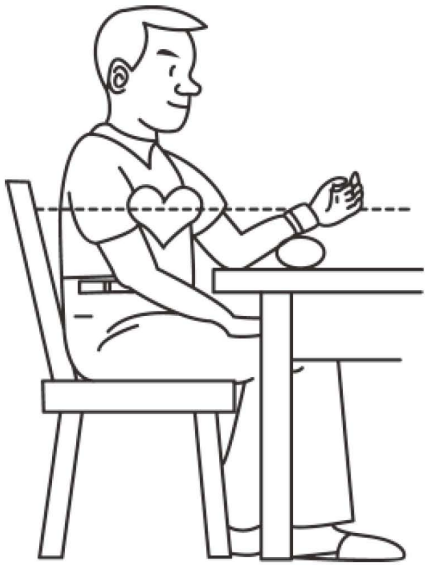
Body Posture during Measurement

Sitting Comfortably Measurement

a. Be seated with your feet flat on the floor, and don't cross your legs.

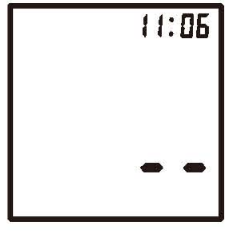
b. Place palm upside in front of you on a flat surface such as a desk or table, with your elbow resting on a chair or table

c. The middle of the cuff should be at the level of the right atrium of the heart.



Body Posture during Measurement

When any result is displaying, keep on pressing button “MEM” for three seconds, all results in the memory bank will be deleted after three “beep” press the button “MEM” or “START”, the monitor will turn off



Explanation of symbols on Unit


Symbol for “TYPE BF APPLIED PARTS” (The cuff is type BF applied part)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MANUFACTURER Andon Health Co. Ltd.No.3 Jin Ping street, Ya An road, Nankai District, Tianjin 300190, P.R.China. Year: 2018

CE 0197 Symbol for “COMPILES WITH MDD93/42/EEC REQUIREMENTS”


Symbol for “DATE OF MANUFACTURE”

Symbol for “SERIAL NUMBER”

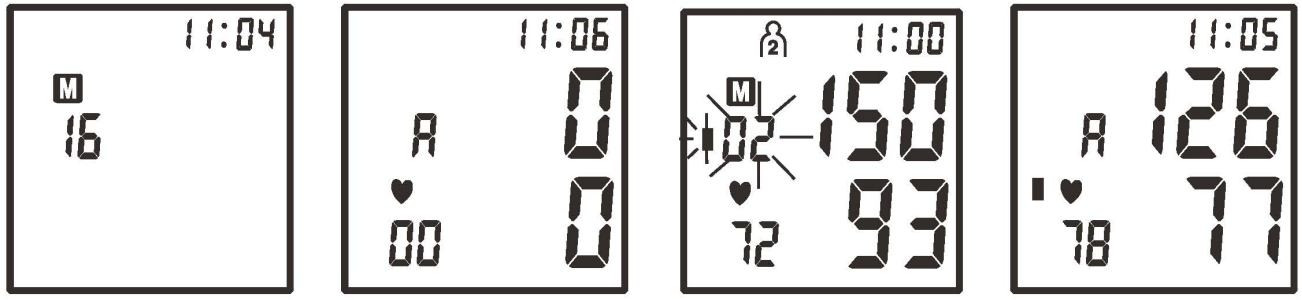

Symbol for “KEEP DRY”


Symbol for “WARNING”

Lotus Global Co., Ltd.
1 Four Seasons Terrace West Drayton, Middlesex, London, UB7 9GG, United Kingdom
Tel: +0044-20-75868010 Fax: +0044-20-79006187

Displaying stored results

a. Press “MEM” button in Clock Mode. The amount of results in the memory bank will be displayed.
b. After about 1 second, the LCD will display the average value of the last three results in the bank. If no result stored, LCD will show.



MAINTENANCE

Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.

⚠ Do not attempt to disassemble this monitor.
If you do not use the monitor for a long time, please remove the batteries.

It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.

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Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.

Please do not share the cuff with other infective person to avoid cross-infection.

Read all of the information in the operation guide and any other literature in the box before operating the unit.

This Electronic Sphygmomanometer 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.

EN 60601-1:2006/AC:2010 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), EN 60601-1-2:2007 /AC:2010 (Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests), EN 1060-1: 1995 + A1: 2002 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements), EN 1060-3: 1997 + A1: 2005 + A2: 2009 (Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems).

If Irregular Heartbeat (IHB) brought by common arrhythmias is detected in the procedure of blood pressure measurement, a signal of))♥((will be displayed. Under this condition, the Electronic Sphygmomanometer can keep function, but the results may not be accurate, it's suggested that you consult with your physician for accurate assessment.

No component can be maintained by user in the monitor. The circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated repairably can be supplied.
The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is maintained after 1,000 open–close cycles of the closure. Battery life: Approx. 120 times.

Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent. It is recommended the cuff should be disinfected 2 times every week if needed 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.

Troubleshooting (1-1)

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD shows low battery symbol 	Low Battery	Change the batteries
LCD shows “Er 0”	Pressure system is unstable before measurement	Don’t move and try again.
LCD shows “Er 1”	Fail to detect systolic pressure	
LCD shows “Er 2”	Fail to detect diastolic pressure	
LCD shows “Er 3”	Pneumatic system blocked or cuff is too tight during inflation	Apply the cuff correctly and try again
LCD shows “Er 4”	Pneumatic system leakage or cuff is too loose during inflation	

Troubleshooting (1-2)

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD shows “Er 5”	Cuff pressure above 300mmHg	Measure again after five minutes. If the monitor is still abnormal, please contact the local distributor or the factory.
LCD shows “Er 6”	More than 3 minutes with cuff pressure above 15 mmHg	
LCD shows “Er 7”	EEPROM accessing error	
LCD twinkling all	Device parameter checking error	
LCD shows “Er 9”	MCU self-verify error	
LCD shows “Er A”	Pressure sensor parameter error	
LCD shows “Er b”	EEPROM backup error	
No response when you press button or load battery.	Incorrect operation or strong electromagnetic interference.	Take out batteries for five minutes, and then reinstall all batteries.

Troubleshooting (2)

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD Display shows abnormal result	The cuff position was not correct or it was not properly tightened	Apply the cuff correctly and try again
	Body posture was not correct during testing	Review the “BODY POSTURE DURING MEASUREMENT” sections of the instructions and re-test.
	Speaking, arm or body movement, angry, excited or nervous during testing	Re-test when calm and without speaking or moving during the test
	Irregular heartbeat (arrhythmia)	It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer.

Electromagnetic Compatibility Information

Table 1

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration - electromagnetic emissions		
The MedTalk Comfort is intended for use in the electromagnetic environment specified below. The customer or the user of the MedTalk Comfort should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The MedTalk Comfort 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 MedTalk Comfort is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2
For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The MedTalk Comfort is intended for use in the electromagnetic environment specified below. The customer or the user of the MedTalk Comfort should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601test 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 %.
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.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3
For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity			
The MedTalk Comfort is intended for use in the electromagnetic environment specified below. The customer or the user of the MedTalk Comfort should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the MedTalk Comfort, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ 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 and d is the recommended separation distance in meters (m).

To be continued

continued **Table 3**

IMMUNITY test	**IEC 60601test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply 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 MedTalk Comfort is used exceeds the applicable RF compliance level above, the MedTalk Comfort should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MedTalk Comfort.
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 MedTalk Comfort			
The MedTalk Comfort is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MedTalk Comfort can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MedTalk Comfort 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 determined 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.			