MODEL 405-HT

Fully Automatic Wrist Cuff Blood Pressure Monitor

(ELECTRONIC SPHYGMOMANOMETER)

OPERATION GUIDE

INDEX

IMPORTANT INFORMATION

NORMAL BLOOD PRESSURE FLUCTUATION

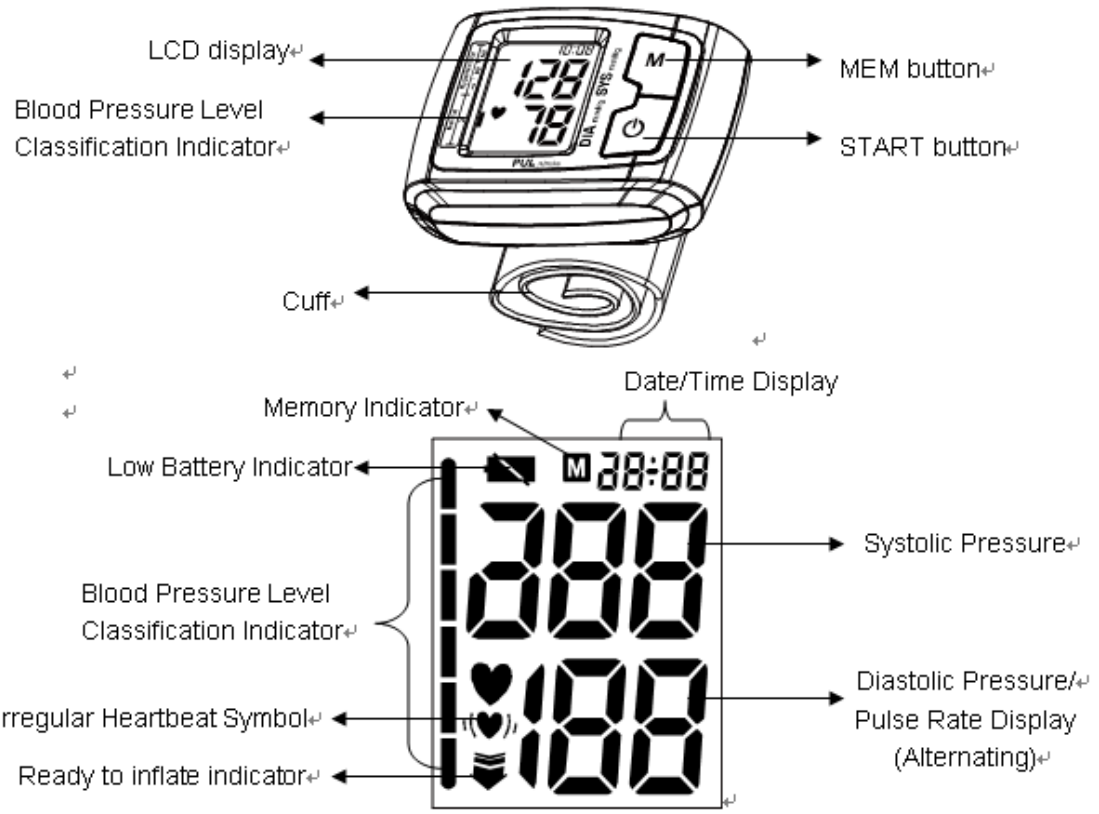
All physical activity, excitement, stress, eating, drinking, smoking, body posture and many other activities or factors (including taking a blood pressure measurement) will influence blood pressure value. Because of this, it is mostly unusual to obtain identical multiple blood pressure readings.

Blood pressure fluctuates continually ----- day and night. The highest value usually appears in the daytime and lowest one usually at midnight. Typically, the value begins to increase at around 3:00AM, and reaches to highest level in the daytime while most people are awake and active.

Considering the above information, it is recommended that you measure your blood pressure at approximately the same time each day.

Too frequent measurements may cause injury due to blood flow interference, please always relax a minimum of 1 to 1.5 minutes between measurements to allow the blood circulation in your arm to recover. It is rare that you obtain identical blood pressure readings each time.

CONTENTS AND DISPLAY INDICATORS



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.

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 LCD display will show blood pressure and pulse rate. The most recent 60 measurements can be stored in the memory with

date and time stamp. The Electronic Sphygmomanometers 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), IEC 80601-2-30：2009+Cor.2010/EN 80601-2-30:2010(Medical electrical equipment –Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers),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: Blood Pressure Monitor
2. Model: 405-HT
3. Classification: Internally powered, Type BF applied part,IPX0,No AP or APG,Continuous operation
4. Machine size: Approx. 85mm x 64.5mm x28mm (3 11/32″ x 2 17/32″ x 1 3/32″)
5. Cuff circumference: 14cm - 19.5cm(5 1/2” - 7 11/16”)
6. Weight: Approx. 110g (3 7/8 oz.) (exclude batteries)
7. Measuring method: Oscillometric method, automatic inflation and measurement
8. Memory volume: 60 times with time and date stamp
9. Power source: batteries: 2 ×1.5V ⎓ SIZE AAA
10. Measurement range:
    Cuff pressure: 0-300mmHg
    Systolic: 60-260mmHg
    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
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. Battery life: Approx 270 times
18. All components belonging to the pressure measuring system, including accessories: Pump,Valve, LCD, Cuff, Sensor

Note: These specifications are subject to change without notice.

NOTICE

1. Read all of the information in the operation guide and any other literature in the box before operating the unit.
2. Stay still, calm and rest for 5 minutes before blood pressure measurement.
3. The cuff should be placed at the same level as your heart.
4. During measurement, neither speak nor move your body and arm.
5. Measuring on same wrist for each measurement.
6. Please always relax at least 1 or 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 above15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your wrist.
7. 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;
   5) Need to check the blood circulation of the user.
8. ⚠ This Electronic Sphygmomanometers 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.
9. Do not use this unit in a moving vehicle, This may result in erroneous measurement.
10. 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.
11. 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.
12. 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 Sphygmomanometers can keep function, but the results may not be accurate, it's suggested that you consult with your physician for accurate assessment.

There are 2 conditions under which the signal of IHB will be displayed:

1) The coefficient of variation (CV) of pulse period >25%.

2) The difference of adjacent pulse period≥0.14s, and the number of such pulse takes more than 53 percentage of the total number of pulse.

13. Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
14. ⚠ 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.
15. ⚠ Please do not share the cuff with other infective person to avoid cross-infection.
16. 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

17. 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 (2) this device must accept any interference received, including interference that may cause undesired operation.

18. This blood pressure monitor is verified by auscultatory method. It is recommended that you check annex B of ANSI/AAMI SP-10:2002+A1:2003+A2:2006 for details of verification method if you need.

SETUP AND OPERATING PROCEDURES

1. 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 , replace all batteries with new ones.

Rechargeable batteries are not suitable for this monitor.

Remove the batteries if the monitor will not be used for a month or more to avoid relevant damage of battery leakage.

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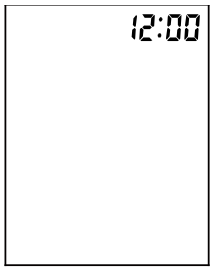
⚠Avoid the battery fluid to get in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.

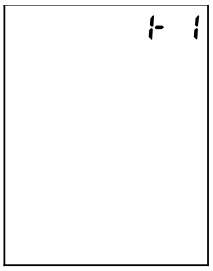
The monitor, the batteries and the cuff, must be disposed of according to local regulations at the end of their usage.

2. CLOCK AND DATE ADJUSTMENT

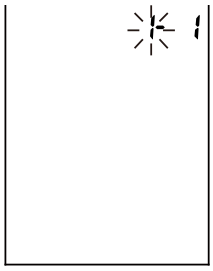
a. Once you install the battery or turn off the monitor, it will enter Clock Mode, and LCD will display time and date by turns. See picture 2&2-1.



Picture 2



Picture 2-1



Picture 2-2

b. While the monitor is in Clock Mode, pressing both the “START” and “MEM” button simultaneously, a beep is heard and the month will blink at first. See picture 2-2. Press the button “START” repeatedly, the 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, then the time and date is confirmed.

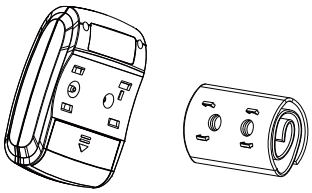
d. The monitor will turn off automatically after 1 minute of no operation, with the time and date unchanged.

e. Once you change the batteries, you should readjust the time and date.

3. CONNECTING THE CUFF TO THE MONITOR

The cuff is attached to the monitor when it is packaged. Should the cuff become unattached, align the two plugs and four brackets of the cuff with the plug sockets and bracket sockets of

the monitor and press the cuff to the monitor until the plugs and brackets are securely attached.



4. 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:

1. Please refer to the cuff circumference range in “SPECIFICATIONS” to make sure that the appropriate cuff is used.
2. Measuring on same wrist each time.
3. Do not move your arm, body, or the monitor during measurement.
4. Stay quiet, calm for 5 minutes before blood pressure measurement.
5. Please keep the cuff clean. Clean the cuff by wet soft cloth and mild detergent if the cuff becomes dirty. Do not remove the cuff from the monitor.Clean the cuff after the usage of every 200 times is recommended.

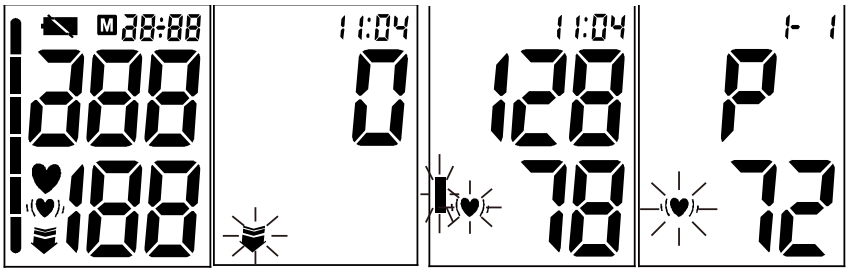
5. BODY POSTURE DURING MEASUREMENT

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

6. TAKING YOUR BLOOD PRESSURE READING

a. After applying the cuff and your body is in a comfortable position, press the “START” button. A beep is heard and all display characters are shown for self-test. See picture 6. Please contact the service center if segment is missing.



Picture 6 Picture 6-1 Picture 6-2 Picture 6-3

b. Then the monitor starts to seek zero pressure. See picture 6-1.

c. 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 screen separately. Irregular heartbeat symbol (if any) will blink. See picture 6-2&6-3. The result will be automatically stored in the memory bank.

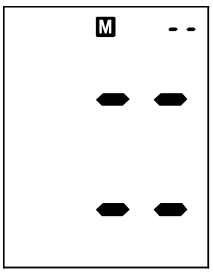
d. After measurement, the monitor will turn off automatically after 1 minute of no operation. Alternatively, you can press the “START” button to turn off the monitor manually.

e. During measurement, you can press the “START” button to turn off the monitor manually.

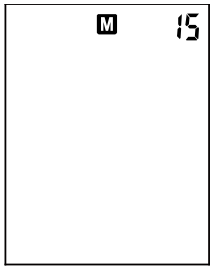
Note: Please consult a health care professional for interpretation of pressure measurements.

7. DISPLAYING STORED RESULTS

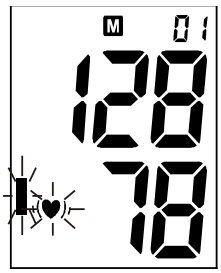
a. After measurement, you can review the results in the memory bank by pressing the “MEM” button. Alternatively, you can press “MEM” button in Clock Mode to display the stored results. If it no result stored, LCD will show dashes as picture 7, while press the button “MEM” or “START”, machine will turn off. If there are results in the memory bank, the LCD will display the amount of the results in the memory bank. See picture 7-1.



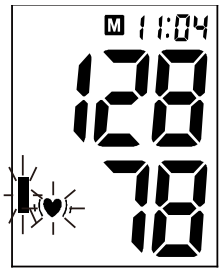
Picture 7



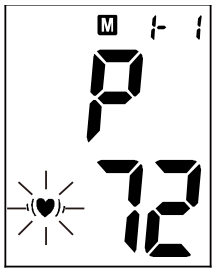
Picture 7-1



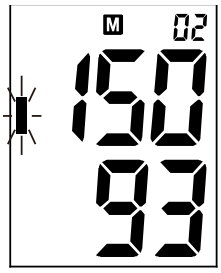
Picture 7-2



Picture 7-3



Picture 7-4



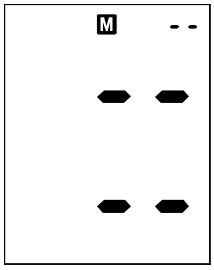
Picture 7-5

b. And then, the most recent result will be displayed with date and time stamp. See picture7-2. Followed by, the blood pressure and pulse rate will be shown separately. Irregular heartbeat symbol (if any) will blink. See picture7-3&7-4. Press “MEM” button again to review the next result. See picture7-5. In this way, repeatedly pressing the MEM button displays the respective results measured previously.

c. When displaying the stored results, the monitor will turn off automatically after 1 minute of no operation. You can also press the button “START” to turn off the monitor manually.

8. DELETING MEASUREMENTS FROM THE MEMORY

When any result is displaying, keeping on pressing button “MEM” for three seconds, all results in the current memory bank will be deleted after three “beep”. LCD will show picture 8, Press the button “MEM” or “START”, the monitor will turn off.

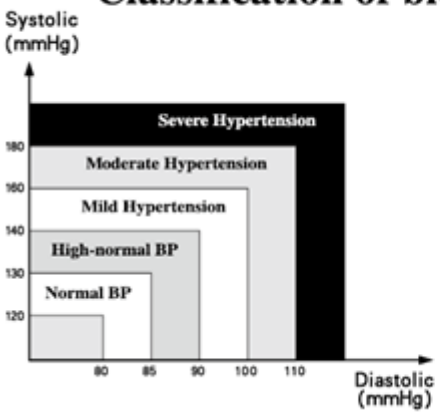


Picture 8

9. ASSESSING HIGH BLOOD PRESSURE FOR ADULTS

The following guidelines for assessing high blood pressure (without regard to age or gender) have been established by the World Health Organization (WHO). Please note that other factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration. Consult with your physician for accurate assessment, and never change your treatment by yourself.

Classification of blood pressure for adults



BLOOD PRESSURE CLASSIFICATION	SBP mmHg	DBP mmHg
Optimal	<120	<80
Normal	120-129	80-84
High-Normal	130-139	85-89
Grade 1 Hypertension	140-159	90-99
Grade 2 Hypertension	160-179	100-109
Grade 3 Hypertension	≥180	≥110

WHO/ISH Definitions and Classification of Blood Pressure Levels

10. TECHNICAL ALARM DESCRIPTION

The monitor will show 'HI' or 'Lo' as technical alarm 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.

The technical alarm condition (outside the rated range) is preset in the factory and cannot be adjusted or inactivated. This alarm condition is assigned as low priority according to IEC 60601-1-8.

The technical alarm is non-latching and need no reset. The signal displayed on LCD will disappear automatically after about 8 seconds.

11. TROUBLESHOOTING (1)

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.

12. TROUBLESHOOTING (2)

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	
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 shows “Er 8”	Device parameter checking error	
LCD shows “Er A”	Pressure sensor parameter 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.

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. If you do not use the monitor for a long time, please remove the batteries.
6. It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
7. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
8. 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.
9. 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.
10. It is recommended the cuff should be disinfected 2 times every week if needed (For example, in a hospital or in a clinic). Wipe the inner side (the side that contacts the skin) of the cuff by a soft cloth squeezed after moistened with Ethyl alcohol (75-90%), then dry the cuff by airing.

EXPLANATION OF SYMBOLS ON UNIT


Symbol for" THE OPERATION GUIDE MUST BE READ"(The sign background color: blue. The sign graphical symbol: white)


Symbol for "WARNING"


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


Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice".


Symbol for "MANUFACTURER"

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


Symbol for “DATE OF MANUFACTURE”

Symbol for “EUROPEAN REPRESENTATION”

SN Symbol for “SERIAL NUMBER”


Symbol for “KEEP DRY”

WARRANTY INFORMATION

Only charge the cost of components and transport.

SERVICE CENTER


DIABETIC SUPPLY OF SUNCOAST, INC..
HR 3 Box 7017
Dorado, PR 00646
Tel: 1-866-373-2824

Lotus Global Co., Ltd.
15 Alexandra Road, London UK, NW8 0DP
Tel: +0044-20-75868010 Fax: +0044-20-79006187

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture’s declaration - electromagnetic emissions		
The [405-HT] is intended for use in the electromagnetic environment specified below. The customer or the user of the [405-HT] should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The [405-HT] 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	Class B	The [405-HT] is suitable for use in all

CISPR 11		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 [405-HT] is intended for use in the electromagnetic environment specified below. The customer or the user of the [405-HT] 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.

Table 3

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

Guidance and manufacturer's declaration - electromagnetic immunity

The [405-HT] is intended for use in the electromagnetic environment specified below. The customer or the user of the [405-HT] 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 [405-HT], 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). 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 [405-HT] is used exceeds the applicable RF compliance level above, the [405-HT] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [405-HT].

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/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 [405-HT]			
The [405-HT] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [405-HT] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [405-HT] 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.