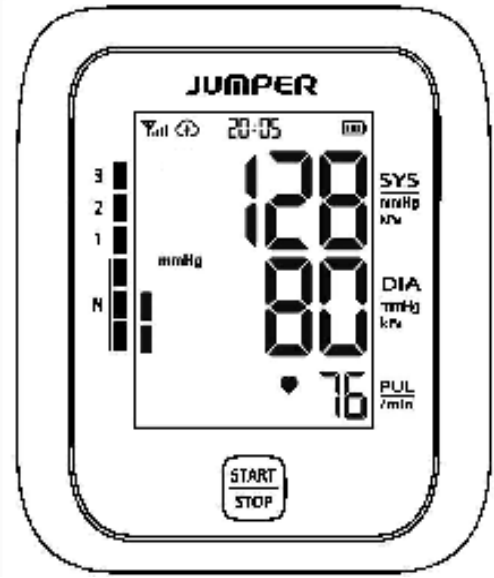
Electronic Blood Pressure Monitor



JPD-HA100 User Manual

Version: 3.0

Revision Date: 2024.03

CE 0598

Product Composition

The product is comprised of the host machine and the Upper-arm-type cuff of Electronic Blood Pressure Monitor(measured arm circumference 22-36cm or 22-42cm).

Intended use & Intended User &Intended patient population

The Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.The intended user is professional or lay user. The device is intended to be used by adults over 12 years old.

Working Principle

This product is designed based on the principle of Oscillographic method to measure the blood pressure of patients. Inflatable cuff is used to block arterial blood flow during the oscilloscope measurement. Because of the hemodynamic action of the heartbeat, the pulse wave synchronized with the heart beat is overlapped on the sleeve pressure. The pulse wave disappeared when the air sleeve pressure was much higher than the systolic pressure. As the sleeve pressure drops, the pulse begins to appear. When the cuff pressure is higher than the contraction pressure down to the systolic pressure, the pulse wave suddenly increases and reaches the maximum value when the average pressure is reached. Then the pulse wave attenuates with the decrease of cuff pressure. Then blood pressure is calculated according to the relationship between pulse wave amplitude and the corresponding time sleeve pressure.

Safety Precautions

The warnings and illustrations shown in the User Manual enable you to use the product safely and correctly, thus preventing you and others from being injured, specifically as follows:

Legend, mark and meaning	
	Warning message
	Anti-electric shock degree is Type BF of the application part
	When the product life expires and the end users discard the products, send them to the designated collecting and separating place for disposal according to the requirements from the local environmental protection authority.
	Consult the instructions for use.
	This product complies with the MDR 2017/745 requirements.
IP21	Degree of protection against the ingress of water.
	Information of manufacturer
	Date of manufacture
	Authorized European Representative
	Medical Device

Quick Start Guide

Avoid smoking, eating, drinking caffeinated drinks or exercising for 30 minutes before taking measurement.

1.Sit upright in a chair with both feet on the floor.

2.Remove tight fitting clothing from your upper arm along with any thick clothing.

3.Pull on the end of the cuff until it wraps securely around your upper arm. Place your arm on a table so that the cuff will be at the same level as your heart.

4.The cuff will automatically inflate and the measurement will start, upon pressing the "START/STOP" button.

5.When the measurement is complete, the cuff will automatically deflate and your systolic and diastolic pressure values and pulse rate will be displayed.

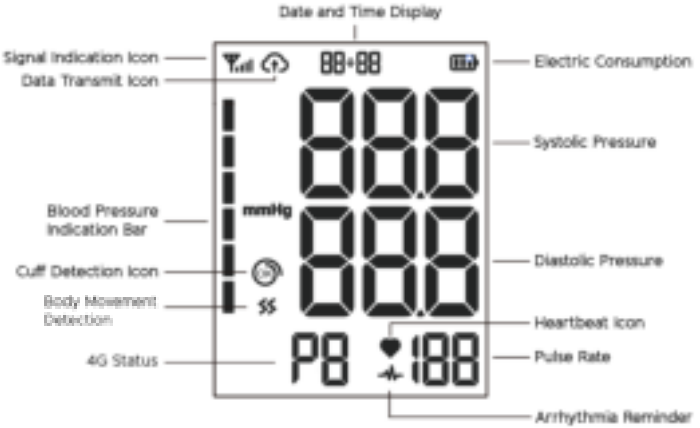
Overview

Monitor

Features

- **Universal Cuff**
- **Irregular Heartbeat Detector**
- **Auto Power Off**
- **Operated by 4 AA batteries (USB 5V optional)**
- **Body movement detection**

Display



Packing List

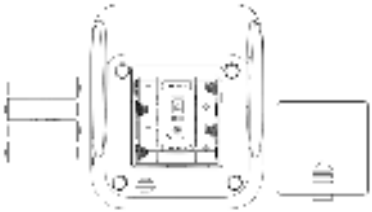
No.	Name	Quantity
1	Electronic Blood Pressure Monitor	1
2	Cuff	1
3	Dry Battery (AA)	4
4	User Manual	1
5	Zipped Carrying Bag	1

Preparation

2.1 Battery Installation

a）Open the battery cover as shown in the picture.

b） Place 4 AA dry batteries. Pay attention to the battery electrode indication.



2.2 Battery power indication and replacement

After the product is turned on, if low power symbol appears on the screen , the measurement cannot be performed, and the battery must be replaced.

Do not use any expired battery;

If the product is not used for over 3 months, please take out the batteries.

2.3 USB Power Supply

USB line can be connected for power supply of the product without battery.

If need connect Separate power supply , please note the following:

1) Output: DC 5 V; 0.5 A.

2) Rated input voltage shall not exceed 500 V.

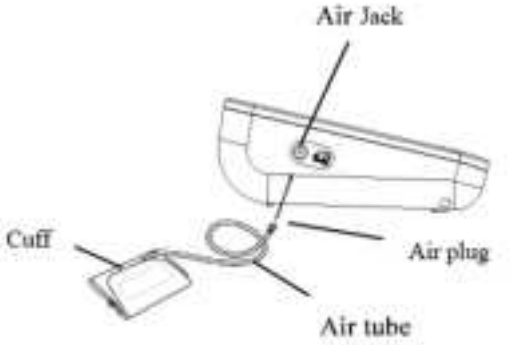
3) Classification of protection against electric shock: Class II

Note: Please select the USB power supply that is supplied by the manufacturer or that complies with the relevant safety standards (e.g. IEC 62368 and IEC 60601-1).

2.4 Cuff

The applicable arm circumference range of the cuff is 22-36cm or 22-42cm.

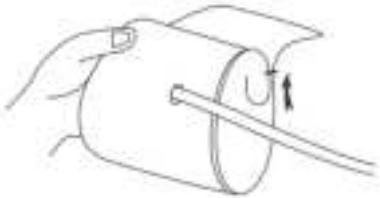
Connection: Insert the air plug of cuff air tube into air jack of the Electronic Blood Pressure Monitor. Figure shown as below:



Correct Method of Use

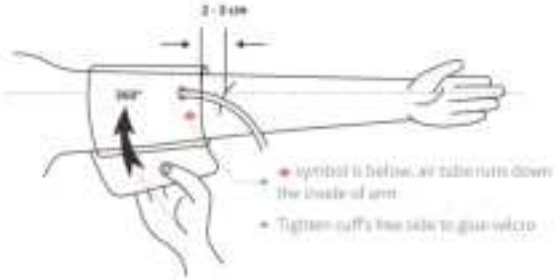
3.1 How to use the cuff

(1) Place the cuff flat on the table, leave the hook & loop downwards, and pass the end of cuff through the metal ring to form a loop. The hook & loop shall point outwards.



(2) Pull the cuff through the upper arm to be measured, and wear the

cuff correctly based on the downward icon “ Φ ”, the air tube runs down the inside of your arm.Hook up the cuff on the upper arm according to the illustration, ensure that the lower edge of cuff is 2~3cm away from the elbow joint. Tighten the free edge of cuff to stick the hook & loop.



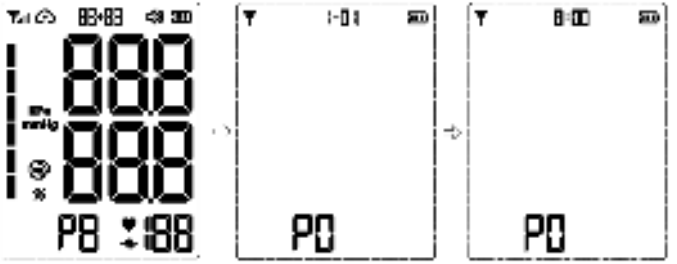
(3) The cuff should be wrapped on the upper arm comfortably, with tight space for two fingers. Before measurement, remove tight fitting clothing from your upper arm along with any thick clothing.Place the lower arm flat on the desktop, leaving the center of palm naturally upwards, sitting upright, and ensuring the center of cuff and the heart are at the same level. Note that the tube of cuff cannot be folded or bent.

Note: If you cannot use the left arm for measurement, please use the right arm for measurement. All the measurements must be performed on the same arm for comparison.

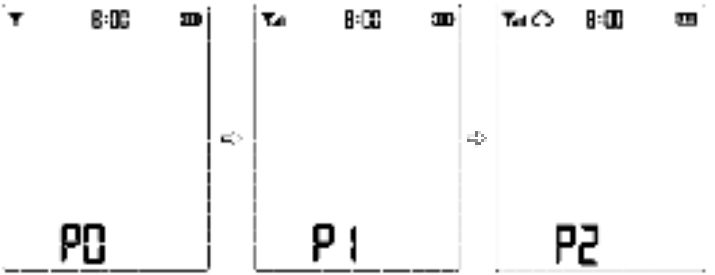
3.2 Pairing

(1) Pairing the mobile network

When the device is turned on for the first time after installation or battery replacement, the default values of “date” and “time” will be displayed alternately on the screen. This indicates that the device is searching for or pairing with a mobile network as shown in the figure below:

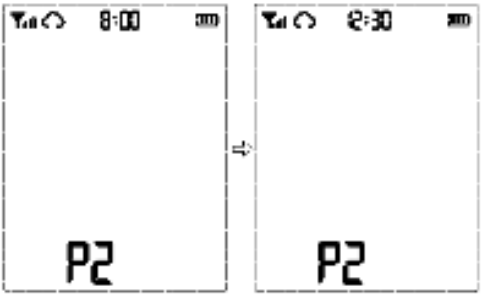


During the pairing process, the device will automatically assess the strength of the network signal. A stronger signal will speed up the pairing process. When the symbol appears on the screen, it confirms successful network pairing.



(2) Time synchronization

Once paired successfully, the device will synchronize time with the server



Note:

(1) After successful pairing, the device will automatically shut down if there is no operation for about 30 seconds.

(2) The duration of network pairing varies based on signal strength. With a strong signal, pairing typically takes about 15 seconds. In case of abnormal pairing or poor signal, the pairing process will be repeated and the time extended.

3.3 Starting measurement

Power on state, after you wear the cuff correctly, the cuff detection icon lights up, then you can start the measurement:

(1) Press the “START/STOP” button, and the device will return to zero automatically, the air pump will start to inflate the cuff, and the screen will display the change of the pressure in the cuff.

(2) When reaching the stable pressure upon inflation, the air pump will

stop the inflation, and the pressure in the cuff will be reduced gradually and displayed on the screen. If the inflated pressure is insufficient, the device will reinflate the cuff automatically for a higher pressure;

(3) When the pulse is measured, the screen will display the "heart" symbol and start flashing. The flashing "heart" symbol will be displayed on the screen.

(4) Upon measurement completion, the measured values of systolic pressure, diastolic pressure and pulse will be displayed on the screen.

(5) The screen will continue to display the measurement results, unless your long-press on the " START/STOP " button to turn off the device. If there is no operation, the device will be powered off automatically in 30s.

Note:

(1) When the icon shows up, it means body movements during the measurement, which may result in incorrect measurement.

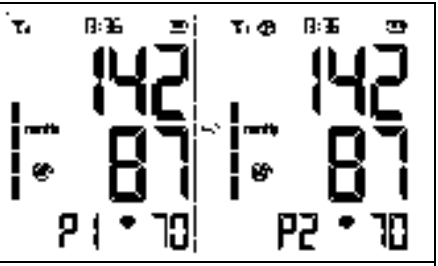
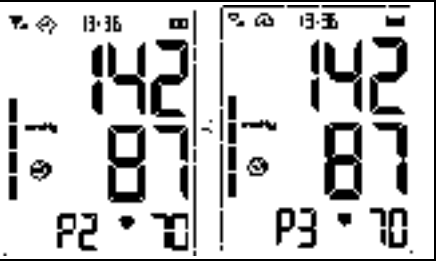
(2) Irregular heartbeat symbol appears in the result when irregular rhythm is detected 2 or more times during a measurement. If it continues to appear, we recommend you to consult with and follow the directions of your physician. (An irregular heartbeat rhythm is defined as a rhythm that is 25 % less or 25 % more than the average rhythm detected while your monitor is measuring blood pressure

(3) If you suffer from an irregular heartbeat, measurements taken with this device should be evaluated with your doctor.

3.4 Measurement uploading

After the measurement, the data transmission automatically starts.

Status	Meaning	Screen Display
P0	The symbol will appear on the LCD, the data transmission starts.	
P1	appears. Detecting the signal	

P2	appears. Data transferring	
P3	appears. Data transmission completed	

Note:

(1) After successful date uploaded, press the button to continue with the next measurement. The device will automatically power off after 30 seconds if there is no other operation.

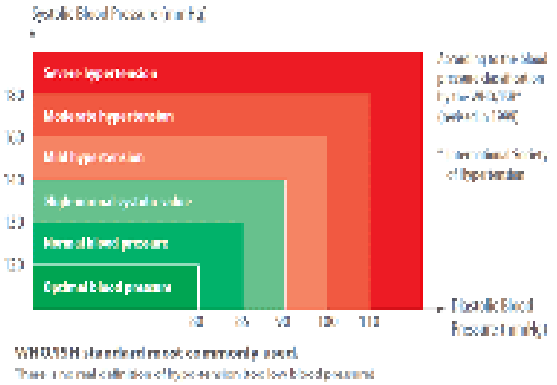
(2) If the measurement data is not uploaded promptly or fails to upload, it will be saved on the device and will be sent when a successful connection is achieved. The device can store up to 99 readings.

(3) The readings stored in the device will be automatically uploaded after each measurement until all stored data is uploaded. Up to five readings can be uploaded at a time.

(4) If the BP monitor is performed without prior network configuration, the device will automatically configure the network after the measurement, synchronize the time with the server, and then upload the blood pressure data.

3.5 Classification standard for blood pressure condition

There is no definition of hypotension yet. Generally, if the systolic blood pressure is less than 90mmHg (12kPa), it is hypotension.



Contraindications, Precautions, Warnings and Prompt Instruction

The device has no side-effects if administered correctly and residual risk is acceptable.

(1) Warning:

 Keep the device out of the reach of the children under 12 and people who can't express their intention. When children of 12~18 use the device, they should be accompanied by the adults. Pregnant women shall use under the guidance of doctors.

 Do not wrap the cuff over a wound, as this can cause further injury.

 Do not use cuff in the arm which has invasive treatment device or arteriovenous shunt,otherwise will cause hurt.

 Do not apply the cuff and its pressurization on the arm on the side of a mastectomy.

 Do not use the cuff for a long time, avoid allergies.

 This model of Electronic Blood Pressure Monitor is suitable for the arm circumference range of 22-36cm or 22-42cm, and if the arm circumference exceeds this range, you might fail to obtain the correct measured value of blood pressure;

 This model of Electronic Blood Pressure Monitor is not suitable for newborns or young children;

 The blood pressure is constantly changing. You shall not judge

the blood pressure condition with just one measurement result. The repeated measurement data over a period of time will be more reliable;

 For any patient, do not measure more than 3 times continuously, it should be at least above 5 minutes of interval rest between any two measurements, otherwise will cause extravasated

 blood.

Do not make self-diagnosis according to the measurement results. Please consult your professional doctor with the measurement result record(s).The treatment based on the self-diagnosis of measurement

 results is very dangerous;

Before you start measuring, make sure the connecting tube is free of

 kinks that could cause unmeasurement or other damage.

Please use the cuff follow the use manual, pay attention to the use of the

 hose, avoid twining due to excessive length.

Please do not use mobile phone, computer,electric kettle and the other

 can cause interference device around the device.

No servicing/maintenance while the device is in use.

Don’t use accessories and detachable parts not specified or authorized

 by manufacturer. Otherwise, it may cause damage to the unit or danger to the user or patients.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

(2) Precautions:

 Do not repair, disassemble or modify the Electronic Blood Pressure Monitor without permission;

 Do not collide or drop the host to avoid collision or strong impact on the device;

 Do not mix old and new batteries of different brands for use.

Indoor temperature, environment, noise, user's body position, speech or exercise might affect the blood pressure measurements. The body movement, magnetic field and improper wearing of cuff and sensor will affect the measurement as well.

 The equipment is not suitable for use in the public places or in electrosurgery.

 The Electronic Blood Pressure Monitor has clinically investigated according to the requirements of ISO 81060-2.

Troubleshooting

* If you have trouble using the device, please check the following instruction.

Problem		Possible cause	How to correct
No display when press the Power button		Low battery	Replace new batteries or use the USB for power supply.
		The polarities of batteries are installed wrongly.	Install the batteries in correct polarities.
No pressurizing		The air plug is loosely installed.	Make sure the air plug is securely inserted in the main unit
		The air tube is broken or leaked.	Purchase a new cuff.
The cuff leaks		The cuff wrapped too loose	Please tighten the cuff
		The cuff is broken	Replace with a new cuff
Error massage in measurement display	"Er 1" displayed	The leakage is too fast or the pulse signal is too weak	Please check the cuff, tie it up and try again

	“Er 2” displayed	The blood pressure signal cannot be detected due to too much noises.	Please remove the noise sources and measure again
	“ Er 3 ” displayed	The result of blood pressure is abnormal.	Please remeasure in the right way.
	“Er P” displayed	The inflation fails	Please check the cuff, tie it up and try again.
	“HI” displayed	The inflation pressure is greater than 295 mmHg (39kPa)	Please measure again.
Error massage in 4G status display	“E 1” displayed	Communication failure	Please contact customer support for after-sale service.
	“E 2” displayed	SIM card is not detected or SIM card is abnormal	Check and re-install the SIM card. If the issue persists, contact customer support.

	“E 3” displayed	Data transmission error	Re-measure at a location where you get strong cellular signal with your mobile phone. If the issue persists,contact customer support.
	“E 4” displayed	Network registration error	Re-measure at a location where you get strong cellular signal with your mobile phone, or change a new SIM card.
	“E 5” displayed	No signal detecting	Re-measure at a location where you get strong cellular signal with your mobile phone. If the issue persists,contact customer support.
 **Note: If your problem cannot be solved by the above, please contact customer service. Do not disassemble the device!**			

Storage & Maintenance

- Keep the device away from direct sunlight, extreme temperatures, humidity or moisture.
- Use a dry, soft cloth to clean the device, or if desired, use a cloth lightly dampened with water.
- Do not use corrosive cleaner, benzene, thinner or other volatile liquids to clean the device.
- Do not wash or expose the arm cuff to liquid.
- Remove batteries from the device when it will not be used for more than 3 months.

Disinfection:

Recommended disinfecting agent:

- Isopropanol solution with 70% concentration
- Medical alcohol with 75% concentration

Do not disinfect by such method as high temperature steam or ultraviolet irradiation, which might damage the instrument or accelerate the aging!

It is suggested to disinfect the electronic blood pressure monitor before and after use each time. Each time of disinfection shall be completed within 1min. The number of repeated disinfection each time shall not exceed 2 times.

Cleaning and disinfection shall be carried out in the following environment: temperature: +5 °C~+40 °C (50°F-104°F), relative humidity: 15%~85%RH, non-condensing, atmospheric pressure: 70kPa~106 kPa.

Specifications

Product Name	Electronic Blood Pressure Monitor	
Model	JPD-HA100	
Display Mode	Digital display mode	
Measuring Mode	Oscillographic method	
Measuring Body Part	Upper arm	
Measuring Range	Pressure value	0-295mmHg（0kPa-39.3kPa）
	Pulse value	40-199 pulse beats/min
Static measurement accuracy	Pressure value	±3mmHg（±0.4kPa）
	Pulse value	± 5% of read value
LCD display	Pressure	Unit : mmHg/ kPa
	Pulse	Pulse rate per minute, displaying three digits
Power supply	4 AA dry batteries /DC 5V USB external power supply	
Power Off Mode	Manual power-off/ Auto power-off	
Device weight (without batteries)	About 285g	
Monitor Size	138mm (length) *120mm (width) * 59mm (height)	
Screen Size	60mm (length) *77mm (width)	
Cuff	Upper-arm-type cuff (measured arm circumference 22-36cm or 22-42cm)	
Annexure	Cuff, User Manual, Dry battery, Zipped Carrying Bag	

<table>
<tr><td>Software version</td><td colspan="3">1.5</td></tr>
<tr><td>Battery Life</td><td colspan="3">High-performance dry battery can be used for about 300 times at normal temperature</td></tr>
<tr><td>Service Life</td><td colspan="3">5 years</td></tr>
<tr><td>Date of Production</td><td colspan="3">See label</td></tr>
<tr><td rowspan="3">Operating environment</td><td>Temperature Condition</td><td>5 ℃-40 ℃</td><td rowspan="3">If the device is stored and used in the environment out of the designated temperature & humidity ranges, it cannot operate normally.</td></tr>
<tr><td>Humidity Condition</td><td>15%-85%RH</td></tr>
<tr><td>Atmospheric Condition</td><td>70kPa-106kPa</td></tr>
<tr><td>Transportation and Storage Environment</td><td colspan="3">Avoid strong impact, direct impact, exposure or rain during transportation. The packaged Blood Pressure Monitor shall be stored indoors at the temperature of -20℃~55℃ and the relative humidity of 10%~93%, atmospheric Condition: 70kPa-106kPa, without corrosive gas and with good ventilation.</td></tr>
<tr><td>Alarm system</td><td colspan="3">The test result is abnormal.</td></tr>
</table>

EMC Information-Guidance and Manufacture's Declaration

1* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
2* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper

operation.

3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 1

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Table 2

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable
Power frequency (50/60 Hz) magnetic field	30 A/m	30 A/m

IEC 61000-4-8		
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	Not applicable
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
Note* - 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.
Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal

FCC Compliance Statements

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.

Note: 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.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

US Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

After-sale Serice

After-sale service unit: Shenzhen Jumper Medical Equipment Co., Ltd.

Address: D Building, No. 71, Xintian Road, Fuyong Street, Baoan, Shenzhen, Guangdong, China

Tel: +86-755-26696279

E-mail: info@jumper-medical.com

Website: www.jumpermmed.com

www.jumper-medical.com

Postal Code: 518103

Statement:

- The lay operator or lay responsible organization should contact the manufacturer or manufacturer's representative on the following issues:

  Assistance in setting up, using, or maintaining the equipment or system when needed.

  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authorities of your Member State.
- Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair.

Authorized European Representative:

MedPath GmbH

EC REP

Mies-van-der-Rohe-Strasse 8, 80807 Munich,
Germany

JUMPER

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