AUTOMATIC BLOOD PRESSURE MONITOR

(Wrist Cuff Type)

INSTRUCTION MANUAL

Models: FT-B04, FT-B04-V

English Instruction Guide

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IMPORTANT INFORMATION

- Please read this instruction manual thoroughly so that you completely understand the operations, cautions, performance and limitations with this monitor.After reading this manual, please keep it for future reference.
- You should not use this blood pressure monitor for self-diagnosis,self-treatment or to change medication without consulting your physician or other health care professional. Should you have any doubt or question about your blood pressure measurements, you should consult your physician or other health care professional.
- This device is contained high-precision parts; therefore, avoid exposing it to extreme temperature or humidity or to direct sunlight, shock and dust. Fudakang guarantees the accuracy of this monitor only when it is stored and used properly.
- Do not attempt to calibrate or repair this monitor. If you have any questions regarding the function or operation of this monitor, please contact our service agent so we can provide you with accurate information.
- Should the monitor or cuff need cleaning, use a dry, soft cloth or a cloth dampened with water and a mild detergent. Never use alcohol, benzene, thinner or other harsh chemicals to clean the monitor or cuff.
- Remove and replace the batteries if the monitor is not used for more than 6 months. Alkaline batteries recommended.

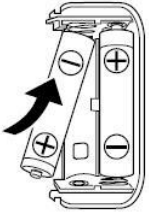
PRECAUTION FOR USE

The FDK Wrist Automatic Blood Pressure Monitor is designed to be operated by anyone who is eighteen years and older or by medical professionals to monitor blood pressure (systolic and diastolic) and pulse rate.

BEFORE YOU START

Please make sure you have installed 2 - AAA (3 volt) batteries (alkaline batteries are recommended). To install batteries or replace batteries if the "Low Battery" symbol appears on the display, proceed as follows:

■ Battery Loading



★ Remove the battery compartment cover by gently pushing down on arrow and sliding cover forward.

★ Place batteries with positive "+" and negative "-" terminals into compartment and make sure they match the indicated terminals in the compartment.

★ Close the battery cover by gently sliding it into the compartment and pressing it into place.

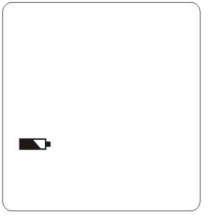
Note:

★ When the LCD display shows "Low Battery" signal ▬,the batteries must be replaced for accurate readings.

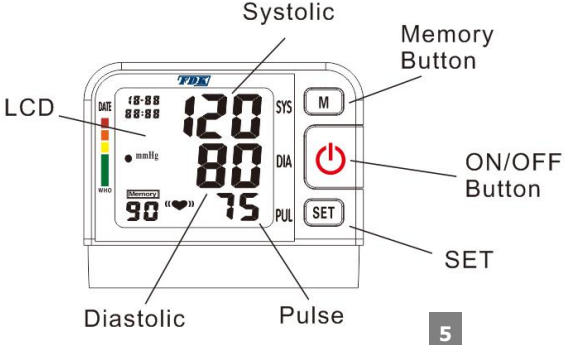
★ Do not use rechargeable batteries *(voltage 1.2V)*. They are not suitable for this product, can damage the monitor and will caused inaccurate readings to be obtained.

★ Remove the batteries if the monitor will not be used for six month or longer to avoid damage from the possibility* of leaking batteries.

★ All the measurements will remain in the memory should the batteries become drained, removed, or replaced.



MONITOR COMPONENTS



★ "SET" Button / Calendar, Clock Setting Mode

★ "MEMORY" Button / Calendar, Clock Adjustments

★ LCD Display

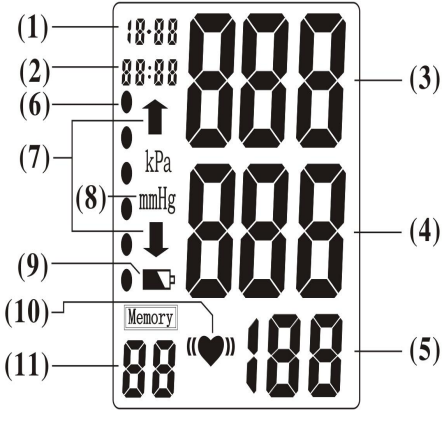
★ ON/OFF Button

★ Systolic Indicator

★ Diastolic Indicator

★ Pulse Indicator

DISPLAY OF LCD



Mode for LCD display:

(1) Date: Month - Day
(2) Time: Hour - Minute
(3) Systolic Blood Pressure
(unit: mmHg)
(4) Diastolic Blood Pressure
(unit: mmHg)
(5) Pulse (unit: beat/minute)
(6) WHO BP Classification Indicator
(7) Inflation / Deflation Indicator
(8) Blood Pressure Measurement Unit
(9) Low Battery Indicator
(10) Irregular heartbeat Indicator
(11) Memory Record Number

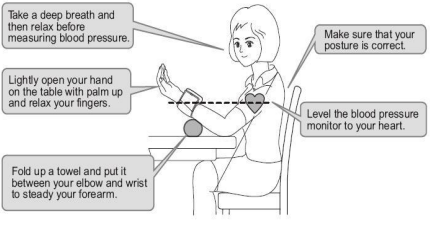
TIPS FOR BLOOD PRESSURE MONITORING

★ Relax for about 5 minutes before measurement.
★ Do not smoke or ingest caffeine at least 30 minutes prior to measurement.
★ Remove any constricting clothing and place the cuff on a bare wrist.
★ Keep still and do not talk until the measurement is complete.
★ The cuff must be neither too tight nor too loose. Using a little force, you should be able to place two fingers between the cuff and your wrist..

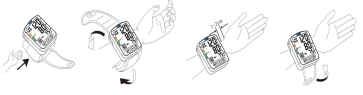
TAKING A MEASUREMENT

CORRECT POSTURE FOR TAKING BLOOD PRESSURE MEASUREMENT

★ Make yourself comfortable and sit-up straight.
★ Place and rest the wrist with the cuff in front of you on the table with your palm facing up. Do not bend your wrist or curl your fingers.
★ Cuff should be at approximately the same height as your heart.



HOW TO PLACE/WRAP THE CUFF ON YOUR WRIST?



★ Place the cuff around your bare wrist ½" - ¾" above the wrist joint on the opened-hand *(inside)* side of the wrist.

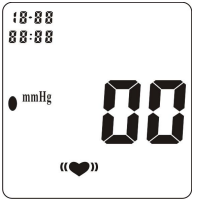
★ Keep the cuff at approximately the same level as your heart.

★ Unless your physician recommends otherwise, use the left wrist to measure pressure.

★ The cuff should be snug but not too tight. You should be able to insert two fingers between the cuff and your wrist.

TAKING YOUR BLOOD PRESSURE

After you are in a comfortable position, press the "ON/OFF" button. The device will perform a self verification/check. During this verification/check the LCD will display all "8's". At the conclusion of the verification/check the LCD will display "00".



PROGRAM DATE, CLOCK AND LANGUAGE

★ During the monitor is turned off, if you continually press and the "**SET"** buttons for about 5 seconds, the number of the ***YEAR*** signal will begin to blink on the LCD display. Press the **"M" (for memory)** button to change the ***YEAR***. Each time when you press the **"M"** button, it will change one ***YEAR*** forward.

★ When the ***YEAR*** is set up, if you continually press and release the **"SET"** button, the ***MONTH*** signal will begin to blink. Press the **"M"** button to change the ***MONTH***. Each time when you press the **"M"** button, it will change one ***MONTH*** forward.

★ When the ***MONTH*** is set up, if you continually press and release **"SET"** button once, the ***DAY*** signal will begin to blink. Press the **"M"** button to change the ***DAY***. Each time when you press the **"M"** button, it will change one ***DAY*** forward.

★ ***REPEAT THIS PROCESS FOR SETTING THE TIME***.
Use the **"SET"** button to change *(Hours/Minutes)* and the **"M"** button will change the numbers forward.

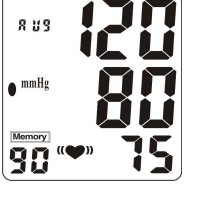
★After you have set the **YEAR, MONTH, DAY, HOUR** and **MINUTE** press the **"SET"** button. The **"SP"** in the lower left corner of the LCD display will begin to blink. This will allow you to set up your preferable language by choosing "01" for ENGLISH or "02" for SPANISH voice announcement from monitor, that will be performed when the monitor is placed in **"TALKING"** mode.

★ **WHEN EVERYTHING IS SET-UP COMPLETELY, THE MONITOR WILL AUTOMATICALLY SWITCH OFF. BUT, WHEN YOU PRESS "ON/OFF" BUTTON AGAIN, THE MONITOR WILL ACTIVATE.**

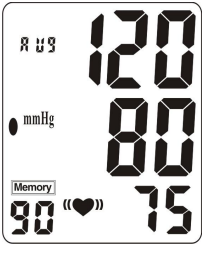
NOTE: *When batteries are replaced, the time and date must be reset.*
NOTE: *Time is maintained using a 24 HOUR clock. AM/PM is not displayed.*

IRREGULAR HEARTBEAT INDICATOR:

If an irregular heartbeat is detected, the **IRREGULAR HEARTBEAT** symbol will appear and blink in the display screen.



READING THE AVERAGE OF THE LAST THREE MEASUREMENTS (AVg):



★ Each time, when you press and release the **"M"** button during the monitor's being turned off condition, the LCD will display **"AVg"** symbol on the left upper corner of the LCD screen to show the average of the last three measurements record; the voice processor will be verbally announced at the same time.

★ To review other results that are in memory – Press the **"M**" button to scroll through previous measurements. Each time you press and release the **"M"** button the next oldest result will be displayed. If the **"TALKING"** function is turned **ON,** each result will be verbally announced

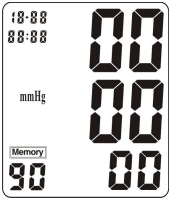
2-PERSON MEASUREMENTAND RESULTS STORAGE

This model has a 2-person memory bank with 90 memories storage capacity for each person.
To set the monitor for Person 1: With the monitor off, press and release the "SET" button. "P1" will show in the lower left corner. Press the "On/Off" button and the display will go blank. The monitor is now set for Person 1.
To Set the monitor for Person 2: Follow the above steps pressing and releasing the "SET" button.

DELETING MEASUREMENT FROM THE MEMORY:

★ Press and hold the **"MEMORY"** button until all the numbers change to 'ZERO'. All results in memory are now deleted.

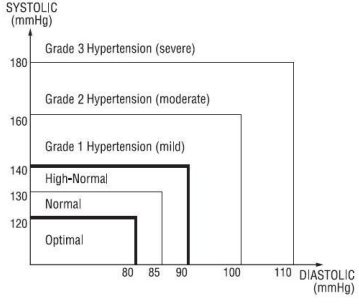
NOTE: *Date and time settings are not changed by using the memory delete function.*



ACCESSING BLOOD PRESSURE FOR ADULTS

The following standards for assessing high blood pressure (without regard to age or gender) have been established as a guide according to WHO (World Health Organization). Please note that other risk factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration and may affect these figures. Always consult with your physician or other health care professional for accurate assessment.

WHO CLASSIFICATION OF BLOOD PRESSURE



Blood Pressure Classification	SBP (mmHg)	DBP (mmHg)	COLOR INDICATOR
Optimal	<120	<80	GREEN
Normal	120-129	80-84	
High-Normal	130-139	85-89	
Stage 1 Hypertension	140-159	90-99	YELLOW
Stage 2 Hypertension	160-179	100-109	ORANGE
Stage 3 Hypertension	≥180	≥110	RED

SPECIFICATIONS

Model No.:	FT-B04 (No voice), FT-B04-V (Voice)
Type:	Oscillometric; Automatic air inflation by air pump and automatic deflation
Measurement Range:	Pressure: 40~280mmHg Pulse: 30~160 Pulses
Accuracy:	Pressure: within ±5mmHg Pulse: within ±5%
Power Supply:	3V DC (2 "AA" batteries)
Battery Life:	Approx. 250 times (180mmHg, once /day, 22°C)
Operation Environment:	Temperature: 5~40°C Humidity: < 85%RH
Storage Environment:	Temperature: -20~60°C Humidity: < 95%RH
Classification:	Class II, type B
Cuff Size:	290mm (L) x 72mm (W) (+/-5mm)
Memory:	2 x 90-Memory measurements including date and time
Dimensions:	74mm (2..91inch)-------(L) 70.7mm (2.78nch) ---------(W) 34.2mm (1.35inch) -------(H)
Weight:	112g (025 LBS)

TROUBLE SHOOTING (1)

Abnormality	Probable Reason	Corrective action
LCD shows Low Batter symbol 	Batteries are low.	Install new batteries.
The unit does not measure. Readings are too high or too low.	Pneumatic system blocked or cuff is too tightly wrapped.	Make certain the cuff is wrapped around your wrist correctly and re-measure.
	Pressure system was unstable before measurement.	Measure again. Stay calm. Do not move or speak during measurement.
	The cuff position is not correct.	Sit comfortably and still. Make sure the cuff is at the same level at your heart.
An irregular heartbeat symbol occurs. 	Irregular heartbeat	Relax for about 5 minutes and measure again. If the symbol appears again, consult your physician or other health care professional..
Voice processor	Unclear announcement by voice processor	Batteries may be low. Please install new batteries and then take a measurement again,
Incorrect operation	Some interference in inflation or wrong operation during measuring	Refer to the inflation step in “Taking blood pressure” and process again.

TROUBLE SHOOTING (2)

Abnormality	Reason	Checkout
LCD shows "Er U"	Insufficient inflation	Wait for 5 minutes and re-measure. If operation is still abnormal, contact manufacture or agent (see the last page)
LCD shows "Er H"	Inflation over 305 mmHg	
LCD shows "Er 1"	Undetectable the pulse	
LCD shows "Er 2"	Radiation interference	Move away the radiation source
LCD shows "Er 3"	Measured result appears wrong	Measure again

LIMITED WARRANTY POLICY

Fudakang guarantees that the Digital Blood Pressure Monitor will be free manufacturing defects under normal use for two years the original purchase.

This warranty covers only normal use, and does not apply to use in clinical or commercial applications. This warranty does not cover batteries or other power sources that may be provided with or used with the Digital Blood Pressure Monitor. This warranty is voided if the Digital Blood Pressure Monitor product is misused or abused in any manner. If the Digital Blood Pressure Monitor falls to operate during the time original purchaser owns it, please email us the reason you would like to return at **info@fdkmedical.com**. **If you purchased this product via other marketplaces but not FDK's service directly, please check up your invoice or receipt for the contact info of your vender for the return policy.**

How to Return Your Products:

1. Email us to obtain or confirm a return authorization ("RA") number. Repair or replacement can not be processed without a valid RA number.

2. Write your RA number on the return label that will be created at the time you call to receive RA number. Enclose your sales receipt (or photocopy) in the shipping box.

3. Mail your product back to Fudakang by any carrier you wish (USPC, UPS, Fed Ex, etc.), but please make sure the package has the proper amount of postage. We will not be able to process your repair or replacement if the package is lost. (We recommend that you insure the package and request a receipt for your records, to avoid any liability for damage or loss.)

Important: Do not send the package C.O.D. Our receiving warehouse is unable to accept C.O.D. shipment.

Returns are typically processed within 48 hours of receipt excluding weekends. Please allow 30 days to receive the repaired or replaced product. Repair or replacement of defective unit, at the warrantor's option, is the sole remedy under this warranty. ANY IMPLIED WARRANTIES WHICH THE PURCHASER MAY HAVE ARE LIMITED IN DURATION TO THE TIME THAT THE ORIGINAL CONSUMER PURCHASER OWNS THE PRODUCT. Some states do not allow limitations or how long an implied warranty lasts, so the above limitation may not apply to you.

This warranty constitutes the warrantor's only responsibility and obligation to repair and/or replace materials or components, without refund the purchase price. The warrantor will not be responsible for any indirect, incidental, special, consequential, or punitive damages or other loss, including, but not limited to, damage to or loss of other property or equipment and personal injuries, whether to purchaser or others. The warrantor shall in no event be liable to the purchaser for any amount in excess of the cost of repair and/or replacement of the unit. Some states do not allow the exclusive or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. This warrant gives you specific legal rights, and you may also have other rights which vary from state to state.

Distributed By:
Fudakang Industrial LLC.
Hamilton,NJ 08619
info@fdkmedical.com
www.fdkmedical.com

Manufacturer
Fudakang Industrial Co., Ltd
No.8 Yinghe Road, Yuanjiangyuan
Management Zone, Changping Town,
Dongguan, Guangdong, China
T.:+86-769-81098181; F:+86-769-81098187
sales@fudakang.com; www.fudakang.com

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BLOOD PRESSURE RECORD
REGISTRO DE LA PRESION ARTERIAL

Name: Age: Weight:
Nambre: Edad: Peso:

Date:	AM	SYS/DIA	PULSE		PM	SYS/DIA	PULSE
Fecha:	AM	SYS/DIA	PULSE		PM	SYS/DIA	PULSE

Note: By monitoring and controlling high blood pressure, you can lower your risk of stroke, heart attack, heart failure and kidney disease

STATEMENTS AND DECLARATIONS:

1. Wrist Blood Pressure Monitor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS

2. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d = 3,3 m away from the equipment.
(Note. As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3,3 m at an IMMUNITY LEVEL of 3 V/m)

3. The manufacturer are available for request of circuit diagrams, component part lists, descriptions ,calibration instructions ,or other information that will assist service personnel to repair those parts of the device

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

Guidance and manufacturer's declaration

Guidance and manufacture' s declaration – electromagnetic emission		
The Wrist Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer of the user of the Wrist Blood Pressure Monitor should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Wrist Blood Pressure Monitor use 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 emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture’ s declaration – electromagnetic immunity			
The Wrist Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Wrist Blood Pressure Monitor should assure that it is used in such an environment.			
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 floor are covered with synthetic material, the relative humidity should be at least 30%. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast	±2 kV for power supply		Mains power quality should be

transient/burst IEC 61000-4-4	lines ±1 kV for input/output lines	Not applicable	that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode. ±2 kV common mode	Not applicable	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% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TL-100Drequires continued operation during power mains interruptions, it is recommended that the TL-100Dbe powered from an uninterruptible power supply or a battery.

Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture’s declaration – electromagnetic immunity			
The Wrist Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Wrist Blood Pressure Monitor 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	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Wrist Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.167\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 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 not Applicable. 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 Wrist Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Wrist Blood Pressure Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Wrist Blood Pressure Monitor.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

portable and mobile RF communications equipment and the Wrist Blood Pressure Monitor.

The Wrist Blood Pressure Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wrist Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Wrist Blood Pressure Monitor 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 $d = 1.167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.333\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**

10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

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.

Explanation of Symbols:

LOT Symbol for batch code

CE 0598 Symbol for 'CE"

Symbol for manufacturer

IP22 Symbol for "the IP classification"

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 "TYPE BF APPLIED PART"

Symbol for "Follow operating instructions"

Customer Care Center

Fudakang Industrial LLC

PO Box. 718

Princeton Junction, NJ 08550-0718

info@fdkmedical.com

www.fdkmedical.com