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UPPER ARM ELECTRONIC BLOOD PRESSURE MONITOR Procore Instruction Manual MODEL: 240388 ONIOFF **C E** 0413

TABLE OF CONTENTS NOTES ON SAFETY......2 ABOUT BLOOD PRESSURE......6 PRECAUTIONS BEFORE USE.....8 FEATURES OF THE PRODUCT.....9 PARTS IDENTIFICATION......10 INSERT OR REPLACE BATTERIES......11 TIME AND SYSTEM SETUP...... UNIT CONVERSION mmHg/kPa DISPLAY......13 WHO BLOOD PRESSURE CLASSIFICATION DISPLAY......14 ATTACHING THE ARM CUFF.......15 HOW TO TAKE PROPER MEASUREMENTS 16 SPECIFICATIONS......20 TROUBLESHOOTING......21

The Monitor uses the oscillometric method of blood pressure measurement.

Measurement Automatic Electronic Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on adult each time, with an arm cuff around the left upper arm according to the instruction in the "ATTACHING THE ARM CUFF", The expected life of the product is 5 years.

INTRODUCTION

The product complies with the electromagnetic compatibility requirement of EN60601-1-2 and safety standards of EN60601-1 and performance of

IEC 80601-2-30 as specified in EEC directive 93/42/EEC. NOTES ON SAFTEY

* The warning signs and sample icons shown here are listed for your safe and correct use of the unit, so as to prevent injuries or damages to the device.

* The icons and meanings are as follow. Examples of signs The \otimes icon indicates prohibitions (what you should not do). Matters involving actual prohibitions are indicated by text or pictures in or

near ⊗. The left icon refers to "general prohibition".

FDA Approved

The **1** icon indicates something that is compulsory (what must always be observed). Matters involving actual compulsory actions are indicated by text or pictures in or near • .The left icon refers to "general compulsion". The \strace{0} icon indicates something can't be disassembled or "Don' disassemble" Matters involving actual compulsory actions are indicated by text or pictures in or near \(\mathbb{O} \) . The left icon refers to "general prohibition".

Type BF Applied part The following symbol indicates that the device is MR-unsafe: Please refer to the instructions for use Indicates a medical device that needs to be protected from moisture.

Marking of electrical and electronic equipment in accordance with 11(2) of Directive 2002/96/EC (WEEE)

Article

avoid any injury to patient.

otherwise will cause extravasated blood.

monitor measuring. This device can not be used for Patient transport and surgical care .It can be used in household or fixed places only. Please press "on/off" button to stop work when you feel uncomfortable with the arm, or if the air is inflating abnormally without stop. Do not let a child below 12 years old and the people who can't express one'

The device should not be used to judge illness, first aid and continuously

Patient must follow doctor's instruction and should not perform

Self-diagnosis of measured results and treatment are dangerous,

self-judgment and self-treatment by the measuring result,

s intention. When it is used by the people of 12~18 years old, it should accompanied by the Adult. May cause accident or trouble. Do not use the unit for purpose other than measuring blood pressure. May cause accident or trouble.

Please do not use mobile phone around the device. Please do not use the device around the magnetic field. The device is prohibited from being used during movement.

Do not use the equipment in outdoor or shower rooms.

Do not disassemble, repair, or remodel the main unit or the arm cuff of the blood pressure monitor. Will cause the unit to function erroneously.

-The PATIENT is an intended OPERATOR. -Not servicing and maintenance while the ME EQUIPMENT is in use.

2. What is hypertension and how is it controlled?

the maintenance instructions of manual.

1. What is blood pressure?

6

06

Do not measure your blood pressure over 6 times each day. Do not apply the cuff over a wound as this can cause further injury. Do not measure on the arm which is on the side of a mastectomy, otherwise it could cause injury. Observe the air pressure value from the LCD display. When measuring, it could not exceed 280 mmHg, otherwise Please press "on/off" button to stop

Requests from Manufacturer

Make sure there is no connection tubing kinking before start measuring to

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

Do not use force to bend the arm cuff or the air tube. Do not knock or drop the main unit. Always use the specified accessories in the manual, the use of other parts not approved by the manufacturer may cause faults or injuries.

Blood pressure measured at a clinic or doctor's office may cause apprehension

and produce an elevated reading, 25 to 30 mmHg higher than that measured at

home, Home measurement reduces the effects of outside influences on blood

pressure readings, supplements the doctor's readings and provides a more

110 105 100

For service information, parts list etc., please contact the dealer.

5

Do not smoke Exercise regularly

accurate, complete blood pressure history. 4. WHO blood pressure classification Standards for assessment of high blood pressure, without regard to age, have been established by the World Health

Organization (WHO), and shown in

Reduce salt and fat intake

3. Why measure blood pressure at home?

Maintain proper weight

chart below. 5. Blood pressure variations An individual's blood pressure varies greatly on a daily and seasonal basis. It may vary by 30 to 50 mmHg due to various conditions during the day. In

to "Trouble shooting" of the manual.

8.Cuff pressure range 0-299mmHg

1. Memory can store 90 measurements. 2. Large and clear LCD display.

devices or turn them off.

steady mood at home.

CAUTION

11

13

15

17

CAUTION

19

ARM CUFF

95 Grade 1 hypertension (mild) 90 High-norma 85 80 Optimal 120 130 140 150 160 170 180 Systolic blood pressure 2. For people with irregular or unstable peripheral circulation problems due to diabetes, liver disease, hardening of the arteries, etc., there may be fluctuation in

Reference Material: Journal of Hypertension

Grade 3 hypertension (severe)

Grade 2 hypertension (moderate)

Have regular physical checkups

1999, Vol 17 No.2

Blood pressure is the force exerted by blood against the walls of the arteries. Systolic pressure occurs when the heart contracts. Diastolic pressure occurs when the heart Blood pressure is measured in millimeters of mercury (mmHg). One's natural blood pressure is represented by the fundamental pressure, which is measured first thing in the morning while one is still at rest and before eating.

-The user can maintain the product, the maintenance method is described in

ABOUT BLOOD PRESSURE

-Stop using the equipment immediately, if it is in contact with water.

Hypertension, an abnormally high arterial blood pressure, if left unattended, can cause many health problems including stroke and heart attack. Hypertension can be controlled by altering lifestyle, avoiding stress and with medication under a doctor's supervision. To prevent hypertension or keep it under control:

Typical fluctuation within a day hypertensive individuals, variations are (Measured every five minutes) mmHg even more pronounced. Normally, the blood pressure rises while at work or play and falls to its lowest Pressi levels during sleep. So, do not be overly concerned by the results of one measurement. Take measurements at the same time every day using the procedure described in this

Be sure to note date and time when recording your blood pressure. Consult your

1. If you are taking medication, consult with your doctor to determine the most

appropriate time to measure your blood pressure. NEVER change a prescribed

PRECAUTIONS BEFORE USE

3. WHO blood pressure classification display. 4. Easy to use, Press a button to automatically measure, record the measurement values and measurement time. 5. Automatically turns off (within 1 minute) to save power.

medication without first consulting with your doctor.

manual, and know your normal blood pressure.

Many readings give a more comprehensive

doctor to interpret your blood pressure data.

blood pressure history.

Component:

the products.

1. Press "SET" key to turn on.

flashes on LCD to enter setting mode.

· Battery short circuit must be prevented.

PARTS IDENTIFICATION To prevent such interference, use the monitor at a sufficient distance from such 4. Before using, should wash your hands. SYMBOLS ON DISPLAY 5. Do not measure on the arm which simultaneously used monitoring ME Equipment, otherwise it could cause loss of function. 6. Consult your doctor if the unexpected readings are obtained, also please refer

9

blood pressure values measured at the upper arm versus at the wrist.

3. Measurements may be impaired if this device is used near televisions, microwave

ovens, X-ray, mobile phone equipment or other devices with strong electrical fields.

7. The reading is probably a little lower than measured in the hospital due to the

FEATURES OF THE PRODUCT

INSERT OR REPLACE BATTERIES 1. Remove the battery cover. 2. Insert new batteries into the battery compartment as shown, taking care that the polarities(+) and (-)are correct. 3. Close the battery cover, Use only LR6, AA batteries.

> Disposal of empty battery to the authorized collecting party subject to the regulation of each individual territory.

• Insert the batteries as shown in the battery compartment. If not, the device will not work.

 Battery life varies with the ambient temperature and may be shorten at low • The batteries may leak and cause a malfunction. • Use the specified batteries only. The batteries provided with the device are for testing monitor performance and may have a shorter life.

• Batteries, which have fluid on surface or be modified, can not be inserted into

Accessory

10

• When [] (LOW BATTERY mark) blinks in the display, replace all batteries with new ones. Do not mix old and new batteries. It may shorten the battery life, or cause the device to malfunction. (LOW BATTERY mark) does not appear when the batteries run out. • Please ensure to distinguish positive polar "+" and negative polar "-" of batteries when replacing batteries.

3. Press "MEM" key to adjust the year, then press "SET" key again to save your setting and enter the month setting mode. 4. Press "MEM" key to adjust the month. Following the same steps to adjust date/hour/ minute

I- 1 - 0:00

date

hour

0:00

minute

- -- 1 0:00

month

UNIT CONVERSION mmHg/kPa DISPLAY

The goods have mm Hg(mmHg), kPa (kPa) two kinds of blood pressure display

ATTACHING THE ARM CUFF

1. Wrap the arm cuff around the upper arm, about (2-3) cm above the elbow, as shown, place the cuff direct the skin, as clothing may cause a faint pulse, and

2.constriction of the upper arm, caused by rolling up a shirtsleeve, may prevent

3. Secure the arm cuff with Velcro Strip in such a way that it lies comfortably and is

not too tight. Lay the arm on the table(palm upwards) so that the arm cuff is at the

4. Measure your arm circumference for cuff selection, refer to "Specifications"

same height as the heart. Make sure that the tube is not kinked.

vear

units(mmHg factory to express).

result in a measurement error.

accurate readings.

 Used batteries may leak and damage the main unit. Pleases observe the following * If you are not going to use the unit for a long period of time (approximately three months or more), remove the batteries.

SETUP TIME OF SYSTEM

* Replace worn batteries with their polarities in the correct direction.

2. Press and hold "SET" key until the year number displays and

Press "ON / OFF" button for 10 seconds to display unit switching interface, then

press "MEM" key to select mmHg / KPa, press "ON / OFF" button to exit.

The units will be chosen by the above shows mmHg/kPa after decontrol, After the

WHO BLOOD PRESSURE CLASSIFICATION DISPLAY

Also select memory unit value changes.

nomal boot unit values are shown as blood pressure.

Diastolic blood pressure Grade 2 hypertension (moderate) Reference material: journal of Grade 1 hypertension (mild) hypertension 1999. vol 17 No.2 High-normal Normal Optimal

HOW TO TAKE PROPER MEASUREMENTS For the most accurate blood pressure measurement: PATIENT position in NORMAL USE, including: 1) comfortably seated.

2) legs uncrossed.

3) feet flat on the floor.

4) back and arm supported.

time continuous measuring.

5) middle of the CUFF at the level of .

thirty minutes before taking the measurement.

• It could affect the readings in the below conditions:

the buttons(UP). "SET" button for the memory (DOWN)

button read out the latest measurement of memory.

display "∏a" has been to delete all memory.

from damage, follow the directions listed below: Keep the monitor in the storage case when not in use.

Do not fold the arm cuff too tightly.

Indication

Accuracy

storage condition

Dimensions

Classification

AC adapter

E1:can't normally

Increase pressure

E3 inflate pressure

E2E4:have shaking

while measurement

too high

Upper arm circumference

Weight

Memory

• Measure your blood pressure at about the same time every day.

• Do not measure right after physical exercise or a bath. Take a rest for twenty or

• Within in an hour after dinner, after having wine ,coffee, red tea, sports, bathing; talking, being nervous, being in unsteady mood, bending forward, moving, room temperature dramatically changing during measuring; In the moving vehicles, long

READ MEMOR Y

DELETE MEMOR Y

Press "MEM" button, a memory reading out the latest measurements, "MEM" for

Power Measurement closure or after the end of the state .can press the "MEM"

The state read out the memory press the (memory) button five seconds, the LCD

• Remain still and keep quiet during measurement. • Relax as much as possible and not talk during the measurement process.

Grade 3 hypertension (severe)

14

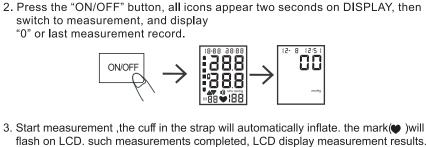
16

HOW TO MEASURE BLOOD PRESSURE 1. Set up the arm cuff to your upper arm as previous section of "ATTACHING THE switch to measurement, and display "0" or last measurement record.

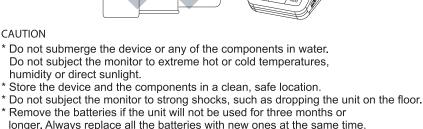
58

Clean the monitor and cuff with a soft dry cloth.

Do not use any abrasive or volatile cleaners.



Arm cuff



• This product is designed for use over an extended period of time; however, it is generally recommended that it be inspected and calibrated every two years

По To keep your digital blood pressure monitor in the best condition and protect the unit

Measuring Method Oscillometric Measurement Digital LCD display Measuring Range Pressure:(30~280)mmHg Pulse:(40~199)Beat/min Static Pressure: ± 3 mmHg Pulse: $\pm 5\%$ 90 Memories 4x1.5V Batteries(LR6 or AA) Power supply use alkaline battery, measure above 200 times. +5°C~+40°C. 15%RH~93%RH Operating condition

Type BF

Check your arm cuff if any

Pressure value of more

Hand or body shaking

while measurement

air leakage

than 299mmHg

(22~32)cm

Atmospheric pressure: 70kPa~106kPa

Atmospheric pressure:50kPa~106kPa

Approx: 96(W)X130(H)X60(D)mm

Approx: 380g, excluding batteries

INPUT: 100-240V~ 50/60Hz, 0.2A

Replace arm cuff with new one

Re-measurement or send back

22

24

dealer for re-calibrate pressure

keeping static and correct

gesture to measure again

OUTPUT: 6V === 500mA * Specifications may be changed without notice in the event of improvement being made.

-20°C~+55°C. 0%RH~93%RH

The fabric fastener could touch the inner surface of the arm cuf and damage it.

SPECIFICATIONS

1. Type of protection against electric shock: INTERNALLY POWERED EQUIPMENT. 2. Degree or protection against electric shock: TYPE BF APPLIED PART. 3. Mode of operation: CONTINUOUS OPERATION. 4. Equipment not suitable for category AP&APG equipment use in presence. the system might not meet its performance specifications if stored or used outside

ERROR DISPLAY

Nothing is displayed

When you push the

■ Battery icon flash

that it is used in such an environment.

POWER button or

Emissions test

RF emissions

CISPR 11

Surge

short

IEC 61000-4-5

Voltage dips,

interruptions

and voltage

variations on

power supply

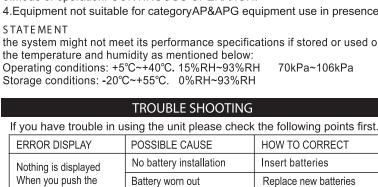
IEC 61000-4-1

input lines

21

to ensure proper function and performance.

(* Pressure calibration is done by EU representatives)



Insert battery in the correct

polarities

Electromagnetic environment – guidance

The Model 240388 uses RF energy only for

its internal function. Therefore, its RF emissions

Mains power quality should be

that of a typical commercial or

Mains power quality should be

that of a typical commercial or

hospital environment. If the user

operation during power mains

that the Model 240388 be

interruptions, it is recommended

powered from an uninterruptible

of the Model 240388 product

hospital environment.

name requires continued

power supply or a battery.

are very low and are not likely to cause any

interference in nearby electronic equipment.

The polarities of batteries

Guidance and manufacturer's declaration-electromagnetic emission

The Model 240388 is intended for use in the electromagnetic environment

specified below. The customer or the user of the Model 240388 should assure

placed wrongly

Appendix 1 Guidance and Manufacturer Declaration Tables

Compliance

Group 1

±0.5 kV, ±1 kV

differential

mode line-line

0% UT (100%

cycle at 0°, 45°,

90°, 135°, 180°,

1 (100% dip in UT)

for 1 cycleat 0°

(30% dip in UT)

for 25/30 cycles

0% UT(100% dip in UT) for 250/

315°

0% UT

70% UT

225°, 270°, and

	RF emissions CISPR 11	Class B	The Model 240388 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
	Harmonic emissions IEC 61000-3-2	А		
	Voltage fluctuations /flicker emissions IEC 61000-3-3	Complied		
-	23			

±0.5 kV, ±1kV

differential

mode line-line

0% UT (100%

cycle at 0°, 45°,

90°, 135°,180°,

225°, 270°, and

(100% dip in UT)

for 1 cycle at 0°

(30% dip in UT)

for 25/30 cycles

0% UT(100% dip

in UT) for 250/

dip in UT) for 0.5 dip in UT) for 0.5

315°

0% UT

70% UT

Replace battery and measure again Battery icon on Battery low power 1.The arm cuff was held The systolic pressure lower than your heart Value or diastolic 2. The arm cuff was not Pressure value attached properly keeping correct position too high 3. You moved your body or and gesture to measure spoke during measurement again The systolic pressure 1.The arm cuff was held Value or diastolic higher than your heart Pressure value 2.you moved your body or too low Spoke during measurement Guidance and manufacturer's declaration – electromagnetic immunity 240388 are intended for use in the electromagnetic environment specified below. The customer or the user of the Model 240388 should assure IEC 60601 Compliance Electromagnetic environment -

± 2 kV for power Electrostatic ±2 kV for power Mains power quality should be transient/burst that of a typical commercial or supply lines100 supply lines 100 kHz repetition kHz repetition hospital environment. IEC 61000-4-4 frequency ±1 kV frequency ±1 kV for input/output for input/output lines lines Power Power frequency magnetic frequency fields should be at levels (50/60 Hz) 30 A/m,50/60H | 30 A/m,50/60Hz characteristic of a typical magnetic field location in a typical commercial or hospital environment. IEC 61000-4-8 NOTE: UT is the a. c. mains voltage prior to application of the test level.

300 cycle at 0° 300 cycle at 0° 25 Portable and mobile RF communications equipment should be used no closer to any part of the Models 240388. including cables, than the recommended separation distance calculated from the equation applicable to the frequency of Conducted RF 3 Vrms the transmitter. 6 V 150 kHz to Recommended separation distance IEC 61000-4-6 80 MHz 6 Vrms 150 kHz to 80 MHz outside $d = \frac{\acute{e}12}{\acute{e}V_2} \dot{\mathring{u}} \sqrt{P}$ ISM bandsa $d = \frac{\acute{e}12\grave{u}}{\acute{e}E_1} \frac{\acute{u}}{\acute{u}} \sqrt{P} \quad 80MHz \ to \ 800MHz$ $d = \frac{\acute{e}23\grave{u}}{\acute{e}E_1} \mathring{u} \sqrt{P} \quad 800MHz \text{ to } 2.7GHz$ 27

Radiated RF 10 V/m power rating of the transmitter in watts (W) according to the IEC 61000-4-3 80 MHz to 10 V/m transmitter manufacturer 2.7 GHz and d is the recommended separation distance in metres(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: $((\bullet))$ NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

communications equipment and the Model 240388 Model 240388 can help prevent electromagnetic interference by maintaining a (transmitters) and the Model 240388 as recommended below, according to the

30

interference if it is inadvertently brought into patient areas.

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.

31

1.2 1.2 1.2 2.3 3.8 3.8 3.8 7.27 100 12 12 12 23 For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to

80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0, 15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50 0 MHz to 54 0 MHz NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz to decrease the likelihood that mobile/portable communications equipment could cause

C05

a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80

5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz. b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges. c 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 29

Rated maximum output of 150 kHz to 80 150 kHz to 80 80 MHz to 800 MHz to transmitte MHz outside MHz in 800MHz 2,7 GHz ISM bands ISM bands W $d = \frac{\acute{e}3.5}{\acute{e}} \frac{\grave{u}}{V_L} \frac{\grave{v}}{\acute{u}} \sqrt{P}$ $d = \frac{\acute{e}12}{\acute{e}V_2} \dot{\mathring{u}} \sqrt{P}$ $d = \frac{\acute{e}12}{\acute{e}} \dot{u} \sqrt{P}$ $d = \frac{\acute{e}23\grave{u}}{\grave{e}E_1} \mathring{u} \sqrt{P}$ 0.01 0.12 0.12 0.12 0.23 0.1 0.38 0.38 0.38 0.73 10

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. electromagnetic site survey should be considered. If the measured field strength MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to in the location in which the Model 240388 is used exceeds the applicable RF compliance level above, the Model 240388 should be observed to verify 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between normal operation. If abnormal performance is observed, additional measures 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to may be necessary, such as re-orienting or relocating the Model 240388 d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m. Recommended separation distances between portable and mobile RF The Model 240388 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the minimum distance between portable and mobile RF communications equipment maximum output power of the communications equipment. Separation distance according to frequency of transmitter NOTE 2 The ISM (industrial, scientific and medical) bands between 0,15 MHz and

that it is used in such an environment Immunity test test level Electrostatic ±8 kV contact ±8 kV contact Floors should be wood, concrete discharge or ceramic tile. If floors are (ESD) ±2 kV, ±4 kV, ±2 kV, ±4 kV, covered with synthetic material. ±8 kV, ±15 kV the relative humidity should be at ±8 kV, ±15 kV IEC 61000-4-2 least 30 %. air air

Guidance and manufacturer's declaration-electromagnetic immunity 240388 are intended for use in the electromagnetic environment 240388 should assure specified below. The customer or the user of the Model that it is used in such an electromagnetic environment. IEC 60601 Compliance Electromagnetic environment - guidance Immunity test test level level Where P is the maximum output

28

26

32