B.Well
Caring for everyone

EN Instruction for use

PRO-30

Semi-automatic Upper Arm
Blood Pressure Monitor

B.WELL SWISS CONTROLLED

1. INTRODUCTION

Thank you for purchasing the B.Well upper arm blood pressure monitor PRO-30. Designed for convenient and easy operation, this device provides fast and reliable measurement of systolic and diastolic blood pressure as well as heart rate using the oscillometric measurement method.
The PRO-30 is a semi-automatic upper arm blood pressure measuring device.

Important advantages of PRO-30

- The Pulse Arrhythmia Detection technology
- Traffic Light Indication according to European Society of Hypertension (ESH).
- Last measurement memory.
- Fan-shape anatomic cuff for arm, washable.
- Battery life indicator.
- Automatic switch off.
- This device is easy to use and has been proven in clinical studies to provide excellent accuracy.

2. CLASSIFICATION OF BLOOD PRESSURE VALUES

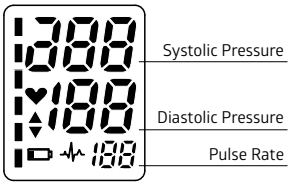
Table for classifying blood-pressure values (unit: mmHg) according to European Society of Hypertension (ESH)

Range	Systolic blood pressure	Diastolic blood pressure	Measures
Grade 3: severe hypertension	Higher or equal to 180	Higher or equal to 110	Urgently seek medical advice!
Grade 2: moderate hypertension	160-179	100-109	Consult your doctor immediately
Grade 1: mild hypertension	140-159	90-99	Consult your doctor
High normal	130-139	85-89	Consult your doctor
Normal	Lower than 130	Lower than 85	Self-check
Optimal	Lower than 120	Lower than 80	Self-check

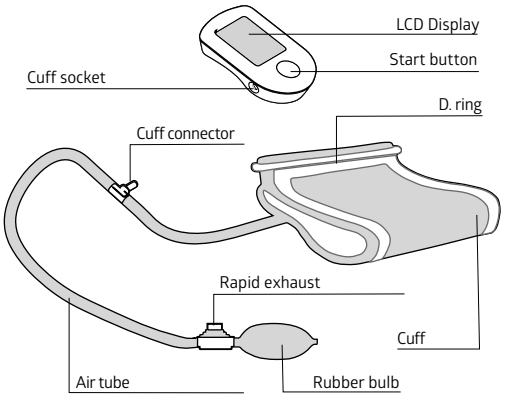
ⓘ **NOTE:** Show the measured values to your doctor. Never use the results of your measurements to change the doses of drugs prescribed by your doctor.

3. CONTENTS AND DISPLAY INDICATORS

Model PRO-30



- Heart beat symbol
- You can begin to measure
- Zero-seeking symbol
- Batteries are running out
- Low battery symbol
- Pulse Arrhythmia Detection symbol
- Indication of blood pressure level



4. INTENDED USE

The digital semi-automatic 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 upper arm. The cuff circumference is limited to 22 cm – 48 cm.

5. CONTRAINDICATION

It is inappropriate for people with serious arrhythmia to use the digital semi-automatic blood pressure monitor.

6. PRECAUTIONS

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 left arm for each measurement.
6. Please always relax a minimum moment of 1 to 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 above 15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your arm.
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 digital semi-automatic blood pressure monitor 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. Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
13. ⚠ 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.
14. ⚠ Please do not share the cuff with other infective person to avoid cross-infection.
15. Please note that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
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.

7. SETUP AND OPERATING PROCEDURES

7.1. Battery loading

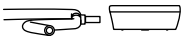
a. Open battery cover at the back of the monitor.
b. Load two "AAA" size batteries. Please pay attention to polarity.
c. Close the battery cover.
d. Once you install the batteries or turn off the monitor, the LCD does not display anything. Now the monitor is in Off Mode.

⚠ If the LCD display battery symbol ▭ while the monitor is on,the batteries are running out.
⚠ If the batteries are run out, battery symbol ▭ will blink for 10 seconds. Then the monitor will always display battery symbol and ▭ cannot open. Please 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.
⚠ 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.

7.2. Connecting the cuff to the monitor

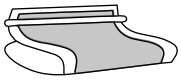
Insert the Air Tube Plug firmly into the Air Tube Socket on the side of the Monitor. Make certain that the Plug is completely inserted in order to prevent air leakage during use.

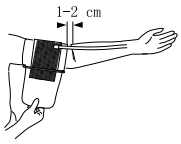


⚠ Avoid compression or restriction of the connection tubing during measurement, which may cause inflation error, or harmful injury due to continuous cuff pressure.

7.3. Applying the cuff

a. Pulling the cuff end through the medal loop (the cuff is packaged like this already), turn it outward (away from your body) and tighten it and close the Velcro fastener.
b. Place a cuff around a naked hand 1-2 cm higher than an elbow pole.
c. Being in a sitting position, put a hand palm up before yourself on a plain surface, for example, on a table. Arrange a cuff on a hand so that its bottom edge was apart 1-2 cm above an elbow bend. The red tag (Artery mark) has to be over an elbow pole.
d. The cuff has to cover densely a hand, otherwise the result of measurement will be the improper. It is not recommended to dress a cuff over clothes.





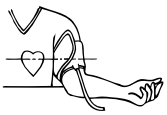
7.4. Carrying out a measurement

Before the measurement:

- Avoid eating, smoking as well as all forms of exertion directly before the measurement. All these factors influence the measurement result. Try and find time to relax by sitting in an armchair in a quiet atmosphere for about ten minutes before the measurement.
- Remove any garment that fits closely to your upper arm. Measure always on the same arm (normally left).
- Attempt to carry out the measurements regularly at the same time of day, since the blood-pressure changes during the course of the day.

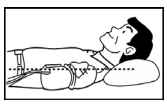
Sitting Comfortably Measurement

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.



Lying Down Measurement

d. Lie on your back.
e. Place your left arm straight along your side with your palm upside.
f. The cuff should be placed at the same level as your heart.



Common sources of error:

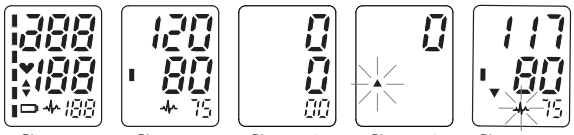
- Movement during measurement.
- The arm artery lies considerably lower (higher) than the heart.
- The cuff does not fit you in size.
- Loose cuff or a sideways protruding air-pocket.

ⓘ **Note:** With repeated measurements, blood accumulates in the respective arm, which can lead to false results. Correctly executed bloodpressure measurements should therefore first be repeated after a 1 minute pause.

7.5. 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 5. Please contact the service center if segment is missing.
b. The LCD will momentarily display the last measurement stored in the memory. See picture 5-1.

If the monitor has no measurement stored in the memory, the LCD will display show "0" for blood pressure and pulse rate. See picture 5-2.



Picture 5 Picture 5-1 Picture 5-2 Picture 5-3 Picture 5 -4

c. After that, LCD will show "0" mmHg that indicates you can begin to measure. See picture 5-3.
d. Squeeze the bulb till the pressure is over your normal systolic pressure by 50 mmHg, if you don't know your normal systolic pressure, squeeze the bulb till the pressure reaches 190 mmHg. 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. Irregular heartbeat symbol (if any) will blink. A bar or several bars, indicating blood pressure level, will appear. See picture 5-4.
e. After reading the result, press the exhaust valve which is located in the front of the bulb to release the air.
f. When all the air is pushed out of the cuff, monitor will blink ▲, then you can begin to measure again.
g. After measurement, the monitor will turn off automatically after 3 minutes of no operation. Alternatively, you can press the "START" button to turn off the monitor manually.
h. During measurement, you can press the "START" button to turn off the monitor manually.
i. During measurement, you can press the exhaust valve which is located in the front of the bulb to release the air.
j. If you have initially pumped the insufficient level of pressure in a cuff, then on the display all figures will be out and there will be symbol blinking and ▲ directed up. In that case it is necessary to pump air in a cuff additionally till the figures will be shown on the display.

ⓘ **Note:** Please consult a health care professional for interpretation of pressure measurements.
ⓘ **Note:** The monitor can memorize the last result. If you change the batteries, the last result may be lost.

7.6. Pulse Arrhythmia Detection

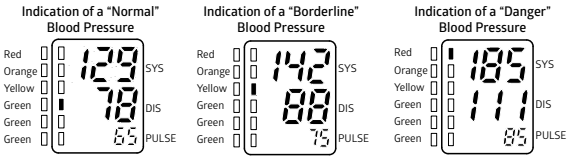
Appearance of the Arrhythmia indicator

The appearance of the symbol signifies that a certain pulse irregularity was detected during the measurement. The result can vary from your normal blood pressure. As a rule this is not a cause for concern; however, if the symbol appears more frequently (e.g. several times per week on measurements performed daily) or if it suddenly appears more often than usual, we recommend you inform your doctor. There are 2 conditions under which the signal of Pulse Arrhytmia Detection 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.

7.7. Traffic Light Indication in the Display

The coloured bars on the left-hand edge of the display show you the range within which the indicated blood pressure values lies. Depending on the height of the bar, the readout value is either within the normal (green), borderline (yellow and orange) or danger (red) range.
The classification corresponds to the 6 ranges in the Table as defined by the ESH and described on the table of the point 2. The recommendations of the European Society of Hypertension (ESH) allow to diagnose and treat the hypertension more effectively and do not contradict World Health Organization recommendations.



7.8. 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 SPECIFICATIONS. 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.

7.9. Troubleshooting (1)

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

7.10. Troubleshooting (2)

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

8. 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. It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
6. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
7. 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.
8. 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.
9. It is recommended the cuff should be disinfected 2 times every week if needed (For example, in hospital or in clinique). Wipe the inner side (the side contacts skin) of the cuff by a soft cloth squeezed after moistened with Ethyl alcohol (75-90%), then dry the cuff by airing.
   The cuff cover can be hand-washed at 30°C. Remove the bladder beforehand through the special technological hole in the cover.

⚠ **WARNING!** Do not wash the bladder! Do not iron the cover!
The technological hole does not need to be sewn up!

9. SPECIFICATIONS

1. Product name: Blood Pressure Monitor, model: PRO-30
2. Classification: Internally powered, Type BF applied part, IPX0, No AP or APG, Continuous operation
3. Machine size: 91 mm x 57 mm x 19 mm (3 19/32" × 2 1/4" × 3/4")
4. Cuff circumference: 22 cm ~ 42 cm (8 21/32" ~ 16 17/32") or 22 cm~32 cm (8 21/32"~ 12 19/32") (depending on picking of the device)
5. Weight: approx. 50g (6 3/4 oz.) (exclude batteries and cuff)
6. Measuring method: oscillometric method, air inflation and measurement
7. Memory volume: only the last measurement stored in the memory
8. Power source: DC 6V ⎓ 600 mA, batteries: 2 × 1.5V ⎓ SIZE AAA
9. Measurement range: cuff pressure: 0-300 mmHg, systolic: 60-260 mmHg, diastolic: 40-199 mmHg, pulse rate: 40-180 beats/minute
10. Accuracy: pressure: ±3 mmHg, pulse rate: ±5%
11. Environmental temperature for operation: 10°C ~ 40°C (50°F ~ 104°F)
12. Environmental humidity for operation: ≤85% RH
13. Environmental temperature for storage and transport: -20°C ~ 50°C (-4°F ~ 122°F)
14. Environmental humidity for storage and transport: ≤85% RH
15. Environmental pressure: 80 KPa – 105 KPa
16. Battery life: Approx. 270 times
17. Blood pressure monitor set: M-L size's fan shape cuff (upper arm circumferenze 22-42 cm) or M size's fan shape cuff (upper arm circumferenze 22-32 cm) (depending on picking of the device), a storage bag, AAA batteries – 2 pieces, the instruction manual.

ⓘ **Note:** These specifications are subject to change without notice.

10. APPLIED STANDARDS

The digital semi-automatic blood pressure monitor 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 (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).

11. SYMBOL INFORMATION

THE OPERATION GUIDE MUST BE READ (The sign background colour: blue. The sign graphical symbol: white)
WARNING
TYPE BF APPLIED PARTS (The cuff is type BF applied part)
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
MANUFACTURER'S NAME
REF NAME ARTICLE NUMBER
MD MEDICAL DEVICE
SN SERIAL NUMBER
CE 0044 CE mark (0044) COMPILES WITH MDD93/42/EEC REQUIREMENTS
10°C ~ 40°C OPERATION CONDITION OPERATING CONDITION, TEMPERATURE 10°C ~ 40°C
-20°C ~ 50°C STORAGE CONDITION STORAGE CONDITION, TEMPERATURE –20°C ~ 50°C
KEEP DRY
IP20 HOUSING INGRESS PROTECTION RATE
UDI UNIQUE DEVICE IDENTIFICATION
EC REP EC REPRESENTATIVE

12. WARRANTY INFORMATION

Warranty period is 3 years from the date of purchase for monitor and 1 year for cuff and bulb. This warranty doesn't cover any damages caused by improper using, and also battery, and packaging. When a manufacturing defect is revealed during the warranty period a faulty unit would be repaired or, if repairing is impossible, replaced with another one.

Manufacturing date is in a serial number: WWYYXXXXX.
The manufacturer may change units partially or completely if necessary, without prior notice.

13. ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1
For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions

The PRO-30 is intended for use in the electromagnetic environment specified below.
The customer or the user of the PRO-30 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic enviroment-guidance
RF emissions CISPR 11	Group 1	The PRO-30 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The PRO-30 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	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 PRO-30 is intended for use in the electromagnetic environment specified below.
The customer or the user of the PRO-30 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 floors are covered with synthetic material, the relative humidity should be at least 30%
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

NOTE: UT is the a.c. mains voltage prior to application of the test level.

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

Guidance and manufacturer's declaration – electromagnetic immunity

The PRO-30 is intended for use in the electromagnetic environment specified below. The customer or the user of the PRO-30 should assure that it is used in such an environment.

Immunity test	IEC 60601 test 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 PRO-30, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d=1,2√P d=1,2√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2,5 GHz *where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer 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:

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 PRO-30 is used exceeds the applicable RF compliance level above, the PRO-30 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PRO-30.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 4
For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the PRO-30

The PRO-30 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PRO-30 can help prevent electromagnetic interference by maitaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PRO-30 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√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 2.3√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 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.

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B.Well
Caring for everyone