



Operator's Manual





This Operator's Manual is designed for use with
BpTRU™ Vital Signs Monitor
(model numbers BPM-100 and BPM-200).

BpTRU, the BpTRU logo and collection of these marks are
trademarks of BpTRU Medical Devices

© Copyright 2014
BpTRU Medical Devices
All rights reserved.

Contents



Introduction	1
Product Overview	1
BPM-100	1
BPM-200	2
Safety Information.....	2
Indications for Use	2
Contra-indications for Use	2
Safety Symbols and Definitions	3
Warnings and Cautions	4
General Warnings.....	4
General Precautions	5
Display Reference.....	7
Displays	7
Indicators – All Models.....	8
Indicators – BPM-200	8
Buttons.....	9
Buttons – All Models	9
Audio Tones.....	11
Blood Pressure Measurement	13
Obtaining Accurate BP Measurements.....	14
Select an Appropriate Size of Cuff.....	14
Position the Patient Carefully.....	15
Apply the Cuff	16
Single BP Measurements (Single Mode).....	17
Take the Single BP Measurement	17

Series of Measurements (Automatic Mode)	18
Results of an Automatic Series of Measurements.....	20
Reviewing Measurements	20
Review Measurements in Single Mode	20
Review Measurements in Automatic Mode	21
Recovering from Sleep Mode	21
Troubleshooting	23
Troubleshooting Guide	24
System Errors (E0 to E15).....	27
Analysis Errors (E20 to E27)	29
Unrecoverable System Errors.....	31
Setup Instructions	33
Examine the BpTRU Before Use	33
Mounting the BpTRU	34
Find a Suitable Location	34
Mount the BpTRU	34
Connecting Cuffs	36
Connect the Coiled Tube	36
Powering the BpTRU	37
Powering the BPM-100.....	37
Powering the BPM-200.....	38
Battery Management	39
Replacing the Battery	40
Functional Assessment of the BpTRU.....	41
Maintenance.....	43
Frequency of Inspection and Care.....	43
Inspection	44
Cleaning / Disinfection	45

Maintenance	46
Storage and Disposal Requirements	46
Technical Information.....	47
Specifications: BPM-100.....	47
Specifications: BPM-200.....	49
Standards	51
CE Mark Information	52
EMC Guidance and Declarations	53
Technical Modes of Operation.....	58
Alert/Silent Mode	58
Hide Mode (dash in Cycle display)	59
Zero Calibration Check	59
Reference Gauge Calibration Check	60
USB Connectivity (BPM-200 model).....	61
Accessories.....	63
Blood Pressure Cuff Sizes.....	63
Supplies and Accessories.....	64
Blood Pressure Cuffs and Tubing.....	64
Mounting Accessories.....	64
Power Supplies, Power Cords and Batteries.....	65
Owner Information	66
Warranty.....	67
Limited Warranty.....	67
Exclusions.....	68
Index.....	69

Introduction



Congratulations on the purchase of your BpTRU Vital Signs Monitor.

Product Overview

BpTRU is a non-invasive, automated blood pressure monitor designed specifically for primary care. It measures systolic and diastolic pressure and pulse rate, and requires no manual calibration.

The patented Automatic mode increases accuracy of blood pressure measurements by averaging multiple readings to help reduce white-coat hypertension.

BPM-100

The BPM-100 has the following features:

- Measurement intervals from 1 to 5 minutes for multiple measurements in Automatic mode
- Continuous, automatic zero-offset calibration, assuring that the instrument gives consistent, accurate readings
- Automatic inflation to 180 mmHg on first measurement and smooth, linear deflation
- Includes three adult cuff sizes (child and extra-large cuffs are available)
- Wall-mountable

BPM-200

The BPM-200 has the following features (in addition to the features of the BPM-100):

- Rechargeable spill-proof lead acid battery
- USB port for transfer of data to electronic medical records
- Permits roll stand, table top or wall mount applications

Safety Information

This section describes the indications for use, contra-indications, safety symbols, general warnings, and general precautions that you should be aware of when using the BpTRU.

Indications for Use

The BpTRU:

- measures systolic and diastolic blood pressures and pulse rates in subjects 3 years of age and older.
- is intended for use in physicians' offices, nursing units, and patient care areas of hospitals.
- is to be operated only by physicians, nurses, or trained medical professionals.

Contra-indications for Use

The BpTRU:

- is not designed for use with neonates, infants, or children under 3 years of age.
- is not designed, sold, or intended for use except as indicated.

Safety Symbols and Definitions

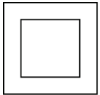
Safety symbols found on the labels on the back and bottom of the BpTRU monitor and in this operator's manual have the following definitions:



Conforms to CSA standards for electro-medical devices for United States and Canadian markets, with specific standards listed beside symbol.



The CE Mark on this product indicates it has been tested to and conforms with the provision noted with the 93/42/EEC Medical Device Directive, Annex II.



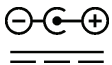
Class II electrical equipment.



Type BF applied part, signifying that the monitor is defibrillator proof. After exposure to defibrillation voltage, the BpTRU shall continue to perform its intended function. A recovery time is not required.



Attention. Consult accompanying documents for further information.



Power symbol, showing that DC power with the specified polarity should be used with the BpTRU. Only the specified power supply should be used with the monitor.



Device malfunction. Consult the Error Messages and Troubleshooting section.

Warnings and Cautions



WARNING

Warnings contain instructions to prevent serious injury or death of the patient or operator.



CAUTION

Cautions contain instructions to prevent minor injury to the patient or operator, or damage to the equipment.

General Warnings



WARNING

You should be familiar with all operating instructions before using this monitor.



WARNING

Prolonged, excessive, or incorrect use of the BpTRU may lead to tissue injury, venous pooling, and impairment of circulation in the arm of the patient.



WARNING

The blood pressure cuff should not be used on the same arm as an IV or any other medical equipment that relies on the circulatory system distal to the cuff.



WARNING

Do not use a metal tool to install or remove a battery. The terminals may short and lead to an electrical safety hazard.



WARNING

Substitution of a component, such as a blood pressure cuff, different from that supplied may result in measurement inaccuracy.

General Precautions

**CAUTION**

Avoid compressing or restricting the coiled tubing, which may restrict inflation or deflation of the cuff and cause mechanical failure of the tubing.

**CAUTION**

Significant physical damage to the BpTRU could result in inaccurate results or even injury.

**CAUTION**

Exercise care when moving the BpTRU to avoid the risk that dropping it could cause an injury.

**CAUTION**

Stop using the monitor if there is evidence of any of the damage listed in “Inspection” on page 44. Replacement of damaged parts or accessories is mandatory for correct functioning of the monitor.

**CAUTION**

The BpTRU and accessories are not designed to be sterilized by autoclaving. Autoclaving will damage the monitor and accessories.

**CAUTION**

Excessive wetting or immersion of the BpTRU and accessories may lead to electrical safety hazards or to blockage of connectors and tubing. Do not attempt to use the monitor without allowing sufficient time to air dry.

**CAUTION**

If it is necessary to clean the battery, use a dry cloth only. Do not use fluids.



CAUTION

The use of a power supply other than that supplied with the BpTRU may result in damage to the monitor or measurement inaccuracy.



CAUTION

The use of accessories, transducers, and cables other than those specified may result in increased EMF emissions or decreased immunity of the system to EMF within the surrounding environment.



CAUTION

When using the optional roll stand, ensure that the BpTRU and accessories are mounted according to instructions supplied with the stand to ensure stability.

If using an alternate roll stand, ensure that the BpTRU and accessories are sufficiently stable by tilting the assembly to 10° from the vertical. If the assembly returns to the upright position on its own, it is sufficiently stable.



CAUTION

Using batteries beyond their recommended lifetime may result in damage to the BpTRU device.

Display Reference



The BpTRU front-panel LED monitor displays the measurement readings, as well as the current operating mode and status.

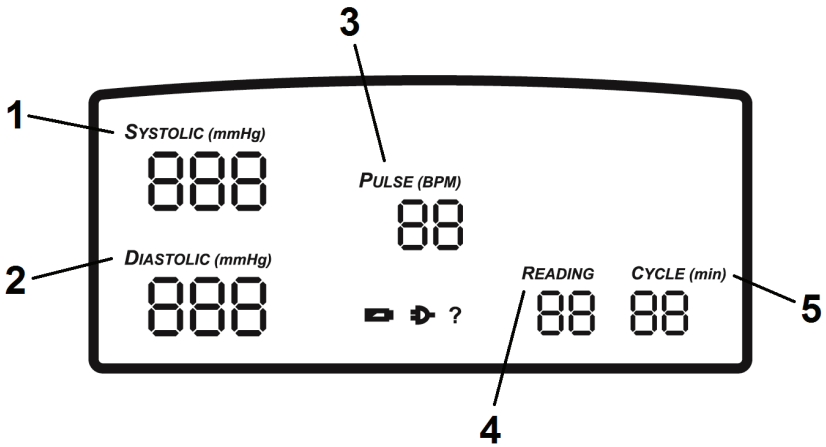


Figure 1: Front Panel Display

Displays

The BpTRU has five multi-digit LED displays to present data.


- 1. Systolic** Systolic pressure displayed in millimeters of mercury (mmHg).
- 2. Diastolic** Diastolic pressure displayed in millimeters of mercury (mmHg).
- 3. Pulse** Pulse rate displayed in beats per minute (bpm).

- 4. Reading** Indicates which measurement's results are shown in the systolic, diastolic, and pulse displays.
- A number indicates that the result of one measurement of a single or automatic series is being displayed. E.g., if three blood pressure measurements have been taken, the **Reading** display shows "3" and the other displays show the result of the latest measurement.
 - "A" indicates that the average of an automatic series of BP measurements is being shown in the other displays.
- 5. Cycle** "SP" (Single Pressure) indicates that the BpTRU is operating in Manual mode.
A number from 1 to 5 indicates the cycle time used (in minutes) when operating in Automatic mode.



If the **Cycle** display shows a dash in the left segment, the unit is in Hide Mode, see page 59.

The BpTRU also has several smaller LED indicator displays that show its operating mode and status.

Indicators – All Models

-  Device Malfunction (see "Unrecoverable System Errors" on page 31)

Indicators – BPM-200

-  Charging battery
-  Low Battery

Buttons

The buttons on the front panel control the BpTRU.

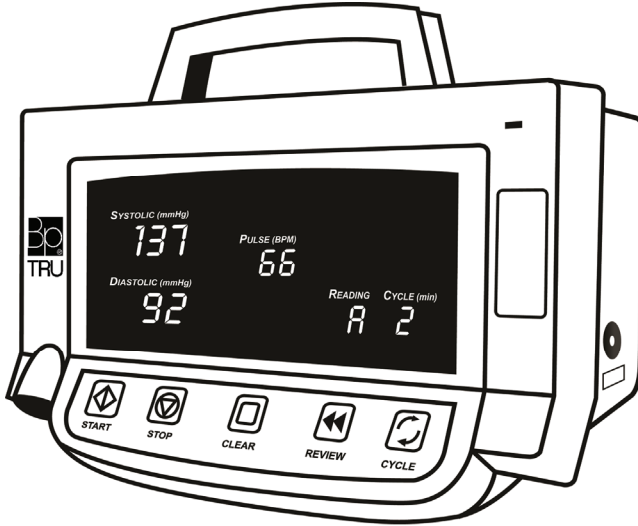


Figure 2: Front Panel Buttons

Buttons – All Models



START

Initiates blood pressure measurement.
Cuff will inflate.



STOP

Stops current blood pressure measurement and deflates cuff if a measurement is in progress (an automatic measurement may be resumed by pressing **START**).

Pauses between measurements, if in automatic mode (resumed by pressing **START**).



CLEAR

Clears memory of all stored readings in both Single and Automatic mode.

Memory must be cleared before a new series of automatic measurements can be initiated, or when switching between Automatic and Single modes.



REVIEW

Reviews readings stored in memory.

In Automatic mode, reviews previous individual readings and the average reading if pressed when the series of measurements is complete. Also suspends measurements and allows measurements to be reviewed if pressed while a series of measurements is still in progress. (Press **START** to resume.)

In Manual mode, reviews all stored measurements (up to a maximum of 99 measurements).



CYCLE

Selects mode of operation (Single or Automatic) and, in Automatic mode, the time between BP measurements. Refer to the **Cycle** display description, page 8.

Audio Tones

The BpTRU emits audio tones to indicate certain operating conditions or functions, as described in the following table. (To disable sound, see “Alert/Silent Mode” on page 58.)

Audio Tone	Meaning
3 short beeps followed by 1 long tone	Sounds when the BpTRU is initializing itself on start-up.
1 long tone	A series of 6 BP readings has completed.
2 short beeps every 30 seconds	The battery charge is low.
2 short beeps	AC power is disconnected. The BpTRU is now running on battery power.
1 short beep	AC power is connected. The BpTRU is no longer running on battery power.

The BpTRU also emits audio tones to indicate certain system errors, as described in the following table.

Audio Tone	Error Code
3 beeps	E3, E4, E5, E6, E7, E9 and E13
3 beeps, followed by a 3-second pause, then another 3 beeps (pattern continues until the condition is removed)	E2, E10, E11, E12

Refer to “Troubleshooting” on page 24 for a description of the error codes.

Blood Pressure Measurement



The BpTRU can perform either a single non-invasive blood pressure (BP) measurement or an automatic series of measurements.

- For advice on obtaining accurate BP measurements, refer to “Obtaining Accurate BP Measurements” on page 14.
- For single BP measurements, refer to “Single BP Measurements (Single Mode)” on page 17.
- For multiple automatic BP measurements, refer to “Series of Measurements (Automatic Mode)” on page 18.
- To review separate measurements in Manual mode or to review the individual readings taken in Automatic mode, refer to “Reviewing Measurements” on page 20.

Reviewing the individual readings for a patient allows the clinician to note the high and low readings for systolic and diastolic blood pressure and pulse rate, as well as assess any trending in the individual readings or error codes.



WARNING

Warnings contain instructions to prevent serious injury or death of the patient or operator.



NOTE

Initiate rapid deflation of the cuff at any time by pressing the **STOP** button or turning off the power.



WARNING

Prolonged, excessive, or incorrect use of the BpTRU may lead to tissue injury, venous pooling, and impairment of circulation in the arm of the patient.

If the low-battery indicator appears, a maximum of 20 blood pressure measurements may be taken before the BpTRU will prevent further operation. Plug the BpTRU into a wall outlet to charge the battery. Note that it is still possible to perform measurements while the battery is charging.

To allow auto-calibration to complete, wait at least 5 seconds after turning on the monitor before pressing the **START** button.

Obtaining Accurate BP Measurements

Careful patient treatment and use of the BpTRU will result in more accurate blood pressure measurements.

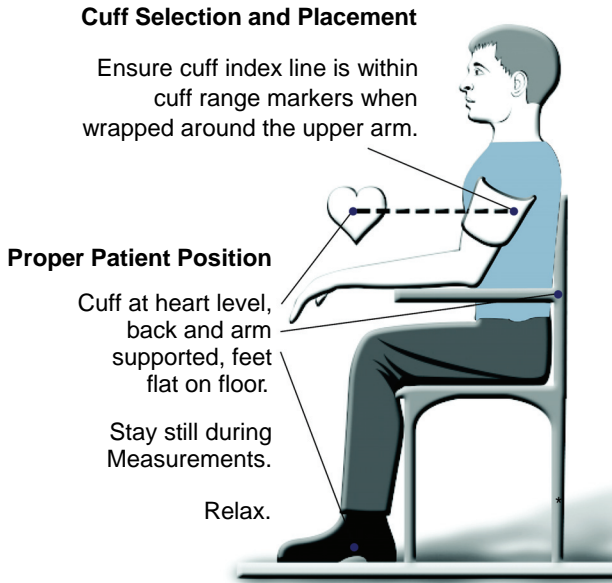
Select an Appropriate Size of Cuff

The BpTRU may not provide accurate readings if you use the wrong size of cuff. The five available cuff sizes are listed below, with the range of arm circumferences appropriate for each. The child and extra-large adult sizes may be ordered separately.

- Child 13 - 18 cm
- Small adult 18 - 26 cm
- Regular adult 26 - 34 cm
- Large adult 32 - 43 cm
- Extra-large adult 41 - 52 cm

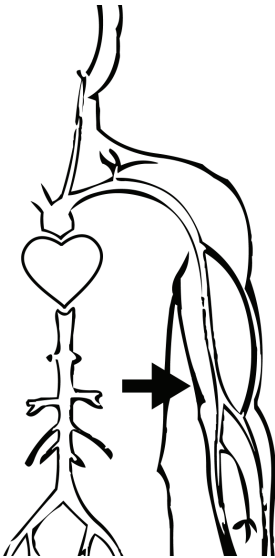
Position the Patient Carefully

1. Ensure that the patient avoids smoking or caffeine for at least one hour before test.
2. Ensure that the patient is comfortable and relaxed, either sitting or lying down. The position shown in the illustration below is ideal.
3. Ensure that the upper arm is at heart level and supported.

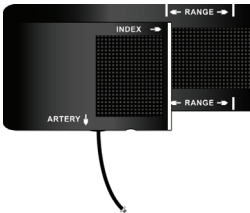


At your discretion, BP can be taken while lying down or standing.

Apply the Cuff



1. Align the artery indicator on the cuff over the brachial artery of the patient's arm (shown in the figure to the left).
2. Wrap the cuff around the arm and check that the white index marking on the edge of the cuff falls within the white range markings on the inside surface of the cuff.



3. Check that the index falls within the range markers. If the index does not fall within the range markers, replace the cuff with a smaller or larger cuff, as indicated.

4. Ensure that the cuff is tight but that it is still possible to insert two fingers between the cuff and the arm.
5. Measure BP on both arms initially, and then use the arm with the higher reading for all subsequent measurements.

During the measurement:

- Ensure that the patient's arm and body do not move.
- Avoid talking to other people in the room.
- To improve the accuracy of the results, leave the patient alone in a room for the full six measurements (with the BpTRU on an automatic cycle of one or two minutes), as recommended by the American Heart Association.

Single BP Measurements (Single Mode)

This section describes how to obtain a single blood pressure measurement. Begin by positioning the patient and attaching the cuff as described in “Obtaining Accurate BP Measurements” on page 14.



WARNING

The blood pressure cuff should not be used on the same arm as an IV or any other medical equipment that relies on the circulatory system distal to the cuff.



CAUTION

Avoid compressing or restricting the coiled tubing, which may restrict inflation or deflation of the cuff and cause mechanical failure of the tubing.

Take the Single BP Measurement



1. Press **CLEAR** to ensure that any previous measurements are cleared from the BpTRU memory.



2. Select Manual mode by pressing the **CYCLE** button until “SP” is displayed in the **Cycle** display.



3. Initiate a single blood pressure measurement by pressing the **START** button.

The cuff will inflate to the 180 mmHg pressure level, and then may inflate by 30 mmHg increments as required to obtain an accurate BP result. During inflation and deflation, the **Systolic** display indicates the cuff pressure.

**NOTE**

Initiate rapid deflation of the cuff at any time by pressing the **STOP** button or turning off the power.

It is important for the patient to remain still and not talk during inflation and deflation of the cuff.

Once the measurement is complete, the cuff quickly deflates and the **Systolic**, **Diastolic** and **Pulse** displays show the appropriate readings.

You can initiate the next measurement in Manual mode by pressing the **START** button again. Wait five seconds after the completion of a measurement before pressing the **START** button to allow circulation in the patient's arm and to allow the cuff to fully deflate. The BpTRU will not start a new measurement until the cuff is fully deflated.

Series of Measurements (Automatic Mode)

Automatic mode performs a series of six blood pressure measurements, discarding the first and averaging the remaining five. The interval between measurements is 1, 2, 3, 4 or 5 minutes, depending on your selection.

Individual readings are displayed after each measurement, and the individual and averaged readings can be reviewed during or after the series of measurements (refer to "Reviewing Measurements" on page 20).

1. Select a cuff that is appropriate for the patient. Refer to "Select an Appropriate Size of Cuff" on page 14
2. Apply the cuff to the patient. Refer to "Position the Patient Carefully" on page 15 and "Apply the Cuff" on page 16.

**WARNING**

The blood pressure cuff should not be used on the same arm as an IV or any other medical equipment that relies on the circulatory system distal to the cuff.



3. Press **CLEAR** to ensure that any previous measurements are cleared from the BpTRU memory.



4. Select Automatic mode by pressing the **CYCLE** button until the cycle time you want (i.e., the interval between BP measurements) shows in the **Cycle** display. (“SP” indicates a single measurement.)



5. Initiate the series of measurements by pressing the **START** button.

During each measurement, the cuff will inflate to the minimum required preset pressure level. While inflating and deflating, the **Systolic** display indicates the cuff pressure.

**NOTE**

Initiate rapid deflation of the cuff at any time by pressing the **STOP** button or turning off the power.

It is important for the patient to remain still and not talk during inflation and deflation of the cuff.

During the series of measurements, the **Reading** display shows the number of the measurement currently being taken. The most recent **Systolic**, **Diastolic** and **Pulse** measurements are shown in the respective displays until the next measurement begins.

If you select a one- or two-minute cycle time and the patient’s blood pressure is high, any individual measurement may take longer than one or two minutes.

The BpTRU will not begin a new measurement until the cuff is fully deflated from the previous measurement.

Results of an Automatic Series of Measurements

The BpTRU performs the following actions at the completion of six measurements.

- A tone sounds (unless the tone has been disabled as described in “Technical Modes of Operation” on page 58).
- The results of the last measurement are displayed for five seconds, while the **Reading** display shows “6.”
- After five seconds, the average of the last five **Systolic**, **Diastolic** and **Pulse** measurements is shown in the respective display, while the **Reading** display shows “A” (for average).

The first measurement is always discarded from the average as it is often elevated due to patient stress (white-coat effect). If an error code is displayed for any measurement, then that measurement is not included in the average. The average can be computed from less than five measurements.

Reviewing Measurements

Use the **REVIEW** button to review previous measurements.

Review Measurements in Single Mode



In Manual mode you can review previous manual measurements by pressing the **REVIEW** button. The **REVIEW** button cycles through all measurements taken since Manual mode was invoked, or since the last time the **CLEAR** button was pressed (up to a maximum of 99 previous measurements).

Pressing the **REVIEW** button during a measurement has no effect.

Review Measurements in Automatic Mode



Upon completing a series of measurements in Automatic mode, you can review each measurement in the series by pressing the **REVIEW** button. (You cannot review the first measurement of the series because it is always discarded.) As the result of each reading is shown, the reading number (“2” through “6”) is shown in the **Reading** display. The value “A” in the **Reading** display indicates that the average of the last five readings is being shown.

If you press the **REVIEW** button between measurements during an automatic series of measurements, the BpTRU suspends measurement. You can then cycle through the measurements taken to that point using the **REVIEW** button.



Press the **START** button to resume the automatic series. Pressing the **REVIEW** button during a measurement has no effect.

Recovering from Sleep Mode

The BpTRU will enter sleep mode if left idle for 10 minutes. All displays will go blank. If the displays are blank, press any button to reenter the normal operating mode.

All the data stored in memory is still available and can be viewed using the **REVIEW** button. Recorded measurements are only lost when the **CLEAR** button is pressed or power is turned off.

Troubleshooting



This chapter describes all of the system errors that the BpTRU may report, and gives troubleshooting information for other problems you could encounter.

- For general troubleshooting, refer to “Troubleshooting Guide” on page 24.
- For error codes E0 through E15, refer to “System Errors (E0 to E15)” on page 27.
- For error codes E20 through E27, refer to “Analysis Errors (E20 to E27)” on page 29.
- If your BpTRU has made a five-second alarm tone and displayed the ? (device malfunction) indicator, refer to “Unrecoverable System Errors” on page 31.

If the troubleshooting information in this manual does not solve your problem, contact your distributor or BpTRU Customer Support.

Troubleshooting Guide

Symptoms	Possible Causes	Corrective Actions
Power is on (green indicator light is on) but START button does not initiate inflation.	<p>BpTRU is in Automatic mode and six readings have already been taken.</p> <p>Cuff pressure from previous measurement not yet fully released.</p> <p>Zero pressure calibration not complete.</p>	<p>Press CLEAR to clear the memory and then press START to initiate a new BP measurement.</p> <p>Check pressure in system if the problem persists. Perform a Zero Calibration Check (page 59) or Reference Gauge Calibration Check (page 60).</p> <p>Wait 5 seconds and push the START button again.</p>
Power is on (green indicator light is on), but displays are all blank.	BpTRU is in sleep mode.	Press any button to restore the display.
Power is on (green indicator light is on) and device malfunction LED is displayed (?).	Unrecoverable system error has occurred.	<p>Turn power off and ensure cuff is deflated.</p> <p>Turn power on again.</p> <p>Refer to “Unrecoverable System Errors” on page 31.</p>
Power is on (green indicator light is on) but there is only a dash (-) in the left digit of the Cycle display.	BpTRU is in hide mode. Refer to “Hide Mode” on page 59.	Turn the BpTRU off if it is on. Hold down the CYCLE button while turning the BpTRU on again.

Symptoms	Possible Causes	Corrective Actions
Power is on and E15 displays when START button is pressed.	Battery is low.	Plug BpTRU into a wall outlet to charge the battery.
Monitor turns off automatically and cannot restart when power applied.	Blown fuse.	Contact distributor or BpTRU Customer Support.
No power (green indicator light is off).	Power supply is not plugged into wall outlet.	Plug power supply into wall outlet.
	Power supply is not plugged into BpTRU.	Plug power supply into BpTRU.
	Wall outlet is not powered.	Have qualified technician inspect wall outlet and power breaker.
	Battery is fully discharged.	Plug BpTRU into wall outlet to charge the battery.
	Power supply is plugged in properly and power indicator light does not turn on with power switch.	Have qualified technician inspect output of power supply.
	Undetermined causes.	Contact distributor or BpTRU Customer Support.
All displays remain lit on power up.	BpTRU is not powered down properly.	Turn power off, wait 10 seconds, and turn power on again.

Symptoms	Possible Causes	Corrective Actions
Buzzer does not sound at end of sixth measurement in Automatic mode.	BpTRU is set to Silent mode.	Exit Silent mode by turning off power and then holding STOP button down while turning power back on.
Cuff does not inflate during operation.	Cuff or tubing is not attached properly.	Check all cuff and tubing connectors for tightness. Perform a Zero Calibration Check (page 59) or Reference Gauge Calibration Check (page 60).
	Leakage in cuff or tubing.	Check cuff and tubing for cracks and tears which may lead to leakages Perform a Zero Calibration Check (page 59) or Reference Gauge Calibration Check (page 60).
	Internal leakage.	Contact distributor or BpTRU Customer Support.
Systolic display shows software version number (e.g. 1.90) and Pulse and Reading displays show varying numbers.	BpTRU is set to Zero Calibration Check or Reference Gauge Calibration Check.	Exit Zero Calibration Check or Reference Gauge Calibration Check by turning power off and then on again.

Symptoms	Possible Causes	Corrective Actions
Monitor enters low-power state often or turns off automatically (BPM-200).	Insufficient charging. End of battery life	Charge battery for 12 hours. Replace battery.
Battery charging indicator remains on for longer than 24 hours during charging.	End of battery life.	Replace battery.

System Errors (E0 to E15)

If a system error occurs during operation, an error code will be displayed in the **Systolic** display only. All other displays remain blank.

Press the **START** button to resume measurements.

Code	Description	Corrective Action
---	User-cancelled measurement.	None required.
E0 ^a	Too few pulses detected.	Check patient for pulse. Tighten cuff on arm and check BpTRU for leaks in tubing or cuff.
E07	Loss of calibration data.	Contact distributor or BpTRU Customer Support.
E1 ^a	Excessive motion artifacts (motion induced errors).	Ensure that patient is sitting quietly and the cuff and upper arm are comfortably elevated to the level of their heart in order to reduce motion artifacts during measurement.
E2	Cuff overpressure.	Ensure that patient is sitting quietly to reduce motion artifacts during inflation. Ensure that cuff is applied properly and tubing is not kinked.

Code	Description	Corrective Action
E3	Inflation too slow.	Check cuff and tubing for leaks due to cracks and tears. Check connections for tightness.
E4	Inflation too fast.	Check cuff and tubing for kinks.
E5	Deflation too slow.	Check cuff and tubing for kinks.
E6	Deflation too fast.	Check cuff and tubing for leaks due to cracks and tears and connectors for tightness.
E7	Pressure offset calibration not complete.	<p>E7 will occur if you press START while the Zero Calibration Check is still in progress.</p> <p>Wait for the E7 error code to disappear (typically less than 5 seconds) and push the START button again.</p> <p>If the E7 error code occurs when you have not pressed START, or if it does not disappear, contact distributor or BpTRU Customer Support.</p>
E8 ^a	Low pulse amplitude.	Check patient for pulse. Tighten cuff on arm and check BpTRU for leaks in tubing or cuff.
E9	Vacuum detected.	Push CLEAR button. Disconnect cuff and wait 15 seconds before reconnecting. Perform zero-offset check.
E10	Cuff over 300 mmHg for more than 5 seconds.	Ensure patient is sitting quietly to reduce motion artifacts during inflation. Check cuff and tubing for kinks.
E11	Cuff pressurized for more than 130 seconds.	Check cuff and tubing for leaks due to cracks and tears. Check connectors for tightness. Check cuff and tubing for kinks.

Code	Description	Corrective Action
E12	Automatic cycling timing violation.	Check cuff and tubing for kinks.
E13	Device reset.	Readings in memory, if any, are available for review. Check monitor environment for electromagnetic interference (ESD, power interruptions). Connect USB cable between measurements or when monitor is powered off.
E14	Data corrupted after reset.	Power the BpTRU off, wait 5 seconds and power on again.
E15	Low battery	Charge the battery

- a. In Automatic mode these errors are recorded in memory and measurements continue. The measurement on which the error was detected is not included in the average of measurements displayed at the end of the series of measurements.

Analysis Errors (E20 to E27)

If an analysis error occurs in the determination of any BP reading, an error code is displayed in the corresponding display. All other valid readings are still displayed in the corresponding displays.

If an analysis error occurs during Automatic mode, the error code is stored in memory and the series automatically continues until six measurements are taken.

Pressing the **REVIEW** button shows error codes in the appropriate display (**Systolic**, **Diastolic** or **Pulse**) for each reading where an error was detected. The averages for systolic blood pressure, diastolic blood pressure, and pulse rate exclude all results for any of the readings where an error was detected.

Code	Description	Corrective Action
E20	Indeterminate systolic blood pressure (likely due to inadequate inflation threshold).	Check patient for pulse. Tighten cuff on arm and check BpTRU for normal inflation pressures.
E21	Indeterminate diastolic pressure (premature deflation, excessive motion artifacts, or diastolic below 40 mmHg).	Check patient for pulse. Tighten cuff on arm, check for leaks in tubing or cuff, and ensure that patient is sitting quietly with arm comfortably elevated to level of heart to reduce motion artifacts during measurement.
E22	Indeterminate pulse rate.	Check patient for pulse. Tighten cuff on arm, check for leaks in tubing or cuff, and ensure that patient is sitting quietly with arm comfortably elevated to the level of heart to reduce motion artifacts during measurement.
E23	Systolic blood pressure under-range (<60 mmHg).	Check patient manually for blood pressure and pulse.
E24	Diastolic blood pressure under-range (<40 mmHg).	Check patient manually for blood pressure and pulse.
E25	Systolic blood pressure over-range (>250 mmHg).	Check patient using auscultation for blood pressure and pulse.
E26	Diastolic blood pressure over-range (>160 mmHg).	Check patient using auscultation for blood pressure and pulse.
E27	Arithmetic overflow in data calculation.	Repeat measurement.

After an analysis error, the corrective action should allow a return to normal operation for the next measurement. If the problem persists, discontinue use and return the monitor for servicing.

Unrecoverable System Errors

? Certain system errors could result in abnormal operation of the BpTRU, which could present a hazard to the operator or patient. To prevent such a hazard, the BpTRU monitors the following functions and parameters.

1. Proper internal voltage supply.
2. Proper functioning of the microcontroller.
3. Over-inflation of the cuff (maximum 330 mmHg).
4. Overtime inflation of the cuff (over 10 mmHg for maximum 3 minutes).

If any of the above conditions occur, the BpTRU will perform the following actions:

1. Deflate the cuff.
2. Sound a five-second alarm tone to signify that an unrecoverable system error has occurred.
3. Deactivate the main display and display the device malfunction indicator (**?**).

To resume normal operation, turn the power off and then back on again.

If normal operation does not resume, contact your distributor or BpTRU Customer Support.

Setup Instructions



Examine the BpTRU Before Use

Before using your BpTRU, confirm that it does not suffer from any of the following forms of damage.

1. Frayed electrical cords or broken electrical connectors.
2. Cracked or broken enclosure.
3. Broken LED displays.
4. Water damage - possible water in the monitor or discoloration.
5. Torn or missing labels on monitor or accessories.
6. Broken or stripped cuff or tubing connectors.
7. Cracked or deteriorating blood pressure cuffs.
8. Cracked or deteriorating coiled tubing.
9. Battery irregularities such as cracks, deformation, leakage, or corrosion.

If any damage is evident, do not use the BpTRU. Call your distributor or BpTRU Customer Support.



CAUTION

Significant physical damage to the BpTRU could result in inaccurate results or even injury.

Mounting the BpTRU

Parts (included):

- wall mount bracket
- 1/4" metal bushings (4)
- screws (4)
- drywall anchors (4)

Tools required:

- Phillips #2 screwdriver
- hammer
- drill with a 1/8" drill bit
- pencil

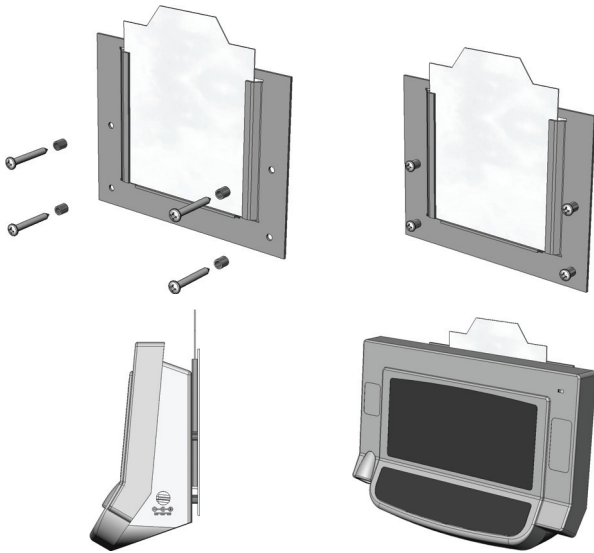
Find a Suitable Location

Ensure that:

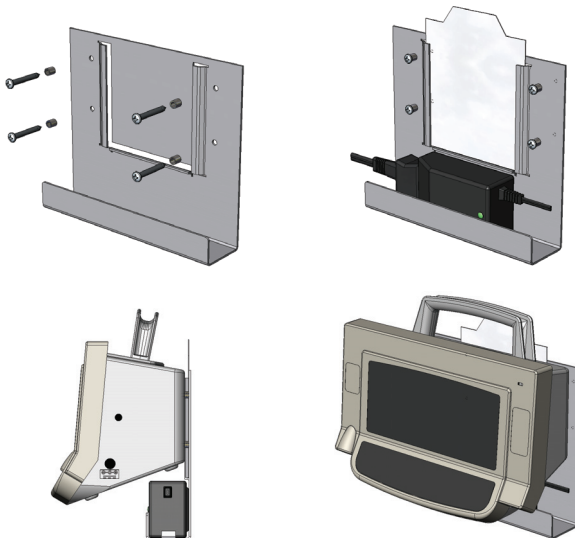
- the power cord will reach a wall outlet.
- the blood pressure cuff and coiled tubing will reach the patient.
- no wall studs will interfere with the drywall anchors.

Mount the BpTRU

1. Use the bracket as a template to mark the screw locations.
2. Use the 1/8" bit to drill holes through the drywall in the locations marked.
3. Gently tap the drywall anchors into the holes with a hammer.
4. Place the metal bushings on the screws.
5. Holding the bracket against the wall, screw through the bracket holes into the wall anchors. Do not over tighten.
6. Insert the reference card into the mounting bracket.
7. Align the four holes in the back of the BpTRU with the heads of the bracket screws, then push back and down so that the metal bushings are engaged in the slots above the mounting holes.



BPM-100



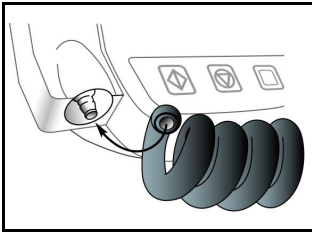
BPM-200

Note: Insert the power supply into its support at the bottom of the bracket prior to mounting the BPM-200 as shown above.

Connecting Cuffs

The BpTRU is equipped with a coiled tube that can remain permanently attached. The individual blood pressure cuffs connect to this tube via a threaded fitting.

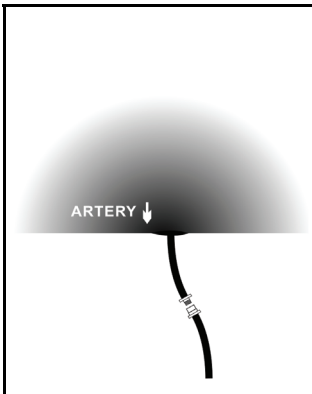
Connect the Coiled Tube



The coiled tube comes with a threaded fitting inserted in one end which connects to the cuff.

Push the bare end of the coiled tube (the end without the fitting) onto the barbed fitting on the front of the BpTRU, near the **START** button.

Ensure that the tube is fully and snugly attached to the barbed fitting. Loose connections may result in faulty inflation and deflation of the cuff and lead to inaccurate readings.



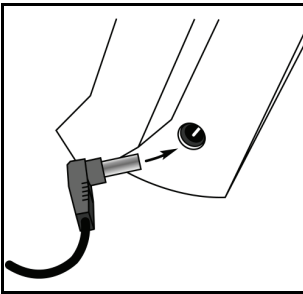
Thread the other end of the coiled tube onto the fitting on one of the cuffs. Refer to “Obtaining Accurate BP Measurements” on page 14 for instructions on selecting an appropriate size of cuff.

Powering the BpTRU

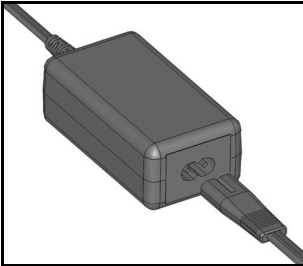
The BPM-100 must be connected to a standard wall outlet while the BPM-200 can be powered either from a wall outlet or by the internal battery.

Powering the BPM-100

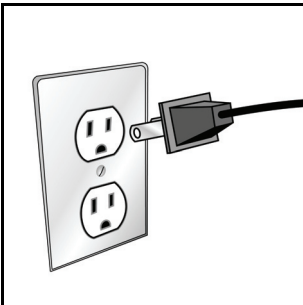
The BPM-100 includes an 8 VDC universal input power supply with a cord set specific to each geographical region. Connect the BPM-100 as follows:



1. Insert the output plug of the 8 VDC universal input power supply into the power receptacle on the BpTRU.



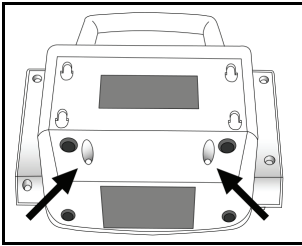
2. Plug the cord set into the universal power supply.



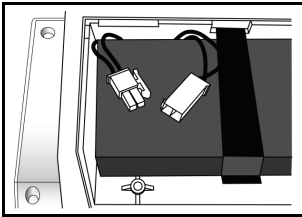
3. Insert the cord set plug into an AC wall outlet.

Powering the BPM-200

The BPM-200 is shipped with the internal, rechargeable battery disconnected to prevent discharge and to prolong battery life. It includes a 10 VDC universal input power supply with a cord set specific to each geographical region.



1. Open the battery door at the back of the BpTRU. Use a Phillips screwdriver (provided) to remove both screws. Tear the battery tag from the harness and discard.

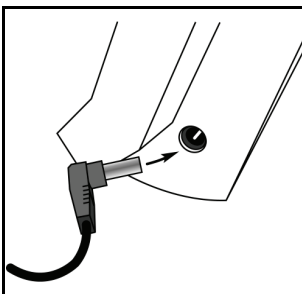


2. Join the two battery harness connectors, they only fit one way.
3. Close the battery door and secure it with the two screws.

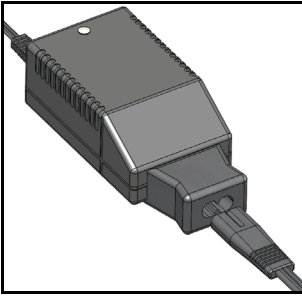


WARNING

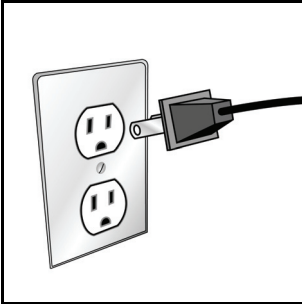
Do not use a metal tool to install or remove a battery. The terminals may short and lead to an electrical safety hazard.



1. Insert the output plug of the 10 VDC universal input power supply into the power receptacle on the BpTRU.



2. Plug the cord set into the universal power supply.




3. Insert the cord set plug into an AC wall outlet. The charging indicator should now be lit indicating that the battery is charging.

On initial setup of the BpTRU, charge the battery for at least 12 hours.

Battery Management

The following techniques and practices will help ensure proper battery performance and prolonged battery life.

- It is recommended to charge the BpTRU overnight if it has been used during the day.
- Charge the battery as soon as the low-battery indicator is displayed ().
- Do not store the BpTRU with the battery in a discharged state.
- Charge and then disconnect the battery if the BpTRU is to be shipped or stored for longer than one month.
- The battery should be charged every four months if the device is not in use.
- Avoid exposing the battery to heat. Its service life is shortened considerably at temperatures above 30°C.

The low-battery indicator lights when the BpTRU needs charging. It will also emit a short double beep every 30 seconds when the battery is low. When these indications

occur, plug the power cord into a wall outlet to charge the battery. Note that it is possible to perform measurements while the battery is charging.

If the battery charging indicator remains on for longer than 24 hours during charging, the battery may need to be replaced.

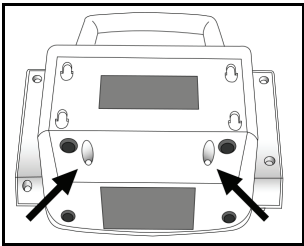
It is recommended that the battery be replaced every 2 years. Refer to “Replacing the Battery” on page 40 for replacement instructions.



CAUTION

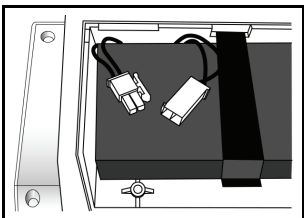
Using batteries beyond their recommended lifetime may result in damage to the BpTRU.

Replacing the Battery



1. Open the battery door at the back of the BpTRU. Use a Phillips screwdriver (provided) to remove both screws.

2. Squeeze the release tab and disconnect the battery wiring harness. Undo the Velcro strap holding the battery and remove the battery. Do not use a metal tool. Do not pull on the wires.



3. Insert the new battery. Join the battery harness connectors, they only fit one way. Replace the Velcro strap.

4. Close the battery door and secure it with the two screws.

5. Dispose of the battery safely. Refer to “Storage and Disposal Requirements” on page 46.

**WARNING**

Do not use a metal tool to install or remove a battery. The terminals may short and lead to an electrical safety hazard.

Functional Assessment of the BpTRU

When the BpTRU is turned on, all displays will illuminate, showing “888” and the buzzer will sound for a few seconds. If the displays or buzzer do not activate the BpTRU may not be working properly. Consult the Troubleshooting section.

If you are concerned about the accuracy of the pressure measurements obtained with the BpTRU, use the Zero Calibration and Reference Gauge Calibration checks to verify the pressure measurement accuracy. See “Technical Modes of Operation” on page 58.

Please contact your distributor or BpTRU Customer Support for information on how to order a BP Reference Gauge Calibration Kit.

Frequency of Inspection and Care

The BpTRU and its accessories should be inspected for any damage that may affect safety and accuracy at the following times. Note that no manual calibration is required.

- After initial setup
- Monthly
- After any mishandling (for example, if the BpTRU is knocked off the mounting bracket)

Clean the BpTRU and accessories as required, using a damp cloth and mild detergent.

The accuracy of the pressure measurement circuitry in the BpTRU should be checked annually or if you have any concerns about the accuracy of the monitor. Refer to the following sections for instructions on using these modes of operation:

- “Zero Calibration Check” on page 59
- “Reference Gauge Calibration Check” on page 60

The operation of the BP overpressure and overtime safety features of the BpTRU should be checked annually or if there are any concerns about the safety of the monitor. Refer to “Reference Gauge Calibration Check” on page 60.

Replace the battery every 2 years. Refer to “Replacing the Battery” on page 40.



CAUTION

Using batteries beyond their recommended lifetime may result in damage to the BpTRU.



CAUTION

Stop using the monitor if there is evidence of any of the damage listed below. Replacement of damaged parts or accessories is mandatory for correct functioning of the monitor.

Inspection

- All labels on the BpTRU should be examined for integrity and legibility (i.e., they should not be peeling). Damaged or missing labels may lead to misuse of the monitor.
- The BpTRU and power supply with cord should be examined for possible electrical hazards caused by any loose connectors, cracks or other broken parts, including damage which might permit access to the interior of the chassis or power supply.
- All electrical cables should be examined for possible electrical hazards caused by cracked or broken connectors or wires.
- The BpTRU and power supply should be examined to ensure that they do not rattle (indicating loose components inside which may lead to faulty operation).
- Prior to using the monitor or after replacing the battery, check for battery irregularities such as cracks, deformation, leakage, corrosion, or other problems. Discontinue use and replace the battery if any such problems arise.
- The coiled tubing, blood pressure cuffs, and their connections should be examined for cracks or breaks which may lead to air leakage during inflation and deflation.
- The blood pressure cuffs should be examined for tears in the material and seams of the cuff which may lead to the cuff rupturing when inflated. The cuffs should also be inspected for legibility of cuff markings, particularly the

cuff model and the markings for arm size range and index.

Cleaning / Disinfection

- The BpTRU may be cleaned as required by wiping with a cloth dampened with warm water and a mild detergent solution. Allow sufficient time to air dry.
- The BpTRU and accessories may be disinfected as required (for example, if bodily fluids come into contact the monitor) by wiping with a cloth dampened with a diluted, non-staining disinfectant solution such as bacteriostatic detergent. Allow sufficient time to air dry.
- The coiled tubing and power supply cabling may be cleaned by wiping with a cloth or sponge dampened with warm water and a mild detergent solution. If further cleaning is required, coiled tubing and cuffs may be cleaned using rubbing alcohol. Do not use harsh solvents such as acetone as they may destroy these parts.
- The blood pressure cuffs may be cleaned by wiping with a damp cloth or sponge and a mild detergent solution. Allow sufficient time to air dry.



CAUTION

Excessive wetting or immersion of the BpTRU and accessories may lead to electrical safety hazards or to blockage of connectors and tubing. Do not attempt to use the monitor without allowing sufficient time to air dry.



CAUTION

If it is necessary to clean the battery, use a dry cloth only. Do not use fluids.



CAUTION

The BpTRU and accessories are not designed to be sterilized by autoclaving. Autoclaving will damage the monitor and accessories.

Maintenance

- Maintenance of the BpTRU should consist of periodic inspection and cleaning of the monitor and accessories.
- Customer calibration of the BpTRU is not required.
- Accessories including the battery should be replaced as required.
- There are no user serviceable parts inside the BpTRU. Opening the BpTRU voids the warranty.

Storage and Disposal Requirements

The BpTRU can be transported and stored in the following environmental conditions.

- Temperature from -20 to +50 degrees Celsius
- Humidity from 15 to 95 percent RH (non-condensing)

For transport, shipping or storage, use the original packaging, including the inserts, to protect the BpTRU. If the original packaging is not available, wrap the BpTRU in such a manner that it will not be scratched or otherwise damaged during shipping.

If shipping the BpTRU or if storing it for more than one month, disconnect the battery.

Contact local authorities for disposal requirements for electronic devices and for lead-acid batteries (same as automobile batteries). Do not throw the battery in the regular garbage.

Technical Information



Specifications: BPM-100

Item	Specification
Pressure measurement range	0 to 290 mmHg
Pressure measurement accuracy	Meets or exceeds ANSI/AAMI SP10:1992 Within 3 mmHg or 2%, whichever is greater
Systolic blood pressure measurement range	60 to 250 mmHg
Diastolic blood pressure measurement range	40 to 160 mmHg
Pulse rate measurement range	40 to 200 beats per minute
Blood pressure measurement efficacy	Meets or exceeds ANSI/AAMI SP10:1992 standard for overall efficacy of blood pressure measurements versus standard auscultation (using the 5 th Korotkoff sound) Average error within +/- 5 mmHg Standard deviation within 8 mmHg
Pulse rate measurement efficacy	Meets or exceeds specification against a clinical reference Average error within +/- 1 beats per minute Standard deviation within 3 beats per minute
Maximum operating cuff pressure	290 mmHg
Maximum possible cuff pressure	330 mmHg

Item	Specification
Maximum possible cuff inflation time	Over 10 mmHg for 3 minutes
Input power requirements to universal power supply	100 – 240 VAC, 500 mA max, 50 – 60 Hz
Output power of universal power supply	8 VDC, 1.0 A
Cord set connector type	IEC 320 C7 connector
Cord set plug types	North American, Continental Europe, United Kingdom, Australia
Cord set length	1.8 m, 6.0 feet
Environmental operating ranges	Temperature: 10 to 40 degrees Celsius Humidity: 15 to 90% RH (non-condensing) Elevation: -170 to 1,700 m (from sea level)
Monitor lifetime	10,000 full scale BP cycles of 0 to 290 mmHg and back
Physical dimensions	Height: 15 cm Width: 23 cm Depth: 8 cm
Weight	2.5 kg, including accessories

In the interest of continued product improvement, we reserve the right to change specifications without notice.

Specifications: BPM-200

Item	Specification
Pressure measurement range	0 to 290 mmHg
Pressure measurement accuracy	Meets or exceeds ANSI/AAMI SP10:1992 Within 3 mmHg or 2%, whichever is greater
Systolic blood pressure measurement range	60 to 250 mmHg
Diastolic blood pressure measurement range	40 to 160 mmHg
Pulse rate measurement range	40 to 200 beats per minute
Blood pressure measurement efficacy	Meets or exceeds ANSI/AAMI SP10:1992 standard for overall efficacy of blood pressure measurements versus standard auscultation (using the 5 th Korotkoff sound) Average error within +/- 5 mmHg Standard deviation within 8 mmHg
Pulse rate measurement efficacy	Meets or exceeds specification against a clinical reference Average error within +/-1 beats per minute Standard deviation within 3 beats per minute
Maximum operating cuff pressure	290 mmHg
Maximum possible cuff pressure	330 mmHg
Maximum possible cuff inflation time	Over 10 mmHg for 3 minutes

Item	Specification
Input power requirements to universal power supply	100 – 240 VAC, 350 – 150 mA, 50 – 60 Hz
Output power of universal power supply	10 VDC, 1.0 A
Cord set connector type	IEC 320 C7 connector
Cord set plug types	North American, Continental Europe, United Kingdom, Australia
Cord set length	1.8 m, 6.0 feet
Battery voltage and capacity	8 V, 3.0 - 3.2 Ah
BP measurements per battery charge	200 at 2 minute cycle time
Battery charge time	12 hours, trickle charge
Battery charge cycles	250
Environmental operating ranges	Temperature: 10 to 40 degrees Celsius Humidity: 15 to 90% RH (non-condensing) Elevation: -170 to 1,700 m (from sea level)
Physical dimensions (table top)	Height: 15 cm Width: 23 cm Depth: 15 cm
Weight	4 kg, including accessories

Standards

The BpTRU monitor (BPM-100 and BPM-200 models) complies with the following standards:

- CAN/CSA C22.2 No. 601.1-M90, Medical Electrical Equipment – Part 1: General Requirements for Safety, 1990.
- UL 2601-1:1988, Medical Electrical Equipment – Part 1: General Requirements for Safety, 1988.
- ANSI/AAMI, SP10:1992, Electronic or Automated Sphygmomanometers, 1992.
- IEC 60601-1 (1988), Medical Electrical Equipment – Part 1. General Requirements for Safety, 1988 (equivalent to EN 60601-1).
- International Safe Transit Association, Pre-shipment Test Procedures (Procedure 2-A), 1996.
- IEC 60601-1-2 (2001), Medical Electrical Equipment – Part 1. General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests, 2001 (equivalent to EN 60601-1-2).
- IEC 60601-2-30 (1999), Medical Electrical Equipment – Part 2-30: Particular Requirements for Safety, including Essential Performance of Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment, 2000 (equivalent to EN 60601-2-30).

CE Mark Information



The CE Mark on this product indicates it has been tested to and conforms with the provision noted with the 93/42/EEC Medical Device Directive, Annex V.

European contact for regulatory compliance:

Mika Reinikainen

Abnovo Ltd.

Suite 115

Wey House

15 Church Street

Weybridge

Surrey KT13 8NA

United Kingdom

tel: +44 (0) 1932 821354

email: mika@abnovo.eu


EMC Guidance and Declarations

The BpTRU family of monitors has the electromagnetic compatibility and immunity characteristics outlined in the following tables.

Guidance and manufacturer's declaration – electromagnetic emissions for the BpTRU monitor		
The BpTRU monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the BpTRU monitor should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11 / EN 55011	Group 1	The BpTRU monitor uses RF energy only for its internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 / EN 55011	Class A	The BpTRU monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (BPM-100) IEC 61000-3-2:2000 + A1:2001	Class A	
Harmonic emissions (BPM-200) IEC 61000-3-2:1995	Class D	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The BpTRU monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the BpTRU 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 floors are covered with synthetic material, the relative humidity should be at least 30%. The BPM-200 monitor should be powered-off or not taking a measurement when the USB cable is installed or removed.
Electrical fast transients/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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% U_T for 0.5 cycles 40% U_T for 5 cycles 70% U_T for 25 cycles <5% U_T for 5 sec	 40% U_T for 5 cycles 70% U_T for 25 cycles <5% U_T for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the continued operation of a BPM-100 is required during power mains interruptions, power the BPM-100 from an uninterruptible power supply or battery.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The BpTRU monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the BpTRU monitor should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
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. Portable and mobile RF communications equipment should be no closer to any part of the BpTRU monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter, as shown below.

Guidance and manufacturer's declaration – electromagnetic immunity			
The BpTRU monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the BpTRU monitor should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V rms, 150 kHz to 80 MHz</p> <p>3 V/m, 80 MHz to 2.5 GHz</p>	<p>3 V rms</p> <p>3 V/m</p>	<p>Recommended separation distance:</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ <p>(80 MHz to 800 MHz)</p> $d = 2.3\sqrt{P}$ <p>(800 MHz to 2.5 GHz)</p> <p>where P is the maximum output power rating of the transmitter in Watts, according to the transmitter manufacturer, and d is the recommended separation distance in metres.</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

- a. Field strengths from fixed transmitters, such as base stations or 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 BpTRU monitor is used exceeds the applicable RF compliance level above, the BpTRU monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BpTRU 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 BpTRU monitor

The BpTRU monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the BpTRU monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BpTRU 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at maximum output power not listed above, the recommended separation distance d in metres (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, separation distance for the higher frequency applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Cables and acceptable lengths	
Cable	Length
AC power cord-set	1.8 m (6 ft)
USB cable	3.0 m (10 ft)



CAUTION

The use of accessories and cables other than those specified may result in increased EMF emissions or decreased immunity of the system to EMF within the surrounding environment.

Technical Modes of Operation

Technical modes of operation are available for the BpTRU to change configurations, check functionality and accuracy, and to connect the monitor to a computer.

Alert/Silent Mode

As well as the power-up tone, the BpTRU makes a short audible tone after completing a series of measurements in Automatic mode. This feature is enabled by default, but can be disabled and re-enabled as follows:

1. Turn the BpTRU off using the power switch.
2. To toggle Alert/Silent Mode, hold the **STOP** button while turning the BpTRU on.



Repeating this toggles the BpTRU to the previous state.

Alert Mode is indicated by three short beeps followed by one long tone during power up.

Silent Mode is indicated by three short beeps during power up without a final long tone.

Hide Mode (dash in Cycle display)

Hide mode allows the operator to hide blood pressure readings that would normally appear at the end of each measurement. By default the BpTRU does not start in Hide mode. Turn on Hide mode as follows.



1. Turn the BpTRU off using the power switch.
2. To toggle the Hide Mode, hold the **CYCLE** button while turning the BpTRU on.

Repeating this toggles the BpTRU to the previous state.

Hide mode is indicated by a dash (-) in the leftmost digit of the **Cycle** display.

When a blood pressure measurement is taken, the applied pressure is indicated in the **Systolic** display in the usual manner. However, when the measurement is complete dashes are displayed in the **Systolic**, **Diastolic** and **Pulse** displays.

In Hide mode, error messages are displayed in the usual manner and the **Review** button works in the usual manner.

Zero Calibration Check

The BpTRU does not normally need to be recalibrated. It automatically performs a zero calibration check each time it starts up, and reports error code E7 if this check does not pass (see “System Errors (E0 to E15)” on page 27).

The Zero Calibration Check mode allows you to check this automatic zero-offset calibration function.



1. Turn the BpTRU off using the power switch.
2. Disconnect the coiled tubing from the BpTRU.
3. To select Zero Calibration Check mode, hold **START** while turning the BpTRU on.
4. Release **START**. The monitor now performs an automatic zero-offset calibration.

The BpTRU indicates that it is in Zero Calibration Check mode by displaying the software version (e.g., 1.90) in the **Systolic** display.

After approximately five seconds, the applied pressure is displayed in whole mmHg in the **Pulse** display and in hundredths of mmHg in the **Reading** display.

A properly calibrated monitor reads "0" in the **Pulse** display and less than "10" in the **Reading** display.

Return to normal operation by powering the BpTRU off and then on again.

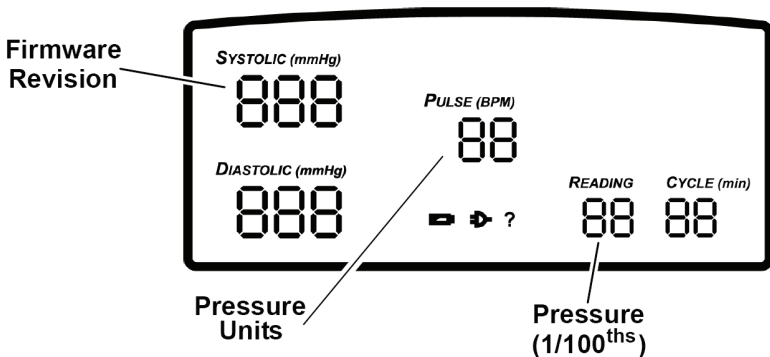
Reference Gauge Calibration Check

The Reference Gauge Calibration Check is a feature that allows you to compare the accuracy of the BpTRU pressure transducer against a reference pressure gauge of known accuracy. (An electronic pressure gauge is recommended, but a mercury gauge or an aneroid gauge is acceptable.)

1. Turn the BpTRU off using the power switch.
2. Disconnect the coiled tubing from the BpTRU.
3. To select the Reference Gauge Calibration Check mode, hold **START** while turning the BpTRU on.
4. Release **START**. The monitor now performs an automatic zero-offset calibration.



Reference Gauge Calibration Check mode is indicated by the software version being displayed on the **Systolic** display. The applied pressure is displayed in whole mmHg in the **Pulse** display and in hundredths of mmHg in the **Reading** display, as shown below:



5. Connect a reference pressure gauge and pressure source in parallel with the BpTRU cuff connector to form a closed system.



6. Press **START** to close the BpTRU valve. This closes the pneumatic system and allows pressure to be applied to the BpTRU pressure transducer.

The maximum time for the valve to remain closed is approximately 3 minutes. After this time, the valve is opened and the **Pulse** display shows “ccc.” When the valve has cooled, the pressure display will re-illuminate.

7. Apply a static pressure of up to 300 mmHg, and compare the pressure displayed in the BpTRU **Pulse** and **Reading** displays to the reference pressure gauge to verify accuracy.

A properly calibrated monitor should read within 3 mmHg of the reference pressure gauge at all pressures.



8. Apply static pressure greater than 330 mmHg, or pressure greater than 10 mmHg for 3 minutes, to check if overpressure or over inflation time safety mechanisms are operating properly and error codes are displayed. Remove the fault condition and press **CLEAR** to remove the error code. Note that the valve will remain open for 30 seconds following activation of a safety mechanism.



9. Press **STOP** to open the valve.
10. Return to normal operation by turning the BpTRU off and then on again using the power switch.

USB Connectivity (BPM-200 model)

The USB port allows a PC-based software application to communicate directly with the BpTRU. The application can command the BpTRU to perform a BP measurement and also to collect data onto a PC.

Due to the large number of electronic medical record programs in use, the BPM-200 is not supplied with software to integrate collected BP measurements into these programs.

Contact BpTRU to obtain the BpTRU Programmer's Reference Guide and software demonstration kit as an aid in developing a customized interface. Third-party software is also available, contact BpTRU for information.



CAUTION

The USB port on the BpTRU is susceptible to electrostatic discharges (ESD), and in an ESD event the monitor may reset and display an error code.

Precautions should be taken when using the USB cable with the monitor, including turning off the monitor and not taking any measurements while the USB cable is being installed or removed.

The USB cable used with the BpTRU monitor must be less than 3 metres (10 feet) in length.

Accessories



WARNING

Substitution of a component, such as a blood pressure cuff, different from that supplied may result in measurement inaccuracy.



CAUTION

The use of a power supply other than that supplied with the BpTRU may result in damage to the monitor or measurement inaccuracy.

Blood Pressure Cuff Sizes

BpTRU Cuff	BPM Catalog Number	Arm Circumference Range (cm)
child	BPM-100-09	13 - 18
small adult	BPM-100-10	18 - 26
regular adult	BPM-100-11	26 - 34
large adult	BPM-100-12	32 - 43
extra large adult	BPM-100-13	41 - 52

Note: All cuffs include connector.

Supplies and Accessories

Blood Pressure Cuffs and Tubing

BPM-100-09	child cuff assembly
BPM-100-10	small adult cuff assembly
BPM-100-11	regular adult cuff assembly
BPM-100-12	large adult cuff assembly
BPM-100-13	extra large adult cuff assembly
BPM-100-14	coiled neoprene tubing (with connector)
BPM-100-19	coiled neoprene tubing extension (with connectors)
CAL-001-01	BP reference calibration check card and T-connector

Mounting Accessories

BPM-300-45	BpTRU mobile stand unit includes: <ul style="list-style-type: none">• pole and rolling base assembly• basket• BpTRU monitor mounting hardware
BPM-100-40	wall mount bracket <i>BPM-100 model only</i>
BPM-300-64	wall mount bracket <i>BPM-200 model only</i>

Power Supplies, Power Cords and Batteries

Part No.	Description	Model
BPM-100-30	power supply, 8V, Universal - requires power cord, see below	100
BPM-300-35	power supply, 10V, Universal - requires power cord, see below	200
BPM-300-66	power cord, North America plug	All models
BPM-300-31	power cord, United Kingdom plug	All models
BPM-300-32	power cord, Continental Europe plug	All models
BPM-300-33	power cord, Australia plug	All models
BPM-300-36	battery, lead acid, includes harness	200

Please contact distributor or manufacturer for a complete catalogue list.

Owner Information

Serial Number _____

Date of Purchase _____

Dealer _____

Dealer Telephone _____

Dealer Representative _____

Dealer Representative
Telephone _____

Warranty



Limited Warranty

The BpTRU™ device (BPM) sold by the manufacturer or an authorized reseller is warranted to the original purchaser to be free of defects in material, parts and workmanship under normal use and service for a period of two (2) years from the date of original purchase.

BPM accessories sold by the manufacturer or an authorized reseller are warranted to the original purchaser to be free of defects in material, parts and workmanship under normal use and service for a period of one (1) year from the date of original purchase.

This warranty does not cover damage caused by accident, abuse or neglect due to the misuse of the product. This limited warranty is non-transferable.

Unauthorized attempts to open, repair or modify the BPM will void this warranty.

The use of the BPM with accessories or other products not authorized by the manufacturer; or failure to maintain the BPM in accordance with the manufacturer's recommended procedures; or any cause other than the intended normal use of the BPM can void the warranty.

If the BPM requires warranty service within the warranty period, the purchaser's sole and exclusive remedy, and the manufacturer's sole obligation, at its sole discretion, will be to:

- repair the BPM to conform to its specifications; or
- replace the BPM with a comparable product; or
- refund to the purchaser the original price paid for the BPM.

Repaired or replaced products or parts may be new or reconditioned, and are subject to this limited warranty through the end of the original warranty period.

To obtain warranty service, the purchaser must:

- contact the manufacturer or an authorized reseller during the warranty period
- provide the manufacturer with dated proof of original purchase or have completed their BPM registration with the manufacturer
- ship the BPM to the manufacturer by prepaid delivery
- have packaged the BPM appropriately for safe shipment

Do not return items without prior authorization. Items returned without a valid return authorization number may not be accepted.

Exclusions

To the full extent allowed by law, this limited warranty is the purchaser's sole and exclusive remedy, and no other warranties, conditions or guarantees of any kind shall apply, whether statutory, written, oral, express or implied, including without limitation warranties, conditions or guarantees of merchantability, fitness for a particular purpose, performance, quality, or durability, all of which are disclaimed. In no event will the manufacturer be liable for any special, extraordinary, indirect or consequential damages of any kind whatsoever, including without limitation damages for loss of data, lost profits, loss of opportunity, business interruption, personal injury or death, or any other loss arising out of, relating to, or in connection with, the BPM, even if the manufacturer is advised of the possibility of such damages.

Liability limitations: if, as a result of or in connection with any use of the BPM, the manufacturer becomes liable to the purchaser or any other person for any damages, losses, costs, expenses, or other liabilities whatsoever, and regardless of the form of action (in contract, tort or pursuant to statute), then the manufacturers aggregate liability to all such persons will be limited to an amount equal to the purchase price paid for the BPM.

The exclusion of certain conditions and warranties and the limitation of certain liabilities is prohibited in some jurisdictions, so these limitations and exclusions may not apply to some purchasers.

This limited warranty is governed solely by the laws of the Province of British Columbia, Canada and applicable federal laws of Canada, excluding any rules of private international law or the conflict of laws which would lead to the application of any other laws, and the courts of British Columbia, Canada shall have exclusive jurisdiction over any claims relating to this limited warranty.

Index



A

alarms	11
alert mode	
Alert/Silent mode.....	58
Automatic mode (series of measurements)	
operating in	18
results	20
reviewing measurements	21

B

battery	
charging indicator.....	8
disposal.....	46
good battery management	39
installing.....	38
low-battery indicator.....	8
replacing	40
beeps	11
BP measurements	
Automatic mode.....	18
series of measurements.....	18
single measurement.....	17
Single mode	17

C

calibration	
reference gauge calibration check	60
zero calibration check	59
cautions/warnings	4–6
ccc in pulse display	60
cleaning/disinfection	45
Clear button	9
cuff	
available sizes.....	63
selecting size	14
Cycle	
button.....	10
display.....	7

D

dash in Cycle display	59
data transfer by USB.....	61
diastolic	

display	7
Hide mode	59
measuring diastolic pressure	13
range	47
dimensions	47
disinfection/cleaning	45
displays	
dash in Cycle display.....	59
defined.....	7
Hide mode	59
Pulse reads ccc	60
disposal of battery	46

E

electromagnetic interference	53
emissions (EMC)	53
environmental ranges	47
error codes	
?.....	31
E0.....	27
E07.....	27
E1.....	27
E10.....	28
E11.....	28
E12.....	29
E13.....	29
E14.....	29
E15.....	29
E2.....	27
E20.....	30
E21.....	30
E22.....	30
E23.....	30
E24.....	30
E25.....	30
E26.....	30
E27.....	30
E3.....	28
E4.....	28
E5.....	28
E6.....	28
E7.....	28
E8.....	28
E9.....	28

F		
functional assessment	41	
H		
hazards		
familiarity with instructions	13	
impairment of circulation	13	
Hide mode.....	59	
I		
indications on start-up.....	41	
inspection.....	43	
interference (EMC).....	53	
M		
maintenance	46	
measurement		
efficacy.....	47	
ranges	47	
multiple BP measurements (Automatic mode).....	18	
O		
operating conditions.....	48	
P		
power		
requirements	47	
pressure range.....	47	
pulse		
display.....	7	
display reads ccc.....	60	
measuring rate	13	
pulse rate range	47	
Q		
question mark (error code).....	31	
R		
ranges, measurement	47	
reading display.....	7	
reference gauge calibration check	60	
results		
series of BP measurements	20	
Review button.....	10	
reviewing measurements		
Automatic mode (series of measurements).....	21	
Single mode (BP).....	20	
S		
series of BP measurements (Automatic mode)	18	
silent mode		
Alert/Silent mode	58	
Single (manual) mode		
reviewing measurements.....	20	
taking BP measurements.....	17	
single BP measurement (Single Mode)	17	
specifications.....	47	
Start button	9	
start-up indications	41	
Stop button	9	
storage requirements.....	46	
systolic		
display	7	
Hide mode	59	
measuring systolic pressure	13	
range of measurement.....	47	
T		
taking BP measurements	18	
technical specifications		
BPM-100.....	47	
BPM-200.....	49	
tones.....	11	
transferring data by USB	61	
U		
USB, connecting.....	61	
W		
warnings/cautions.....	4–6	
warranty.....	67	
weight of units.....	47	
Z		
zero calibration check.....	59	



For further information contact:

Customer Support
BpTRU Medical Devices
Unit 1, 1850 Hartley Avenue
Coquitlam, BC
Canada V3K 7A1

Tel: +1 604 540 7887

Fax: +1 604 540 7875

North American Toll Free: 1 866 921 7887

web: www.BpTRU.com
e-mail: support@BpTRU.com