BP+ User's Manual

Central Blood Pressure Measuring Device

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BP+ User Manual (R7)

Part Number: 0760024-00

Pertains To: BP+ (BPPLUS-R7)

Version: 10.3

CE
0123

Table of Contents

How to Use this Manual

This manual uses some conventions intended to make it easier to understand.

Warning statements convey safety information to mitigate against the potential for death or injury and are displayed in a red box with a warning symbol to the left.

Caution statements convey information about the potential to damage equipment, produce inaccurate data or invalidate a procedure and are displayed in a dashed box with a caution symbol to the left.

Statements conveying helpful hints and notes are displayed with an information symbol to the left.

Individual instructions are displayed in blue italics with accompanying text.

Text displayed on the device screen is drawn enclosed in a box.

Glossary

The following terms and abbreviations are used in this manual.

Term	Description
SYS BP	Systolic Blood Pressure
DIA BP	Diastolic Blood Pressure
MAP	Mean Arterial Pressure
Central SYS BP	Central Systolic Blood Pressure
Central DIA BP	Central Diastolic Blood Pressure
cMAP	Central Mean Arterial Pressure
AI	Augmentation Index
PR	Pulse Rate
sPR	Syprasystolic Pulse Rate
PP	Pulse Pressure
cPP	Central Pulse Pressure
Incident wave	A wave propagating directly from the heart
NIBP	Non-invasive blood pressure
PC	Personal computer
POST	Power On Self-Test
Reflected wave	A wave propagating from a reflection site
SD	Secure Data, type of non-volatile removable storage card
Slot	A place to store a single measurement
Pulse wave	Pertaining to something above systolic, for example a signal recorded at a cuff pressure above systolic pressure

Symbols

The following symbols appear on the BP+ device and in accompanying labelling and documentation.

Symbol	Description
	Class II equipment (IEC 60601-1)
	Type BF applied part (IEC 60601-1) - Blood Pressure Cuff
	Direct current
	Warning, consult safety information
	Consult instructions for use
	Information
	Caution
	Serial interface
	USB interface
	Do not dispose of the BP+ as unsorted municipal waste
	Manufacturer
	Date of manufacture
	Device serial number
	Device model number
	Indicates the temperature range
	Indicates the humidity range

Table 1: Symbols on BP+

The following symbols when used in this manual refer to hardware buttons on the device.

Symbol	Button Name	Functions
	Start	Start measurement Cancel measurement in progress
	Right	Move to the next item Cancel measurement in progress
	Menu / OK	Show the menu or OK Cancel measurement in progress
	Left	Move to the previous item Cancel measurement in progress

Table 2: Buttons on BP+

The following symbols when used in this manual refer to icons that appear on the device LCD Screen.

Symbol	Description
	Secure Data (SD) Card inserted and ready
	Secure Data (SD) Card inserted but BP+ cannot use the card

Table 3: BP+ screen icons

Safety Information

Electric Shock Hazards:

- The BP+ may be isolated from the mains supply by disconnecting the power supply from the mains supply outlet or by disconnecting the power supply from the monitor.
- Do not open the enclosure of the BP+ or power supply unit, especially while they are connected to an AC supply outlet.
- Disconnect the BP+ and power supply unit from the AC supply outlet before cleaning. Do not use liquid or spray detergents.
- Avoid ingress of liquid into any part of the BP+ or power supply unit. Do not submerge any component in liquid. This may cause fire or electrical shock.

Explosion Hazard: Do not use the BP+ in a flammable atmosphere or where concentrations of flammable anaesthetics may occur.

Power Supply:

- Ensure the AC supply voltage is correct and the correct mains power adaptor is securely fitted in place before connecting the BP+ and mains power supply to the AC supply outlet.
- Use only the mains power adapter supplied with the BP+ or a genuine replacement part (GlobTek Inc, model GTM41060-2512).
- This product is intended for indoor use only.
- Protect from excessive force or shock.
- Do not pull output plug with excessive force.

Accessories and Equipment: Use of accessories or equipment not approved by Uscom, or not complying with safety standards equivalent to those met by the BP+, may lead to a reduced level of safety of the resulting system or failure of the BP+ to operate correctly.

Connection to Personal Computer: Equipment connected to the serial or USB port of the BP+ must be certified to applicable IEC standards (IEC 60950 for data processing equipment and IEC 60601-1 for medical electrical equipment). All configurations must comply with the medical electrical equipment standard IEC 60601-1 Clause 16. Anyone who connects equipment to the BP+ configures a medical system, and is responsible for ensuring that the system complies with the requirements of the medical electrical equipment standard IEC 60601-1 Clause 16.

Device Modification: No modification of the BP+ is allowed.

Removal from Use: If any of the following situations occur, stop using the BP+:

- The AC supply cable or attachment plug is damaged.
- The device has been exposed to excessive moisture.
- The device has been dropped and damaged or shows obvious signs of breakage.
- The device display remains blank when turned on.

Contact with Patient: Do not touch any exposed metal parts on the BP+ (in particular interface connectors) while simultaneously touching a patient.

Too frequent measurements can cause injury to the patient due to blood flow interference.

Measurement in an arm where intravascular access or therapy or an arterio-venous shunt is present could result in injury to the patient.

Pressure applied during measurement may cause discomfort or injury where the patient has had a mastectomy on the side the cuff is applied.

Operator Attendance: The operator must be in continual attendance while using the BP+.

The operator should check, by observation that operation of the BP+ does not result in prolonged impairment of the circulation of the blood of the patient.

Other Equipment: Pressurisation of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.

Caution: Do not clean the BP+ with concentrated bleach, corrosive chemicals or abrasive cleaning compounds.

Electromagnetic Compatibility: The BP+ complies with the electromagnetic compatibility requirements of IEC 60601-1-2. Operation of the device may affect, or be affected by, nearby equipment due to the effects of electromagnetic interference. If this happens:

- Increase the separation between the BP+ and the other device.
- Connect the devices to AC supply outlets on separate circuit branches.
- Refer to section 5.1 for further compliance information and advice relating to electromagnetic interference.

The use of a mains power adapter not approved by Uscom may result in increased electromagnetic emissions or decreased electromagnetic immunity of the BP+.

1 Product Overview

Congratulations on your acquisition of the Uscom BP+. Designed for ease of use, accuracy and repeatability, the BP+ will easily integrate into many different clinical and research environments. The BP+ measures brachial and central blood pressure, and other cardiac and arterial parameters, using the cuff oscillometric method.

1.1 Intended Use

BP+ is a non-invasive, compact standalone measurement device that automatically measures systolic and diastolic pressure, and pulse rate in adult and paediatric patients. BP+ also provides non-invasive central (aortic) systolic and diastolic blood pressure, augmentation index, pulse waveform and other parameters intended for use in adult patients.

BP+ performs measurements using a conventional oscillometric method via a brachial cuff on the upper arm.

The device is intended to be used under supervision by qualified healthcare personnel. The device is not intended for operating theatre, intensive care, or continuous patient monitoring use.

The device is not intended to be used in the Home Healthcare Environment.

1.2 Contraindications

This device is not intended for use on neonates, infants, or children under the age of 3 years.

The device is not intended for operating theatre, intensive care, or continuous patient monitoring use.

BP+ central blood pressure measurements have been validated for patients aged between 18 and 80 years.

The device is not intended for measurement of blood pressure in subjects who are pregnant.

Caution: BP+ should not be used on neonatal subjects. A paediatric subject age is 3 years or greater, an infant is considered to be less than 3 years of age.

Caution: Federal (USA) law restricts this device to sale by or on order of a physician.

1.3 Setting Up

To start using the device you will need to supply power, connect an inflatable cuff, and insert an SD Card if you wish to save the measurement data.

1.4 Supplying Power

The BP+ requires DC power input to the device. The mains power adapter provided with the monitor can provide the required DC power from most international mains power outlets from 100 to 240 VAC and 50 to 60 Hz mains input.

The mains power adapter is supplied with interchangeable blades. *Attach the blades that match your wall sockets.*

Insert the plug at the end of the cable attached to the AC wall adapter into the device in the socket indicated as the External DC input socket labelled ⎓.

Use only the mains power adapter supplied with the BP+ or a genuine replacement part (GlobTek Inc, model GTM41060-2512).

1.4.1 Turning Device On

The device will turn on automatically when the AC power is attached.

1.4.2 Turning Device Off

To turn off the device, remove the AC power.

Turning the device off will release pressure in the cuff. A more effective way to quickly release pressure from a subject's arm is to remove the cuff from their arm.

1.4.3 Power On Self-Tests

Once the device is turned on, the device will load the BP+ application into the device internal memory. During this time it will display the following screen.

Figure 1: Boot up screen

BP+ will begin execution once loaded. The BP+ initial screen will start a power on self-test (POST). An example initial screen is shown in Figure 2.

Figure 2: Start-up POST Screen

Once the POST is complete, the device will clear the display and present the Device Ready screen as shown in Figure 3.

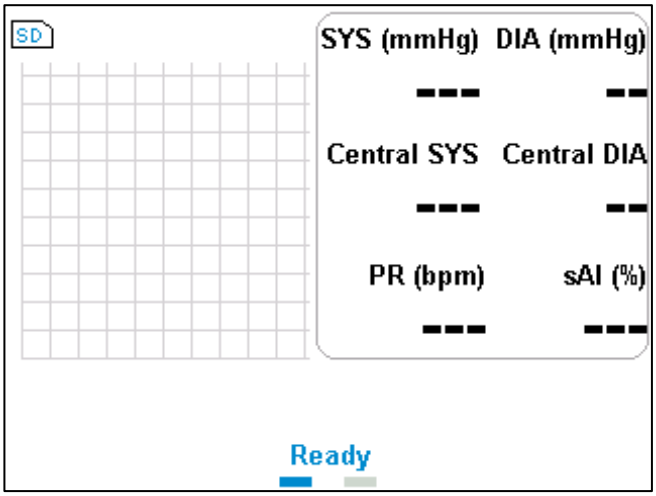


Figure 3: Ready Screen

1.5 Connecting a Cuff to BP+

In order to take a measurement, you will need to connect an inflatable blood pressure cuff using the hose supplied with the cuff.

To connect the cuff hose push the air fittings together until you hear and feel a positive “click”.

To disconnect the cuff hose, pull gently on the metal hose fitting to release the internal lock, and remove hose from device.

The BP+ has been developed using specific cuff designs. Using alternate cuff designs may significantly alter the accuracy of measurement.

Avoid compression or kinking the air hoses connecting the device to the cuff. Such actions, particularly during a measurement, may result in prolonged inflation of the cuff which cannot be resolved by the device’s built-in safeguards. Prolonged over-inflation of a cuff may result in harm to the patient.

The operator should ensure that application of the cuff does not result in prolonged impairment of the circulation of blood.

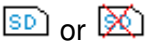
Do not connect cuffs with luer lock connectors to Intravenous System (IV).

1.6 Saving Measurements

The BP+ can store measurements if an SD Card is inserted. The BP+ supports full size SD Cards with a storage capacity up to 32GB with FAT or FAT32 format.

Insert the SD Card with the logo facing up to the user.

Note: Measurements will not be stored if a compatible SD Card is not inserted into the BP+. Look for the SD Card icon on the top left of the screen. If the icon is not present, then no SD Card is inserted. If the icon has a red cross through it, then the BP+ does not recognise the SD Card.



Do not remove the SD card while a measurement is being performed or until the measurement is finished saving. Removing the SD card whilst a measurement is being saved can cause corruption of the SD card file system. If the SD card is accidently removed during a save operation its integrity should be checked using a PC.

2 Common Procedures

The BP+ is designed for simple operation through the four buttons on the front of the device. These buttons are described in Table 2.

2.1 Preparing for a measurement

The entire measurement procedure usually takes less than 90 seconds. However, it is recommended that preparations for taking a measurement follow similar good practice procedures to those for taking non-invasive blood pressure.

Ensure the subject is sitting comfortably upright with adequate back support. The subject's legs should be uncrossed and feet should be flat on the floor.

Instruct the subject to relax, remain still, breathe normally, cease talking and avoid any movement during measurement. It is recommended that the subject is at rest for at least five minutes before the first measurement and to repeat the measurement at least three times, recording the median of the measurements.

2.2 Placing the cuff

Apply the deflated cuff to the subject's left upper arm. Choose a cuff of the correct size, as indicated by the range markings on the cuff. The cuff should be wrapped around the arm firmly, but not tightly. The artery marker on the cuff where the hose enters the cuff should be placed over the brachial artery. Avoid placing the cuff over thick clothing. Avoid bunching up clothing above the cuff, which may partially occlude the artery.

To reduce the risk of cross-infection and further abrasion, do not apply the cuff to broken skin.

Support the subject's forearm on a stable, horizontal surface such as a table top, at a height such that the cuff is at the approximate level of the subject's heart and held away from the subject's torso. Generally, a palm-down position is found to be more comfortable. If the recommend instructions are not followed, any reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition.

2.3 Taking a measurement

When performing a measurement, the operator should be in a position to observe the patients' arm/cuff and the BP+ display.

Press Start 

button while the main screen is displayed as in Figure 4*:*

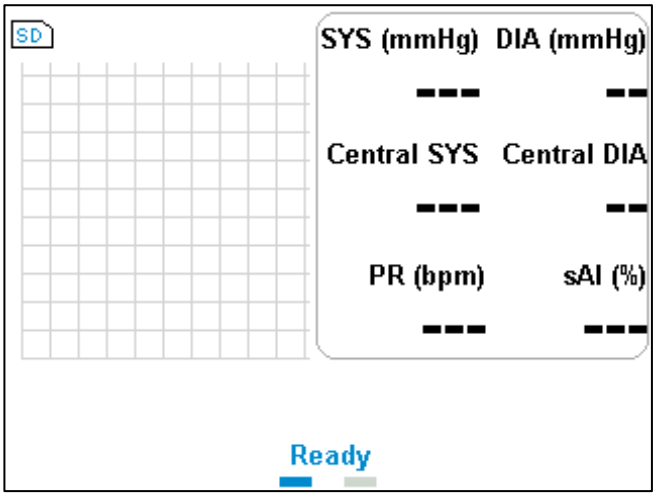


Figure 4: Main measurement screen

There may be a short pause while the device performs a pre-measurement check. The device will then begin inflating the cuff. During this time the status area will display Measuring Blood Pressure and the current cuff pressure will be displayed.

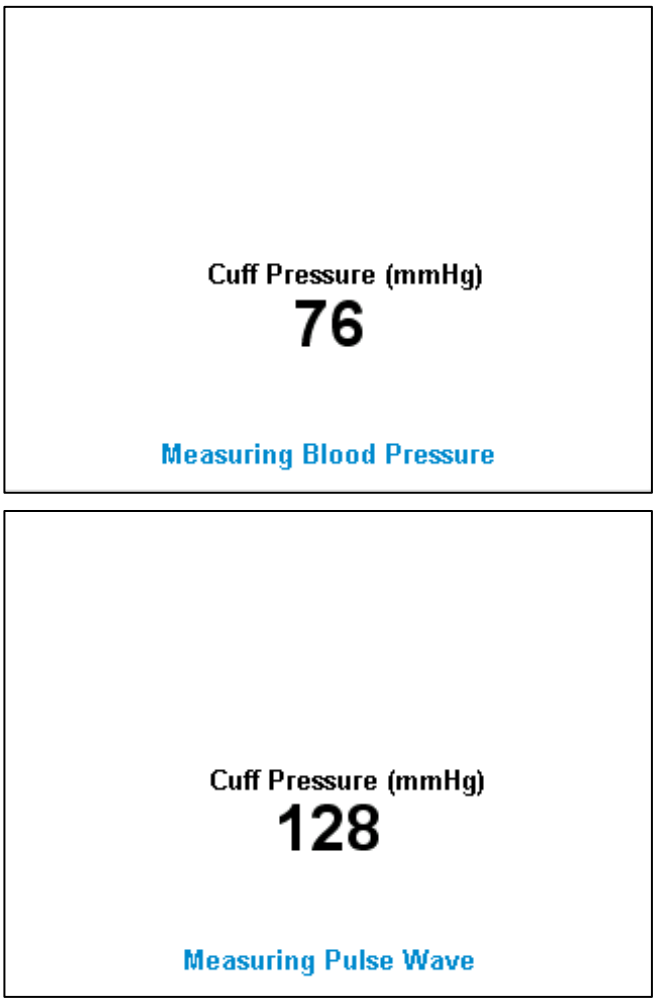


Figure 5: Measuring screen

If your model of BP+ supports "Measurement on Inflation", the device will attempt to determine the systolic, mean and diastolic pressures and pulse rate as the cuff is inflated. If the model does not support measurement on inflation, or the device is unable to determine the blood pressure during inflation, once the pre-set target pressure is reached, the device will gradually deflate the cuff at a controlled rate of approximately 3 mmHg/s. During this time, the device will attempt to determine the systolic, mean and diastolic pressures, as well as pulse rate as the cuff is deflated. If the initial inflation pressure is less than the systolic pressure, the device will re-inflate the cuff to a higher pressure before the controlled deflation. If the BP+ does not successfully measure the subject's blood pressure, selecting a higher or lower inflation target may help.

If your model of BP+ supports "Measurement on Inflation", and it successfully determines the blood pressure during inflation, the device will directly inflate the cuff to the suprasystolic pulse wave pressure. Otherwise, once the blood pressure and pulse rate has been determined by deflating the cuff, the device will re-inflate the cuff to the suprasystolic pressure (approximately 30 mmHg above the measured systolic pressure). This suprasystolic pulse wave pressure will be maintained for around 12 seconds. During this time, the status area will display Measuring Pulse Wave. After the pulse wave measurement is finished, the cuff pressure will be completely released. This marks the completion of the entire measurement cycle. The BP+ will then process the acquired data and display the result on the screen.

2.4 Displaying the Result

Once the measurement is completed, the monitor will display all results under the respective labels as follows:

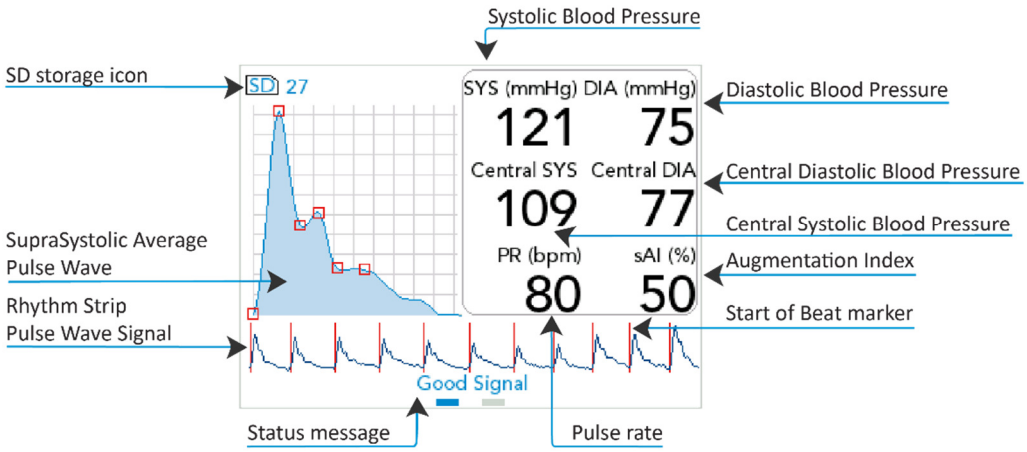


Figure 6: BP Result Screen

10 seconds of the pulse wave signal are displayed along the bottom of the display. Vertical red lines indicate the start of each pulse. This display can provide a visual indication of any arrhythmias and inter-beat variability (such as that caused by respiratory load).

Measurement results may not be accurate in the presence of arrhythmias. Arrhythmias may be apparent on the rhythm strip.

The main screen will also display the average pulse wave pulse.

2.5 Cancelling the measurement

Press any button during a measurement to cancel the measurement and deflate the cuff.

Note: While the device is calculating results it will not respond to button presses.

2.6 Interpreting Signal Quality

The signal quality of the pulse wave measurements will be measured by the device and expressed as a Signal-to-Noise Ratio (SNR) on a logarithmic scale (dB). An increase in the SNR by 3 indicates a tenfold increase in the signal quality. The SNR acceptability is indicated on the results screen as a text status message and can vary from Invalid, Poor, Acceptable, Good, through to Excellent as shown in Table 4: Signal quality classification. The numeric value of SNR is displayed on the Pulse Wave Analysis screen as shown in Figure 7.

Measurements with a SNR below 6 (Poor or Invalid) should be discarded. The device will not display the augmentation index and central pressures in these circumstances. It is recommended to repeat the measurement and to confirm the patient is remaining still and not talking during the measurement. (Patients often move when talking.)

Signal-to-Noise Ratio (dB)	Signal Quality Classification	Colour on Results screen
SNR < 0	Invalid	Red
0 ≤ SNR < 6	Poor	Red
6 ≤ SNR < 9	Acceptable	Yellow
9 ≤ SNR < 12	Good	Green

Signal-to-Noise Ratio (dB)	Signal Quality Classification	Colour on Results screen
12 ≤ SNR	Excellent	Green

Table 4: Signal quality classification

2.7 Displaying Pulse Wave Analysis

Press button from the main screen. The monitor will display the Pulse Wave Analysis screen as follows:

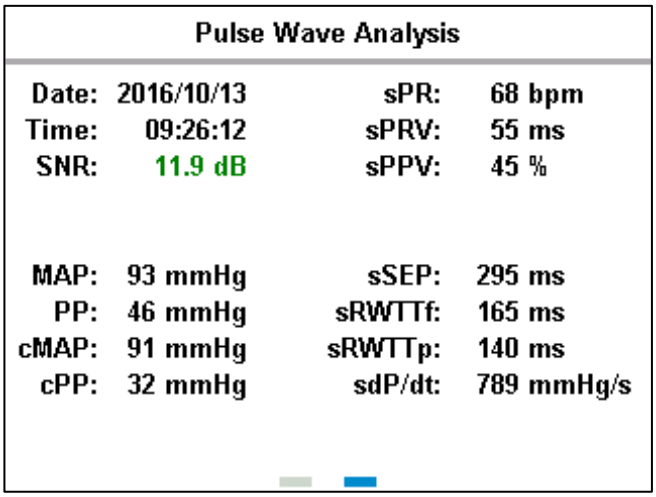


Figure 7: Pulse Wave Analysis Screen

2.8 Settings Menu

The BP+ provides a Settings menu for configuring different functions of the monitor. The setting options include: Inflation Target, Measure on*, Screen* delay, Set Date and Time and Select Language*.

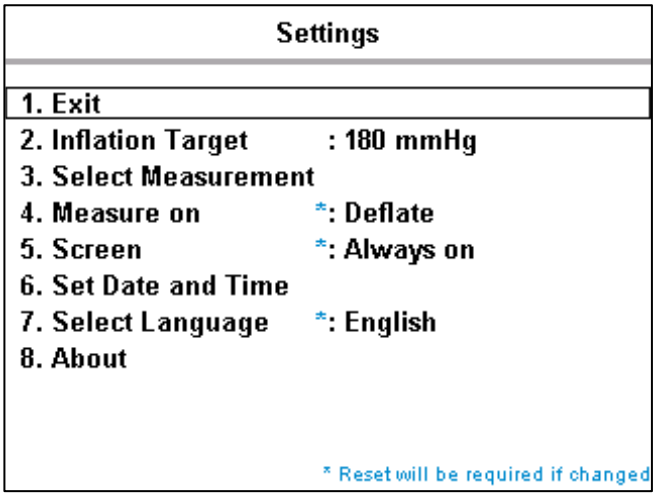


Figure 8: Settings Menu Screen

Changing some setting options require a device reset as indicated by an asterisk (*). Whenever a change is made to an asterisk (*) setting option, the first option – Exit on the Settings menu will be changed to Restart. To exit and reset select Restart and then press to reset the monitor.

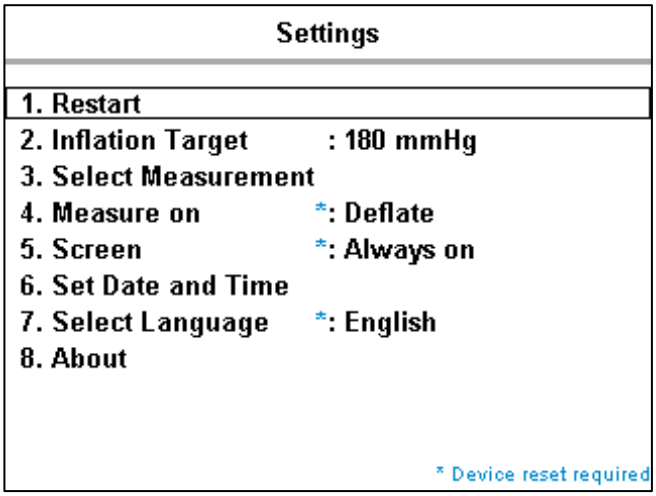


Figure 9: Settings Menu Screen – Restart

2.9 Setting Inflation Target

By default, the BP+ will initially inflate the cuff to 180 mmHg. If the actual systolic pressure is higher than this, then the device may automatically re-inflate additional times to measure the systolic pressure. If you have an estimate of the systolic pressure then you may wish to set the initial inflation target to avoid these additional inflation cycles.

Press to display the Settings menu. Navigate to the Inflation Target option using the arrow buttons and press to select that option. The Inflation Target menu will be displayed with the current inflation target highlighted. *Press* to confirm your selection or use the arrow keys to highlight another value and then *press to select the new value.* You will be returned to the Settings screen. Note that the Inflation Target will default to Automatic if the BP+ is restarted.

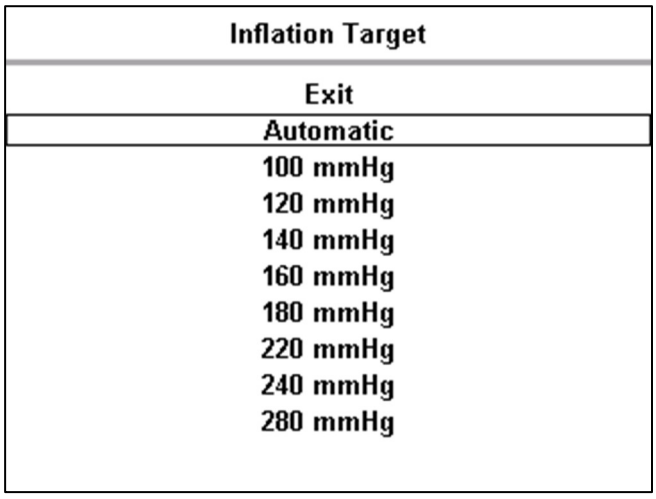


Figure 10: Inflation Target Setup Screen

Note - If the subject's actual systolic pressure is significantly lower than the setting you may reduce measurement time and discomfort by reducing the initial inflation target.

2.10 Reviewing saved measurements

Measurements saved to the SD Card (if used) can be accessed through the menu for review.

Press the Settings menu will be displayed. Navigate to the Select Measurement option and press and the Select Measurement menu will be displayed. If no SD Card is inserted, then the device will prompt you to insert one.

The Select Measurement screen will display a list of measures available from the SD Card. The most recent measurement is at the top of the list, indicated by the Start of List entry. *Use and to highlight the measurement to review.* The screen can display up to 7 measurements. The current selection is displayed in a different colour.

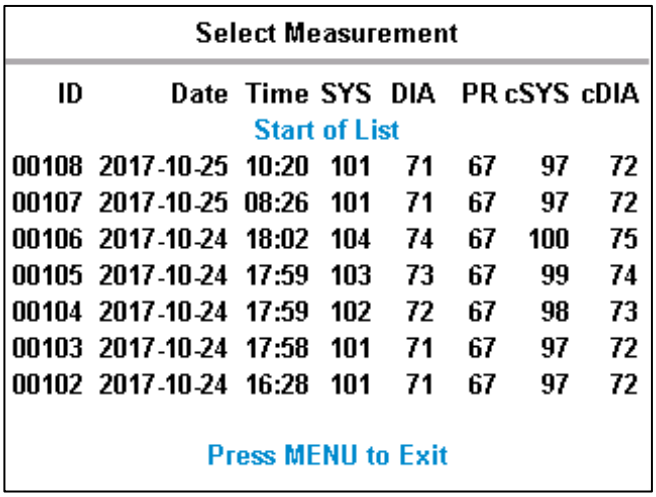


Figure 11: Selecting Saved Measurement

When more than 7 measurements are present on the SD Card, moving past the last displayed measurement will scroll to the next page of measures. When the end of the list is reached End of List will be displayed as the last entry.

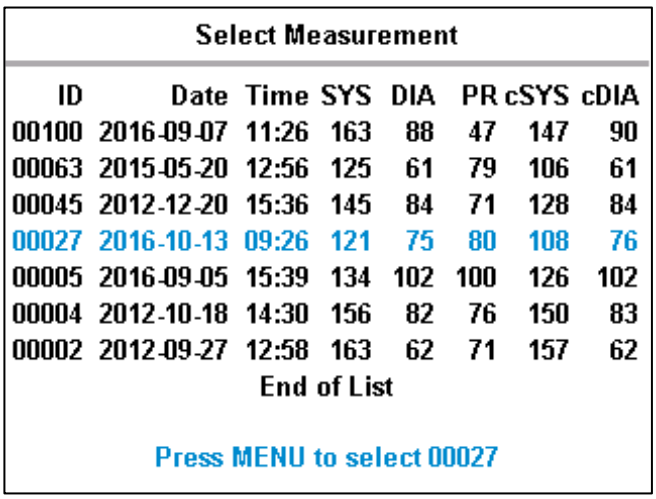


Figure 12: Saved Measurement Navigation

Press to confirm your selection. The BP+ will begin to reprocess the measurement after which it will be displayed on the main screen. If you do not wish to open a measurement for review select Start of List or End of List and Press.

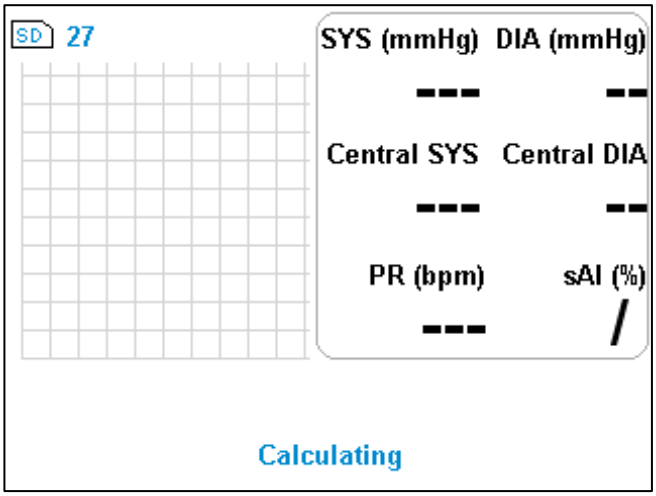


Figure 13: Calculating Measurement

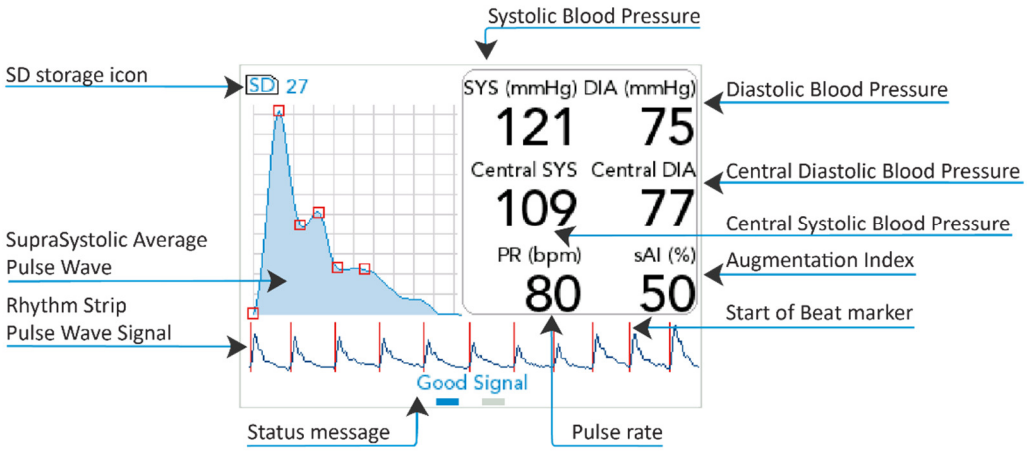


Figure 14: BP Result Screen

2.10.1 Reviewing saved measurements on a Computer

Additional measurement data and saved waveforms may be viewed and printed by reviewing BP+ measurements on a Computer. The easiest option is using BP+ Reporter.

Optionally measurement files can be copied from the SD card to a Computer. This process also acts as a backup of the measurement files.

Saving the BP+ measurement data from the SD card to a Computer is just like saving any files from a similar card used in a digital camera or any external storage.

Eject the SD card from the BP+ and insert into the appropriate slot on the Computer or use an external memory card reader.

Files can be copied to your chosen file location on the Computer.

Open the SD card drive containing the files and either copy or drag and drop the folder called “BPplus” to copy all saved measurements.

2.10.2 Exporting measurements

Exporting measurements from the BP+ can be done using BP+ Reporter or by copying measurement files from the SD card. BP+ Reporter supports exporting several BP+ measurements as a table of values in a Comma-Separated-Variable (CSV) file that is easily imported into Excel or similar application for further analysis.

2.11 Screen

Pressing with Screen Always on setting highlighted will change the setting to Screen Off after 10 min. The BP+ will then switch the screen off after approximately 10 minutes of inactivity.

The BP+ is still powered and ready to perform a measurement, only the screen is switched off. Pressing any button or interacting with the BP+ via BP+ Reporter application will trigger the BP+ to switch the screen on again. The button press will be ignored, permitting any button to be pressed to activate the BP+.

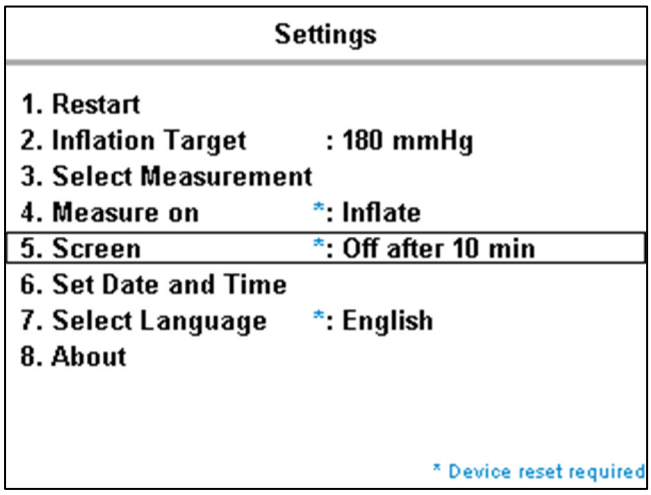


Figure 15 : Screen 10 minute timeout

The BP+ will restart to save and activate this setting if it is changed.

2.12 Setting Date and Time

The BP+ provides a Set Date and Time menu for setting the date and time values on the monitor.

Press . The Settings menu will be displayed. Select the Set Date and Time option and press . The date time setting menu will be displayed.

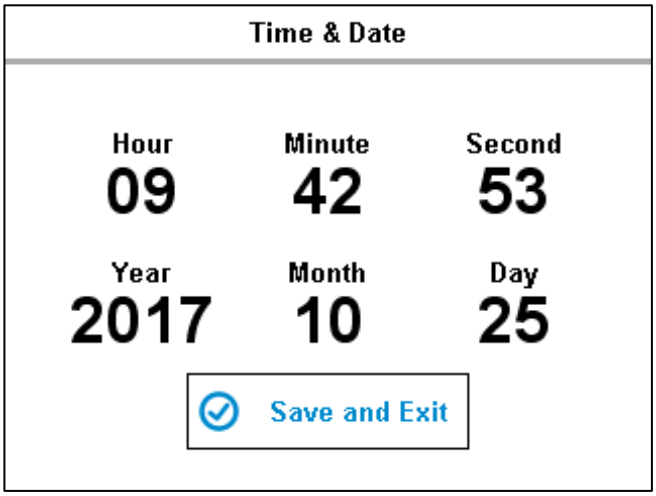


Figure 16: Date Time Setting Screen

Press to highlight a different date time element and use to select it. Then *use and to change the value of the highlighted date time element.* When finished press . The monitor will automatically store the changed value and

does not require any reset of the monitor. To return to the main screen, select Save and Exit and press .

2.13 Selecting Language

By default, the language displayed on the monitor is English. The BP+ monitor may support different language displays for some countries.

Press . The Settings menu will be displayed. Then navigate to the Select Language option and press . The Select Language menu will be displayed with the current language highlighted.

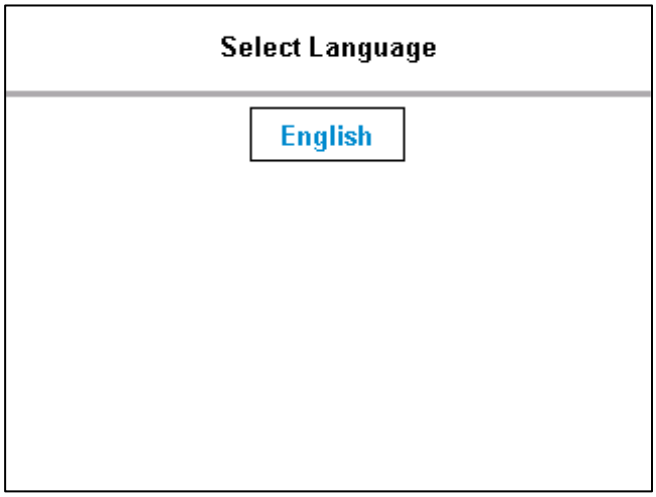


Figure 17: Select Language Screen

Use the arrow keys to select the desired language. Press to return to the Settings menu screen selecting the highlighted language. You will be returned to the Settings menu screen and a reset is required - refer to *2.8 Settings Menu* for device reset.

Some versions of monitor might only provide one language option for some countries. Please contact Uscom for more information using the contact information at the front of this manual.

2.14 About Informational Screen

Selecting the About option on the settings menu will display various version numbers for the software systems in the device along with the unique device ID for the specific BP+.

3 Theory of Operation

3.1 Physiology of wave reflection

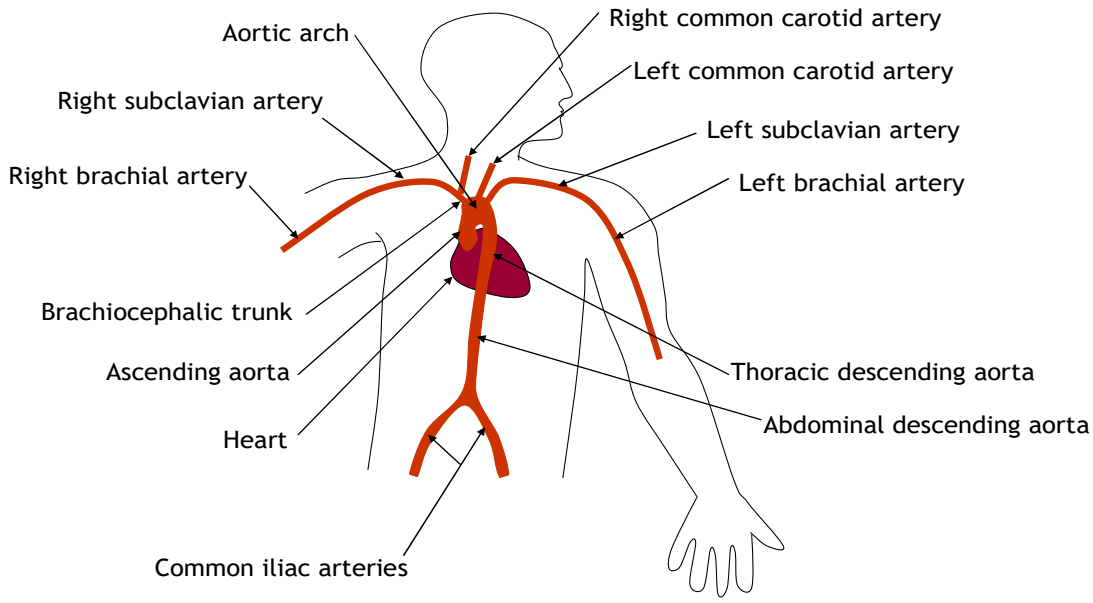


Figure 18: Arteries of the upper body

The Uscom BP+ monitor has been developed using Pulse Wave Oscillometric technology (referred to as **BP+**) and a scientific understanding of pressure wave propagation in the arterial system. The arteries most relevant to BP+ measurement technique are shown in Figure 18.

The theory of wave reflections implies that the pressure at any location in the arterial tree can be considered to be the sum of forward- and backward-going pressure waves.

The initial forward-going pressure wave is generated by the contraction of the heart's left ventricle. Backward-going pressure waves are created when the forward-going pressure wave encounters a change in the properties and geometry within the arterial system. At such a point, the forward-going wave is partly reflected, creating the backward-going pressure wave. There are multiple reflection sites within the human arterial system.

3.2 Blood Pressure Measurement

The Cardiovascular monitor is designed to measure pressure-related information from the upper arm using an inflatable cuff. As shown in Figure 19, the pressure wave generated by the heart can be considered to take two paths to the upper arm cuff, generating what are known as the incident wave and reflected wave.

- The incident wave travels from the heart, through the ascending aorta, subclavian artery and brachial artery to reach the cuff.
- The reflected wave travels from the heart, through the ascending aorta, aortic arch and down the descending aorta to the effective reflection site in the abdominal aorta. At this location, some of the forward-going wave is reflected and travels back up the descending aorta, through the subclavian and brachial arteries before arriving at the cuff.

Measurement should be performed on the left arm. In cases where left-arm measurement is contraindicated, measurement from the right arm can be performed. Validation has only been performed on the left arm. As with all oscillometric blood pressure measurements due to the additional complexity of

the wave path to the right brachial artery, results from the right arm will differ and are not directly comparable with left-arm results.

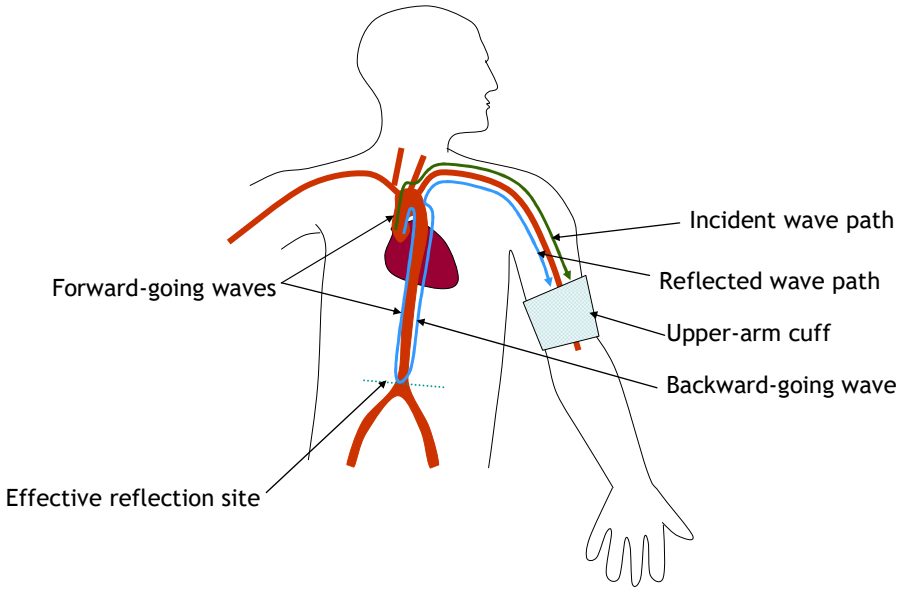


Figure 19: Pressure wave reflection in the arterial system

3.3 Display of Pulse Waveform and Rhythm strip

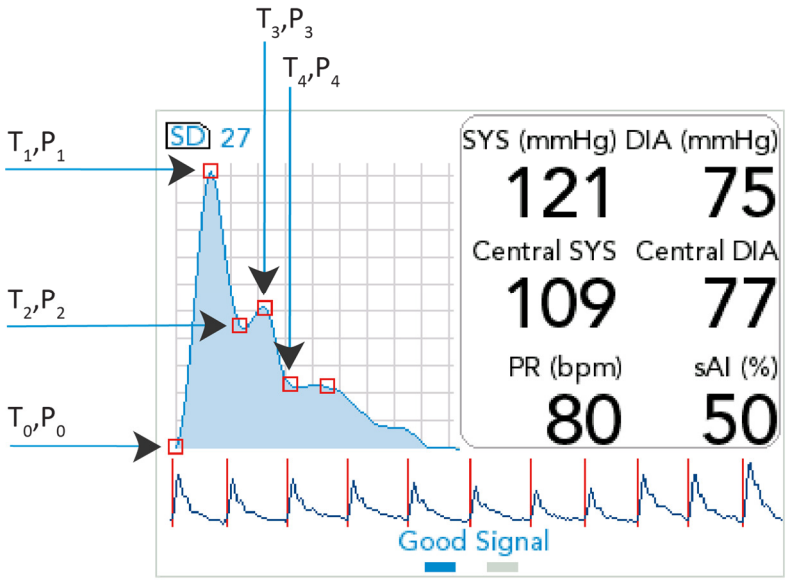


Figure 20: BP Result Screen, mean beat feature points

The following are the points of interest on the pulse waveform, as indicated in Figure 20.

- Start of the pulse, t_0, p_0
- Peak of the incident wave, t_1, p_1
- Trough between incident and reflected wave, t_2, p_2
- Peak of the reflected wave, t_3, p_3
- Trough of the dicrotic notch, t_4, p_4
- Peak following the dicrotic notch, t_5, p_5

3.4 Central Blood Pressure

The BP+ uses a physics-based model of the subclavian to brachial artery branch to calculate central blood pressure. This model has been validated against invasive pressure data obtained from the aortic arch, with measurements taken on the left arm.

Central blood pressure measurement results may not be accurate in subjects who are not similar to those used in validation.

3.5 Pulse Wave Parameters Calculations

Referring to Figure 20, the equations for calculating pulse wave parameters displayed on the main screen and Pulse Wave Analysis screen are:

Suprasystolic Augmentation index (%):

$$\mathrm{sAI} = \frac{p_3 - p_0}{p_1 - p_0}$$

Suprasystolic Pulse rate variability (milliseconds):

$$\mathrm{sPRV} = \sqrt{\frac{1}{N-2}\sum_{n=1}^{N-2}\left((t_{0,n+1} - t_{0,n}) - (t_{0,n} - t_{0,n-1})\right)^2}$$

Suprasystolic Pulse Rate (beats per minute):

$$sPR = 60/\left[\frac{1}{N-1}\sum_{n=1}^{N-1}\left(t_{0,n} - t_{0,n-1}\right)\right]$$

Signal to Noise Ratio (decibels):

$$\mathrm{SNR} = 10\log_{10}\left(\frac{\overline{\left(p(t) - \overline{p(t)}\right)^2}}{\frac{1}{N}\sum_{n=0}^{N-1}\overline{\left(p_n(t) - p(t)\right)^2}}\right)$$

where $\overline{f(t)} = \frac{1}{T}\int_{t=0}^{T} f(t)dt$

Systolic ejection period (milliseconds): $\mathrm{sSEP} = t_4 - t_0$

Reflected wave transit time (peak-to-peak, milliseconds): $\mathrm{sRWTT_p} = t_3 - t_1$

Reflected wave transit time (foot-to-foot, milliseconds): $\mathrm{sRWTT_f} = t_2 - t_0$

Suprasystolic Pulse Pressure Variation (%) of the rhythm strip with n pulses:

$\mathrm{sPP_n} = \max(p_n) - \min(p_n)$ and then $\mathrm{sPPV} = \dfrac{\max(sPP_n) - \min(sPP_n)}{\frac{1}{2}(\max(sPP_n) + \min(sPP_n))}$

Maximum Suprasystolic pressure gradient (mmHg/s):

$$\mathrm{sdP/dt} = \max_t\left(\frac{dP(t)}{dt}\right)$$

4 Maintenance and Troubleshooting

4.1 Servicing

The Uscom BP+ contains no user-serviceable parts. Opening the BP+ enclosure voids any applicable warranty.

Some frequently asked questions are answered below. If your question is not answered, or for additional service information, please contact Uscom using the contact information at the front of this manual.

When contacting Uscom with service related enquiries, please provide the following information:

- Device Part Number
- Serial Number
- Description of any fault, including:
    - Circumstances and operation preceding the fault
    - Environment in which the device was being used at the time of the fault

4.2 Routine Maintenance

The BP+ is designed so that no periodic adjustment or calibration is required, if it is stored and used within the temperature and humidity ranges given in section 5 Specifications. The BP+ might not meet its performance specifications if stored or used outside of these ranges.

The accuracy of the cuff pressure measurement should be checked annually by a trained service technician.

The cuffs provided with the BP+ may become worn with routine use and require replacing.

4.3 Cleaning

The device may be cleaned using lint-free cloth dampened with a mild solution of detergent and water, 10% bleach solution, or a commercial disinfectant.

After cleaning, dry all areas with a lint-free cloth.

Avoid ingress of liquid into any part of the BP+ or power supply unit. Do not submerge any component in liquid. This may cause fire or electrical shock.

To clean the cuff and tubing, apply a mild detergent to a slightly damp cloth and wipe clean. Allow to dry thoroughly.

4.4 Disposal

Dispose or recycle the BP+ in accordance with regulations of your country.

Do not dispose of the BP+ as unsorted municipal waste at the end of the product's lifetime. The BP+ must be recycled in accordance with the WEEE Directive 2002/96/EC (for EU) or according to the regulations of your country. To arrange for return or disposal of the BP+ please contact your local supplier.

4.5 Frequently Asked Questions

I cannot connect the air hose to the device.

Ensure that you have the Uscom provided cuffs. When the hose connector is fitted you will hear a click.

The cuff deflates during a measurement and "Safety Rule Violated" is displayed.

There may have been an overpressure condition. For safety reasons, the cuff will deflate if the device detects a very high pressure in the cuff, or if a significant pressure is held for a long period of time.

The screen is completely white when I turn the device on.
The screen flickers when I turn the device on.
The device resets by itself.

Check that an appropriate AC adapter is being used.

I get the message "Cuff Too Tight or Kinked Hose" when trying to take a measurement.

The device is having trouble inflating the cuff. Ensure that the cuff is on firmly but not tightly, and that the hose to the cuff is not kinked, compressed or blocked.

I get the message "Invalid Signal" after taking a measurement.

This can occur when the signal is too noisy to process. Ensure the cuff is applied firmly and the subject remains still during the measurement.

The signal is consistently very noisy (SNR < 6) even under ideal measurement conditions.

There may be a slow leak in the pneumatic circuit. Check for damaged air connectors, split hoses or punctured cuffs. You may wish to use a different hose and cuff set to verify the problem.

If the problem persists, contact Uscom.

The measured blood pressure is unexpected.
The measurements change a lot each time they are measured.

Ensure that good blood pressure measurement practice is being followed as described in Section 2.1 Preparing for a measurement. Multiple successive measurements may be used to calculate an average value for all parameters.

4.6 Error Message

4.6.1 Main Screen Message

Message	Reason	User Action
Systolic BP too High	Brachial pressure was measured and found to be too high to proceed to the Pulse Wave measurement. Generally, it is not possible to do the PWA measurements when the subjects Brachial SYS is above 255 mmHg.	Redo another measurement after checking the correct size of cuff is applied, the artery marker is placed correctly, no kinks in the hose and hose is attached correctly to the BP+. Ask the patient to relax, sit still, not to talk, no arm or finger movement on the arm being measured (left), feet flat on floor, back supported, etc. Refer to section **2.1** & **2.2**. If error persists, consult Uscom / certified servicing technician (Please make a note of any error number displayed along with the error message.)
Unable to measure BP: Range Exceeded (####) (Where #### is the error number)	The upper arm systolic (SYS), diastolic (DIA), or mean arterial pressure (MAP) measured is outside the measurement range of the device. If the subjects BP is expected to be in range, the error may be caused if pulse signal is too small (use bare arm), subject movement (reminder to sit still), or arrhythmia. If the error occurs frequently, check the blood pressure with other methods to confirm it is in range. The device cannot proceed to do the Pulse Wave measurement.	
Unable to Calculate Results	Calculation errors occur when there is excessive movement during the pulse wave measurement or there is extremely low pulse pressure in the cuff. The latter may occur when attempting to measure over clothing that is too thick. Ideally measure with the cuff applied to bare skin.	
Unable to Start	Device detects an internal error when it starts the blood pressure measurement.	
Poor Signal	The signal quality is poor.	
Unable to measure BP: Please Repeat (####) (Where #### is the error number)	Device detects a blood pressure measurement related error when it is doing the blood pressure measurement.	
Measurement Timeout Or Unable to measure BP: Timeout (####) (Where #### is the error number)	Blood pressure measurement could not be completed within the maximum permitted time. Safety system has cancelled the measurement.	

Message	Reason	User Action
Unable to measure BP: (####) (Where #### is the error number)	Blood pressure measurement failed. This can occur if there is too much patient movement or a tremor in the upper arm. It can also occur if the hose is kinked or blocked. Where the error number starts with "E", there may be an internal error.	Power the BP+ off and on and try again. Consult Uscom/Uscom certified servicing technician with the BP error number if the error cannot be resolved.
Unable to measure BP: Check Pneumatics (####) (Where #### is the error number)	Device detects pneumatics error when it is doing the blood pressure measurement	Check the correct size of cuff and hose is attached correctly. Check there are no air-leaks or kinks in the cuff or hose. Set the Inflation Target to Auto or try a different Inflation Target. If the problem persists, consult Uscom or Uscom certified servicing technician. Please make a note of the error number.
Invalid Measurement Data	The target measurement record being retrieved from the SD card is corrupted or is from an older BP+.	Delete the corrupted/invalid record from the SD card. This can be done by inserting the SD card into a computer and deleting the appropriate file. Optionally retain a copy of the file on the PC before deletion.

Message	Reason	User Action
Unable to Measure BP: Over Pressure (####) (Where #### is the error number) **or** **Safety Rule Violated**	Cuff Pressure is over the 300 mmHg safety limit.	Remove the cuff from the arm and device. Check with the subject if they moved or clenched their arm muscle as this may push the cuff pressure above the safety limit. Check the correct size of cuff is selected and correct placement on the arm. Make note of the artery marker. Check the hose has no kinks nor is it blocked in some way. E.g. try to inflate the cuff by blowing air into the hose and confirm the cuff inflates. If a source of error is corrected, then attempt to perform the measurement again. If the problem persists, try power off and on the BP+. Contact Uscom support if the problem cannot be resolved. Note: Device will automatically deflate the cuff pressure immediately.

4.6.2 Memory Mode Message

Message	Reason	User Action
Please replace SD Card. Full or Invalid	SD card is full or invalid	Delete the old record(s) or replace with an empty SD card formatted to FAT/FAT32
Error Reading SD card	Invalid SD card format	Format the SD card to FAT16 or FAT32 on computer
	Large capacity of SD card is inserted, device does not support capacity larger than 2GB	Check the capacity of the SD card and make sure it is not larger than 2GB

4.6.3 SD Card Icon Message

Message	Reason	User Action
Not Saved	No SD inserted when device is trying to save the measurement data.	Insert a compatible SD card. Repeat the measurement
	When device is trying to save the measurement data: - Oversize SD card is detected, device does not support capacity larger than 32GB	Check the capacity of the SD card and make sure it is not larger than 32GB, is SD or SDHC compatible, and formatted as FAT or FAT32. Use a different SD Card if available
	When device is trying to save the measurement data. - SD card is full	Delete the old record(s) or replace with an empty SD card
	When device is trying to save the measurement data. - The format of SD card is detected to be invalid	Format the SD card to FAT16 or FAT32
Save Failed	The measurement will not be saved due to a calculation error	Redo another measurement and make sure subject sits still and no arm movement, refer to section **2.1 and 2.2**. If error persists, consult Uscom / certified servicing technician.

5 Specifications

Non-invasive upper-arm blood pressure

- Oscillometric method using step controlled deflation
- Adult and pediatric patients
- BP Measurement range:
  - Systolic: 40 to 280 mmHg
  - Diastolic: 20 to 200 mmHg
  - Mean: 25 to 245 mmHg
  - Cuff Pressure: 0 to 300 mmHg
  - BP Measurement accuracy: Static Accuracy: ± 3 mmHg
  - Clinical Accuracy: Mean error is less than ± 5 mmHg Standard Deviation is less than 8 mmHg
- Pulse Rate range: 30 to 240 bpm
- Pulse Rate accuracy: ±5%
- Power-on self-test
- Typical measurement time within 45 seconds

Non-invasive central blood pressure

- Model-based transform of peripheral waveform reports Systolic and Diastolic central pressure

Pulse wave measurement

- Arterial measures:
  - Peripheral Augmentation Index (sAI)
  - Suprasystolic Reflected Wave Transit Times, peak and foot ($sRWTT_p$, and $sRWTT_f$)
- Cardiac function measures:
  - Maximum Suprasystolic pressure gradient (sdP/dt)
  - Suprasystolic Pulse Pressure Variation (sPPV)
  - Systolic Ejection Period (sSEP)
  - Suprasystolic Pulse Rate Variability (sPRV)
- Signal to Noise ratio (SNR)
- Data Sampling Rate: 200Hz

Physical dimensions

- Size: 156 mm × 157 mm × 119 mm
- Weight: 730 g

Display and memory

- 320×240 pixel matrix 3.5” TFT colour display
- Pulse wave waveform display
- Graphical rhythm strip display
- Status and error display
- SD Card slot, hot swappable with cards up to 32 GB

Blood pressure cuff and hose

- Lifetime antimicrobial treatment
- Small Adult, Adult and Large Adult cuffs available
- 1 m hose

Computer interface

- Computer interface specification (serial port) available for customer configuration

Power supply

- Power Supply Unit: GlobTek Inc model GTM41060-2512 medical grade, AC/DC wall adapter
- AC Input: 100–240 V_{AC}, 50–60 Hz, 0.6 A
- DC Output: 12 V_{DC}, 2.08 A
- Use of the BP+ with the Power Supply Unit is considered an ME system

Environmental specifications

- Operating Temperature: 10 to 40 °C (50 to 104 °F)
- Operating Relative Humidity: 15 to 85% (non-condensing)
- Operating Atmospheric Pressure: 80 to 103 kPa
- Transport and Storage Temperature: -20 to 50 °C (-4 to 122 °F)
- Transport and Storage Relative Humidity: 15 to 85% (non-condensing)

IEC 60601-1 standard classification

- Class II Equipment
- Type BF Applied Part (the blood pressure cuff is considered the applied part)
- Continuously powered with measurements being taken upon demand
- Equipment not suitable for use in the presence of a flammable anesthetic mixture, with air or oxygen or nitrous oxide

Warranty

- 12 month warranty on the device
- 6 month warranty on cuffs and extension hose

Reference to standards

- EN 1060-1 /-3 /-4; IEC 60601-1; IEC 60601-1-2 (EMC); IEC 60601-1-11

5.1 Electromagnetic Compatibility

Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BP+ uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The BP+ 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

The BP+ should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BP+ should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration - electromagnetic immunity

The BP+ is intended for use in the electromagnetic environment specified below. The customer or the user of the BP+ 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)	±8 kV contact ±15 kV air	±8 kV contact ±15 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%.
Electrical fast transient / burst (IEC 61000-4-4)	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge (IEC 61000-4-5)	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	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)	240V and 100V: 100% dip 10mS 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º 100% dip 20mS 0º 30% dip 500mS 0º 100% dip 5000mS 0º	240V and 100V: 100% dip 10mS 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º 100% dip 20mS 0º 30% dip 500mS 0º 100% dip 5000mS 0º	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BP+ requires continued operation during power mains interruptions, it is recommended that the BP+ be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF (IEC 61000-4-6)	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM/AM	6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the BP+, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF (IEC 61000-4-3)	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in 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:
	9 V/m - 28 V/m, 385-5785 MHz	9 V/m - 28 V/m, 385-5785 MHz	

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 BP+ is used exceeds the applicable RF compliance level above, the BP+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BP+.

[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 BP+

The BP+ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the BP+ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BP+ 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 a 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, 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.

Essential Performance of the BP+ as required by IEC 60601-1-2 § 3.201.2 is defined as 1) opening of cuff pressure valves if detected cuff pressure exceeds 300 mmHg or 15 mmHg for more than 3 minutes; 2) no degradation of blood pressure measurement accuracy beyond that given in the specification.

6 Accessories and Spare Parts

Small Adult Cuff

Part: U50331

This is a re-useable, latex free cuff suitable for arm circumference 16 to 24 cm.

Adult Cuff

Part: U50332

This is a re-useable, latex free cuff suitable for arm circumference 22 to 32 cm.

Large Adult Cuff

Part: U50333

This is a re-useable, latex free cuff suitable for arm circumference 31 to 45 cm.

Medical grade mains power adapter with international blade set

Model Number: GlobTek Inc GTM41060-2512

Part: U50312

Suitable for use as supply of external DC power to the BP+. Comes with US, Europe, United Kingdom, and Australia/New Zealand blade set. Has medical grade certification for use in hospital environments.