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OPERATION MANUAL

NBP One

24-Hour Ambulatory BP Monitoring System

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Changes

This manual is identified as Part number: NV-54/NBP-ONE. An updated version may be available for download from the Norav Medical website. Should you notice errors or omissions in this manual, please notify us at:

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This manual is for the NBP One, Ambulatory Blood Pressure Monitor (ABPM) System.

CAUTION: US Federal law restricts this device to sale by or on the order of a licensed practitioner

Copyright Information

Manufacturer Information

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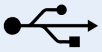
Introduction to Ambulatory Blood Pressure Monitoring

Ambulatory blood pressure monitoring (ABPM) is an accepted clinical tool for collecting multiple blood pressure measurements. ABPM data is intended to better assist clinicians with the diagnosis and management of hypertension by providing data related to: blood pressure variability, estimation of true blood pressure, overnight changes in blood pressure, blood pressure load, sleep blood pressure dipping, and morning surge in blood pressure. In-clinic and home blood pressure measurements cannot provide the same depth of information that a 24-hour study provides. Several studies have shown that ambulatory blood pressure monitoring, when compared to clinic or home blood pressure measurement, is superior in predicting target organ damage, morbid events, or cardiovascular risk.

The data obtained from ambulatory blood pressure monitors is accurate and useful for managing a wide variety of hypertensive situations including:

- White-coat hypertension
- Resistant hypertension
- Masked hypertension
- Childhood hypertension
- Efficacy of anti-hypertensive drug therapy on a 24-hour basis
- Nocturnal hypertension
- Episodic hypertension and/or anxiety disorders
- Hypotensive symptoms
- Changes in diet and daily routine designed to reduce hypertension

Symbols Used in Labeling

Symbol	Description	Standard/Source
	General Warning Sign	ISO 7010-W001
	Batch Code	ISO 7000-2492
	Caution	ISO 7000-0434A
	Refer to Instruction Manual	ISO 7010-M002
	Authorized representative in the European Community	ISO 15223-1
	USB	Industry
	Consult Instructions for Use	ISO 7000-1641
	This product meets the requirements of the applicable Directives	EU Directive
	Disposal in compliance with WEEE Directive	WEEE
	Manufacturer	ISO 7000-3082
	Date of Manufacture	ISO 7000-2497
	Serial Number	ISO 7000-2498
	**CAUTION:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician	
	Cuff index line must fall within range markings	Manufacturer
	Arrow should be placed over artery	Manufacturer
	Symbol indicating limb circumference	Manufacturer
	Index line	Manufacturer
	Not made with natural rubber latex	Manufacturer
	Not made with PVC	Manufacturer
	Reference Number	ISO 7000-2493
	This product is Type BF defibrillator protected	IEC 60417-5334

	Fragile, handle with care	ISO 7000-0621
	Shipping and storage humidity should be kept between 15% to 95%	ISO 7000-2620
	Shipping and storage temperature should be kept between -20˚ C to 70˚C	ISO 7000-0632
	This product and its shipping container should be kept dry	ISO 7000-0626
	Start/Stop a BP measurement	Manufacturer

Overview

Indications for Use

The NBP One System is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with NEMS Software for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult and pediatric (> 3yrs.) patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display to assist a licensed physician in making a diagnosis.

Device Operation

The NBP One monitor is worn by the patient on a waist belt and is connected to a cuff around the non- dominant upper arm. The cuff is inflated automatically at intervals which can be programmed during setup. Blood pressure is measured by the oscillometric method which senses pressure waves in the artery when occluded by pressure in the cuff. Heart rate is determined by the frequency of the pressure waves detected.

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or Automated Sphygmomanometers . The Korotkoff sounds heard over the artery below the compression cuff vary in character as the pressure in the cuff is reduced from above systolic toward zero, or atmospheric pressure. They are divided into phases. Phase 1 (K1) or systolic begins with the sudden appearance of a faint, clear tapping or thumping sound that gradually increases in intensity. Phase 5 (K5) or diastolic begins when silence develops, and was used to determine overall efficacy of the NBP One.

The NBP One meets or exceeds all requirements for validation by the International Protocol of the European Society of Hypertension (ESH) and the British Hypertension Society (BHS) and ISO 81060-2. To obtain results of these studies please send a written request to:

Norav Medical
601 N. Congress Ave. Suite 105, Delray Beach FL 33445, USA

or visit the manufacturer website to review the abstracts: www.noravmedical.com

Products and Accessories

The NBP One System should contain the following items. If you are missing any item, please contact Norav Medical immediately (see Limited Warranty for contact information).

NBP One ABPM System (Included Accessories)

Item Description	Part Number
NBP One ABP Monitor	NBP-ONE-D-00-01
NBP One Software Installation Media	SW-DOK-NBP-ONE-01
USB Cable	C-USB-NBP-ONE-01
ABP Monitor Belt	NBP-ONE-BELT-01
ABP Monitor Shoulder Strap	NBP-ONE-STRAP-01
ABP Monitor Pouch	NBP-ONE-POUCH-01
ABPM Cuff, Size 2 (26cm-34cm)	NBP-ONE-CUFF-1-02
ABPM Cuff, Size 3 (32cm-44cm)	NBP-ONE-CUFF-1-03
ABPM Air Hose	NBP-ONE-HOSE-01

NBP One ABPM Optional Accessories

Item Description	Part Number
ABPM Cuff Size 1 (18-26 cm)	NBP-ONE-CUFF-1-01
ABPM Cuff, Size 4 (42cm-55cm)	NBP-ONE-CUFF-1-04

Biocompatibility and Applied Parts

The ABPM cuff is the only Applied Part (AP) of the NBP One system. All AP have been evaluated for biocompatibility in conjunction with the applicable standards.

Specifications

Method of Measurement	Oscillometric with step
Blood Pressure Range	Systolic: 40-260 mmHg Diastolic: 25-200 mmHg
Heart Rate Range	40-200 bpm
Maximum Inflate Pressure	280 mmHg
Accuracy	Heart Rate accurate within +/-2% or +/-3 bpm, whichever is greater. Blood Pressure results meet or exceed ANSI/AAMI/ISO 81060-2:2013 standards for non- invasive accuracy: ±5 mmHg mean error & 8 mmHg standard deviation.
Validations	Clinically validated to ESH International Protocol, BHS (A/A), and ANSI/AAMI/ISO 81060-2:2013
Operating Conditions Shipping/Storage Conditions	10°C (50°F) to 50°C (122°F) 20-95% RH non-condensing -20°C (°F) to 70°C (°F) 15-95% RH non-condensing
Classification	Continuous operation Power: Two (2) AA batteries, alkaline Data
Data Memory	Flash memory stores up to 250 readings
Calibration Check Recommendation	Minimally, once every two years
Safety Systems	Maximum inflation pressure limited to 300 mmHg; Auto safety release valve for power failure; Maximum measurement time limited to less than 140 seconds
Sampling Periods	24 independently programmable time periods (Time interval options: none, 5, 10, 15, 20, 30, 45, 60, 90, and 120 minutes)

Parameter	Standard	EU Norm
Safety	AAMI/ANSI ES60601-1:2005/(R) 2012 +A1:2012	EN 60601-1 :2006/A1:2013/ IEC 60601-1: 2005/A1:2012
Blood Pressure	IEC 80601-2-30 :2009 + A1:2013	N/A
Usability	IEC 60601-1-6 :2013 Ed. 3.1 IEC 62366:2015 Ed. 1.0	EN 60601-1-6 :2010 EN 62366:2008
EMC/EMI/ESD	IEC60601-1-2:2014	EN 60601-1-2:2015
Home Use	IEC 60601-1-11:2015 Ed. 2.0	EN IEC 60601-1-11:2010
Biocompatibility	ISO 10993-1:2009/(R)2013 ISO 10993-5:2009 ISO 10993-10:2010	EN ISO 10993-1:2009/AC:2010 EN ISO 10993-5:2009 N/A

Symbols	ISO 15223-1:2016	EN ISO 15223-1:2016
Sphygmomanometers	ANSI/AAMI/ISO 81060-2:2013	EN ISO 81060-1:2012
Quality	ISO 13485:2016	EN ISO 13485:2016
Risk Management	ISO 14971:2007 (Ed. 2)	EN ISO 14971:2012
Size	Approximately 100 x 70 x 30 mm	
Weight	Approximately 233 g, including batteries	
Storage Conditions	-20° C to +70° C, 15%-95% RH non-condensing	
Data	USB 3.0 (USB-C)	

⚠ Safety and Effectiveness Considerations

The following safety and effectiveness issues are to be considered prior to the usage of the NBP One monitor.

NOTE: This device is defibrillator protected No precautions specific to the NBP One are required during defibrillation, and defibrillation discharge has no effect on the NBP One.

- The monitor is intended for use following consultation and instruction by a physician.
- The reliability of the device is dependent upon conformance with the operation and service instructions, as detailed in this manual.
- This device has been designed for use on patients with normal sinus rhythms.
- The interpretation of blood pressure measurements should only be made by a physician. The accuracy of any blood pressure recording may be affected by the position of the subject, his or her physical condition, and use outside the operating instructions detailed in this manual.

Disposal

This symbol indicates that the monitor contains materials which may be hazardous to human health. This product complies with the WEEE Directive. Please return the NBP One monitor to Norav Medical for proper disposal. Please dispose of other materials according to local regulations.

⚠ Potential Adverse Reactions

Allergic exanthema (symptomatic eruption) in the area of the cuff may result, including the formation of urticaria (allergic reaction including raised edematous patches of skin or mucous membranes and intense itching) caused by the fabric material of the cuff.

Petechia (a minute reddish or purplish spot containing blood that appears in the skin) formation or Rumple-Leede phenomenon (multiple petechia) on the forearm following the application of the cuff, which may lead to Idiopathic thrombocytopenia (spontaneous persistent decrease in the number of platelets associated with hemorrhagic conditions) or phlebitis (inflammation of a vein) may be observed.

⚠ Cautions for Use

This monitor is designed to perform in conformity with the description thereof contained in this operation manual when operated, maintained and repaired in accordance with the instructions provided. The monitor should not be modified in any way. Ensure pressure compatibility to all patients. If any abnormality occurs in the monitor, suspend the operation immediately and disconnect it from the patient. If the monitor has been used or stored outside its acceptable range (see Specifications page), it may not meet performance specifications. If the cuff fails to deflate, the patient should be instructed on its proper and safe removal.

⚠ Warnings

The general warning sign indicates a potentially hazardous situation which could result in serious injury.

WARNING: Do not use in the presence of flammable anesthetics; this could cause an explosion. This device is not suitable for use in an oxygen enriched environment.

WARNING: Do not immerse the monitor in any fluid, place fluids on top, or attempt to clean the monitor with any liquid detergents, cleaning agents, or solvents. This may cause an electrical hazard. Do not use the monitor if accidental wetting occurs; please return to Norav Medical (see Limited Warranty). Refer to Maintaining and Cleaning the NBP One ABP System, for care instructions.

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

WARNING: The cuff should not be applied over a wound as this can cause further injury.

WARNING: The cuff should not be placed on the arm on the side of a mastectomy. In the case of a double mastectomy use the side of the least dominant arm.

WARNING: Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.

WARNING: Do not use if device is dropped and/or is damaged. Have a qualified service representative check the monitor before using again.

WARNING: Do not attach the cuff to a limb being used for IV infusions or any other intravascular access, therapy or an arterio-venous (A-V) shunt. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.

WARNING: Use only with the cuffs supplied by Norav Medical. Different cuffs have not been validated with NBP One and measurements with non-validated components may not be accurate

WARNING: Use of an ACCESSORY, transducer or cable with ME EQUIPMENT and ME SYSTEMS other than those specified may result in increased EMISSIONS or decreased IMMUNITY of ME EQUIPMENT or ME SYSTEM.

WARNING: The NBP One may be interfered with by other equipment even if the other equipment complies with CISPR Emission Requirements.

WARNING: Performance can be affected by extremes of temperature, humidity and altitude.

WARNING: Do not use the monitor during magnetic resonance imaging (MRI) or in an MRI environment.

⚠ Cautions

The caution symbol indicates a potentially hazardous situation which may result in minor or moderate injury. It may also be used to alert against unsafe practices.

CAUTION: When downloading data from the monitor's communications USB port, the device should not be in use with a patient.

CAUTION: Do not remove monitor covers, except to replace batteries. The monitor does not contain any user serviceable components. Return monitor if service is required.

CAUTION: Do not use on neonates, pediatric patients less than 3 years old, or patients known to be readily susceptible to bruising.

CAUTION: Do not use the monitor if it has failed its diagnostic self test, or if it displays a greater than zero pressure with no cuff attached. The values displayed by such a monitor may be inaccurate.

CAUTION: Substitution of a component different from that supplied may result in measurement error. Repairs should be undertaken only by personnel trained or authorized by Norav Medical.

CAUTION: The NBP One does not contain any user serviceable internal parts and should only be repaired by an authorized Norav Medical service representative. Do not service the product while in use.

CAUTION: If cuff fails to deflate within two and a half minutes, instruct patient on manual removal of cuff.

CAUTION: Check that operation of the monitor does not result in prolonged impairment of the circulation of the patient.

CAUTION: Remove batteries when device is not in use for long periods of time to prevent possible battery leakage and product damage.

CAUTION: A compressed or kinked connection hose may cause continuous cuff pressure resulting in blood flow interference and potentially harmful injury to the patient.

CAUTION: Using an incorrect cuff size could result in erroneous and misleading blood pressure measurement results.

CAUTION: Do not machine wash the cuff bladder.

CAUTION: On hypotensive patients, the device should be used with caution.

Contraindications

The NBP One ABPM system should be used in conjunction with all other available medical histories and diagnostic test information about the patient. The following are reasons to withhold use of the NBP One ABPM system from a patient:

CONTRAINDICATION: Do not use on patients with erratic, accelerated or mechanically controlled irregular heart rhythms, including patients with arrhythmias.

CONTRAINDICATION: Do not use on patients with carotid or aortic valve stenosis.

CONTRAINDICATION: The system is not applicable in generalized constriction or localized spasm of muscular conduit arteries such as seen immediately after hypothermic cardiopulmonary bypass surgery or accompanying Raynaud's phenomena or intense cold.

CONTRAINDICATION: Do not use system on patients who have had a double mastectomy

CONTRAINDICATION: Do not use on the same arm of patients with a peripherally inserted central catheter (PICC) line, Intraveneous (IV) or arterial line.

NBP One At a Glance

Device

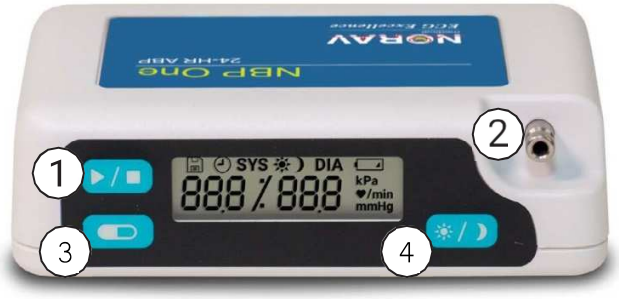


Figure 1: NBP One device

1. Start/Stop Button

   To Power On:

   Press the Start/Stop button.

   To Power Off:

   When not taking a reading, press and HOLD the Start/Stop button until you hear 8 beeps (approx. 5 seconds), then release.

   To Abort a Measurement:

   Press the Start/Stop button any time during a reading.

   To Start a Programmed ABP Study:

   When time is flashing, press the Start/Stop button to take 1st reading.

   To Start a Manual BP Reading:

   When clock is displayed, press the Start/Stop button.

2. Male bayonet NIBP connector
3. Event Marker
4. Day/Night Button

Display

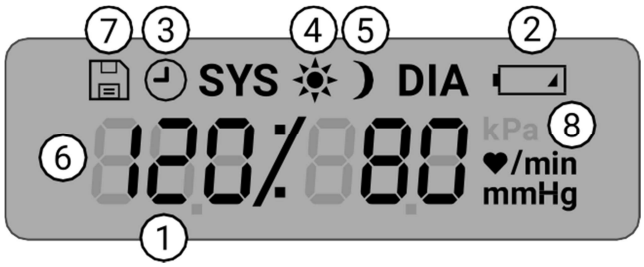


Figure 2: LCD screen

1. Time - Shown when the monitor is not taking a reading.
2. Battery - Indicates low battery; REPLACE BATTERIES.
3. Clock - ABP study in progress.
4. Sun - Indicates AWAKE portion of study.
5. Moon - Indicates ASLEEP portion of the study.
6. BP Reading - During a reading, displays the pressure of the cuff in mmHg or kPa. Immediately after a reading, shows the BP results in mmHg or kPa followed by heart rate in beats per minute.
7. Readings Symbol - Indicates number of BP readings in memory.
8. Measurement unit - indicates the unit of the displayed value in mmHg or kPa (blood pressure) or beats per minute (heart rate)

Button Functionality

Buttons		Functions
Start/Stop		TO POWER ON: Press the Start/Stop button. TO POWER OFF: When the monitor is not taking a measurement, press and hold the Start/ Stop button until you hear five quick beeps, then release. TO STOP A MEASUREMENT IN PROGRESS: Press the Start/Stop button. TO START A PROGRAMMED STUDY: When the time is flashing, press the Start/Stop button. TO START A SINGLE BP READING: When the time is displayed, press the Start/Stop button.
Day/Night		Toggles between day (AWAKE) mode and night (ASLEEP) mode.
Event		Marks an event.

Display Symbols		Description
Time	10:45	Indicates current time. When flashing, the monitor will turn off in 20 seconds unless an ABPM study is in progress.
Pressure	75 mmHg	Indicates the pressure of the cuff in mmHg during a measurement.
Reading Result	120/80 mmHg	Immediately after a measurement is complete, the display shows the results, if enabled. BP in mmHg is shown first, followed by HR in beats per minute.
Clock		Denotes that a programmed ABP study is in progress.
Sun		Denotes the monitor is collecting readings according to the AWAKE program of the study.
Moon		Denotes the monitor is collecting readings according to the ASLEEP program of the study.
Battery		Indicates low battery voltage; BATTERIES NEED TO BE REPLACED.
Save Symbol		Indicates the number of readings in memory.

Setting Up The NBP One System

Setting up the NBP One System involves powering the NBP One, installing NEMS Software on a personal computer (PC), and connecting the NBP One to the PC.

The NBP One ABPM system is packaged with everything you need to start. See Product and Accessories for complete contents.

Powering the NBP One for Use

Install two (2) AA batteries in the bay located at the back of the monitor. The bay shows the orientation in which the batteries should be placed. When batteries are properly loaded, the monitor's display will show the following:

1. Incrementing dashes
2. Software and safety version of the monitor
3. Battery voltage followed by three quick audible beeps
4. The number of BP readings in memory followed by one long audible beep
5. Time flashing

The monitor is now ready to be used.

NOTE: Ensure batteries are inserted with the correct polarity. Improper installation will prevent the monitor from functioning. Batteries are required for NBP One use at all times including programming, scheduling and retrieving.

NOTE: Install batteries before connecting NBP One to PC via USB.

NOTE: Device will not re-charge batteries via USB connection.

CAUTION: Remove batteries when device is not in use for long periods of time to prevent possible battery leakage and product damage.

Connecting the NBP One to the PC

NOTE: Install the NEMS software before connecting the USB cable to the computer.

1. Connect the USB cable to the USB connector on the ABP monitor.
2. Connect the USB end of the cable to the USB port on your PC.

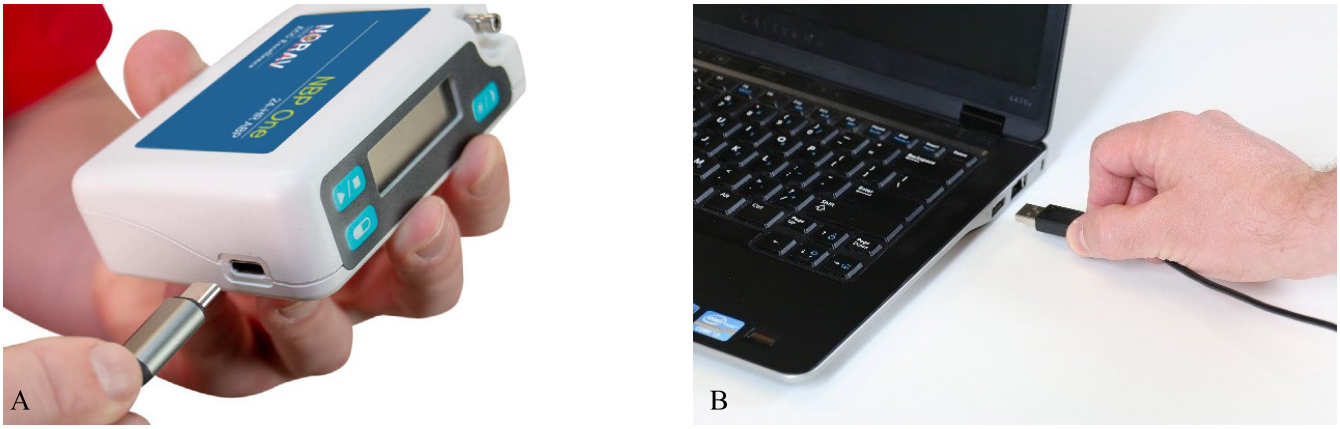


Figure 3: Connecting the NBP One to a PC

NOTE: The cable can be left connected when the PC is off and the monitor is not connected to a patient.

Communicating with the NBP One

To successfully complete an ambulatory blood pressure (ABP) study: Connect the NBP One to the PC then program the study in the NEMS application from your PC. When the patient returns you will again use the NEMS application on your computer to retrieve the collected data.

Conducting an Ambulatory Blood Pressure Study

Programming the NBP One for an ABP Study

Preparing the monitor for an ABP study involves filling out an on-screen form to set the parameters for your study to be programmed into the monitor.

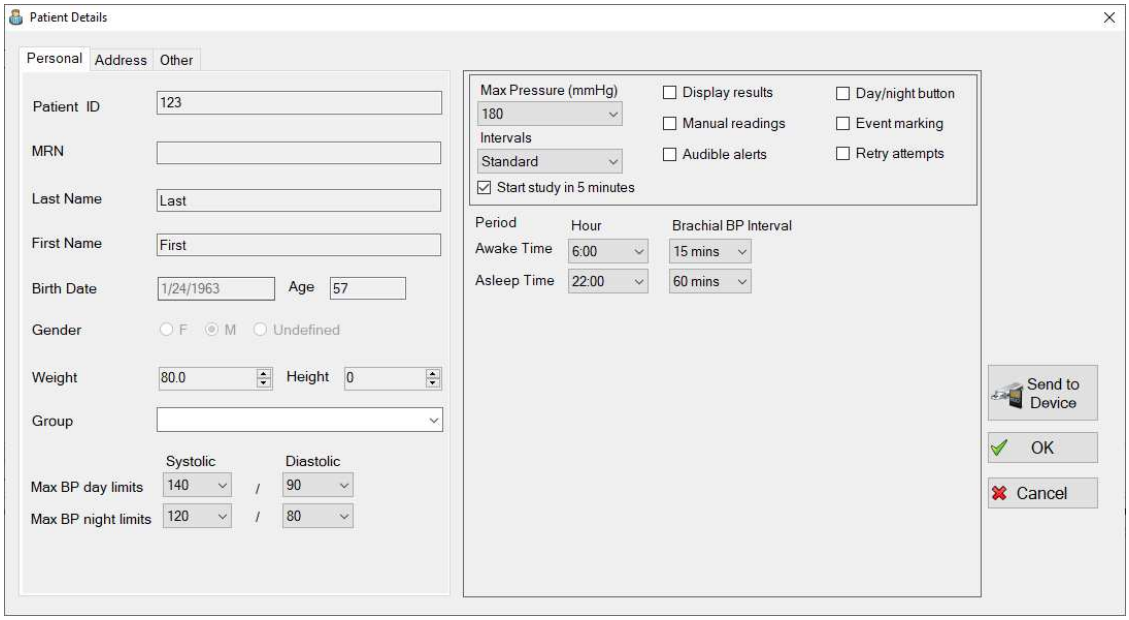


Figure 4: Programming the NBP One

To program the monitor:

1. From the **Patients** window main menu click **New Test**, select **ABPM** test type.
2. Enter the desired parameter settings.
3. Click one of the following:
   - **Send to Device** to transfer the information to the NBP One.
   - **OK** to close and save the current parameters as default for next study.
   - **Cancel** to close without change the default parameters.

Fitting a Patient with the NBP One and ABPM Cuff

After you have successfully programmed the NBP One using NEMS software, you may begin fitting the patient with the monitor and a blood pressure cuff. Cuffs may be used on either arm.

1. Choose the proper cuff size

To determine the correct cuff size for your patient, wrap the cuff around the patient's upper arm without sliding the arm through the sleeve. Use the color- coded **RANGE** indicator on the inside of the cuff and the bold **INDEX** marker to check that the arm circumference falls within the cuff range. If the arm is within range, this cuff size is correct for your patient. If the marker is outside the **RANGE** indicator, select a new cuff size as indicated by color.

CAUTION: Using an incorrect cuff size could result in erroneous and misleading blood pressure measurements.

2. Apply the ABPM cuff

To apply the ABPM cuff, simply slide the sleeve up the patient's arm, ensuring the color size indicator is at the top of the cuff. The cuff should be midway between the elbow and shoulder. Be sure the ARTERY indicator is over the patient's brachial artery, between the bicep and tricep muscles. Wrap the cuff snugly around the patient's upper arm. There should be space for approximately 1 finger underneath the bottom of the cuff.

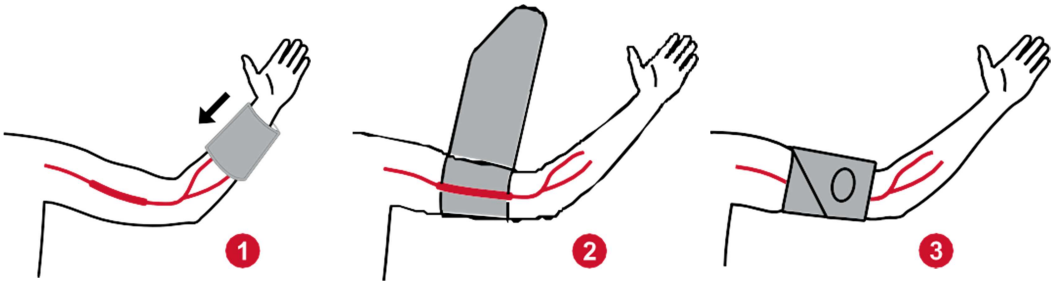


Figure 5: Instructions for Applying the ABPM Cuff

3. Connect the BP hose to the device and the cuff

Connect the BP hose to the NBP One monitor and to the cuff by pushing the fittings together until it is locked into place. The hose can be released by pulling the female fitting away from the male connection. Drape the hose over the patient's shoulder, behind the neck and across to the opposite side of the body.

4. Attach to patient

Insert the NBP One into its pouch with the display showing through the window. Attach the pouch to the patient using the belt.

Figure 6: Fitting the ABPM Cuff to the Patient

Preparing and Educating the Patient

When conducting blood pressure measurements, with an oscillometric NIBP device, it is important to follow suitable procedures to ensure valid, accurate results. Preparing your patient for the ABP study is the most important step to achieving a successful test. Review the following instructions with your patient.

- When the pressure in the cuff increases, the patient must avoid excess movement during measurements. Let the cuffed arm hang loosely, slightly away from the body with the middle of the cuff at heart level. Avoid flexing the muscles or moving the hand and fingers of the cuffed arm.
- The patient can stop a measurement in progress by pressing the Start/Stop button momentarily.
- If the Manual Readings setting is on, the patient can start a measurement at any time by pressing the Start/Stop button momentarily.
- The cuff should not be removed between BP measurements.
- Before sleeping, the patient should make sure that the hose is not kinked and will not become kinked.
- The batteries can be replaced during a study without the data being lost or interrupting the monitor's program. Alternatively, the monitor can be turned off without losing its data.
- Instruct the patient on how and when to fill out the patient diary.
- If the Day/Night button is on, instruct the patient on how to set day and night modes.
- If Event Marking is on, instruct the patient on how and when to mark events.
- Ensure the patient knows how to care for the monitor. Keep the monitor dry and do not drop it.
- If the monitor or cuff causes extreme pain, or pain not normally associated with blood pressure measurement, the patient should remove the cuff and turn off the monitor.
- The patient should not talk during BP measurements. The patient should be seated, standing or lying down. If seated, the patient should have legs uncrossed, feet flat on the floor with back and arms supported.

Starting the Study

Before the patient leaves with the monitor and cuff, verify that the monitor operates correctly. To verify proper monitor operation, ensure that the monitor is on and start a BP reading by pressing the Start/Stop button.
The cuff will inflate and complete the BP measurement. The cuff will then be fully deflated. The clock icon should appear on the display of the NBP One indicating that the study is in progress. If problems occur, review the setup and fitting of the system.

Replace the batteries (2 AA alkaline batteries) for every study with new batteries. Failure to do so may result in incomplete 24-hour studies.

To record an event:

Press the Event button 

The monitor sounds a long audible beep for confirmation, and "rcd : 01" appears on the display (Subsequent recordings use 02, 03, and so on). The monitor can record up to 30 events. If the patient tries to record more than 30 events, the monitor beeps four times, and "No rcd" appears on the display.

Note: If Event Marking is enabled, then the Dosage Response feature will be disabled.

To manually set day (Awake) or night (Asleep) mode:

Press the Day/Night button.

The monitor beeps and displays either the sun or moon icon depending on the mode that it was switched to. If switching to Night mode, the monitor will display a moon icon.
If switching to Day mode, the monitor will display a sun icon.

Finishing the Study

If you wish to finish the study before the patient returns, instruct the patient to turn off the monitor by holding down the Start/Stop button for five (5) seconds. The NBP One will beep five (5) times and the display will turn off.

When the patient returns, take the cuff, monitor, and belt off and download the captured data to NEMS Software for review.

Notes on Blood Pressure Data

Any blood pressure reading can be affected by the measurement site, the position of the patient, motion, or the patient's physiologic condition. Environmental or operational factors which can affect the performance of the device and/or its blood pressure reading are common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, preeclampsia, renal diseases, patient motion, trembling, and shivering.

Retrieving Data from the ABP Monitor

To retrieve the data:

1. Connect the NBP One to the computer.
2. In NEMS Software go to **Devices** page, click the **Scan Recorder** button. After scan completion, patient information appears to confirm patient details.
3. Click **Download** to save the data.
4. When **Download Complete** message appears the BP data is saved to the NEMS database.
   - click **Analyze** to immediately review the study.
   - or click **Close** to review the study later.

CAUTION: If you do not retrieve data from the monitor, this data will be lost when you program it for the next study.

Reviewing and Editing an ABP Study

Each study in a patient file contains data that is displayed in the ABPM review screen.

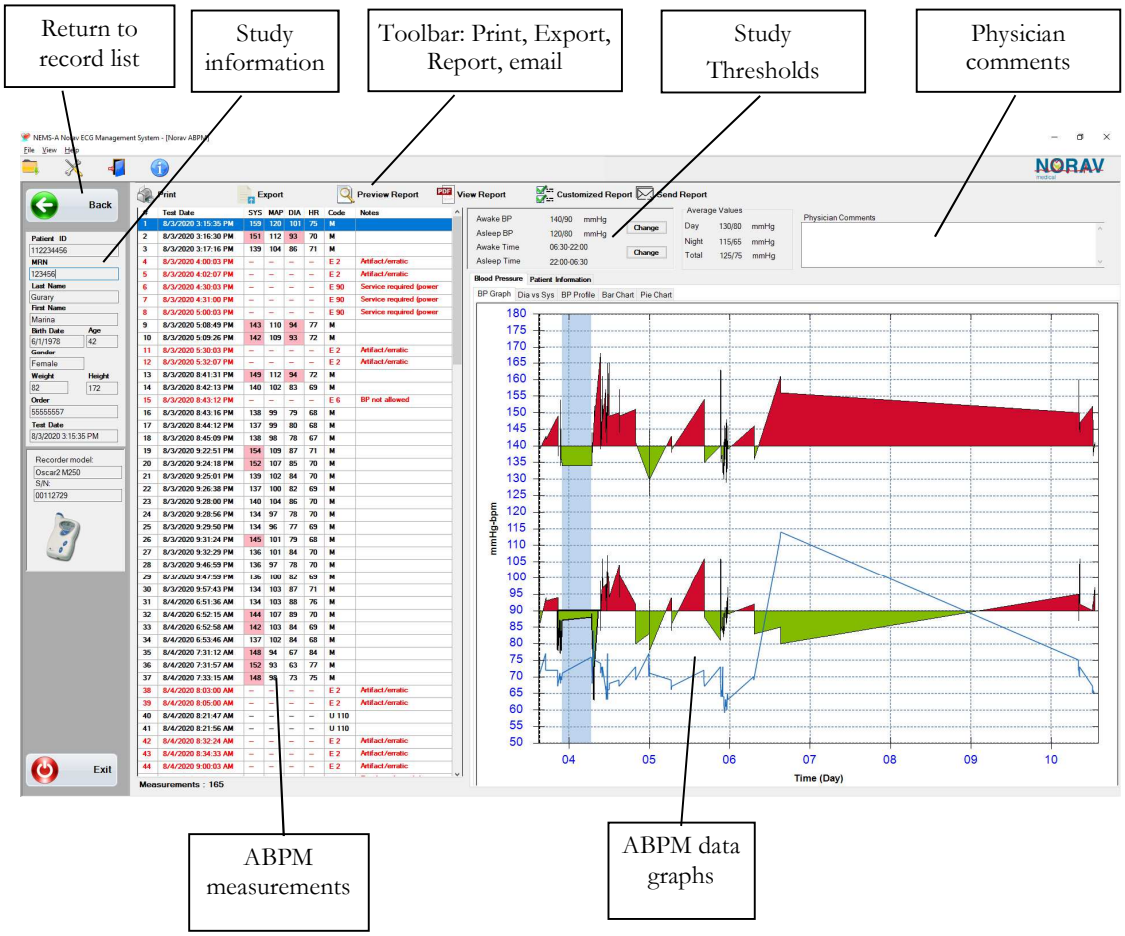


Figure 7: ABPM Review screen

Viewing an Ambulatory Blood Pressure Study

ABP measurements

The ABP measurements table displays the results for each of the BP measurement taken or attempted during the study. The table also includes events recorded by the patient. The highlighted values are measurements that lie outside the defined **thresholds**.

Thresholds

The Threshold panel allows the user to change the Threshold settings on the BP Graph.

BP Graph

The scale of the vertical axis represents blood pressure (mmHg) and heart rate (bpm). The horizontal axis displays the time in clock hours. Clicking on any point, measurement or event, in the graph highlights the corresponding row in the table. Grey Shading on the graph indicates the asleep period of the study .
There are several tabs to the right of the BP graph: Dia vs Sys (AASI graph), BP Profile, Bar Chart and Pie Chart.

Dia vs Sys (AASI Graph)

The AASI Graph plots the diastolic on systolic BP values for each measurement captured in the study. Additionally, this tab lists the calculated AASI value, diastolic as a function of systolic, systolic as a function of diastolic, the correlation coefficient of the linear regression equation, and the coordinate of the average systolic and diastolic.

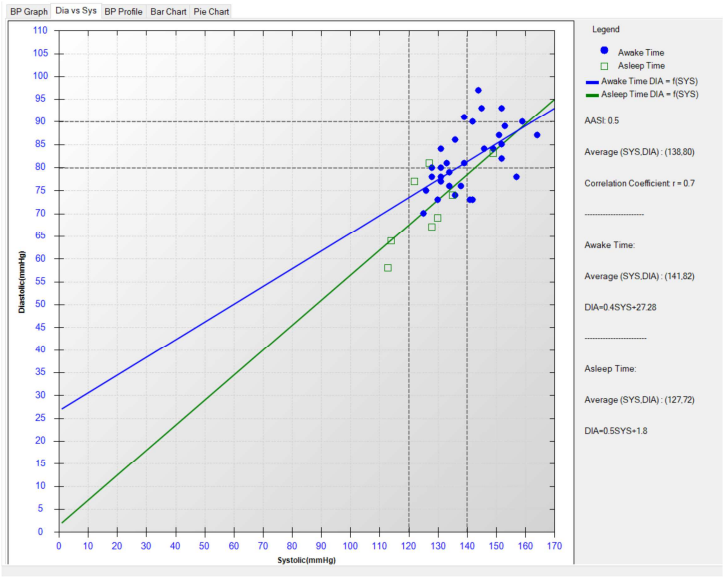


Figure 8: AASI Graph

BP Profile

In addition to the systolic and diastolic BP measurements, there is a white line in the middle which represents the mean values (**MAP**).

The **Heart Rate** graph is represented by the red line.

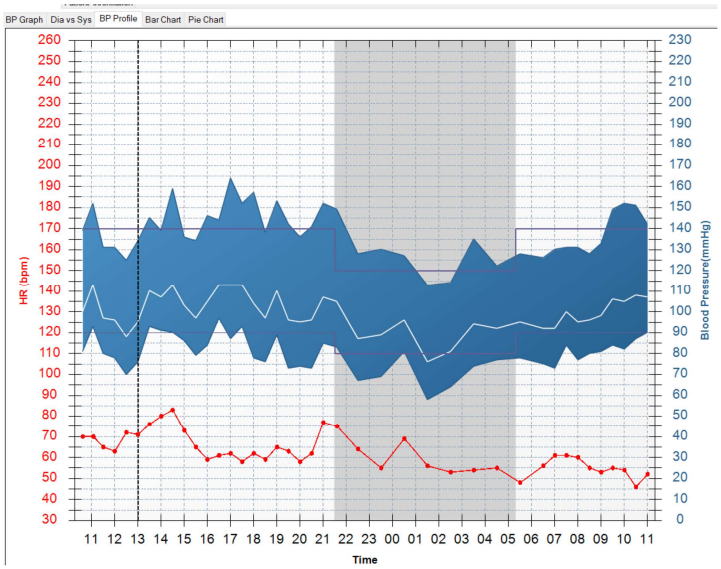


Figure 9: BP Profile graph

Bar Chart

In this graph the following values of the test series will be displayed graphically as a function of time in a bar diagram:

- Systolic values.
- Diastolic values.

The **Heart Rate graph** is represented by the red line.

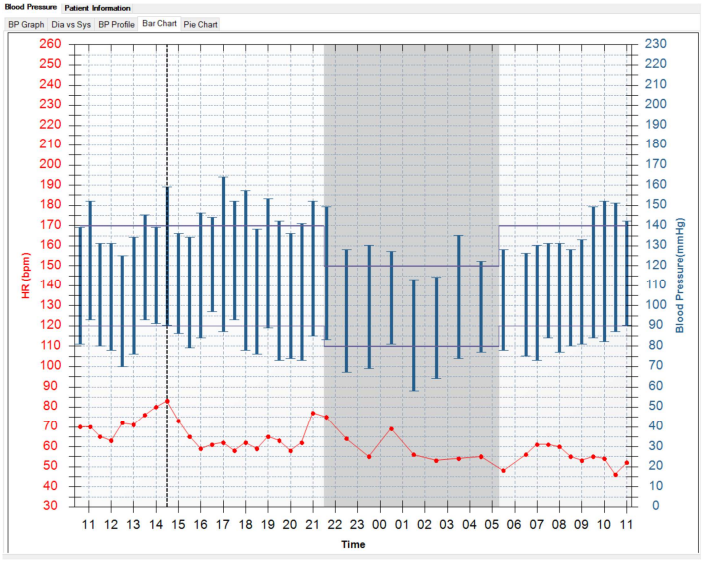


Figure 10: Bar Chart graph

Pie Chart

There is represented the **Values Above Limit** information. The values of one measurement series are analyzed according to the limits set (see in References [20] and [21]) .

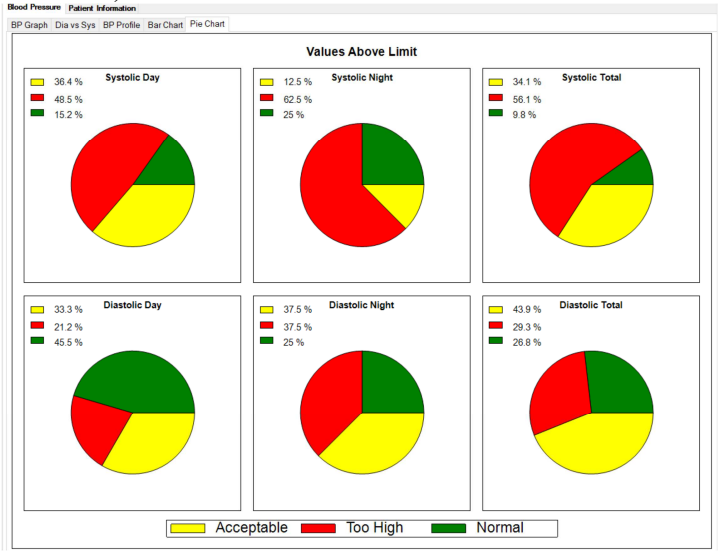


Figure 11: Pie Chart

Reviewing an Ambulatory Blood Pressure Study

In the ABP Data view, you can review an ABP study for accuracy and context. Wrong measurements could be omitted from the analysis of the ABP study displayed in the BP Graphs and other views, but these readings can be printed in the report.

Excluding a measurement

If one measurement is a complete outlier and would therefore falsify a representative 24-hour analysis, you can exclude it: click the column # in the required row. The number of the measurement disappears and that value is now excluded from statistical analyses from now on. To include the measurement back, click the number again.

Commenting on a measurement

Use the **Notes** column, the right-most column in the table, to keep track of patient activity during a BP reading. While activity is only one of the many factors that can affect blood pressure, it can be helpful in understanding a BP reading within the context of the study.

To change BP thresholds and period start times

Users may select the BP thresholds used to calculate the blood pressure load and above threshold values as well the Day/Night period start times.

To adjust thresholds click **Change** button near the needed parameter, adjust the value and then click **Done** to save changes.
Thresholds can be set for Awake and Asleep systolic and diastolic BP. If desired, you can set thresholds to match a published standard:

- JNC7[9] recommends 135/85 mmHg for Awake periods and 120/75 mmHg for Asleep periods.
- The American Heart Association (AHA)[10] recommends a 24-hour average BP of 130/80 mmHg.
- The ESH[11] recommends 135/85 mmHg for Awake periods and 120/70 mmHg for Asleep periods.

To Edit the Medical History and Medications

To edit the medical history and add medications click **Patient Information** tab to the right of the **Blood Pressure** graphs tab.

Creating Reports

Configuring and Customizing the Report

To document a study and its findings, you can create a customized report which can include one or many of the following preconfigured report formats:

- Patient Information.
- BP Graph.
- BP Profile.
- Bar Chart
- Table of Measurements.
- Dia vs Sys (AASI Graph).
- Pie Chart

NOTE: All report pages include the company logo, patient demographics, the test date and physician comments.

To configure or customize your report

- Click **Customized Report** in the main menu
- Choose one or multiple formats listed in the panel.
- Click **Customization** button to edit the report header/footer text, enter the physician name or add a custom logo to the report.

Previewing and Printing the Report

From the menu, click **Preview Report** button. The Print Preview window is displayed. To scroll through the report pages, click the previous or next buttons, or select the page you want to view using the drop-down menu.

To print the report, click **Print**.

Managing Patient Studies

Exporting a Patient Study

You can export BP data files to XML format. XML can be used to create an HL7 compatible file.

1. From main menu click **Export**.
2. Select the target folder, type the filename and click **Save**.

Emailing a Patient Study

(email Client software is required)

1. From main menu click **Send report**.
2. New email dialog will appear with attached PDF report file.
3. Type in the recipient email address(es), a subject for your message, and a message.
4. Send the email.

Event Codes

Event Codes (EC) are used during the review of ABPM data. The codes are displayed in the table on the ABP Data tab and in the Reviewed and Omitted BP data report pages under the columns labeled EC. Event Codes describe the conditions under which the BP measurement was taken. They are also accompanied by solutions, if applicable, that can be taken to avoid their occurrence in the future.

NOTE: Codes do not automatically indicate that a reading is invalid; they serve only as guides to help you review the data.

Event Code Definitions

Code	Description in NBP One Software	Solution or Response
1	Weak or no oscillometric signal	Check position and tightness of the cuff.
2	Artifact/erratic oscillometric signal	Patient should remain still during the BP reading.
3	Exceeded retry count: 2 attempts	Patient should remain still during the BP reading.
4	Exceeded measurement time limit: 140 seconds	Check the air hose connections and make certain the cuff is tight.
5	Results outside of published range: BP: 25-260 mmHg HR: 40-200 bpm	Retry the reading by pushing the Start/Stop button. If the problem persists, return the unit for service.
6	Release interval violation	Retry the reading by pushing the Start/Stop button. If problem persists, return the unit for service.
85	Reading aborted – blocked valves or pneumatics	Check the air hose connections and make certain the air tubing is not crimped.
86	Reading aborted – user abort	Restart the reading by pushing the Start/Stop button.
87	Reading aborted – inflate time-out or air leak	Check the air hose and cuff.
88	Reading aborted – safety time-out	Retry the reading by pushing the Start/Stop button. If the problem persists, return the unit for service.
89	Reading aborted – cuff over- pressure	Check for blocks or kinks in the air hose.
90	Service required – power supply out of range or other hardware problem	Replace the batteries. If the problem persists, return the unit for service.
91	Service required – safety override fitted or auto-zero out of range	Retry the reading by pushing the Start/Stop button. If the problem persists, return the unit for service.
94	Low battery warning	Replace the batteries. If the problem persists, return the unit for service.
96	Calibration Error	Return the unit for service.
97	Service required – transducer out of range	Return the unit for service.
98	Service required – A/D out of range	Return the unit for service.
99	Service required – EEPROM calibration data CRC failure	The unit needs to be recalibrated. Return for service.
110	Event marked by patient	In ABP table, select desired comment.
111	Day to night mode switch	If desired, adjust ABP Data graph to match the time marked by the patient.
112	Night to day mode switch	If desired, adjust ABP Data graph to match the time marked by the patient.

Maintaining and Cleaning the NBP One

The NBP One system is designed to perform in conformity with the description contained in this user manual and accompanying labels and inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided. After use, it is important to perform preventative maintenance to ensure the safe and efficient operation of the monitor. It is your responsibility to:

- Check calibration of the device every two years.
- Never knowingly use a defective device.
- Immediately replace parts that are broken, worn, missing, incomplete, damaged or contaminated.
- Contact the nearest authorized service center should repair or replacement become necessary.

Further, the user of the device bears sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than Norav Medical or authorized service personnel.

While usage will have an impact, it is expected the monitor will be in service for 7 years. Typically, an electromechanical pump determines the lifetime of the monitor. Service and support, including relevant accessories, will be available up to 7 years following the last date this product is manufactured by Norav Medical. For a list of service centers, see the Technical Assistance.

Cleaning After Use

NBP One

The NBP One monitor cannot be sterilized. DO NOT immerse the monitor in any fluid, or attempt to clean with any liquid detergents, cleaning agents, or solvents. You may use a soft, damp cloth to remove dirt and dust from the monitor. If the unit does become immersed in water, do not use; contact our service department.

Orbit ABPM Cuff & Accessories

Remove the bladder for cleaning. Dampen a soft cloth with a mild medical grade disinfectant and wipe the bladder, let it air dry. The fabric shell of the Orbit cuff may be machine-washed in cold water with a mild disinfectant. Line dry this cuff only - machine drying can cause damage to the fabric shell of the Orbit ABPM cuff.

The bladder needs to be inserted back into the cuff sleeve so the pneumatic hose portion of the bladder goes through the tube opening on the cuff. Please note that the pneumatic hose connection should face upward

when using the Orbit ABPM cuff on either the right or the left arm.

CAUTION: Do not machine wash bladder

Maintenance and Repairs After Use

Visually inspect cables, material, pneumatic hoses, and the monitor case for cracks, fraying, or kinks. DO NOT use the monitor or cuff if there are any signs of damage. Please contact our service department if any damage or defects are identified.

The NBP One does not contain any user serviceable internal parts and should only be opened by an authorized service representative. To return for service, please send to your nearest Norav Medical office, listed above, care of Support and Service. Alternatively, please visit our website www.noravmedical.com to request more information.

Calibration Verification Procedure

It is recommended that you check the accuracy of the NBP One once every two years. If needed, an authorized service center may recalibrate the pressure transducers in the monitor. To verify calibration, the NBP One must first be placed into the proper mode. Follow the steps below:

1. Remove and then replace one of the two “AA” batteries.
2. Press and hold down the Start/Stop key.
3. You will hear a click as the valves are closed.
4. You will now see “0 mmHg” displayed.

The monitor’s calibration can now be checked against a calibrated mercury column.

1. Place a t-tube between the hoses connecting the monitor and the cuff.
2. Wrap the cuff around a suitably sized can or bottle. This acts as the reservoir for the unit.
3. Attach the third end of the “T” tube into a calibrated mercury column, which gives you access to the bulb and a reference.
4. Using the bulb of the calibrated mercury column, inflate the cuff to 250 mmHg.
5. Once the pressure has stabilized at this level, the LCD should match the mercury column by ± 2.0 mmHg.
6. Check the unit against the column every 50 mmHg from 250 to 50 mmHg. The monitor should be within ± 2.0 mmHg. If it is not, the monitor needs to be returned to the service department for recalibration or repair.

NOTE: To return the NBP One to its normal operating mode, remove and re-insert one of the batteries.

Limited Warranty

NBP One Ambulatory Blood Pressure Monitoring System

Norav Medical provides to the original purchaser the following limited warranty from the date of original invoice.

Serialized blood pressure monitor	24 months
ABPM Cuffs	6 months
Accessories (i.e. patient hoses, interface cables, etc.)	90 days

Norav Medical, Inc. warrants each instrument to be free from defects in material and workmanship. Liability under this warranty covers servicing of the instruments when returned from the customer's facility prepaid to the prospective factory depending on location. Norav Medical will repair any component(s) or part(s) that it finds to be defective during the period of this limited warranty. Should a defect become apparent, the original purchaser should notify Norav Medical of the suspected defect. The instrument should be carefully packaged and shipped prepaid to the appropriate service center listed in section 18, Technical Assistance.

The instrument will be repaired in the shortest possible time and returned prepaid by the same shipping method as received by the factory.

This limited warranty is void if the instrument has been damaged by accident, misuse, negligence, or serviced by any person not authorized by Norav Medical.

This limited warranty contains the entire obligation of Norav Medical and no other warranties expressed, implied, or statutory are given. No representative or employee of Norav Medical is authorized to assume any further liability or grant any further warranties except as set herein.

Technical Assistance

For any questions, please reference this user manual or our website. If these do not fully address your problem, please contact our service department:

Norav Medical
601 N. Congress Ave. Suite 105, Delray Beach FL 33445, USA.

Tel: +1 (561) 274-4242 Fax: +1 (561) 274-4252
Email: info@norav.com Web: www.noravmedical.com

Radio Frequency Compliance Requirements

This equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document. This equipment has been tested and found to comply with the limits for medical devices to IEC60601-1-2: 2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment
generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult the manufacturer or field service technician for help.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

WARNING: Use of accessories, transducers, and cables other than those specified may result in increased emissions or decreased immunity of the NBP One.

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

Electromagnetic Compatibility System Requirements

Guidance and manufacturer's declaration – electromagnetic emissions		
The NBP One is intended for use in a Home Healthcare Environment within the electromagnetic environment specified below. The customer or the user of the NBP One should assure that it is used in such an environment. This equipment has been tested and found to comply with the limits for medical devices to IEC60601-1-2: 2014.		
Emissions	**Compliance**	**Electromagnetic environment-- guidance**
RF emissions CISPR 11	Group 1	The NBP One uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The NBP One 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	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity

The NBP One is intended for use in a Home Healthcare Environment and 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. This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2: 2014.

Immunity test	Applies to	Compliance level	Electromagnetic Environment–Guidance for Home Healthcare Environment
Electrostatic discharge (ESD) IEC 61000-4-2	All device input and output connections and cables	± 2, 4, 6, 8kV contact ± 2, 4, 8, 15kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 40 %.
Radiated RF EM fields IEC 61000-4-3	All device input and output connections and cables	10V/m 80 MHz to 2700MHz 80% AM at 1kHz	Radiated electromagnetic fields should be at levels characteristic of a typical location in a Home Healthcare Environment
Radiated RF Wireless communication equipment IEC 61000-4-3	All device input and output connections and cables	See Table A below	This device has been subjected to RF wireless communication bands from cell phones, and other communication devices
Electrical fast transient/burst IEC 61000-4-4	N/A	N/A	N/A

Surge IEC 61000-4-5	N/A	N/A	N/A
Power Frequency (50Hz) magnetic field IEC 61000-4-8	All device input and output connections and cables	30A/m	Power Frequency magnetic fields should be at levels characteristic of a typical location in a Home Healthcare Environment or domestic environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	N/A

Note: In the event of an error, the device will auto-recover within 5 seconds.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	N/A	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the monitor including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Minimum separation distance for higher IMMUNITY TEST LEVELS shall be calculated using the following equation. $E = [6/d] \sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) and E is the Immunity Test Level in V/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
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Recommended separation distances between portable and mobile RF communications equipment and the NBP One			
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 $d = 1.2 \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter,
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.
b) Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3V/m

Table A – Test specifications for the device's Signal Input Parts/Signal Output parts to RF wireless communication equipment.

Test Frequency (MHz)	Band a) (MHz)	Service b)	Modulation b)	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
358	380 – 390	TETRA 400	Pulse Modulation b) 18Hz	1,8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM c) 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse Modulation b) 217Hz	0,2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation b) 18Hz	2	0.3	28
1720 1845 1970	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse Modulation b) 217Hz	2	0.3	28

2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation b) 217Hz	2	0.3	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse Modulation b) 217Hz	2	0.3	9
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3						
For some services, only the uplink frequencies are included The carrier shall be modulated using a 50% duty cycle square wave signal As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Product Disposal

Device

Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply. Please dispose of materials according to local regulations for medical waste.

Battery Disposal

The Norav Medical NBP One contains a small lithium ion battery on a Printed Circuit (PC) board that contain materials which may be hazardous to human health. The battery cannot be easily removed and therefore the NBP One must be disposed of in an environmentally responsible way or returned to Norav Medical. A prepaid return label can be obtained. Please see our website for more information about our environmental policy at www.noravmedical.com.

Cuff

Do not return used cuffs. Used blood pressure cuffs may be contaminated medical waste and should be dealt with in accordance to your local regulations for medical waste.

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