

BP10 NIBP Module

Operator's Manual

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- Revision: 6.0

WARNING

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- the product is used in accordance with the instructions for use.

WARNING

- **Only skilled/trained clinical professionals shall operate this equipment.**
 - **It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.**
-
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Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any questions, please contact Mindray.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your BP10 NIBP module.

Conventions

- *Italic text* is used in this manual to quote the referenced chapters or sections.
- [] is used to enclose screen texts.
- → is used to indicate operational procedures.

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1 Safety

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1.1 Safety Information

WARNING

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.**
-

CAUTION

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**
-

NOTE

- **Provides application tips or other useful information to ensure that you get the most from your product.**
-

1.1.1 Warnings

WARNING

- **BP10 is intended to be used for a single patient at a time.**
 - **BP10 must be operated by medical personnel in hospitals or medical institutions.**
 - **To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents.**
 - **Do not use this equipment in conjunction with Electro Surgical Unit (ESU).**
 - **Before putting the system into operation, the operator must verify that the equipment and accessories are in correct working order and operating condition.**
 - **Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.**
 - **Do not touch the patient and live parts simultaneously.**
 - **Do not open the equipment housings. All servicing and future upgrades must be carried out by trained and authorized personnel.**
 - **The physiological data displayed on the system are for reference only and cannot be directly used for diagnostic interpretation.**
 - **Only use parts and accessories specified in this manual.**
 - **Route, wrap and secure the hose to avoid inadvertent disconnection, stumbling and entanglement.**
-

1.1.2 Cautions

CAUTION

- **Do not let BP10 directly touch the patient's skin when the device is on. The device temperature rises when the device is on. If the device contacts the patient's skin for a long time, skin burns may occur.**
- **When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external equipment operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI equipment are a possible source of interference as they may emit higher levels of electromagnetic radiation.**

-
- **Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**
 - **Dry the equipment immediately in case of rain or water spray.**
 - **The system generates and uses the Radio Frequency (RF) energy. If it is not installed correctly or not used as per the manual, RF interference to other equipment could result.**
 - **At the end of its service life, the equipment, and its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products to prevent bringing potential negative consequences to the environment and human health. If you have any questions concerning disposal of the equipment, please contact Mindray.**
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1.1.3 Notes

















NOTE

- **Put the equipment in a location where you can easily see the screen, and access the operating controls.**
 - **Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.**
-

1.2 Equipment Symbols

NOTE

- Some symbols may not appear on your equipment.

Symbol	Description	Symbol	Description
	Defibrillation-proof Type CF applied part		Serial number
	Date of Manufacture		MANUFACTURER
	MR Unsafe – do not subject to magnetic resonance imaging (MRI)	IP32	Protection against ingress of solid foreign objects and fluid
	Non-ionizing electromagnetic radiation		General warning sign
	Refer to instruction manual/ booklet		Authorised representative in the European Community
	Humidity limitation		Temperature limitation
	Atmospheric pressure limitation		Plastics identification symbol
	Dispose of in accordance to your country's requirements		
	This product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive. Note: The product complies with the Council Directive 2011/65/EU.		
	The presence of this label indicates the machine was certified by ETL with the statement: Conforms to AAMI Std ES 60601-1, IEC Std 60601-1-6, IEC Std 60601-1-8, IEC Std 60601-2-27, IEC Std 60601-2-49, ISO Std 80601-2-61, IEC Std. 80601-2-30 Certified to CSA Std C22.2 NO. 60601-1, NO. 60601-1-6, NO. 60601-1-8, NO.60601-2-27, NO. 60601-2-49, NO.80601-2-61, NO.80601-2-30		

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2 General Product Description

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2.1 Intended Use

BP10 NIBP module (hereinafter referred as BP10) can measure, display, review, store the NIBP parameter for ambulating Adult and Pediatric patients over three years old, and transfer the information to TMS60/TM80/TM70 in BeneVision Central Monitoring System.

WARNING

- **Only skilled/trained clinical professionals shall operate this equipment.**
 - **The equipment is not designed for monitoring critically ill patients.**
 - **If the accuracy of any value displayed at BP10 is questionable, determine the patient's vital signs by alternative means and verify that BP10 is working correctly.**
 - **When BP10 transmits the data through the wireless connection, there might be a risk of data loss.**
-

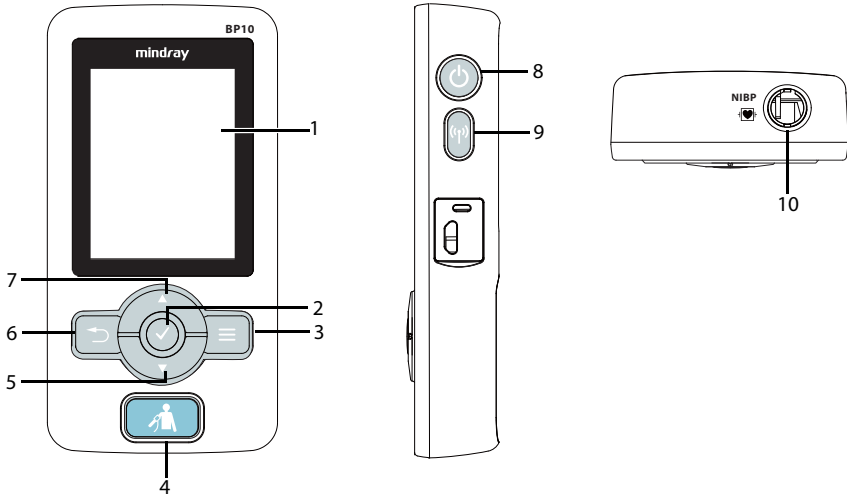
2.2 Applied Parts

The applied part of BP10 is NIBP cuff.

2.3 Major Features

- Small, portable, and lightweighted for patients to wear.
- Utilizes Mindray Patient Area Network (MPAN) to communicate with telemetry.
- Displays the battery status and technical messages.
- Supports two kinds of batteries: AA alkaline and lithium-ion rechargeable battery.

2.4 Physical Views



1. Display
2. Confirmation key

When the desired option is highlighted, press this key to select or activate the corresponding function.

3. Main Menu key

Press this key to turn to the main menu.

4. NIBP start/stop key

- ◆ When NIBP is in process, press this key to stop the NIBP measurement.
- ◆ When NIBP is idle, press this key to start an NIBP measurement.

5. Down key

Press this key to move down along the column of menu options or configuration choices.

6. Return key

- ◆ Press this key to return to the previous menu and save the settings.
- ◆ Press this key to switch between two main screens. Refer to **"Main Screen"** on page 2-5 for additional information.

7. Up key

Press this key to move up along the column of menu options or configuration choices.

8. Power On/Off key

- ◆ When BP10 is powered off, press this key to turn BP10 on.
- ◆ When BP10 is powered on, press and hold this key to display the power off confirmation menu.
- ◆ If the screen display is on, press this key to turn the display off.

9. MPAN key

- ◆ When BP10 is disconnected from the MPAN, press this key to begin the bluetooth pairing process.
- ◆ When BP10 is connected with the MPAN, press this key to unpair any connected bluetooth devices.

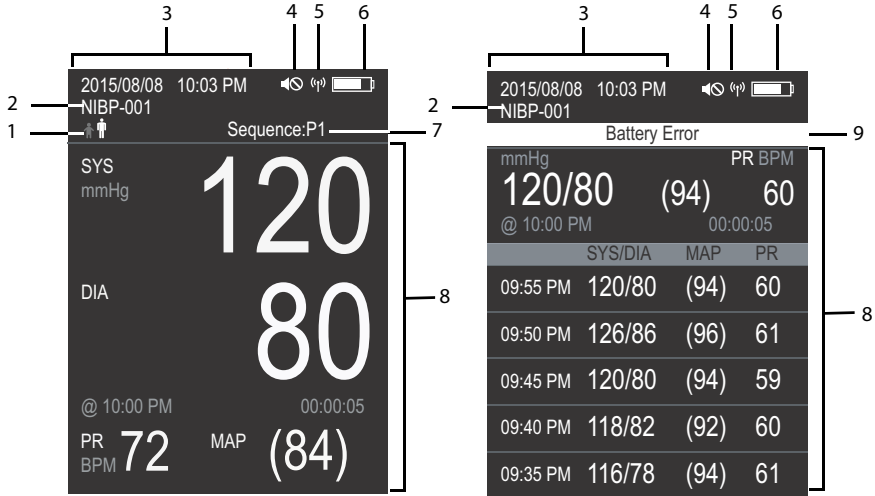
You can also set up the MPAN communication in the main menu. Refer to "**Turning On/Off MPAN**" on page **4-4** for details.

10. NIBP cuff connector

Connect the NIBP hose.

2.5 Main Screen

The main screen displays patient NIBP parameters. The two main screens are shown below.



1. Patient category
The current patient category setting is shown in white.
2. Device name
3. Date and time
This area displays the date and time.
4. Audio off symbol
The audio off symbol displays when the technical audio is turned off.
5. MPAN symbol
The MPAN symbol displays when the MPAN is turned on.
6. Battery symbol
This symbol indicates the battery charge status. Refer to **"Checking the Battery Charge Status"** on page 8-3 for additional information.
7. Operation mode
8. NIBP measurement area
This area shows the current values or measurement list.

- ◆ When the NIBP is measuring, this area shows the real-time measurement values.
- ◆ When more than 30 seconds elapses after an NIBP measurement ends, this area automatically displays the measurement list.

9. Message area

The message area shares the same position as patient category and operation mode. This area displays technical messages if there is any.

This area always flashes. It will temporarily cover the patient category and operation mode area during flashing.

3 Getting Started

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3.1 Safety

WARNING

- **BP10 shall be installed by Mindray authorized personnel.**
 - **The equipment software copyright is solely owned by Mindray. No organization or individual shall resort to altering, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.**
 - **Connect only approved devices to this system. Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any questions, please contact Mindray.**
 - **If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or else an expert in the field, to ensure the necessary safety of patients and all devices concerned will not be impaired by the proposed combination.**
 - **Only Mindray authorized personnel can upgrade BP10.**
-
-

3.2 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or Mindray.

If the packing case is intact, open the package and remove the device and accessories carefully. Check all materials against the packing list and check for any mechanical damage. Contact Mindray in case of any problem.

WARNING

- **Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.**

NOTE

- **Save the packing case and packaging material as they can be used if the device must be reshipped.**

3.3 Environmental Requirements

The operating environment of the device must meet the requirements specified in this manual.

The device operating environment should be reasonably free from noises, vibration, dust, corrosive, flammable and explosive substances.

When the device is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, never start the system before the condensation disappears.

WARNING

- **Make sure that the device operating environment meets the specifications. Otherwise unexpected consequences, e.g. damage to the device, could result.**

NOTE

- **The device transmits data through a wireless connection. External radio frequency interference may result in occasionally data dropout. Contact Mindray for any questions regarding the electromagnetic environment.**

3.4 Installing the Batteries

You can use two AA batteries or a lithium-ion rechargeable battery pack to run BP10.

The runtime depends on the battery solution you choose. A lithium-ion battery pack provides the longer runtime. For details about the recommended AA batteries, refer to **"Miscellaneous"** on page 11-3.

WARNING

- **Only use specified batteries. Use of other batteries will adversely affect the batteries:**
 - ◆ Level reporting
 - ◆ Low battery prompt
 - ◆ Life performance
-

NOTE

- **Always keep the battery compartment dry.**
 - **Never use brute force to install the lithium-ion battery pack or AA battery frame. Otherwise the waterproof ring surrounding the battery frame edge may be broken to affect the waterproof performance.**
 - **The lithium-ion rechargeable battery shall be fully charged prior to first use.**
-

To install batteries, follow this procedure:

1. Lift up the lithium-ion battery pack or AA alkaline battery tray at the bottom of BP10.

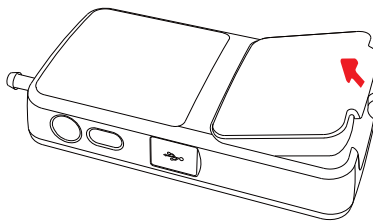


Figure 3-1 Open the Battery Pack

2. Make sure the battery compartment is empty.
3. Install AA batteries or lithium-on battery.
 - ◆ If AA batteries are used, insert two 1.5V alkaline AA batteries according to the diagram at the bottom of the battery frame.

- ◆ If lithium-ion battery is used, align the raised tab on the upper part of the lithium-ion battery pack with the cutout in the base of the battery compartment, as indicated in Figure 3-2.

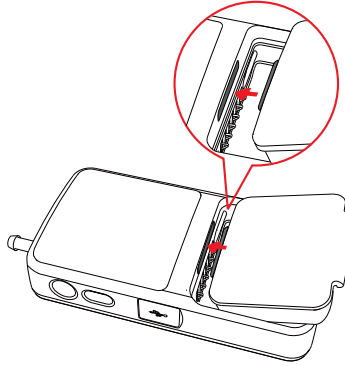


Figure 3-2 Align the Raised Tab on Battery Pack

4. Press down the battery pack until it is installed firmly, as indicated in Figure 3-3.

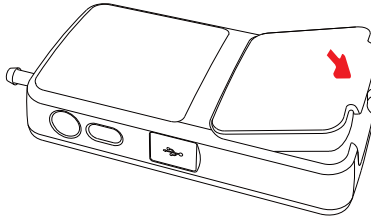


Figure 3-3 Press down the Battery Pack

3.5 Powering On the Device

When the rechargeable lithium-ion or AA battery is properly installed into the compartment door, BP10 will be powered on automatically.

When BP10 is powered off, press the  key to turn on BP10. The startup logo screen displays and a beep sounds.

Upon powering up, there are two situations:

- If BP10 is turned on for the first time, the device will request you to set up language, maintenance passcode, service passcode for the first time startup.
- If BP10 is turned on next time, the device will directly go to the main screen.

WARNING

- **Do not use the equipment for any NIBP measurement on a patient if you suspect the equipment is not working properly or if the equipment is mechanically damaged. Contact your service personnel or Mindray.**
-
-


3.6 Basic Operations

This section describes the basic operations for BP10.

WARNING

- **Patients should be instructed not to open the battery compartment while BP10 is in use.**
-
-

3.6.1 Entering the Main Menu

Press the  key to enter the main menu.

The main menu allows access to most of the system functions and settings.

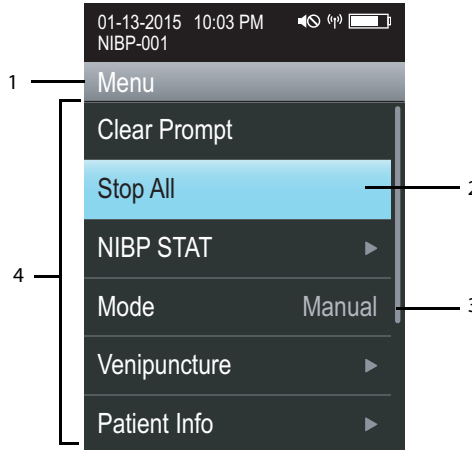




Figure 3-4 Main Menu




A menu may contain the following parts:

1. Heading: displays the current menu title.
2. Highlighted bar: indicates the current cursor position.
3. Scroll bar: shows the current position in a menu.
4. Main body: contains menu options and other controls to configure and operate the device.

Controls	Description
	Accesses a submenu to reveal more options or information.
	Indicates that a password is required.
Submenus	Contains more operations or information related to the corresponding menu.

3.6.2 Selecting and Configuring an Option

To select and configure an option in a menu, follow this procedure:

1. Use the  and  keys to move the highlighted bar to an appropriate position.
2. Press the  key to select the option where the highlighted bar locates.

3. If an option can be configured, the choice place will have up and down arrows, as indicated in Figure 3-5.

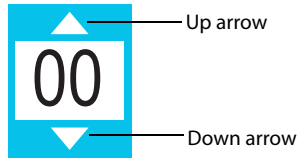








Figure 3-5 Configuring an Option

4. Use the  or  key to scroll the choices.
5. Press the  key to select the appropriate choice when it displays.
6. Press the  key to save the setting.
7. Press the  key to exit the menu.

3.6.3 Turning the Display Off

You can manually turn the display off, or let the display automatically turn off based on the configured timeout.

Press the  key to manually turn the display off.

If no hard key is pressed within the configured period of Display Auto Off, the screen will turn off after the time is reached. For details about configuring the time for Display Auto Off, refer to "**Configuring the Display Auto Off**" on page 4-2.

3.6.4 Turning the Display On

If the screen is off, press any hard key to turn the display on.

3.7 Using the Pouch

BP10 is not intended for direct contact with the patient's skin. During normal use, BP10 should be worn over clothing, in a pocket, or in a pouch. The waterproof pouch with clear front is an appropriate means for holding BP10. For details about the specified pouch, refer to **"Miscellaneous"** on page 11-3.

To secure the pouch, follow the recommended procedure:

1. Place BP10 into the pouch with the NIBP hose exiting from the pouch opening.
2. Pinch the snap-fastener to close the pouch.
3. Secure the pouch on the patient with ties around the patient's shoulder and under the arm, as shown in Figure 3-6 and Figure 3-7.
4. Apply the cuff and hose. You can place the hose around neck (as shown in Figure 3-6) or secure the hose on the waist tie (as shown in Figure 3-7).
5. Prepare the patient and start NIBP measurement. Refer to **Preparing the Patient 6-4** and **Taking a Measurement 6-5** for details.

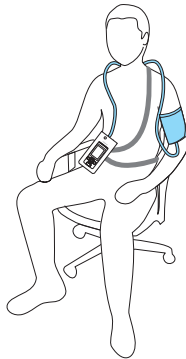


Figure 3-6 Wearing Pouch and Placing Hose around Neck

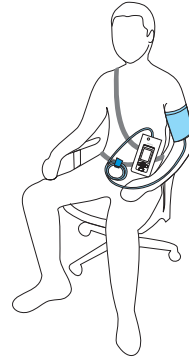


Figure 3-7 Wearing Pouch and Securing Hose on Waist

WARNING

- **While using a pouch with BP10 on the patient, consider the patient's condition. Be careful about the placement of the straps, as the straps could present a strangulation hazard.**
-
-

NOTE

- **The pouch is used only for BP10. The pouch cannot be used for carrying other personal devices, such as a mobile phone.**
-

4 **Configuring BP10**

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4.1 Introduction

This chapter describes the configurations that you may need to do.

4.2 Configuring the Display



4.2.1 Configuring the Display Brightness

To configure the display brightness, follow this procedure:

1. Enter the main menu.
2. Select **System**.
3. Select **Display Brightness**. The **Display Brightness** menu displays.
4. Select **Screen Brightness** and adjust the brightness ranged from 1 to 10. The bigger value indicates a brighter level.
5. Press the  key to save the setting.
6. Press the  key to exit the menu.

4.2.2 Configuring the Display Auto Off

You can configure the display to automatically turn off when the configured time is reached.



1. Enter the main menu.
2. Select **System**.
3. Select **Maintenance**. The correct passcode is required to enter the **Maintenance** menu.
4. Select **Display Auto Off**.
5. Select the appropriate time.
6. Press the  key to save the setting.
7. Press the  key to exit the menu.

4.3 Switching On/Off the Audio

You can independently switch on/off the technical message audio and keypad audio. The method for switching on/off the two kinds of audio is same.

To switch on/off the audio, follow this procedure:

1. Enter the main menu.
2. Select **System**.
3. Select **Audio Volume**.

4. In the **Prompt Volume** or **Keypad Volume** option, select **On** or **Off** respectively.
5. Press the  key to save the setting.
6. Press the  key to exit the menu.


NOTE

- The  icon indicates that the prompt audio is turned off.

4.4 Turning On/Off MPAN

To turn on/off MPAN function, follow this procedure:

1. Enter the main menu.
2. Select **System**.
3. Select **MPAN**, and select **On** or **Off**.

The  key at the side of BP10 has the same function as this menu option. Refer to "Physical Views" on page 2-3 for the hard key function.



4.5 Setting Time and Date

To set the time and date, follow this procedure:

1. Enter the main menu.
2. Select **System**.
3. Select **Time/Date**. Set the following options described in the following table.

Options	Description	Settings*
Time Format	Set the system time format.	12, 24
Time	Set the system time based on the selected time format.	N/A
Date Format	Set the system date format. YYYY represents year. MM represents month. DD represents day.	YYYY/MM/DD MM/DD/YYYY DD/MM/YYYY
Date	Set the system date based on the selected date format.	N/A

* The factory default settings are in bold.

4. Press the  key to save the setting.
5. Press the  key to exit the menu.


4.6 Changing Language

To change the language, follow this procedure:

1. In the main menu, select **System**.
2. Select **Maintenance**, and enter the maintenance passcode.
3. In the **Maintenance** menu, select **Language**.
4. Select an appropriate language.
The message will display: Changing language will restart this device. Are you sure you want to restart?
5. Select **Yes**.


4.7 Changing the Passcode

To change the passcode, follow this procedure:

1. In the main menu, select **System**.
2. Select **Maintenance**, and enter the maintenance passcode.
3. In the **Maintenance** menu, select **Edit Passcodes**.
 - ◆ Select **Maintenance Passcode** and follow the on-screen instructions to change the maintenance password.
 - ◆ Select **Service Passcode** and follow the on-screen instructions to change the service password.
4. Select **Save** to save the changes.
5. Press the  key to exit the menu.

4.8 Changing the Device Name

To change the device name, follow this procedure:

1. In the main menu, select **System**.
2. Select **Maintenance**, and enter the maintenance passcode.
3. In the **Maintenance** menu, select **Device Name**.
4. Enter the device name.
5. Select **Save** to save the setting
6. Press the  key to exit the menu.

NOTE

- Do not set the same device name for BP10s.
-

4.9 Restoring Factory Defaults

You are allowed to re-establish the first time power-up settings and change the original user and device configurations to factory defaults.

To restore the factory defaults, follow this procedure:

1. In the main menu, select **System**.
2. Select **Maintenance**, and enter the maintenance passcode.
3. In the **Maintenance** menu, select **Restore Factory Defaults**.

The following message shows: Are you sure you want to restore factory default settings? All history data will be cleared.

4. Select **Yes**.

4.10 Service Menu

The **Service** menu only allows an authorized service personnel to access.

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5 Patient Management

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5.1 Introduction


The chapter describes how to change the patient category, enter and exit the Standby mode, and discharge the patient in the condition of stand-alone use.

5.2 Changing the Patient Category

NOTE

- **Ensure that patient category selection is appropriate for the patient before taking a measurement.**
 - **Changing patient category restores BP10 to the factory default settings but does not clear patient information or data.**
-

To change the patient category, follow this procedure:

1. In the main menu, select **Patient Info**.
2. In the **Patient Info** menu, select **Patient Category** to select the desired patient category.
The screen displays the "Are you sure you want to change patient category?" message.
3. Select **Yes** to confirm the change.
The selected patient category displays to the right of **Patient Category**.
4. Press the  key to exit the menu.

5.3 Placing a Device in Standby

NOTE

- **BP10 cannot enter the Standby mode when the battery is depleted.**
-

To enter the Standby mode, follow this procedure:

1. In the main menu, select **Standby**.
2. In the **Standby** confirmation menu, select **Yes**.

When entering Standby mode, BP10 does the following:

- Stop all NIBP measurements.
- Clear all current technical messages.
- Display **Standby** and remaining battery charge icon on the screen.

5.4 Exiting the Standby Mode

You can press any hard key to exit Standby mode.

When exiting from the Standby mode, BP10 responds as the follows:

- NIBP measurement does not automatically start.
- Resume the ability to provide the technical messages.

5.5 Discharging the Patient

Discharging the patient will stop monitoring patient, and clear patient information and data at BP10.

A patient can be discharged by selecting **Discharge Patient** in the main menu.

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6 Monitoring NIBP

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6.1 Introducing NIBP Measurement Method

BP10 uses the oscillometric method to measure the non-invasive blood pressure (NIBP). This measurement can be used for adults and pediatric patients. To understand how this method works, we will compare it to the auscultative method.

With auscultation, clinicians listen to the Korotkoff sounds to determine blood pressure when using the auscultatory method. The estimated mean pressure can then be calculated with reference to these.

Since BP10 cannot hear the Korotkoff sounds to determine the blood pressure, it measures cuff pressure oscillation amplitudes. Oscillations are caused by blood pressure pulses against the cuff. The oscillation with the greatest amplitude is the mean pressure. This is the most accurate parameter measured by the oscillometric method. Once the mean pressure is determined, the systolic and diastolic pressures are calculated with reference to the mean.

The auscultation determines systolic and diastolic pressures and calculates the mean pressure. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

As specified by IEC 80601-2-30, NIBP measurements can be performed during discharge of defibrillator.

NIBP diagnostic significance must be decided by the clinician who performs the measurement. Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method or an intra-arterial blood pressure measurement device, within the limits prescribed by the standards of IEC80601-2-30.

6.2 Safety

WARNING

- **Be sure to select the correct patient category setting for your patient before measurement. Do not apply the higher adult settings for pediatric patients. Otherwise it may present a safety hazard.**
 - **Do not measure NIBP on patients with sickle-cell disease or on the limb where skin damage has occurred or is expected.**
 - **Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.**
 - **Do not apply the NIBP cuff on the arm on the side of a mastectomy or lymph node clearance.**
 - **Use clinical judgement to determine whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**
 - **During NIBP measurement, the inflated cuff applies pressure on the application site. The clinician determines if NIBP measurement is suitable for the patient.**
 - **Continuous non-invasive blood pressure measurements may cause purpura, ischemia and neuropathy in the limb with the cuff. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If any abnormality occurs, move the cuff to another site or stop the blood pressure measurements immediately.**
 - **Make sure the hose connecting the NIBP cuff and BP10 is not blocked, twisted, or tangled.**
 - **Sustained cuff pressure due to a kinked hose may interfere with blood flow and could lead to patient injury.**
-

NOTE

- **For known hypertensive patients, you need to set initial cuff pressure to a higher value to reduce the measurement time.**
 - **NIBP reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition. If the NIBP reading seems out of range or inaccurate, determines the patient's vital signs by alternative means and then verify that the monitor is working correctly.**
-

6.3 Measurement Limitations

Measurements are impossible with heart rate extremes of less than 30 bpm or greater than 300 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible:

- If a regular arterial pressure pulse is hard to detect.
- With excessive and continuous patient movement such as shivering or convulsions.
- With cardiac arrhythmias.
- Rapid blood pressure changes.
- Severe shock or hypothermia that reduces blood flow to the peripheries.

NOTE

- **The effectiveness of this sphygmomanometer has not been established in pregnant, including pre-eclamptic patients.**
-

6.4 Measuring NIBP

6.4.1 Preparing the Patient


In order to minimize the NIBP measurement errors, whenever possible make sure the patient is in the following positions.

- Comfortably seated
- Legs uncrossed
- Feet flat on the floor
- Back and arm supported
- Middle of the cuff at the level of the right atrium of the heart

NOTE

- **It is recommended that the patient relaxes as much as possible and keep calm before performing measurement and that the patient does not talk during NIBP measurement.**
 - **It is recommended that 5 minutes should elapse before the first measurement is taken.**
 - **The operator should not touch the cuff or tubing during NIBP measurement.**
-

6.4.2 Taking a Measurement

1. Prepare and make sure the patient is in a correct position. Refer to **Preparing the Patient 6-4** for details.
2. Turn on BP10.
3. Verify that the patient category is correct.
4. If not, press the  key, and then select **Patient Info** → **Patient Category** and set the patient size to **Adult** or **Pediatric**. Connect the extension air hose to the NIBP connector on BP10.
5. Select the appropriate sized cuff by referring to the limb circumference marked on the cuff.

The width of the cuff should be 40% of the limb circumference, or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle at least 50% to 80% of the limb.

6. Apply the cuff to the patient's upper arm at the same level as the heart, and make sure the Φ marking on the cuff is aligned with the artery.

Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities.

Make sure that the edge of the cuff is within the marked range. If it is not, use a cuff that fits properly.

7. Connect the cuff to the extension air hose.

Avoid compression or restriction of NIBP hose. Air must pass unrestricted through the tubing.

6.5 Configuring the NIBP Setup

The NIBP setup includes two levels settings. One group of settings are passcode protected, the other group of settings are not.

6.5.1 General NIBP Setup

Options	Description	How to Enter	Settings*
Mode	Selects the NIBP measurement mode. Refer to " Configuring NIBP Measurement Modes " on page 6-7 for additional information.	Enter the main menu and select Mode .	Manual , Interval, Sequence, ABPM
NIBP Color	Selects the NIBP parameter color.	1. Enter the main menu. 2. Select System . 3. Select NIBP Color .	6 colors The default color is white.
Initial Pressure	Selects the initial cuff inflation pressure.	1. Enter the main menu. 2. Select Patient Info . 3. Select Initial Pressure .	Adult: 80 -280 mmHg. Default: 160mmHg. Pediatric: 80 - 210 mmHg Default:140 mmHg

* The factory default settings are in bold.

6.5.2 Advanced NIBP Setup (Passcode Protected)

The following table lists the configurable options.

Options	Description	How to Enter	Settings*
NIBP Timeout	Configures the retention time of the measurement value each time it is obtained. If OFF is selected, the measurement value retains till the next measurement starts.	1. Enter the main menu. 2. Select System → Maintenance . A passcode screen displays. 3. Enter the correct passcodes.	5 min, 10 min, 15 min, 30 min, 45 min, 60 min, OFF
NIBP Endtone	Configures it to issue a reminder tone at the completion of a NIBP measurement.	4. Select NIBP Settings .	ON , OFF
Measure on Clock	Configures it to automatically take an NIBP measurement on the fixed time based on the interval. For example, in a situation that Measure on Clock is set to ON , and Interval is 20 min , if the first measurement is taken at 14:03, the following measurements will be taken at 14:20, 14:40, 15:00 and so on.		ON , OFF
Units	Configures the NIBP measurement unit.		mmHg , kPa

* The factory default settings are in bold.

6.6 Configuring NIBP Measurement Modes

BP10 provides five measurement modes:

- Manual mode
- Continuous mode
- Automatic mode
- Sequence mode
- ABPM (Ambulatory Blood Pressure Monitoring) mode

The automatic, sequence and ABPM modes need to configure more settings.

NOTE

- **You can initiate a manual or continuous measurement in the course of automatic, sequence and ABPM series measurements.**

6.6.1 Setting the Automatic Mode

In automatic mode, the NIBP measurements are automatically taken on the configured interval.

To enable and set up the automatic mode, follow this procedure:

1. In the main menu, select **Mode** and set it to **Auto**.
2. Select **Interval** and select the appropriate period. The default setting is 15 min.

6.6.2 Setting the Sequence Mode

In the sequence mode, the NIBP measurements are automatically taken in the user-defined sequence, which allows you to set different measurement intervals in consecutive five (5) phases.

To enable and set up the sequence mode, follow this procedure:

1. In the main menu, select **Mode** and set it to **Sequence**.
2. Select **Sequence Settings** and open the **Sequence Settings** screen.
3. Set up the interval and duration in each phase.

Options	Description	Settings
Phase	In a sequence, you can set up to five measurement phases from P1 to P5. Note: If some existing phases need to be removed, set the phase interval to OFF.	/

Options	Description	Settings
Interval	Set up the interval between NIBP measurements in an individual phase.	1 min, 2 min, 2.5 min, 3 min, 5 min, 10 min, 15 min, 20 min, 30 min, 1 h, 1.5 h, 2 h, Off.
Duration	Set up the lasting time of an individual phase.	10 min, 30 min, 1 h, 2 h, 4 h, 8 h, continuous

6.6.3 Setting up the ABPM Mode

In ABPM mode, the NIBP measurements are automatically taken according to the configured intervals for the day and the night.

To enable and set up the ABPM mode, follow this procedure:

1. In the **Menu** screen, select **Mode** and set it to **ABPM**.
2. Select **ABPM Settings** and open the **ABPM Settings** screen.

Set the start time and interval for the day and night respectively.

The default start time of the day is 6:00, and the interval is 15 min.

The default start time of the night is 22:00, and the interval is 30 min.





6.6.4 About Continuous Mode

In the continuous mode, the measurements are taken one after another in a five-minute period. After that, the continuous mode ends, and the device restores to the NIBP mode before the continuous mode starts.

To enable the continuous mode, enter the main menu and select **NIBP STAT**.

6.7 Starting and Stopping Measurement

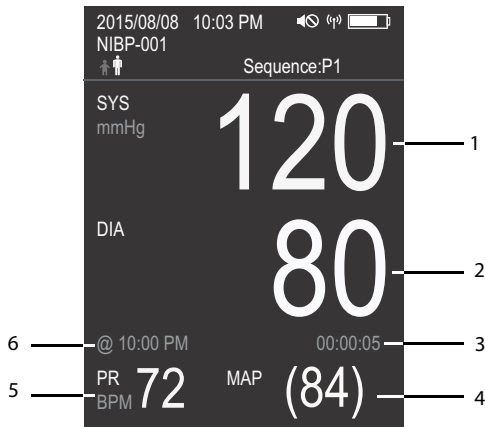
Refer to the following table to start or stop measurements in various modes.

Modes	Tasks	Actions
Manual mode	Start or stop a manual measurement.	Press the  key.
Automatic, Sequence or ABPM modes	Start the series measurements in automatic, sequence or ABPM mode.	Press the  key.
	Stop current measurement in automatic, sequence or ABPM mode.	Press the  key.
	Cancel the series measurements in automatic, sequence or ABPM mode.	Select Stop All in the main menu.
Continuous mode	Start the series measurements in continuous mode.	Select NIBP STAT in the main menu.
	Cancel the series measurements in continuous mode.	Press the  key. or Select Stop All in the main menu.

6.8 Understanding the NIBP Display

6.8.1 Digital Area

The following figure illustrates the elements in the measurement screen.



1. Systolic pressure
2. Diastolic pressure

3. Countdown time
This time is available in automatic, continuous, sequence and ABPM modes.
4. Mean pressure
5. Pulse rate
6. Measurement end time

6.9 Correcting the Measurement when Cuff is not at Heart Level


Apply the cuff to a limb at the same level as the patient's heart. If the cuff is not at the heart level, do the following to the displayed value:

- Add 0.75 mmHg (0.1 kPa) for each centimeter higher; or
- Deduct 0.75 mmHg (0.1 kPa) for each centimeter lower.

6.10 Assisting Venous Puncture

You can use the NIBP cuff to cause sub-diastolic pressure to block the venous blood vessel and therefore help the venous puncture.

To enable the venous puncture, follow this procedure:

1. In the **Menu** screen, select **Venipuncture**.
2. Verify the target pressure is appropriate. Change it if necessary.
3. Select **Inflate**.
The display shows the real-time inflation pressure of the cuff, destination inflation pressure, and the remaining time in venous puncture mode.
4. Puncture vein and draw blood sample.
5. When the puncture is complete, select **Deflate**, or press  key. The cuff deflates automatically after a set time if you do not deflate it.

6.11 Reviewing NIBP Data

You can review the historic measurements at BP10 by selecting **History** in the main menu.

BP10 can store and display up to 500 NIBP measurements. All the stored measurements can resume if there is power interruption.


7 Connection with External Systems

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7.1 Pairing with a TD60/TM80/TM70

You can pair BP10 with a TD60/TM80/TM70. After pairing, TD60/TM80/TM70 can display the NIBP-related data and messages. You can only pair BP10 with the TD60/TM80/TM70 by operating a TD60/TM80/TM70. Refer to ***BeneVision TMS60 Telemetry Monitoring System Operator's Manual*** or ***BeneVision TM80 Telemetry Monitor Operator's Manual*** or ***BeneVision TM70 Telemetry Monitor Operator's Manual*** for the pairing procedure.

WARNING

- **Unpair BP10 with TD60/TM80/TM70 each time you stop monitoring the patient by pressing the  key at BP10.**
- **Always discharge the patient before BP10 is used on the new patient.**
- **Always make sure that BP10 is applied on the correct patient.**

If BP10 is paired with a TD60/TM80/TM70, the following operation is disabled at BP10:

- Entering Standby mode
- Discharging a patient
- Setting NIBP measurement mode
- Changing patient category

CAUTION

- **In ABPM mode, all the historic data at BP10 will be cleared if you select to continue the patient from TD60/TM80/TM70.**

7.2 Connecting with Central Monitoring System

BP10 can be connected to the central monitoring system via TD60/TM80/TM70.

Refer to ***BeneVision Central Monitoring System Operator's Manual (P/N: 046-010879-00)*** for additional information.

8 Battery

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8.1 Introduction

The BP10 can be powered by a lithium-ion rechargeable battery or AA alkaline batteries. This chapter provides instructions on how to use, maintain, and dispose of the batteries.

8.2 Safety

WARNING

- **Keep the batteries out of children's reach.**
- **Keep the batteries in their original package until you are ready to use them.**
- **Do not install the lithium-ion battery pack or the AA battery frame to close the battery compartment during defibrillation.**
- **Only use specified AA batteries or rechargeable lithium-ion battery to power BP10. Other power supply may cause damage to the equipment or lead to body injury.**
- **While installing AA batteries, do not apply reverse polarity.**
- **Only use recommended fresh AA batteries. Using other AA batteries can give unacceptable performance such as running time and low battery alarm.**
- **Do not mix old and new AA batteries.**
- **Only use specified rechargeable lithium-ion battery. Unspecified lithium-ion battery can give unacceptable performance.**
- **Use caution when handling the rechargeable lithium-ion battery. Misuse or abuse may cause bodily injury or device damage.**
 - ◆ Do not short circuit. Take care that the terminals do not contact metal or other conductive materials during transport and storage.
 - ◆ Do not crush, drop or puncture the battery. Mechanical abuse can lead to internal damage and internal short circuits. If a battery has been dropped or banged against a hard surface, whether damage is externally visible or not, remove the battery from use and dispose of it properly.
 - ◆ Do not incinerate batteries or expose them to temperatures above 60°C (140°F).
- **The rechargeable lithium-ion batteries should be charged in the specified central charger.**
- **If a battery shows signs of damage or signs of leakage, replace it immediately. Use caution in removing the battery. Avoid contact with skin. Refer to qualified service personnel.**
- **Some failure conditions, such as short circuits, can cause a battery to overheat during using. High temperature can cause burns to the patient or user. If the device becomes too hot to touch, remove it from the patient and**

place aside until it cools. Then remove the battery from the device, and contact your service personnel to identify the cause of overheating.

- Replace the battery immediately once the “Battery Depleted” message displays. Replace the battery in time once the “Low Battery” message displays. If those conditions are not corrected, device shutdown and cessation of monitoring will result. After replacing the rechargeable lithium-ion battery, charge it in time. Do not store the lithium-ion battery whose batter power is depleted but is not charged yet.
 - To eliminate the risk of electrical shock or burn, do not carry loose batteries on your person, such as placing the battery in clothing pockets.
-
-


CAUTION

- Remove the battery before transporting the device or if the device is not in use or is being stored.
 - AA alkaline batteries should be removed from the device at the end of the battery’s useful life to prevent leakage. In case of battery leakage, use caution to remove the batteries and clean the battery compartment. Install fresh AA batteries and check if BP10 can power on properly. If the BP10 fails to power on, contact your service personnel.
-

8.3 Installing the Battery

Refer to “*Installing the Batteries*” on page 3-4 for details.

8.4 Checking the Battery Charge Status

The battery symbol displaying on the top of main screen indicates the battery charge status. The white part () indicates the remaining battery charge.

8.5 Removing the Battery

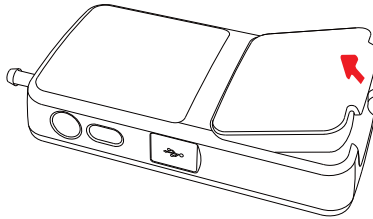
CAUTION

- Some failure conditions, such as short circuits, can cause a battery to overheat during using. High temperature can cause burns to the patient or user. If the device becomes too hot to touch, remove it from the patient and place aside until it cools. Then remove the battery from the device, and contact your service personnel to identify the cause of overheating.
- Avoid scraping the metal contact in the battery compartment while removing the lithium-ion battery pack or AA battery frame. Otherwise, the broken contact will affect the power supply performance.

- **Remove the battery before transporting the device or if the device is not in use or is being stored.**

NOTE

- **Retain the NIBP hose with the device while removing the battery.**
1. Lift up the lithium-ion battery pack or AA alkaline battery tray at the bottom of BP10.



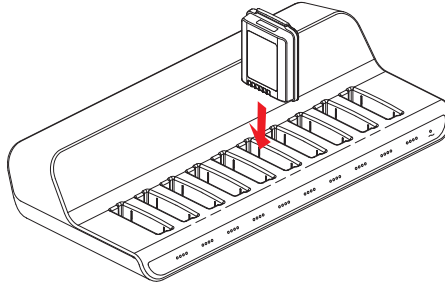
2. Remove the lithium-ion battery pack or AA alkaline battery tray from BP10.

8.6 Charging the Rechargeable Lithium-ion Battery

WARNING

- **Only use the specified central charger to charge to the lithium-ion batteries designated by Mindray.**
 - **Only use the approved power cord with the grounded mains plug to firmly connect the central charger to a grounded AC mains socket. Never refit the mains plug to fit an ungrounded AC mains socket.**
 - **Do not use the Multiple Portable Socket Outlets (MPSO) or AC mains extension cords. Use an IEC 60601-1 approved isolation / separation transformer, otherwise, it may result in leakage current. Insure that the sum of the individual ground leakage currents does not exceed the allowable limits.**
 - **Do not place any shield object (such as cloth or paper) to cover the central charger or batteries, and keep ventilated while charging the lithium-ion batteries.**
 - **Do not connect other devices to the power supply system.**
 - **Do not use the central charger to charge the lithium-ion batteries in high temperature above 40°C.**
-

Use the central charger to charge the lithium-ion batteries. The central charger can charge 10 lithium-ion batteries at one time. For details about the central charger, refer to ***BeneVision Central Charger Instruction for Use (PN: 046-010879-00)***.



8.7 Storing the Batteries

8.7.1 Storing Rechargeable Lithium-ion Battery

When storing batteries, make sure that the battery terminals do not come into contact with metallic objects.

If you need to store the batteries for an extended period of time, place the batteries in a cool, dry place (ideally at 15°C or 60°F) with a partial charge of about 50% capacity (two LEDs illuminated). Storing batteries in a cool place can slow the aging process.

Stored batteries should be charged to about 50% of their capacity every six months. The battery should be fully charged prior to first use.

NOTE

- **Remove the lithium-ion battery from the device if the device is not used for a prolonged time (for example, several weeks), and keep the device in clean place to avoid the dust or liquid entering the battery compartment.**
- **Storing batteries at high temperatures for an extended period of time will significantly shorten their life expectancy.**
- **Do not store the batteries in an environment above 60°C (122°F) or lower than -20°C (4°F).**

8.7.2 Storing AA Batteries

If you remove undepleted AA batteries from BP10 and need to store the batteries, keep the batteries together as a set for later re-use so that all batteries will have the same level of remaining power.

Do not store disposable AA batteries by leaving the batteries in the incorrect polarity position in BP10.

NOTE

- **Replace the AA battery frame on the battery compartment after removing the AA batteries.**

8.8 Maintaining the Rechargeable Lithium-ion Battery

Take care of the rechargeable lithium-ion battery once you receive a new battery for use. The following table describes the battery maintenance activities and recommended frequency.

Activity	Recommended Frequency
Visual inspection	Before installing a battery in BP10.
Charge the battery	Upon receipt, after use, a "Low Battery" or "Battery Depleted" message occurs. To optimize performance, a fully or almost fully discharged battery must be charged immediately.
Clean the battery	At each patient discharge, or in case that the battery is exposed to contaminants. Caution: Do not clean the battery connector during the cleaning.
Charge stored battery to at least 40% of the battery capacity.	Every six months if BP10 is not in use for an extended period of time.
Dispose of the battery	When the "Battery Maintenance Required" message displays on BP10.

The lifetime of a lithium-ion battery depends on the frequency and duration of use. With good maintenance, the useful life is approximately 500 complete charge-discharge cycles. Experience indicates that the incidence of failure may increase with battery service life due to the accumulated stresses of daily use. Therefore, Mindray strongly recommends that lithium-ion battery should be replaced after two years or 500 complete charge-discharge cycles. Using the outdated battery may cause the device abnormality and unacceptable performance.

The age of a lithium-ion battery begins at the date of manufacture. The date of manufacture is listed on the rear of the battery.

NOTE

- **The battery capacity degrades as using time and number of recharge cycles. Toward the end of its useful life, the battery capacity may be reduced by 20% to 25%. If the reduced battery life is unacceptable for your device, Mindray recommends the battery be replaced.**
-

8.9 Disposing of the Batteries

8.9.1 Disposing of the Rechargeable Lithium-ion Battery

Discard the lithium-ion battery in the following situations:

- The battery has visual signs of damage.
- The battery fails.
- The battery is aged and its runtime significantly less than the specification.
- The battery has been used for more than two years or 500 complete charge-discharge circles.

Discharge the battery and insulate the terminals with tape before disposal. Properly dispose of the batteries according to local regulations.

8.9.2 Disposing of the AA Batteries

The batteries may be subject to local regulations regarding disposal. Dispose of batteries in approved containers. Follow local regulations, if any, to recycle the batteries.

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9 **Cleaning and Disinfecting**

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9.1 Introduction

Only use the substances approved by Mindray and methods listed in this chapter to clean or disinfect your device. Our warranty does not cover damage caused by unapproved substances or methods.

Mindray makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.

9.2 Safety

WARNING

- **The responsible hospital or institution shall carry out all cleaning and disinfection procedures specified in this chapter.**
 - **Be sure to shut down the system before cleaning the equipment.**
 - **Non-medical equipment does not provide the same level of protection against electrical shock. Do not touch the patient and any part of non-medical equipment at the same time. Some examples of non-medical equipment are laser printers and nonmedical computers.**
 - **Avoid use of cleaners, materials or chemicals that may damage device surfaces, labels, or cause equipment failures.**
 - **Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these guidelines:**
 - ◆ Always dilute according to the manufacturer's instructions or use lowest possible concentration.
 - ◆ Do not immerse any part of the device into liquid. Do not pour liquid onto the equipment or accessories.
 - ◆ Do not allow liquid to enter the case and the device interior.
 - **Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).**
 - **If liquid has accidentally entered the system or its parts, shut down the system and have the device serviced by authorized service personnel.**
 - **Remove the equipment from use if liquid is spilled on the equipment or accessories. Contact your service personnel.**
 - **When cleaning, avoid the NIBP connector and other connectors.**
-
-

9.3 Cleaning and Disinfecting the Equipment



9.3.1 Approved Cleaning and Disinfecting Agents

The following table lists approved cleaning and disinfecting agents:

Product Name	Product Type	Active Ingredients
Sodium hypochlorite bleach*	Liquid	Sodium hypochlorite bleach 10%
Hydrogen peroxide*		Hydrogen peroxide 3%
Isopropanol*		Isopropanol 70%
1-Propanol*		1-Propanol 50%
CIDEX® OPA Solution		Ortho-Phthalaldehyde 0.55%
Metrex CaviCide1™		Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride 0.28%, Isopropanol 17.2%
Virex® II 256		Didecyl dimethyl ammonium chloride 8.704%, n-Alkydimethyl benzyl ammonium chloride 8.190%
Virex® TB		n-Alkyl dimethyl benzyl ammonium chlorides 0.105%, n-Alkyl dimethyl ethylbenzyl ammonium chlorides 0.105%
Rely+On™ Virkon® Powder * (Used as 1% solution)	Powder	Used as 1% solution Biocidal active: Pentapotassium bis (peroxymonosulphate) bis (sulphate)(500g/kg), Contains dipotassium peroxodisulphate.
Alpet® D2 Surface Sanitizing Wipes	Wipes	Isopropyl Alcohol 58.6000%? Octyl Decyl Dimethyl Ammonium chloride 0.0075%, Dioctyl Dimethyl Ammonium Chloride 0.0030%
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach		Sodium Hypochlorite 0.65%
Clorox Healthcare® Bleach Germicidal Wipes		Sodium Hypochlorite 0.55%

Product Name	Product Type	Active Ingredients
Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes	Wipes	Hydrogen Peroxide 1.4%
Diversey Oxivir® TB Wipes		Hydrogen Peroxide 0.5%
Metrex CaviWipes™		Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride 0.28%, Isopropanol 17.2%
PDI Sani-Cloth® AF3 Germicidal Disposable Wipe		n-Alkyl dimethyl ethylbenzyl ammonium chlorides 0.14%, n-Alkyl dimethyl benzyl ammonium chlorides 0.14%
PDI Sani-Cloth® Bleach Germicidal Disposable Wipe		Sodium Hypochlorite 0.63%, other ingredients 99.37%
PDI Sani-Cloth® HB Germicidal Disposable Wipe		n-Alkyl dimethyl ethylbenzyl ammonium chlorides 0.07%, n-Alkyl dimethyl benzyl ammonium chlorides 0.07%
PDI Sani-Cloth® Plus Germicidal Disposable Cloth		n-Alkyl dimethyl ethylbenzyl ammonium chlorides 0.125%, n-Alkyl dimethyl benzyl ammonium chlorides 0.125%
PDI Super Sani-Cloth® Germicidal Disposable Wipe *		n-Alkyl dimethyl ethylbenzyl ammonium chlorides 0.25%, n-Alkyl dimethyl benzyl ammonium chlorides 0.25%, Isopropyl Alcohol 55.0%,
VIRAGUARD Hospital Surface Disinfectants		Isopropanol 70%, Other ingredients 30%

NOTE

- For equipment with the symbol  , all the listed cleaning and disinfecting agents are available for use. For equipment without the symbol  , only the cleaning and disinfecting agents marked with “*” are available for use.

9.3.2 Cleaning the Equipment

CAUTION

- **Only use the following approved cleaning solutions. The system may become inoperable or halted because of contamination or damage caused by use of unapproved cleaning solution.**
-

Clean your equipment on a regular basis. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Before cleaning the equipment, do the following preparations:

- Install the battery pack or battery tray to firmly close the battery compartment.
 - Insert the NIBP hose into the NIBP cuff connector.
-
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WARNING

- **Never allow the cleaning solutions to spill or enter the connector and battery compartment.**
-
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To clean the equipment, follow this procedure:

1. Shut down the device.
 2. Clean the display screen with wipes or a soft cloth moistened with one of the cleaning agents listed in "**Approved Cleaning and Disinfecting Agents**" on page 9-3 only.
 3. Clean the exterior surface of the BP10 main unit and lithium-ion battery pack with wipes or a soft cloth moistened with one of the cleaning agents listed in "**Approved Cleaning and Disinfecting Agents**" on page 9-3 only.
 4. Wipe off all the cleaning agent residue with a dry cloth.
 5. Dry the equipment in a ventilated, cool place.
-

CAUTION

- **Never immerse the lithium-ion battery pack, AA battery tray and AA batteries. Do not clean them with harsh chemicals such as acetone or nondiluted bleach.**
-

9.3.3 Disinfecting the Equipment

Disinfect the equipment as required in your hospital's servicing schedule using the disinfecting agents list in "**Approved Cleaning and Disinfecting Agents**" on page 9-3. Cleaning before disinfection is recommended.

9.4 Cleaning and Disinfecting the Accessories

To clean and disinfect the extension air hose: CM1907 (P/N: 040-002379-00), refer to instructions in this chapter:

For other accessories, consult instructions for use delivered with the accessories.

NOTE

- **Never clean or disinfect the connectors and metal parts.**
 - **Never immerse or soak the accessories in any liquid.**
 - **Prolonged use of disinfectants may cause fading and discoloration of the cuff.**
 - **Periodically inspect the NIBP air hose and connector for signs of wear or deterioration after cleaning or disinfecting the NIBP air hose. Replace the NIBP air hose if you detect a leak. Dispose of damaged NIBP air hose according to local laws for disposal of hospital waste.**
-

9.4.1 Cleaning

You should clean the extension air hose on a regular basis. Before cleaning, consult your hospital's regulations for cleaning the accessory.

The recommend cleaning agents is water.

To clean the extension air hose, follow this procedure:

1. Clean the accessory with a soft cloth moistened with water.
2. Wipe off all the cleaner residue with a dry cloth.
3. Allow the accessory to air dry.

9.4.2 Disinfecting

We recommend that the extension air hose should be disinfected only when necessary as determined by your hospital's policy. Cleaning the accessory before disinfecting is recommended.

The recommended disinfectants are:

- 70% ethanol
- 70% isopropyl alcohol
- 50% propyl alcohol (1-propyl alcohol)

9.5 Sterilization

Sterilization is not recommended for this equipment, related products, accessories or supplies unless otherwise indicated in the Operating Instructions that accompany the products, accessories or supplies.

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10 Maintenance

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10.1 Introduction

The chapter outlines the routine maintenance guidelines.

The device is designed for stable operation over long periods of time. Under normal circumstances the device should not require technical maintenance beyond that described in this chapter. However, routine maintenance, calibration and safety checks are recommended at least once every two years or more often as required by local statutory or hospital administration practice.

10.2 Safety

WARNING

- **Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.**
 - **The safety checks or maintenance involving any disassembly of the equipment should be performed by service personnel. Otherwise, undue equipment failure and possible health hazards could result.**
 - **No modification of this equipment is allowed.**
 - **To avoid the electric shock, do not open the central charger housing.**
 - **All servicing and future upgrades must be carried out by the service personnel.**
 - **All replaced components and accessories as well as consumables are provided or qualified by Mindray.**
 - **If you discover a problem with any of the equipment, contact your service personnel or Mindray.**
 - **The service personnel must be properly qualified and thoroughly familiar with the equipment operation.**
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-

10.3 Regular Check

Perform a visual inspection before the device is first used every day. Verify that the device meets the following requirements:

- The housing and display screen are free from cracks or other damages.
- All keys function properly.
- Connectors are not loose, cracked, or bent and cables have no cuts, nicks, or fraying.
- NIBP hose is securely connected with the equipment.
- Battery pack is installed and has sufficient charge.

After your device has been used for 6 to 12 months, or whenever your device is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability.

Follow these guidelines when inspecting the device:

- Make sure that the environment and power supply meet the requirements.
- Inspect the device and its accessories for mechanical damage.
- Inspect all plugs and connectors for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are applied.
- Make sure that the Lithium-ion battery meets the performance requirements.
- Make sure that the device is in good working condition.

In case of any damage or abnormality, do not use the device. Contact the hospital's biomedical engineers or your service personnel immediately.

10.4 Battery Check

For details about the battery charge check and maintenance, refer to "***Maintaining the Rechargeable Lithium-ion Battery***" on page 8-6.

10.5 Maintenance and Testing Schedule

The following maintenance and tests, except for visual inspection, power on test, and battery check, shall be carried out by the service personnel only. Contact your service personnel if any maintenance is required. Make sure to clean and disinfect the equipment before any test and maintenance.

Check/Maintenance Item		Recommended Frequency
Visual inspection		When first installed or reinstalled.
NIBP test	Pressure check	1. If the user suspects that the measurement is incorrect.
	Leakage test	2. Following any repairs or replacement of relevant module. 3. Once a year.
Power-on test		1. When first installed or reinstalled. 2. Following any maintenance or the replacement of any main unit parts.
Electrical safety test		At least once every two years or as needed.
Battery check	Functionality test	1. When first installed. 2. Whenever the battery is replaced.
	Performance test	When the battery run time reduced significantly.

10.6 Power-On Test

Verify that the startup logo screen displays and a beep sounds after power on the device.

10.7 Checking the Device Information

To view the information about the device copyright information, serial number, system software, hardware and MPAN version, you can select **System Info** in the main menu.

10.8 NIBP Leakage and Pressure Tests

The NIBP leakage and pressure tests checks the integrity of the system and of the valve. Contact your service personnel to perform NIBP leakage and pressure test.

10.9 Electrical Safety Test

The electrical safety test aims to detect abnormalities that, if undetected, could prove dangerous to either the patient or the operator. Contact your service personnel to perform the electrical safety test.

11 Accessories

NIBP Accessories	11-2
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The accessories listed in this chapter comply with the requirements of IEC 60601-1-2 when in use with the device. The accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1. For details about the accessories, refer to the instructions for use provided with the accessory.

WARNING

- **Use accessories specified in this chapter. Using other accessories may cause damage to the monitor or not meet the claimed specifications.**
 - **Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.**
 - **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
 - **Use the accessories before the expiry date if indicated.**
 - **The disposable accessories shall be disposed of according to the hospital's regulations.**
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11.1 NIBP Accessories

11.1.1 Tubing

Part Number	Description	Applicable property
040-002379-00	Extension air hose	Reusable

11.1.2 Cuff

Part Number	Description	Applicable patient
115-027557-00	Disposable Bladderless Small Adult Cuff	Small Adult
115-027558-00	Disposable Bladderless Adult Cuff	Adult
115-027559-00	Disposable Bladderless Large Adult Cuff	Large Adult
115-027561-00	Disposable Bladderless Adult Long Cuff	Adult
115-027562-00	Disposable Bladderless Large Adult Long Cuff	Large Adult
115-027714-00	Reus-Bladderless Small Adult Cuff(MW)	Small Adult
115-027715-00	Reus-Bladderless Adult Cuff(MW)	Adult
115-027716-00	Reus-Bladderless Large Adult Cuff(MW)	Large Adult
115-027718-00	Reus-Bladderless Adult long Cuff(MW)	Adult

Part Number	Description	Applicable patient
115-027719-00	Reus-Bladderless L-Adult long Cuff(MW)	Large Adult

11.2 Miscellaneous


Part Number	Description
115-026852-00	Main unit of the charger
115-035534-00	BP10 Li-ion battery Package
045-001700-00	BP-2AA battery frame
0000-10-10902	Alkaline 1.5 V AA battery (for service personnel to perform debugging only)
048-005247-00	Disposable pouch

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12 Troubleshooting

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Physiological Alarms with Central Monitoring System	12-4

12.1 General Problems

Symptom	Possible Cause	Solution
Cannot discharge patient, change patient category, or set NIBP measurement related configurations at BP10.	BP10 is paired with TD60/TM80/TM70.	Unpair BP10 from TD60/TM80/TM70 by pressing the  key, and then discharge the patient by selecting Discharge Patient in the main menu at BP10.
The BP10 cannot be paired with the TD60/TM80/TM70.	<ol style="list-style-type: none"> The distance between BP10 and TD60/TM80/TM70 is out of the radio range. Signal is interrupted. The TD60/TM80/TM70 is already paired with other BP10. After BP10 is paired with TD60/TM80/TM70, user turns off and then turns on the MPAN at BP10 or TD60/TM80/TM70. 	Restart the pairing at TD60/TM80/TM70.

12.2 Technical Messages and Solutions

The following table lists the major technical messages displayed in the message area of BP10.

For the clearable technical messages, you can clear them by selecting **Clear Prompt** in the main menu.

Message	Clearable (Yes/No)?	Possible cause	Solution
Low Battery	No	The battery charge is low.	Replace with a new battery.
Battery Depleted	No	The battery charge is almost depleted.	
Voltage Error	No	The lithium-ion battery voltage is out of the specified range.	
Battery Error	No	The lithium-ion battery communication is error.	Verify that the battery is correctly installed. If the error persists, replace with a new battery.
Battery Maintenance Required	No	The lithium-ion battery is aging.	Replace with a new battery.
MPAN Disconnected	Yes	<ol style="list-style-type: none"> The distance between BP10 and TD60/TM80/TM70 is out of the radio range. The TD60/TM80/TM70 is powered off. 	<ol style="list-style-type: none"> Move the BP10 and TD60/TM80/TM70 closely. Power on the TD60/TM80/TM70.

Message	Clearable (Yes/No)?	Possible cause	Solution
Clock Needs to Be Reset	Yes	The button cell does not have sufficient charge.	Reset the system time.
NIBP Module Error	No	<ul style="list-style-type: none"> ■ An error occurred to the NIBP module. ■ There is a problem with communications between the module and the telemetry. 	Restart the device.
NIBP Cuff Loose	Yes	<ul style="list-style-type: none"> ■ The NIBP cuff is not properly connected. ■ There is a leak in the airway. 	<ol style="list-style-type: none"> 1. Check the patient's condition and verify patient type. 2. Replace with an appropriate cuff and connect it correctly.
NIBP Airway Error	Yes	The device cannot finish one correct zeroing.	Restart the device. If the error persists, contact your service personnel.
NIBP Weak Signal	Yes	The patient's pulse is weak or the cuff is loose.	Check the patient condition and change the cuff application site. If the error persists, replace the cuff.
NIBP Overrange	Yes	The measured NIBP value is not within the measurement range.	Contact your service personnel.
NIBP Excessive Motion	Yes	Patient's arm moves too much.	Check the patient's condition and reduce the patient motion.
NIBP Cuff Overpressure	Yes	The NIBP airway may be occluded.	Check the airway and measure again.
NIBP Cuff or Airway Leak	Yes	The NIBP airway may leak air.	<ol style="list-style-type: none"> 1. Verify that the cuff is properly connected. 2. Verify that the airway does not leak air.
NIBP Timeout	Yes	<ul style="list-style-type: none"> ■ Time is out. ■ The measurement time is over 120 seconds. 	<ol style="list-style-type: none"> 1. Check the patient's condition and NIBP connections. 2. Replace the cuff.
NIBP Cuff and Patient Mismatch	Yes	The cuff type applied mismatches the patient category.	Verify the patient category and replace the cuff.
Intervals Not Set	Yes	No interval in Sequence mode is not set.	Set the intervals.

Message	Clearable (Yes/No)?	Possible cause	Solution
NIBP-S Overrange	No	The measured NIBP value is not within the measurement range.	Contact your service personnel.
NIBP-D Overrange	No		
NIBP-M Overrange	No		

12.3 Technical Alarms with TD60/TM80/TM70

When BP10 is connected to TD60/TM80/TM70, the technical messages will internally convert into alarms and send to TD60/TM80/TM70.

Refer to ***BeneVision TMS60 Telemetry Monitoring System Operator’s Manual or BeneVision TM80 Telemetry Monitor Operator’s Manual or BeneVision TM70 Telemetry Monitor Operator’s Manual*** for technical alarm details.

12.4 Physiological Alarms with Central Monitoring System

BP10 does not provide any physiological alarms or messages.

When BP10 is connected to TD60/TM80/TM70, the NIBP parameter measurements at BP10 will send to TD60/TM80/TM70, and then TD60/TM80/TM70 transmits them to the CMS. The CMS is the sole system to provide the physiological alarms and message for BP10 NIBP measurements.

A Product Specifications

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A.1 Classifications

The Telemetry Monitoring System is classified, according to IEC60601-1:

Type of protection against electrical shock	BP10: energized from an internal electrical power source. Central Charger: Class I.
Degree of protection against electrical shock for BP10	Type CF defibrillation proof for NIBP.
Mode of operation	Continuous
Degree of protection against harmful ingress of water	BP10: IP32 Central Charger: IPX0
Degree of protection against hazards of explosion	Not suitable: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air with oxygen or nitrous oxide.
Degree of protection against hazard of dropping for BP10	No damage by dropping from a height of 1.5m.
Sterilization or disinfection	According to the method(s) of sterilization or disinfection recommended by the manufacturer.

A.2 Environmental Specifications

WARNING

- **The device may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges.**

Item	Operating conditions	Storage conditions
Temperature	0 °C to 40 °C	-20 °C to 60 °C
Relative humidity (noncondensing)	15% to 95%	10% to 95%
Barometric	427.5 mmHg to 805.5 mmHg, or 57.0 kPa to 107.4 kPa	120 mmHg to 805.5 mmHg, or 16.0 kPa to 107.4 kPa

A.3 Power Supply Specifications

A.3.1 BP10

BP10 is powered by batteries.

Battery type	AA batteries (two) Rechargeable lithium-ion battery (one)
Capacity for lithium-ion battery	1800 mAh
Charge time	At the room temperature: ≤ 5 hours The charge time definition: the time for the battery from the exhausted status to 90% battery charge (within the operating temperature range declared for the unit).
Safety and authentication for lithium-ion battery	UL62133, IEC62133, UN38.3
Run time	In the condition of turning off the display, the batteries perform as follows. One lithium-ion battery: At least 700 NIBP measurements Two AA batteries: At least 300 NIBP measurements
Shutdown delay in low battery	At least 10 NIBP measurements after the Low Battery message first occurs. At least 30 seconds after the Battery Depleted message first occurs.

A.3.2 Central Charger

The central charger is powered by external AC power.

Input voltage	100 VAC to 240 VAC (± 10%)
Frequency	50 Hz/60 Hz (±3 Hz)
Input current	1.5 A to 0.75 A
Overcharge protection function	The charger automatically stop charging when the lithium-ion battery charge is full.

A.4 Physical Specifications

A.4.1 BP10

Size	121 mm × 64 mm × 24 mm (without the NIBP cuff and any other accessories)
Weight	210 g ± 30g(with batteries, without the NIBP cuff and any other accessories)

A.5 Hardware Specifications

A.5.1 BP10

Display	
Screen type	Color TFT LCD screen
Screen size	2.4"
Resolution	320 pixels × 240 pixels
Display activation (Power On/Off) time	The switch time is no more than two seconds.
Audio Indicator	
Beeper	1
External Connectors	
NIBP cuff connector	1
USB connector	1

A.5.2 Central Charger

Charger slot	10
LED	10, which indicates the battery charge status.
AC power indicator	1
Installation mode	Place on the desktop.

A.6 MPAN Specifications

A.6.1 Technique Specification

Protocol	Bluetooth low energy 4.0
Modulation mode	GFSK
Operating frequency	2402 MHz to 2480 MHz
Channel spacing	2 MHz
Wireless baud rate (data rate)	1 Mbps
Output power (transfer power)	≤ 2.5 mW
Data Security	Private protocol

A.6.2 Wireless Functions

- BP10 transmits measurement information (e.g. real-time measurement status, results, NIBP countdown) to TD60/TM80/TM70.
- TD60/TM80/TM70 transmits control information (e.g. NIBP start/stop, NIBP STAT) to BP10.

A.6.3 Function Specifications

Data integrity	Code error ≤ 1%
Transmission distance	Distinct vision distance between BP10 and TD60/TM80/TM70 is greater than or equal to 3 m.
System capacity	Five pairs of BP10 and TD60/TM80/TM70 can communicate in 10 m ² space at the same time.
Resistance to wireless interference	<p>The MPAN communication function is normal when the distance between the following interfering devices and the TD60/TM80/TM70 or BP10 is as follow:</p> <ul style="list-style-type: none"> ■ greater than 1 m for microwave ovens. ■ greater than 0.2 m for cellular mobile communication networks, Wi-Fi devices, interphones, or cordless phones.
Communication interruption prompt message	After the MPAN communication is interrupted, BP10 shows prompt message.

A.7 NIBP Measurement Specifications

Standard	Meet standards of IEC80601-2-30		
Technique	Oscillometry		
Mode of operation	Manual, Automatic, Continuous, Sequence and ABPM		
Automatic mode repetition intervals	1min, 2min, 2.5min, 3min, 5min, 10min, 15min, 20min, 30min, 1h, 1.5h, 2h, 3h, 4h or 8h.		
Maximum measurement time	Adult and pediatric: 120 seconds		
Measurement ranges (mmHg)	Systolic	Diastolic	Mean
Adult	25 to 290	10 to 250	15 to 260
Pediatric	25 to 240	10 to 200	15 to 215
Accuracy	Maximum mean error: +/- 5 mmHg Maximum standard deviation: 8 mmHg		
Resolution	1 mmHg		
Static pressure measurement range	0 to 300 mmHg		
Static pressure measurement accuracy	+/-3 mmHg		
Initial cuff inflation pressure (mmHg)	Range	Default	Step
Adult	80 to 280	160	10
Pediatric	80 to 210	140	10
Auxiliary Venipuncture (mmHg)	Range	Default	Step
Adult	20 to 120	80	10
Pediatric	20 to 80	60	10
Pulse Rate			
Measurement range	30 bpm to 300 bpm		
Accuracy	+/-3 bpm or +/-3%, which ever is greater		
Resolution (bpm)	1 bpm		

B EMC

The system complies with the EMC standard IEC60601-1-2:2020.

WARNING

- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.**
- **Use of this device adjacent to or stacked with other devices should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.**
- **The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.**
- **This device is intended for use in professional healthcare facility environment. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.**

Guidance and Declaration - Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment — guidance
Radio frequency (RF) emissions CISPR 11	Group 1	The system 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.
Conducted and radiated RF EMISSIONS CISPR 11	Class B	The device 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.
Conducted and radiated RF EMISSIONS CISPR 11	Class A (Used with Telemetry Monitor)	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Harmonic distortion IEC 61000-3-2	Not applica- ble	/
Voltage fluctuations and flicker IEC 61000-3-3		

NOTE

- **The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
 - **Other devices may affect this device even though they meet the requirements of CISPR.**
 - **When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.**
 - **The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.**
 - **If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location or stopping using the monitor and contact the service personnel.**
-

If the system is operated within the electromagnetic environment listed in Table Guidance and declaration - electromagnetic immunity, the system will remain safe and provide the following essential performance:

■ **Operating mode**

No cessation or interruption of any intended operation.

■ **Accuracy**

The change of the parameter's numerical value shall not exceed the specified accuracy.

■ **Function**

Each function of the device shall work as intended, including the parameter, screen and touch screen.

■ **Accessories identification**

The accessories shall be identified normally.

■ **Data stored**

Trend data and events shall be able to be reviewed.

■ **Alarm**

The device shall provide alarm or alarm signal as intended, with no false alarm.

■ **Detect for connection**


The connection status shall be detected normally.

■ **Wireless**

The system shall be able to detect: network connection, data transmission and caution

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 ±2 kV, ±4 kV, ±8 kV, ±15kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kV 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 ± 1 kV for input/output lines (length greater than 3 m)	± 2 kV for power supply lines ± 1 kV for input/output lines (length greater than 3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 0,5$ kV, ± 1 kV line(s) to line(s); $\pm 0,5$ kV, ± 1 kV, ± 2 kV line(s) to earth	$\pm 0,5$ kV, ± 1 kV line(s) to line(s); $\pm 0,5$ kV, ± 1 kV, ± 2 kV line(s) to earth	
Voltage dips and Voltage interruptions IEC 61000-4-11	0% U_T for 0,5 cycle 0% U_T for 1 cycle and 70% U_T for 25/30 cycles 0% U_T for 250/300 cycle	0% U_T for 0,5 cycle 0% U_T for 1 cycle and 70% U_T for 25/30 cycles 0% U_T for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
RATED power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the specified electromagnetic environment. The customer or the user of the device should assure that it is used in such an environment as described below.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced by RF fields IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{V} \right] \sqrt{P} \quad 150\text{kHz to } 80 \text{ MHz}$ $d = \left[\frac{3.5}{E} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$ 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^b , should be less than the compliance level in each frequency range ^c . Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms in ISM bands and amateur radio bands between 0,15 MHz and 80 MHz	6 Vrms	
Radiated RF EM fields IEC61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m (Only BP10)	
Radiated RF EM fields IEC61000-4-3	3V/m 80 MHz to 2.7 GHz	3V/m (Used with Telemetry Monitor)	
Proximity fields from RF wireless communications equipment IEC61000-4-3	27 V/m 380-390 MHz	27 V/m	
	28 V/m 430-470 MHz, 800-960 MHz, 1700-1990 MHz, 2400-2570 MHz	28 V/m	
	9 V/m 704-787 MHz, 5100-5800 MHz	9 V/m	
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: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

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

^c: Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended Separation Distances between Portable and Mobile RF, Communications Equipment and This Equipment

The equipment is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum Output power of Transmitter Watts (W)	Separation Distance According to Frequency of Transmitter (m)		
	150kHz -80MHz	80MHz to 800MHz	800MHz to 2.7GHz
	$d = \left[\frac{3.5}{V} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E} \right] \sqrt{P}$	$d = \left[\frac{7}{E} \right] \sqrt{P}$
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 at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined 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 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.

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

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

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIROMENT – GUIDANCE
Proximity magnetic fields IEC 61000-4-39	8 A/m 30 kHz CW	8 A/m 30 kHz CW	/
	65 A/m 134,2 kHz Pulse modulation 2,1 kHz	65 A/m 134,2 kHz Pulse modulation 2,1 kHz	
	7,5 A/m 13,56 MHz Pulse modulation 50 kHz	7,5 A/m 13,56 MHz Pulse modulation 50 kHz	

C FCC Compliance

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications to this equipment not expressly approved by Mindray may cause harmful radio frequency interference and void your authority to operate this equipment.

RF Parameter (Panlink2 Module)

Type of Radio	Bluetooth Low Energy 4.0
Operating Frequency	2402 MHz to 2480 MHz
Modulation Mode	GFSK
Output Power	≤2.5mW

D Symbols and Abbreviations

Units	D-2
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D.1 Units

A	ampere
Ah	ampere hour
bpm	beats per minute
°C	centigrade
cc	cubic centimeter
cm	centimeter
dB	decibel
DS	dyne. second
°F	fahrenheit
g	gram
h	hour
hPa	hundred pascal
Hz	hertz
in	inch
k	kilo
kg	kilogram
kPa	kilopascal
l	litre
lb	pound
m	meter
mg	milligrams
min	minute
ml	milliliter
mm	millimeters
mmHg	millimeters of mercury
ms	millisecond
mV	millivolt
mW	milliwatt
nm	nanometer
ppm	part per million
s	second
V	volt
VA	volt ampere
Ω	ohm
μA	microampere

μm	micron
μV	microvolt
W	watt

D.2 Symbols

-	minus
%	percent
/	per; divide; or
^	power
+	plus
=	equal to
<	less than
>	greater than
≤	less than or equal to
≥	greater than or equal to
±	plus or minus
×	multiply
©	copyright

D.3 Abbreviations

AAMI	Association for Advancement of Medical Instrumentation
AC	alternating current
ANSI	American National Standard Institute
CISPR	International Special Committee on Radio Interference
CMS	central monitoring system
EMC	electromagnetic compatibility
err	error
ES	electrosurgical
ESU	electrosurgical unit
HT	height
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MPAN	Mindray Patient Area Network
MRI	magnetic resonance imaging
M, MEAN	mean pressure

P	power
PR	pulse rate

