6.0 *Preventive Maintenance*

6.1 User Preventive Maintenance Introduction

This chapter outlines routine user maintenance guidelines. The **Passport V** Monitor is designed for stable operation over long periods of time. Under normal circumstances, the monitor should not require technical maintenance beyond that described in this chapter. However, routine maintenance, calibration, and safety checks are recommended at least once a year or more often as required by local statutory or hospital administration practice.

6.2 Preventive Maintenance Schedule

The following is a list of activities required for periodic maintenance of the **Passport V** monitor. The physical inspection, replacement of consumable items, and performance checks should be performed at the recommended intervals stated below. Mindray DS USA, Inc. is not responsible for component failure or loss resulting from the use of stated consumable items beyond their recommended replacement interval.

6.2.1 Mechanical / Physical / Visual Inspection - Annually

Suggested Inspections for Wear and Abuse:

1. Inspect outer case, line cords, rolling stands, wall mounts, modular accessories and interconnecting cables.
2. Inspect patient interface connections (ECG, IBP, SpO_2, Temp, CO_2, and NIBP).

6.2.2 Visual test

1. Perform when first installed or reinstalled.

6.2.3 Power on test

1. Perform when first installed or reinstalled.
2. Perform following any maintenance or the replacement of any main unit parts.

6.2.4 Perform NIBP Verification and Calibration – Annually

1. Perform NIBP test. See “NIBP Verification” on page 5-14.
2. Perform NIBP calibration. See “NIBP Calibration” on page 5-5.

6.2.5 Perform CO_2 Verification and Calibration – Annually

1. Perform CO_2 test. See “CO2 Operation Verification” on page 5-15.
   Perform every 12 months thereafter, and each time the unit is serviced.
2. Perform CO_2 calibration. See “CO2 Calibration” on page 5-6.
   Perform every 12 months thereafter, and each time the unit is serviced.
3. For DPM CO_2, replace the CO_2 assembly after 20,000 operating hours or as required by the service code.

6.2.6 Perform IBP Verification and Calibration – Annually

1. Perform IBP test. See “IBP 1 and IBP 2 Verification” on page 5-14.
2. Perform IBP calibration. See “IBP Calibration” on page 5-6.

6.2.7 Perform ECG Verification – Annually

1. Perform ECG test. See “ECG” on page 5-13.
2. Perform ECG channels check. See “ECG Channels Check” on page 5-3.

6.2.8 Perform Verification and Gas Calibration – Annually

1. Perform Gas test. See "Verification" on page 5-12.
2. Perform Gas calibration. See "Gas Calibration" on page 5-8.

6.2.9 Temperature Perform Verification – Annually

1. Perform temperature test. See "Temperature Verification" on page 5-14.

6.2.10 SpO_2 Perform Verification – Annually

1. Perform SpO_2 test. See "SpO2 Verification" on page 5-14.

6.2.11 Electrical Safety Tests – Annually

1. Perform test. See "Leakage Current Tests" on page 5-15.

6.3 Cleaning and Disinfection of the Passport V Monitor

WARNING: Be sure to shut down the monitor and disconnect all power cords from the outlet before cleaning.

The equipment should be cleaned regularly. Please consult your hospital's policy for the recommended frequency for cleaning and disinfecting equipment.

The exterior surfaces of the equipment may be cleaned with a clean and soft cloth, sponge or cotton ball, dampened with either of the following cleaning solutions:

- Mild soap (Diluted)
- Sodium hypochlorite bleach (10%)
- Isopropyl alcohol (70%)
- Super sani-cloth (0.5% quaternary ammonia + 55% Isopropyl alcohol)
- Virkon

* If using LpH germicidal detergent, wait 10 minutes then use a clean, dry wipe to dry the unit.

To avoid damage to the equipment:

- ALWAYS use solutions in accordance with the manufacturer's instructions.
- ALWAYS wipe off the excess cleaning solution with a dry cloth after cleaning.
- NEVER submerge the equipment into water or any cleaning solution, or pour or spray water or any cleaning solution on the equipment.
- NEVER permit fluids run into the casing, switches, connectors, or any ventilation openings in the equipment.

6.4 Care and Cleaning of SpO_2 Sensors

NOTE: Refer to the individual instruction sheets that are packaged with each sensor.

1. Check sensors and cables daily for signs of damage. Replace as required.
2. Sensors should be cleaned before and after each new patient.
3. Wipe the patient contact area using a soft cloth with mild soap and water solution or isopropyl alcohol. Hydrogen peroxide can be used to remove dried blood.
4. Allow the sensor to completely dry before using.

CAUTION: When cleaning sensors, do not use excessive amounts of liquid. Wipe the sensor surface with a soft cloth dampened with cleaning solution. Do not attempt to sterilize.

6.4.1 Cleaning and Re-use of a Nellcor® Sensor

Sensors may be reattached to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin. The adhesive can be partially rejuvenated by wiping with an alcohol wipe and allowing the sensor to thoroughly air dry prior to replacement on the patient.

Do not immerse any Oxisensor®, OxiMax®, Durasensor®, Oxiband®, or Duraform® oxygen transducers, the Nellcor® RS-10 or Max-Fast® oxygen transducers, or any Nellcor® adhesive in water or cleaning solution. Clean Durasensor®, Oxiband®, and Duraform® oxygen transducers, and the Nellcor® RS-10 or Max-Fast® oxygen transducers by wiping with a disinfectant such as a solution containing 70% alcohol. Do not sterilize by irradiation, steam, or ethylene oxide. Use a new Oxiband® adhesive wrap or FORM-A adhesive bandage for each patient. Do not re-sterilize Oxisensor® or OxiMax® oxygen transducers.

6.5 Cleaning CO_2 Sensors, Adapters and Sampling Components

Microstream CO_2 patient monitoring accessories are designed for single patient use and should not be cleaned or reused.

6.6 Sterilization and Cleaning of Cuffs

NOTE: Accuracy of cuff-pressure transducers/indicators is to be verified at intervals specified by the manufacturer.

6.6.1 Reusable Cuffs with Bladders

Remove the bladder from the cuff before cleaning and disinfecting the cuff.

Cleaning

The cuff can be hand washed or machine washed in warm water or with mild detergent. The bladder can be cleaned with a damp cloth. Air dry the cuff thoroughly after washing.

NOTE: Machine washing may shorten the service life of the cuff.

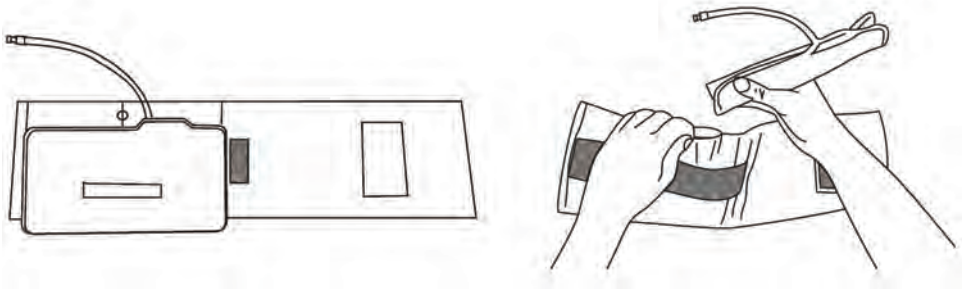
Disinfection

Disinfect the cuff with a damp cloth with 70% ethanol or 70% isopropanol or with ultraviolet. Disinfect the bladder only with ultraviolet.

NOTE: Prolonged use of disinfectant may cause discoloration of the cuff.

Replace the bladder after cleaning and disinfecting the cuff, as follows:

1. Place the bladder on the top of the cuff, as the figure shows.
2. Roll the bladder lengthwise and insert it into the large opening. See the figures below.
3. Hold the hose and the cuff and shake the complete cuff until the bladder is in position.
4. Thread the hose from inside the cuff, and out through the small hole under the internal flap.



CAUTION: Do not dry clean the cuff.
Do not press the cuff with a hot iron.
Do not use detergent and disinfectant other than 70% ethanol or 70% isopropanol.
Clean and disinfect the cuff according to the instructions.

6.6.2 Reusable Bladderless Cuffs

Clean cuffs with warm water and a mild detergent. Do not use a detergent containing hand conditioners, softeners, or fragrances.

NIBP cuffs can be sterilized with gamma sterilization without affecting the repeated performance of the cuff. Steam sterilization is not recommended. Use of a washing liquid containing bleach is not recommended because chlorine will chemically break down the urethane on the inside of the cuff.

Antimicrobial Definition

Bladderless cuffs are treated with an antimicrobial coating. Antimicrobial technology effectively controls a broad spectrum of bacteria, fungi, algae and yeasts on a wide variety of treated substrates.

6.6.3 Disposable Blood Pressure Cuffs

Disposable cuffs are intended for single patient use only. Once a cuff is used on a patient it should be discarded. Do not use the same cuff on any other patient. Do not sterilize or use an autoclave on disposable cuffs.

CAUTION: Disposable cuffs can be cleaned using a mild soap solution and dried with a clean cloth.

6.7 Care and Cleaning of Gas Module

The Gas Module enclosure may be cleaned with a mild soap and water solution or ammoniated window cleaner. Apply cleaning solution to the cloth, not directly onto the Gas Module. DO NOT apply large amounts of liquid. DO NOT use abrasive cleaning agents or organic solvents.

CAUTION: Do not clean the Gas Module while it is on and/or plugged in.

CAUTION: The internal sampling system of the Gas Module does not need to be cleaned or sterilized. There is no reverse flow back to the patient. If the internal sampling system is suspected to be clogged or dirty, the module should be serviced by an authorized service person only.

1. The Water Trap Reservoir must be checked and emptied whenever changing patients or if it is more than half full.

- To remove the water trap, push the water trap latch to the right. The water trap is spring loaded and will pop out. An Air Leak message will be displayed. The monitor will suspend sampling.
- Detach the reservoir from the water trap assembly by pulling it down carefully.
- Empty the reservoir and rinse with water only.
- Re-attach the reservoir to the assembly tightly.
- Re-install the whole unit into the Gas Module making sure the latch is set. Check that the Air Leak message disappears and monitoring resumes.

NOTE: Do not disinfect or open the water trap. If an occlusion message appears it may be necessary to replace the water trap assembly part number 0202-00-0129.

The Water Trap Assembly must be replaced every two months.

6.8 Care and Cleaning of 3- and 5-lead ECG Cables and Leadwires

Recommended cleaning method of ECG cables and leadwires is a cloth wipe using ordinary alcohol-free hand soap or USP green soap tincture. When disinfection is required, a cloth wipe using disinfectants such as isopropyl alcohol, chlorine bleach in water (1:10 mixture) or 2% Glutaraldehyde solution (i.e., Cidex) is recommended. After cleaning, the ECG cables and leadwires should be wiped with water using a clean damp cloth, and then dried with a clean dry cloth.

CAUTION: **To avoid permanent damage, do not expose metal components (pins, sockets, snaps) to disinfectants, soaps or chemicals.**

NOTE: **ECG cables and leadwires must never be immersed, soaked in any fluids, and they should not be cleaned with harsh chemicals such as acetone or non-diluted bleach.**

NOTE: **Do not autoclave, radiation or steam sterilize ECG cables or leadwires.**

NOTE: **Extended exposure to Ethylene Oxide gas may shorten life of the ECG cables and leadwires, leading to poor signal quality.**

6.9 Battery Replacement and Maintenance

6.9.1 Battery Replacement

1. Open battery compartment door, on left side of unit, by pressing the finger grip area and sliding the door to the left.
2. Press the release button, located on the left-upper side of the installed battery. This will eject the battery. Slide out old battery.
3. Slide in replacement battery until it clicks into place.
4. Close battery compartment door by sliding the door to the right until it firmly clicks into place.

6.9.2 Battery Maintenance

The batteries may be subject to local regulations regarding disposal. At the end of the battery life, dispose of the batteries in accordance with any local regulations.

CAUTION: Recharge batteries in the Passport V.

CAUTION: Remove the batteries if the Passport V is not likely to be used for an extended period of time.

Lithium-Ion

Storage of the lithium-ion batteries depends on temperature, time period and the degree of cell charging state. After one month of storage at 23 degree, fully charged lithium-ion batteries have a retention capacity of 96%.

6.10 Local Printer Maintenance

6.10.1 Cleaning the Local Printer Printhead

If the local printer has been used for a long time, deposits of paper debris may collect on the printhead, compromising the print quality and shortening the life of the roller. Follow this procedure to clean the printhead:

1. Take measures against static electricity such as wearing a Disposable Wrist Strap for the work.
2. Open the local printer door and remove the paper.
3. Gently wipe around the printhead using cotton swabs dampened with alcohol.
4. After the alcohol has been dried completely, reload the paper and close the local printer door.

CAUTION: Do not use anything that may destroy the thermal element.

CAUTION: Do not add unnecessary force to the thermal head.

6.10.2 Local Printer Paper Replacement

The instructions below describe the replacement of local printer paper. Use only recommended thermal paper. This ensures that the print quality is acceptable and reduces print head wear.

1. Use the latch at the upper right corner of the local printer door to pull the door open.
2. Remove the empty paper spool.
3. Insert a new paper roll so that it fits snugly into its housing and the sensitive side of the paper faces the print head at the top of the local printer (paper feeding off of the spool from the bottom).
4. Pull out approximately 4 inches of paper.
5. Align the paper across the top of the roller.
6. Holding the paper in place, close the local printer door.
7. To ensure that the paper is aligned properly and has not been pinched in the door, pull the loose edge out a couple of inches. If the paper jams, open the door and return to step 5.

CAUTION: Never pull the local printer paper with force when a recording is in process. Otherwise, it may cause damage to the local printer.

CAUTION: Do not leave the local printer door open unless you reload paper or remove troubles.

6.10.3 Care and Storage of Thermal Chart Paper

Thermal Chart Paper is chemically treated and the permanency of a recording is affected by storage and handling conditions. These conditions are:

- **Ultraviolet Light**
  We recommend storing the recordings in a filing cabinet within a few days of printing. Long term exposure to natural or artificial U.V. sources is detrimental.
- **Storage Temperature and Humidity**
  Keep the recordings in a cool and dry area for a longer lasting image. Extreme temperature and humidity (above 80° F/26° C and 80% humidity) should be avoided.
- **Solvent Reactions**
  Do not store the recordings in plastic bags, acetate sheet protectors, or similar items made from petroleum products. These products emit a small amount of vapor which will, over a period of time, deteriorate the image on the chart paper.
- **Adhesive Tape**
  Never place adhesive tape over recordings. The reaction between the adhesive compound and the chemical/thermal paper can destroy the image within hours.
- **Archives**
  We recommend that if long term archives are required, make a photocopy of the recordings as back-up. Under normal office filing conditions, the recordings should retain acceptable image quality for about five years

6.11 Warranty Statements

Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. warrants that components within the monitor unit will be free from defects in workmanship and materials for the number of years shown on the Mindray invoice. Under this extended warranty, Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. will repair or replace any defective component at no charge for labor and/or materials. This extended warranty does not cover consumable items such as, but not limited to batteries, displays, external cables and sensors.

Recommended preventative maintenance, as prescribed in the service manual, is the responsibility of the user, and is not covered by this warranty.

Except as otherwise provided herein, the terms, conditions and limitations of Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd.'s standard warranty will remain in effect.

6.11.1 USA, Canada, Mexico, and Puerto Rico

Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. warrants that its products will be free from defects in workmanship and materials for a period of one (1) year from the date of purchase except that disposable or one-time use products are warranted to be free from defects in workmanship and materials up to a date one year from the date of purchase or the date of first use, whichever is sooner. This warranty does not cover consumable items such as, but not limited to, batteries, external cables, sensors, cuffs, hoses, or mounts.

Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. will not be liable for any incidental, special, or consequential loss, damage, or expense directly or indirectly arising from the use of its products, liability under this warranty and the buyer's exclusive remedy under this warranty is limited to servicing or replacing at Mindray's option at the factory or at an authorized Distributor, any product which shall under normal use and service appear to the Company to have been defective in material or workmanship.

No agent, employee, or representative of Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. has any authority to bind Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. to any affirmation, representation, or warranty concerning its products, and any affirmation, representation or warranty made by any agent, employee, or representative shall not be enforceable by buyer.

This warranty is expressly in lieu of any other express or implied warranties, including any implied warranty or merchantability or fitness, and of any other obligation on the part of the seller.

Damage to any product or parts through misuse, neglect, accident, or by affixing any non-standard accessory attachments or by any customer modification voids this warranty. Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. makes no warranty whatever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that this equipment or any accessories which are claimed to be defective be returned when authorized by Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd., freight prepaid to Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd.. Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. shall not have any responsibility in the event of loss or damage in transit.

Calibration may be performed without the need to disassemble the instrument. It is the responsibility of the purchaser to perform calibration as necessary, in accordance with the instructions provided in this manual.

6.11.2 International (excluding North America)

Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. warrants that its products will be free from defects in workmanship and materials for a period of two (2) years from the date of purchase except that disposable or one-time use products are warranted to be free from defects in workmanship and materials up to a date one year from the date of purchase or the date of first use, whichever is sooner. This warranty does not cover consumable items such as, but not limited to, batteries, external cables, sensors, cuffs, hoses, or mounts.

Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. shall not be liable for any incidental, special, or consequential loss, damage, or expense directly or indirectly arising from the use of its products, liability under this warranty and the buyer's exclusive remedy under this warranty is limited to servicing or replacing at Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd.'s option at the factory or at an authorized Distributor, any product which shall under normal use and service appear to the Company to have been defective in material or workmanship.

No agent, employee, or representative of Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. has any authority to bind Mindray DS USA, Inc. /Shenzhen Mindray Bio-Medical Electronics Co., Ltd. to any affirmation, representation, or warranty concerning its products, and any affirmation, representation or warranty made by any agent, employee, or representative shall not be enforceable by buyer.

This warranty is expressly in lieu of any other express or implied warranties, including any implied warranty or merchantability or fitness, and of any other obligation on the part of the seller.

Damage to any product or parts through misuse, neglect, accident, or by affixing any non-standard accessory attachments or by any customer modification voids this warranty. Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. makes no warranty whatever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that this equipment or any accessories which are claimed to be defective be returned when authorized by Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd., freight prepaid to Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd.. Mindray DS USA, Inc./Shenzhen Mindray Bio-Medical Electronics Co., Ltd. shall not have any responsibility in the event of loss or damage in transit.

Calibration may be performed without the need to disassemble the instrument. It is the responsibility of the purchaser to perform calibration as necessary, in accordance with the instructions provided in this manual.

6.11.3 Phone Numbers and How To Get Help

Mindray DS USA, Inc. maintains a network of service representatives and factory-trained distributors. Prior to requesting service, perform a complete operational check of the instrument to verify proper control settings. If operational problems continue to exist, contact the Service Department (800) 288-2121or (201) 995-8000 for assistance in determining the nearest field service location.

Please include the instrument model number, the serial number, and a description of the problem with all requests for service.

Any questions regarding the warranty should be directed to the closest authorized location. A list of international offices, along with their phone numbers, is provided at the end of this manual.

6.11.4 Manufacturer's Responsibility

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. (hereinafter called Mindray) is responsible for the effects on safety, reliability and performance of the equipment only if:

- **a.** Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by Mindray; and
- **b.** The electrical installation of the relevant room complies with the appropriate requirements; and
- **c.** The equipment is used in accordance with the instructions for use.