

PRODUCTS COVERED	ABP AND HOLTER DEVICES
TITLE	CLEANING, DISINFECTING AND STERILIZATION
AFFECTED ITEMS	ABP DEVICES: 90207, 90217, 90217A, 90227 (ONTRAK) HOLTER DEVICES: 98900 ECLIPSE MINI AND 98700 ECLIPSE PRO, LIFECARD CF (LCF), EVO (TAY) RESTING ECG DEVICES: CARDIOEXPRESS SL6A, 12A, AND 18A
NUMBER	077-0356-00 Rev C
DATE	19 SEPTEMBER 2023

Purpose

To provide customers with a detailed procedure for cleaning, disinfecting, and sterilization, with warnings and recommendations of proper cleaning agents.

Only use the following disinfectant and cleaning solution products that have been tested with Spacelabs products.

Always follow the solution manufacturer's instructions for diluting concentrates. Stronger concentrations may damage the product.

The following website matches the content provided in this document:

<https://spacelabshealthcare.com/support/cleaning-instructions/>

Link to this document at:

<https://spacelabshealthcare.com/wp-content/uploads/2023/09/077-0356-00-RevC-CSN-Cardiology-Cleaning-instructions-links.pdf>

Links within this document:

[Cleaning pouches and lanyards](#)

[Cleaning patient cables](#)

Links to products within this document:

[OnTrak Cleaning and disinfecting ABP monitor cases](#)

[Eclipse Pro and Mini](#)


[Lifecard CF](#)


[Evo recorder](#)

[CardioExpress ECG machine](#)

[CardioPulse Go and Prime ECG machines \(USA only\)](#)

Warnings, Cautions, and Notes – All Listed Products

	<ul style="list-style-type: none">• Use only recommended cleaning solutions, or you may void the manufacturer’s warranty.• Harsh chemical agents, some germicidal and other harsh cleaning compounds are known to damage some plastics by weakening the structural integrity and compromising the electrical insulating properties.• Disconnect the equipment from the patient and the electrical supply before cleaning.• Do not allow liquid to enter the interior of the equipment.• Do not immerse the equipment or cables in water or cleaning solutions.• Do not autoclave.• Accelerated Hydrogen Peroxide (AHP) and quaternary ammonia-based products ARE NOT RECOMMENDED for cleaning monitors and cables. These chemicals degrade plastics used in ABP monitors and can cause the electrical insulating properties and structural integrity of the equipment break down.• Cavicide, Virex, Virex 256, PDI Sani-Cloth Bleach Plus, Super Sani-Cloth, and Sani-Cloth AF3 are common quaternary ammonia germicidal products. The manufacturers of these solutions advertise that these germicidal products are safe for use on hard, non-porous surfaces, such as linoleum floors, Formica countertops, and stainless steel. The manufacturers discourage the use of quaternary ammonia germicidal products on computer-grade plastics and on data, cables, which are classified as porous materials.
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	<ul style="list-style-type: none">• Use caution when cleaning cable connectors so that liquid is not permitted to collect around the electrical contacts or seep inside the connector. Trapped liquids and surface residues provide an unintentional electrical path, which may cause communication failure.• Questions and concerns about cleaning issues should be directed to a Spacelabs Healthcare representative.
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Notes:

- *For cleaning instructions for an Original Equipment Manufacturer (OEM) device, refer to the user manual for that product. This document does include OEM products' cleaning information from the products' user manuals.*
- *Accelerated Hydrogen Peroxide (AHP) contains hydrogen peroxide and low concentrations of phosphoric acid. AHP is different from cleaners containing hydrogen peroxide mixed with alcohols and specifically NOT recommended for cleaning Spacelabs Healthcare products.*
- *Over time, repeated use of a chlorine bleach solution may cause some colors to fade.*
- *Tape adhesive can be removed with Spacelabs Healthcare adhesive tape remover pads (P/N 392196-001).*
- *Follow your hospital protocol for the handling of blood and body fluids.*
- *Where provided, obey the manufacturers' instructions concerning disposable and reusable supplies.*
- *As applicable, obey your hospital protocol concerning cleaning, disinfection, and/or sterilization of reusable supplies.*
- *Obey hospital protocols to dispose of used and contaminated single-use accessories.*

Recommended cleaners

- Mild soap and water solution
- U.S. Pharmacopoeia (USP) green soap
- Sodium hypochlorite solution (1:10 dilution of household chlorine bleach in water)
- Phenolic germicidal detergent (1% aqueous solution)
- Isopropyl alcohol (70% solution)
- PDI Sani-Cloth Bleach (sodium hypochlorite 0.63%).

OnTrak monitor cleaning

Visually inspect the monitor, air hose, and pressure cuff for dirt, debris, frayed or worn areas, etc. prior to patient use.

In extreme cases where the monitor becomes soiled or very dirty, please return to the physician.

All cleaning should be carried out at ambient conditions.



- It is recommended that the monitor is cleaned between uses in order to prevent potential cross infection.
- Use only recommended cleaning solutions, or damage to the unit may result voiding the manufacturer's warranty.
- Harsh chemical agents degrade plastics and will compromise the safety of the device and may lead to a reduced service life and decreased immunity for electromagnetic interference.
- Before cleaning the monitor or cuff, disconnect from the patient
- Do not allow liquid to enter the interior of the equipment in order to prevent damage the unit
- Do not immerse the equipment or cables in water or cleaning solutions
- DO NOT AUTOCLAVE - this unit CANNOT be sterilized as this will potentially cause damage to the circuit.



- DO NOT USE Ammonia based products to clean either the 90217A unit, cuff or bladder as ammonia, over time, causes irreversible damage to these items and may lead to a reduced service life.

To clean the exterior of monitor, modules, and cables:

- Prepare the cleaning solution according to the manufacturer's instructions
- Wet a clean cloth with the selected cleaning solution
Note: the wet cloth should be gently squeezed to remove excess fluid, so it is wet, not dripping wet.
- Remove excess liquid from the cloth and squeeze dry
- Wipe exposed surfaces of the equipment and cables
- Remove any soap residue by gently wiping with a clean damp cloth
- Wipe dry with a clean dry cloth

ABP – OnTrak and ABP monitors

Cleaning and disinfecting OnTrak and ABP monitor cases

1. Remove the batteries and close the battery cover.
2. Remove the download cable and cuff hose (if fitted).
3. Rub the monitor with a cloth wetted in a mild detergent solution.
Note: the wet cloth should be gently squeezed to remove excess fluid, so it is wet, not dripping wet.
4. Dry the monitor thoroughly.
5. Prepare the cleaning solution chosen from the list of recommended cleaning solutions, according to the manufacturer's instructions.
6. Wet a clean cloth with the selected cleaning solution.
Note: the wet cloth should be gently squeezed to remove excess fluid, so it is wet, not dripping wet.
7. Remove excess liquid from the cloth and squeeze dry.
8. Wipe all exposed surfaces of the equipment.
9. Leave the monitor for the required contact time, during which it should remain wet.
10. Remove any soap residue by gently wiping with a clean damp cloth.
11. Wipe dry with a clean dry cloth.
12. Remove disinfectant residues in accordance with the disinfectant labelling.

Cleaning the 90227 (OnTrak) buttons

Clean the buttons by wetting a small brush with a mild detergent solution and gently scrubbing around and across the buttons. Dry the buttons with a rubbing action.

To disinfect the buttons, repeat the procedure using 70% isopropyl alcohol which can be left to dry naturally and does not require any rinse procedures.

Cleaning the 90227 (OnTrak) display

Clean the display with a soft cloth moistened with either 70% isopropyl alcohol solution or soapy water.

Cleaning battery covers

Clean around the battery cover with a small brush using a mild detergent solution.

Disinfect using the same method with 70% isopropyl alcohol to provide low level disinfection.

Open the battery cover and inspect for contamination. Clean using a small brush, taking care not to allow liquid to enter the body of the ABP.

Wipe with 70% isopropyl alcohol to provide low level disinfection. This agent can be left to dry naturally and does not require any rinse procedures.

Eclipse PRO and MINI

Eclipse PRO and MINI are easy to clean and safe to handle. They have been tested with a multitude of frequently used cleaning products and designed without straight edges, gaps or other traps for dust and debris. Eclipse PRO and its snap-in lead sets eliminate the need for individual connectors, simplifying device hook-up.

Cleaning and Disinfecting the Recorder

Cleaning and disinfecting the recorder should be performed after each use. The device and its accessories are not required to be cleaned by the patient.



The use of alternative cleaning materials are not recommended and may result in damage to the recorder.

Cleaning the recorder

Clean the patient cable (Eclipse PRO only) and recorder (Eclipse PRO & MINI) separately using a soft damp cloth. A mild detergent solution may be used, provided that it is wiped off with a damp cloth and the recorder is dried afterwards.

Disinfecting the Eclipse MINI and PRO recorders

If low-level surface disinfection is necessary, wipe the recorder and cable (Eclipse PRO only) thoroughly with Isopropyl Alcohol, 70% (such as isopropyl alcohol prep pads).

The following cleaning brands or concentrated agents have been tested at the manufacturer's recommended dilutions on and can be safely used for disinfecting the patient cables and the recorder.

1. DIVERSEY Oxivir Tb wipes
2. PDI SANI-CLOTH 70% Wipes
3. Clinell Universal wipes
4. 99% Isopropyl Alcohol
5. Cidex OPA (For high-level disinfection)
6. 95% ethyl alcohol (ethanol)
7. Diversy Virex II 256

8. PDI Super SANI-CLOTH
9. 10% Hydrogen Peroxide
10. Clinell Alcohol Wipes
11. Virusolve+ Sporidical wipes

Contamination by Body Fluids

If you suspect that the Eclipse PRO has been contaminated by body fluids:

- Wear protective gloves before handling the recorder.
- Seal the recorder and patient cable in a hospital bag clearly marked for contaminated material.
- Contact Spacelabs Healthcare Limited for advice.
- Do NOT return the recorder or cable to your supplier or Spacelabs Healthcare before taking these precautions.

In the case of severe contamination, the recorder may be beyond repair. Please contact Spacelabs Healthcare for further advice.

Lifecard CF Recorders

The plastic parts of the recorder are strong and generally very durable, but some chemicals can attack them. Such chemicals may be found in specialist cleaning products, disinfectants, and skin-care products (e.g., sunscreens).

Due to the enormous range of chemical products, and the fact that some are corrosive in very small quantities, it is often impossible to find out what has caused damage. To ensure trouble-free service from your recorders, use only the cleaners and disinfectants recommended here.

Cleaning Lifecard CF:

1. Clean the patient cable and recorder while they are fitted together, using a soft damp cloth. A mild detergent solution may be used, provided that it is wiped off with a damp cloth and the recorder is dried afterwards. Alternately, a wipe can be supplied that is applicable to cleansing the patient's skin and to cleaning the recorder. Please request our Alcohol-Free Cleansing Wipe. DO NOT allow moisture inside the case or permanent damage may result.
2. Removing Adhesive Residues: It can be difficult to remove adhesive residues from the patient cable. Spacelabs Healthcare recommends isopropyl alcohol swabs (see below), ensure the wipe is used gently to avoid damaging the cables.

Cleaning Pouches and Lanyards:

The pouches, lanyard and harness can all be washed in hot soapy water.

Disinfecting the Lifecard CF:

1. If low-level surface disinfection is necessary, wipe the recorder and cable thoroughly with isopropyl alcohol, 70% (such as isopropyl alcohol prep pads). To avoid damage to the display window, wipe the alcohol off with a soft damp cloth and then dry the window.
2. Contamination by Body Fluids - If you suspect that the Lifecard CF has been contaminated by body fluids:

- Wear protective gloves before handling the recorder.

- Seal the recorder and patient cable in a hospital bag clearly marked for contaminated material.
- Contact Spacelabs Healthcare Limited for advice.
- Do NOT return the recorder or cable to your supplier or Spacelabs Healthcare before taking these precautions.

Evo Recorders

The plastic parts of the recorder are strong and generally very durable, but some chemicals can attack them potentially leading to a reduced service life and decreased immunity for electromagnetic interference. Such chemicals may be found in specialist cleaning products, disinfectants, and skin-care products (e.g., sun blocks).

Due to the enormous range of chemical products, and the fact that some are corrosive in very small quantities, it is often impossible to find out what has caused damage. To ensure trouble-free service from your recorders, use only the cleaners and disinfectants recommended here.

Cleaning Evo

1. Clean the recorder using a soft damp cloth. A mild detergent solution may be used, provided that it is wiped off with a damp cloth and the recorder is dried afterwards. Alternatively, you may use an Alcohol-Free Cleansing Wipe
2. It can be difficult to remove adhesive residues from the patient cable. We recommend Uni-Patch UP228 swabs, which are also applicable to removing residue from the patient's skin and to cleaning the recorder. Alternatively, Isopropyl alcohol swabs may be effective but in either case the wipe must be used gently to avoid damaging the cables. The patient electrodes are single-use-disposable - do not attempt to clean or reuse them.
3. The belt pouch can be cleaned with isopropyl alcohol or a soft, damp cloth and the belt can be washed in hot soapy water.
4. Do not autoclave - this unit CANNOT be sterilized.

Disinfecting the Evo recorder

If low-level surface disinfection is necessary, wipe the recorder and cable thoroughly with isopropyl alcohol, 70% (such as isopropyl alcohol prep pads). To avoid damage to the display window, wipe the alcohol off with a soft damp cloth and then dry the window.

CardioExpress ECG machines

Precautions



1. Turn off the power before cleaning and disinfection. If mains supply is used, the power cord should be unplugged out of the outlet. Prevent the detergent from seeping into the equipment.
2. Do not immerse the unit or patient cable into liquid under any circumstances.
3. Do not clean the unit and accessories with abrasive fabric and avoid scratching the electrodes.
4. Any remainder of detergent should be removed from the unit and patient cable after cleaning.

5. *Do not use chloric disinfectants such as chloride and sodium hypochlorite etc.*
6. *Do not autoclave - this unit CANNOT be sterilized.*
7. *The operator should make every effort to keep the device dry. If device gets wet, they should power the device OFF and return it to Spacelabs Healthcare for service.*

Cleaning CardioExpress

If the equipment or accessory has been in contact with the patient, then cleaning and disinfecting is required after each use. The validated cleaning agents for cleaning the electrocardiograph and patient cable are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

The validated cleaning agent for cleaning the reusable electrodes is mild near neutral detergent. Cleaning agents should be applied or removed using a clean, soft, non-abrasive cloth or paper towel.

Cleaning the CardioExpress Main Unit



Turn off the power before cleaning. The mains supply must be switched off if it is used.

1. Switch off the main unit and disconnect it from the power cord.
2. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
3. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
4. Dry the main unit for at least 30 minutes in a ventilated and cool place.

Cleaning the Patient Cable

1. Wipe the patient cable with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.
3. Wipe off with a dry cloth to remove residual moisture.
4. Leave the patient cable to air dry.



Any remaining cleaning solution should be removed from the main unit and the patient cable after cleaning.

Cleaning the Reusable Electrodes

1. Wipe off with a soft cloth to remove residual gel.
2. Wipe the suction bulbs of chest electrodes and the clamps of limb electrodes with a soft cloth dampened with the cleaning solution until no visible contaminants remain.

3. Wipe off the cleaning solution with a fresh cloth or towel dampened with tap water after cleaning until no visible cleaning agent remains.
4. Wipe off with a dry cloth to remove residual moisture.
5. Leave the suction bulbs and clamps to air dry.

Disinfection

To avoid permanent damage to the equipment, it is recommended that disinfection is performed only when it is considered as necessary according to your hospital's regulations. Clean the equipment and reusable accessories before they are disinfected. The validation disinfectants for disinfecting the electrocardiograph and patient cables are:

- Ethanol (75%)
- Isopropanol (70%)

The validated disinfectant for disinfecting the reusable electrodes is:

- Isopropanol (70%)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.



1. *Do not use high-temperature, high-pressure vapor or ionizing radiation as disinfection methods.*
2. *Do not use chloric disinfectants such as chloride, sodium hypochlorite etc.*
3. *Clean and disinfect reusable electrodes after each use.*

Disinfecting the Main Unit



Turn off the power before disinfection. The mains supply must be switched off if it is used.

1. Switch off the main unit and disconnect it from the power cord.
2. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
3. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
4. Dry the main unit for at least 30 minutes in a ventilated and cool place.

Disinfecting the Patient Cable

1. Wipe the patient cable with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the patient cable to air dry for at least 30 minutes.

Disinfecting the Reusable Electrodes

1. Wipe the suction bulbs of chest electrodes and the clamps of limb electrodes with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.

3. Leave the suction bulbs and clamps to air dry for at least 30 minutes.

CardioPulse Go and Prime ECG machines

The CardioPulse ECG machines are not available outside the US market.



Switch the device off before cleaning and disconnect it from the AC power by removing the plug. Do not, under any circumstances, immerse the device in cleaning liquid and do not sterilize it with hot water, steam, or air.



- Do not autoclave the device and accessories.
- Do not immerse the device in liquid.
- Do not spray liquid onto the device/cable.
- The use of detergents with a high acid content or detergents that are otherwise unsuitable can damage the device (i.e. cracks and wear of the plastic casing).
- Always follow the usage instructions provided by the manufacturer of the cleaning solution.
- With time, the casing may become less resistant:
 - if an alkaline cleaner or a cleaner with a high alcohol concentration is left for a long time on the surface, or
 - if a warm disinfectant or detergent is used. Spacelabs Healthcare therefore recommends using only cleaning agents that are adequate for sensitive materials such as plastics, and using them at room temperature (approx. 68 °F).
- Never use any of the following solutions or similar products to clean the equipment: Ethyl alcohol, acetone, hexane, abrasive or scouring powder or material, any cleaning material that damages plastic.
- The patient cable and other cable assemblies must not be exposed to excessive mechanical stress. Whenever disconnecting the leads, hold the plugs and not the cables. Store the leads in such a way as to prevent anyone stumbling over them or any damage being caused by the wheels of instrument trolleys.
- When cleaning, ensure that all labels and safety statements, whether etched, printed or stuck to the device, remain in place and remain readable.

Thoroughly inspect the device and the accessories before cleaning.

Look for any signs of damage and make sure that the keys and connectors work correctly.

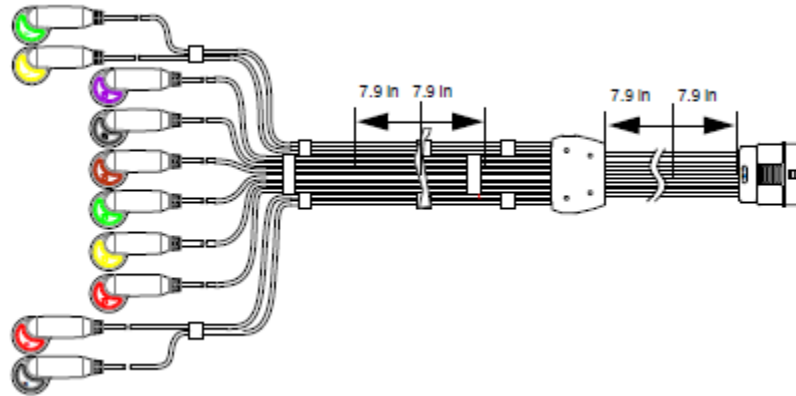
- Gently bend and flex cables, inspecting them for damage or extreme wear, exposed wires, and bent connectors.
- Confirm that all connectors engage securely.

The casing of the CardioPulse Go, CardioPulse Prime, and the cable assemblies can be cleaned with a cloth slightly moistened (not wet) on the surface only. If necessary, a domestic noncaustic cleaner or

a 50 % alcohol solution can be used to remove grease stains and fingerprints. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions (listed below). Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, switches, or gaps. If liquid gets into connectors, dry the area with warm air and check that the device operates properly.

Cleaning the cable assembly

1. Before cleaning, inspect the cable for damage. Gently bend and flex all parts of the cable. Inspect for splits in the sheathing, damage or extreme wear, exposed wires or bent connectors.
2. Wipe the cable with a cloth slightly moistened (not wet) with one of the approved cleaning solutions listed below.
3. Gently grip the cable with the damp cloth in the center of the cable and slide the cable through the cloth 7.9 inches at a time until clean. Do not clean the whole length in one single action as this may cause 'bunching' of the insulation sheathing.



CardioPulse Go

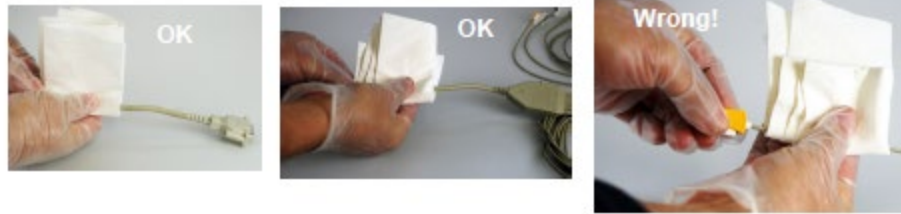


CardioPulse Prime

4. Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, switches, or gaps. If liquid gets into connectors, dry the area with warm air.



CardioPulse Go



CardioPulse Prime

Approved cleaning solutions

- 50 % isopropyl alcohol
- neutral, mild detergent
- all products designed for cleaning plastic.

Non-admissible detergents

- Ethyl alcohol
- Acetone
- Hexane
- Abrasive cleaning powder
- Plastic-dissolving products

Disinfection

Disinfection removes certain bacteria and viruses.

Use commercially available disinfectants intended for clinics, hospitals, and medical practices. Please refer to the information about the manufacturer's disinfectants for the application. Disinfect the units in the same way as described for cleaning the units (previous page).

Approved disinfectants

- Isopropyl alcohol 50%
- Propanol (35 %)
- Aldehyde (2-4 %)
- Ethanol (50 %)
- all products that are suitable for sensitive surfaces, such as:
 - BacilloI® 30 foam/ BacilloI® 30 Tissues (10% Propanol-1, 15 % Propanol-2, 20 % Ethanol)
 - Mikrozyd® AF (25 % Ethanol, 35 % 1Propanol-1)

Non-admissible disinfectants

Never use products containing the following:

- Organic solvents
- Ammonia-based detergent
- Abrasive cleaning agents
- 100 % alcohol

- Conductive solution
- Solutions or products with the following ingredients:
 - Acetone
 - Quaternary ammonium compound
 - Betadine
 - Chlorine, wax, or wax compound
 - Ketone
 - Sodium salt