Canon

Disinfection Guide for Aplio 300/500 Systems

CANON MEDICAL SYSTEMS CORPORATION

20.1   Technical Descriptions

For technical descriptions about this system, refer to the following manuals.

- Installation manual

- Maintenance manual

- Disposal manual

20.2   Outline of Preventive Maintenance

Daily checks, periodic inspection, and replacement of consumable parts/
periodically replaced parts are included in preventive maintenance.
For replacement of periodically replaced parts, special techniques are required
because special tools are used or there are special risks involved.

Canon Medical Systems provides preventive maintenance services requiring
special techniques on a pay-for-service basis.

Canon Medical Systems requests that the user sign a preventive maintenance
contract to arrange for periodic inspection and cleaning by Canon Medical
Systems service personnel in order to ensure reliable system operation.

If you have any questions concerning preventive maintenance or preventive
maintenance contracts, contact your Canon Medical Systems service
representative.

⚠**WARNING**   **Shall not be serviced or maintained while in use with a patient. Doing so may subject the patient or operator to electric shock or cause damage to the system.**

⚠**CAUTION**   **1. If preventive maintenance is performed by the user, special care must be taken to ensure safety.**

2. If any abnormality of the system is found as a result of inspection, stop using the system and contact your Canon Medical Systems service representative for repair.

NOTE   The following message is displayed in the information display area when the period of operation (time) set for the system has elapsed (factory setting: 600 hours). When this message is displayed, it is recommended that the user submit a request for inspection by a service engineer. The interval for display of this message can be changed. Contact your Canon Medical Systems service representative.

> **ⓘ** System inspection is recommended. A long time has passed since last system inspection.

20.3   Preventive Maintenance Performed by the User

20.3.1   Cleaning the system

⚠ **CAUTION**   1. **Before cleaning the system, be sure to disconnect the system power plug from the outlet of the facility. If the system is defective, an electric shock may occur.**

2. **Do not spill or spray liquids such as water onto the system or peripheral units (printer, UPS, etc.). If a liquid such as water enters the system or peripheral units, an electric shock may occur.**

3. **Do not use any chemicals or methods other than those specified to clean the system.**
If this is not observed, deterioration or discoloration of the surface of the system may result.

CAUTION   Do not use solvents (such as paint thinner, benzine, or alcohol) or abrasive cleansers to clean the system. These substances may cause deterioration or discoloration of the system.

(1) Cleaning the transducer

Clean, disinfect, and sterilize the transducer referring to the operation manual provided with the transducer.

(2) Cleaning the transducer holder and gel holder

(a) Wipe off any stains on the transducer holder and gel holder using a soft, dry cloth.

(b) If it is difficult to remove stains, wipe them off using a soft cloth moistened with mild detergent.

(3) Cleaning the reference signal cable

CAUTION

1. Do not allow the reference signal cables to become wet (with water or chemical solution). If wet clips are used, the ECG tracing will not be displayed correctly.

2. Do not immerse the connector in water or chemical solution. If moisture enters the connector, the system may fail. Wipe the connector with a dry cloth only.
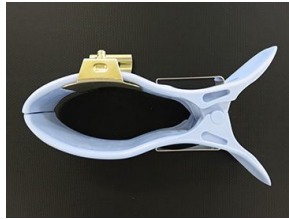

Clean the reference signal cable regularly.

(a) Wipe off all organic materials (such as blood or other body fluids) from the reference signal cable using a soft cloth moistened with any of the following (as appropriate).

• Purified water

• Mild detergent diluted with purified water

• Ethanol for disinfection
(76.9 to 81.4 vol% at 15°C)

(b) Wipe the cables with a clean, soft, dry cloth and then dry the cables. When drying the cables, do not use heat.

(c) Confirm that the cables show no signs of damage, deformation, or peeling.

(4) Cleaning the ECG limb clips (clip-type electrodes)

CAUTION   Before drying the ECG limb clips, make sure that there is no electrolyte cream remaining on the clips, and that all water and chemical solution has been wiped off. Otherwise, ECG tracing will not be displayed correctly.

Clean the ECG limb clips regularly.

(a) Wipe off all organic materials (such as blood or other body fluids) from the ECG limb clips using a soft cloth moistened with any of the following (as appropriate).

- Purified water

- Mild detergent diluted with warm water (39°C or less)

- Cationic detergent diluted with warm water (39°C or less)

- Ethanol for disinfection (76.9 to 81.4 vol% at 15°C)

(b) Wipe the ECG limb clips with a clean, soft, dry cloth and then dry them. Do not use heat to dry the electrodes.

(c) Confirm that the ECG limb clips show no signs of damage, deformation, or peeling.

(5) Cleaning the PCG sensor and the pulse sensor

CAUTION Do not immerse the PCG sensor or the pulse sensor in water or chemical solution. If moisture enters the connector, the system may fail.

PCG sensor

Pulse sensor

Clean the PCG sensor and the pulse sensor regularly.

(a) Wipe off all organic materials (such as blood or other body fluids) from the PCG sensor or the pulse sensor using a soft cloth moistened with any of the following.

- Purified water

- Mild detergent diluted with purified water

- Ethanol for disinfection (76.9 to 81.4 vol% at 15°C)

(b) Wipe the PCG sensor or the pulse sensor with a clean, soft, dry cloth and then dry the PCG sensor or the pulse sensor. Do not use heat to dry it.

(c) Confirm that the PCG sensor or the pulse sensor show no signs of damage, deformation, or peeling.

(6) Cleaning the monitor

CAUTION

1. Do not hit or apply excessive force to the LCD screen during cleaning. Doing so may damage the monitor.

2. Never use a stiff or hard cloth to clean the monitor. Doing so may damage the monitor cover or LCD screen.

3. Do not allow liquid droplets to remain on the LCD screen. The droplets may cause small stains when they dry or may enter the LCD screen, possibly resulting in failure.

(a) Monitor cover

- Clean the monitor cover using a soft cloth moistened with mild detergent.

(b) LCD screen

- Use a soft cotton cloth or lens cleaning paper to clean the LCD screen.

- If stains on the LCD screen are difficult to remove, wipe it gently with a soft cloth slightly moistened with water and then wipe it with a soft, dry cloth.

(7) Cleaning the surface of the touch panel

(a) Clean the surface of the touch panel using a commercially available eyeglass cleaning cloth (non-woven rayon cloth etc.).

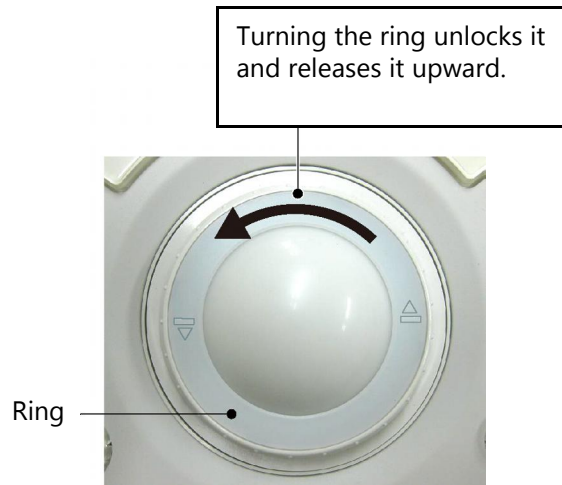(b) If necessary, use a piece of soft cloth moistened with water or mild detergent and then tightly wrung out.

(8) Cleaning the system, main panel, and transducer connector

(a) Wipe the system using a soft cloth moistened with mild detergent.

(b) Clean around the switches or keys on the main panel using cotton buds.

(c) Wipe the transducer connector with a soft, dry cloth.
If it is difficult to remove all the stains with a dry cloth, use a soft cloth moistened with water.
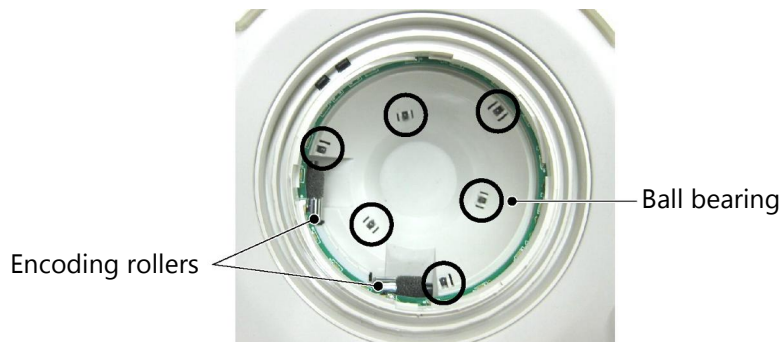
(9) Cleaning the trackball

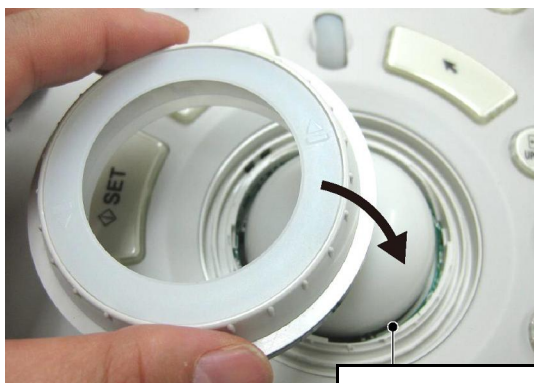   (a) Turn the ring on the trackball case in the direction indicated by the arrow to remove the dial.

Turning the ring unlocks it and releases it upward.

Ring

CAUTION   To prevent malfunction, be careful when removing the dial.

    (b) Remove the ball carefully and place it in a cardboard box or other suitable container to prevent it from dropping.

    (c) Clean the ball and ball bearings, being sure to remove all dirt and foreign matter.

Ball bearing

Encoding rollers

CAUTION   Do not touch the encoding rollers.
                  If foreign matter has adhered to the encoding rollers, contact your Canon Medical Systems service representative.

(d) Lightly place the ball in the trackball assembly, and then place the dial over it.

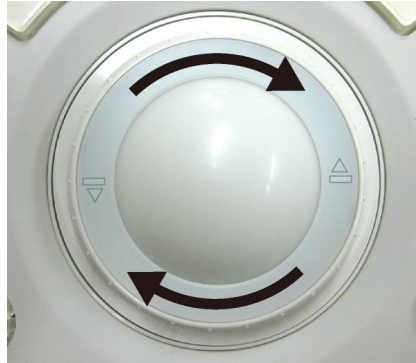Make sure that there are no foreign objects inside the trackball assembly.

(e) The arrows on the dial should be in the position shown below.

Make sure that the dial is correctly set in place.

CAUTION   Set the dial so that it is properly seated.
           If the ring is locked with the dial not properly seated, the palm switch may be damaged.

(f) Turn the ring in the direction shown to tighten it.

(g) After the trackball is assembled, confirm the following:

- The ball and dial operate smoothly, there is no abnormal sound, and the ball is not loose.

- The trackball works normally after the power is turned ON.

(10) Cleaning the air filters

Check and clean the air filters to prevent overheating of the system or a reduction in system performance/reliability due to clogging of the filters.

CAUTION   Do not boot up the system while the air filters are removed.
The system may malfunction.

(a) Remove the air filters (3 locations).

(b) Remove all dust from the filters using a vacuum cleaner at a location away from the system.

(c) Remount the air filters.

20.3.2 Disinfecting the system

This subsection describes the procedures and precautions for disinfecting the system.

For disinfection of transducers, refer to the operation manuals provided with the transducers.

⚠ DANGER   **After disinfecting the system, ventilate the room fully before turning the system ON.**
If flammable and explosive gas remains near or in the system, it may cause a fire or explosion.

⚠WARNING   1. **Before disinfecting the system, be sure to disconnect the system power plug from the outlet of the facility. If the system is defective, an electric shock may occur.**

2. **Do not spill or spray liquids such as water onto the system or peripheral units (printer, UPS, etc.). If a liquid such as water enters the system or peripheral units, an electric shock may occur.**

⚠CAUTION   1. **Observe the following precautions to prevent infection.**

   • **Wear sterile protective gloves.**

   • **Wear new sterile protective gloves each time disinfection is performed.**

2. **Do not disinfect the system using a method or chemical other than those specified in this manual. The system may not be disinfected properly, or the surface of the system may deteriorate or become discolored.**

3. **After chemical disinfection, dry the surface of the system fully.**

4. **The efficacy of the disinfectants is not guaranteed by Canon Medical Systems. Contact the manufacturer of the relevant chemical for the efficacy of each disinfection agent.**

⚠ **CAUTION** **5. Determine the effectiveness of the chemical based on the criteria (effective period, number of times of use, discoloration of the chemical, results of testing using effectiveness test kits, etc.) described in the documentation provided by the manufacturer of the chemical.**

CAUTION 1. When chemical disinfections are repeated, the surface of the system is changed gradually.

2. If any abnormality related to functions of the product is observed after disinfection, stop using the product and contact your Canon Medical Systems service representative for repair.

(1) Chemicals permitted for use

The chemicals described below are permitted for use. For detailed handling methods, refer to the documentation provided by the manufacturer of the chemical.

<<System main unit>>

- Quaternary ammonium compound (0.75%): Cleanisept$^®$ wipes

- Quaternary ammonium compound (0.50%): SUPER SANI-CLOTH$^®$

- Quaternary ammonium compound (0.25%): SANI-CLOTH$^®$ PLUS

- Sodium hypochlorite (0.65%):
  Dispatch$^®$ Hospital Cleaner or Clorox Healthcare^{TM} Bleach Germicidal Cleaner

- Effervescent Chlorine Tablets, sodium dichloroisocyanurate (NaDCC):
  BIOSPOT$^®$* (5,000 ppm)
  * Not available in the USA.

- Isopropyl alcohol 70 vol%

- Ethanol for disinfection (76.9 to 81.4 vol% at 15°C)

<<Reference signal cable and ECG limb clips (clip-type electrodes)>>

- Alkyldiaminoethylglycine hydrochloride (0.5%)

- Benzalkonium chloride (0.2 w/v%)

- Benzethonium chloride solution (0.2 w/v%)

- Chlorhexidine gluconate solution (0.5 w/v%)

<<PCG sensor and pulse sensor>>

- Ethanol for disinfection (76.9 to 81.4 vol% at 15°C)

CAUTION   Do not use hypochlorite for disinfecting the reference signal cables.

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(2) Area that can be disinfected

The entire system can be disinfected.
However, the following parts cannot be disinfected. Clean these parts using mild detergent as required.

- Screen of the LCD monitor

- Casters

- Footswitch

- Peripheral devices (printer, UPS, etc.)
  Refer to the documentation provided with the peripheral devices.

- Cables

(3) Procedures for disinfecting

Perform the disinfection work according to the instructions by someone with a professional knowledge of disinfection.

(a) Turn the system power OFF, and disconnect the power plug from the outlet of the facility.

(b) Wear protective gloves to prevent infection. Wear new sterile protective gloves each time disinfection is performed.

(c) Be sure to perform cleaning before performing disinfection.

(d) Moisten a piece of soft cloth with a chemical, squeeze it lightly, and wipe the surface of the unit. Pay careful attention not to allow a chemical liquid to enter the unit.

(e) After chemical disinfection, dry the surface of the system fully. Do not heat the unit to dry it.

(f) Confirm that the disinfected parts are not damaged or deformed.

(g) After disinfecting the system, ventilate the room fully before turning the system ON.

CAUTION   1. Do not leave the reference signal cable or ECG limb clips wet with water or chemical solution. Incorrect display of ECG waveforms may result.

2. Do not immerse the reference signal cable connector in water or chemical solution. If moisture enters the connector, the system may fail.

CAUTION   3. The PCG sensor and the pulse sensor are not waterproof. Do not immerse the PCG sensor or the pulse sensor in water or chemical solution.

4. Do not boil the ECG limb clips. They may be damaged.

20.3.3   Creating a backup copy of the system hard disk

As a precaution against deterioration or loss of data stored on the system hard disk, create a backup copy of the hard disk at appropriate intervals.
Refer to subsection 20.3.5 "Backing up the customer-specific data (Backup)" for the detailed procedures.

20.3.4   [Maintenance] menu

This system is provided with a **[Maintenance]** menu that supports maintenance and management by the user.
Use this **[Maintenance]** menu as required.

CAUTION   Do not use the **[Maintenance]** menu during an examination.
The **[Maintenance]** menu must be opened before a patient ID is registered

after system power ON or after an examination is terminated by pressing

in the **[Patient Registration]** menu.

Submenu name	Function
[Backup]	Backup of the HDD data to external storage media can be performed to protect customer-specific data or to transfer such data to another system.