

Using a Philips MobileDiagnost wDR in a COVID-19 Environment

Mobile radiography systems are at the forefront of patient care and diagnosis in the ongoing COVID-19 pandemic. These systems can be used in various areas in a hospital such as the emergency rooms, intensive care units, isolation wards, quarantine zones or operating rooms that may have patients suffering from COVID-19. Many of these systems move from one area to another or sometimes even from one hospital to another to fulfill the diagnostic needs. In such cases, appropriate cleaning and disinfection of these systems is of utmost importance for the safety of healthcare professionals handling the equipment and for the patients undergoing diagnosis by the system.

Here are some topics that address common concerns around the usage of mobile radiography systems under these circumstances:

Equipment cleaning and disinfection:

Please read and follow the cleaning instructions described in the instruction for use (IFU) shipped with the device. Here is an extract from the detailed instructions from MobileDiagnost wDR IFU:

Cleaning and disinfecting Philips Diagnostic X-Ray devices

Avoiding Contamination

During examinations, protect the equipment by covers and drapes as far as reasonably possible. When you avoid contamination, you will minimize the need for cleaning and disinfecting.

Cleaning

All parts should only be wiped clean with a damp cloth and a detergent, and then rubbed down with a dry soft cloth immediately. Never use corrosive cleaning agents, solvents, abrasive detergents or abrasive polishes. If you are not sure about the properties of a cleaning agent, do not use it.

Disinfecting

The disinfection method used must conform to the legal regulations and guidelines regarding disinfecting and explosion protection. Those parts of the product that are suitable for such treatment, including accessories and connecting cables, can be disinfected by wiping with a cloth dampened with a suitable disinfectant. Never use corrosive or solvent disinfectants or sterilizing agents.

Observe the warnings of the manufacturer of the disinfectant. If you are not sure about the properties of a disinfecting agent, do not use it. Use a disinfectant that contains one of the following ingredients:

- Ethanol or Isopropanol (70 %)
- Chlorohexidine or chloride (0.5%) in ethanol (70%)
- Chlorine upto 250ppm in water
- Quaternary ammonia compounds (QATs) for all surfaces except screens, displays and plastic surfaces
- Amines on all surfaces except plastic surface
- Combination of QAT and Amines except on plastic surfaces
- Active Oxygen e.g. Accelerated Hydrogen Peroxide (0.5%), Peracetic acid (1-2%) - except on metal surfaces

You can find restrictions and special instructions for certain components in the IFU (which is delivered with the system). Please follow all the warnings, cautions and notices mentioned in the Instructions for Use.



Environmental cleaning and disinfection

Ensure that environmental cleaning and disinfection procedures are followed consistently and correctly. Detailed information on environmental infection control in healthcare settings can be found in CDC's Guidelines for Environmental Infection Control in Health-Care Facilities (<u>https://www. cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm</u>) and Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings [section IV.F. Care of the environment]. (<u>https://www.cdc.gov/infectioncontrol/</u> <u>guidelines/isolation/index.html</u>) The complete abovereferenced CDC guidance document can be accessed at (<u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/infectioncontrol-recommendations.html</u>)

Hospitals should follow the environmental infection control as per the facility policies and follow any equipment specific precautions as prescribed. Some examples of equipment specific precautions are:

- If performing disinfection of a room by means of sprays or fumigation, the equipment must first be switched off and allowed to cool down. The equipment should be completely covered with plastic cover before the spray disinfection. Do not remove the plastic cover until the disinfectant spray has completely dissipated
- 2. Do not use UV based disinfectants in the interiors of the equipment

» Link to document for more details

Fans in Philips MobileDiagnost wDR

Most medical equipment, including Philips MobileDiagnost wDR have air intake fans inside, that pull in air to cool down the electronic components that heat up through equipment usage. There is no data available on the impact of fans or air movement inside the equipment on the spread of COVID-19. Hospitals should follow the environmental infection control as per the facility policies and follow equipment specific precautions.

Filters in Philips MobileDiagnost wDR

Philips MobileDiagnost wDR does not have HEPA filters to block specific pathogens from entering the system. We do not recommend applying HEPA filters over normal filters as that may lead to insufficient airflow for cooling the electronic components, potentially resulting in loss of function during a procedure.

Transporting Philips MobileDiagnost wDR from one facility to another

When a Philips MobileDiagnost wDR exposed to COVID-19 patients, is being shipped from one facility to another, the following care should be taken:

- 1. Service providers or healthcare practitioners handling the equipment wear appropriate PPEs. Refer 'Adhere to Standard and Transmission-Based Precautions' at <u>https://www.cdc.gov/coronavirus/2019ncov/hcp/infection-control-recommendations.</u> <u>html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.</u> <u>gov%2Fcoronavirus%2F2019-ncov%2Finfection-</u> control%2Fcontrol-recommendations.html for details
- 2. Equipment cleaning and disinfection as per the Instruction for Use (IFU) is done appropriately on all equipment surfaces, including detectors and accessories
- Environmental cleaning practice of the room/area in the healthcare facility where the equipment is kept is followed, with equipment specific precautions.
- equipment specific precautions.
 Keep the MobileDiagnost wDR system in an air circulation room as per facility protocol that follows CDC guidelines on airborne contaminant removal: <u>https://www.cdc.gov/infectioncontrol/ guidelines/environmental/appendix/air.html#tableb1</u>
 As a precaution, maintain a minimum time gap of 24 hours, or as
- 5. As a precaution, maintain a minimum time gap of 24 hours, or as per the hospital airborne contaminant removal protocol, when moving the equipment from one healthcare facility to another.

Philips MobileDiagnost wDR-

Useful features and accessories

Some of these features and accessories with Philips MobileDiagnost wDR can help reduce the risk of cross contamination by minimizing the touch points between the HCPs, COVID patients and the equipment.

- Remote control- Infrared based Remote Control with a range of 10m (32.8 ft) allowing exposure from a safe distance
- 2. Barcode reader- for quick scanning of patient badge, helping increase your productivity
- 3. SkyFlow Plus gridless workflow with SkyFlow Plus offers grid-like image quality and one less item to clean after every patient
- 4. Laser SID Guide- for a quick and easy source to image distance guidance

>> Link to video for more details

Appendices

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- Cleaning and disinfection program DXR
- Cleaning and disinfecting a Philips Diagnostic X-Ray devices after suspected exposure to the COVID-19 virus.



Services & Solutions Delivery

Cleaning and disinfection program

Note: Before cleaning and disinfecting the equipment, please read the "Cleaning and Disinfection" section of the Philips "Instruction for Use" carefully to ensure safety and operability.

Cleaning program

- Enameled parts and aluminum surfaces should be wiped clean with a *damp cloth and a mild detergent*, and then rubbed down with a dry woolen cloth. Never use corrosive cleaning agents, solvents, abrasive detergents or polishing agents. Do not use if unsure of the properties of the cleaning agents.
- Chrome parts should only be cleaned by rubbing down with a *dry woolen cloth*.
 Do not use abrasive polishes. To preserve the finish, use a non-abrasive wax. Plastic surfaces should only be cleaned with *soap and water*. If you use other cleaners (for example with a high alcohol content), the material will turn dull or tend to crack.
- 3. **Standard glass cleaning cleaners** can be used to clean the touchscreen (except products containing ammonia). Spray the glass cleaner on a cloth or towel to clean the touch screen. Dirt and fingerprints will not affect properly a sealed AccuTouch or IntelliTouch touch screens. To prevent the touchscreen malfunction, remove liquid droplets after cleaning immediately.

Cleaning and disinfection techniques for equipment and examination rooms must comply with all applicable local laws or regulations.

Disinfection program

- 1. The disinfection method used must comply with legal regulations and guidelines on disinfection and explosion protection. Parts of the equipment suitable for such treatment, including accessories and connection cables, can de disinfected with a **cloth dampened with a suitable agent**.
- Never use corrosive, solvent-based disinfectants or sterilizing agents.
 Do not use if unsure of the properties of the disinfectant or sterilizing agent.
- 3. Never use flammable or potentially explosive disinfectant sprays. Such sprays create vapors, which can ignite, causing fatal or other serious injury. It is not recommended to disinfect the medical equipment room with sprays, since the vapor may enter the equipment, causing electrical short circuit, metal corrosion or other damages to the equipment.
- 4. If disinfection of a medical equipment room is nevertheless performed by means of sprays, the **equipment must first be switched off** and allowed to cool down. This prevents convection currents drawing spray mist into the equipment. The equipment should be completely covered with plastic cover before the spray disinfection. Do not remove the plastic cover until the disinfectant vapor has completely dissipated. Then the equipment itself can continue to be disinfected following the recommendation above. If a spray is used, the operator should ensure that the disinfectant vapor has completely dissipated before switching on the equipment.

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21/Apr/2020

Name: Michael Mizrachi E-Mail: michael.mizrachi@philips.com

Cleaning and disinfecting a Philips Diagnostic X-Ray devices after Suspected exposure to the COVID-19 virus.

You requested help with how to clean and decontaminate a Philips Diagnostic X-Ray devices that has come in contact with patients and/or bodily fluids that are potentially infected with COVID-19 virus

Please note that as a medical device manufacturer, Philips Healthcare can provide technical support, instructions and recommendations regarding general care and cleaning of our devices and compatible accessories. However, we are <u>not</u> able to provide specific recommendations regarding the choice, efficacy and/or use of any particular cleaning or disinfecting agent(s) in any given clinical environment. It is the responsibility of the healthcare provider operating and using the medical device to establish its own effective protocols for disease and infection control appropriate for both the medical device and the clinical environment at the health facility. In answer to your query, therefore Philips, can only make the following general suggestions:

- Follow the recommendations for infection control in hospitals and other healthcare facilities for the COVID-19 virus provided by the Center for Disease Control (CDC) and the World Health Organization (WHO), including those regarding the disinfection of medical devices.
 - Center for Disease Control (CDC) : <u>https://www.cdc.gov/coronavirus/2019-ncov/index.html</u>
 - World Health Organization (WHO): https://www.who.int/emergencies/diseases/novel-coronavirus-2019
- CDC's "Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings" (as updated on April 1, 2020, and accessible at <u>https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-</u> <u>recommendations.html</u>) recommends in Section 10 that such healthcare settings "Implement Environmental Infection Control" for this specific emerging virus in the following manner:

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- Dedicated medical equipment should be used when caring for patients with known or suspected COVID-19.
 - All non-dedicated, non-disposable medical equipment used for patient care should be cleaned and disinfected according to manufacturer's instructions and facility policies.
- Ensure that environmental cleaning and disinfection procedures are followed • consistently and correctly.
- Routine cleaning and disinfection procedures (e.g., using cleaners and water to preclean surfaces prior to applying an [Environmental Protection Agency (EPA)]registered, hospital-grade disinfectant to frequently touched surfaces or objects for appropriate contact times as indicated on the product's label) are appropriate for SARS-CoV-2 in healthcare settings, including those patient-care areas in which aerosol-generating procedures are performed.
 - Refer to List N on the EPA website for EPA-registered disinfectants that have qualified under EPA's emerging viral pathogens program for use against SARS-CoV-2. [See below for additional information regarding "List N"]
- Management of laundry, food service utensils, and medical waste should also be performed in accordance with routine procedures.
- Additional information about recommended practices for terminal cleaning of rooms and PPE to be worn by environmental services personnel is available in the Healthcare Infection Prevention and Control FAQs for COVID-19

As referenced above, "List N" on the EPA website for "Pesticide Registration" includes the complete current list of products that meet EPA's criteria for use against SARS-CoV-2, which is the novel coronavirus that causes the disease COVID-19. List N can be accessed at https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2.

- Clean the Diagnostic X-Ray device before disinfecting. Follow the cleaning instructions described in the Instructions for Use (IFU) shipped with the device.
- Note that sterilization is not allowed for this Diagnostic X-Ray device, related products, • accessories or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies.
- Disinfect the Diagnostic X-Ray device according to the individual healthcare provider's • protocols and the information provided in the IFU for the medical device. Note that contamination that is not part of the visible surface will remain as a potential source of contamination even after cleaning and disinfecting the surfaces.
- Cleaning and disinfection agents approved for use with your Diagnostic X-Ray device are ٠ listed in the IFU and you will find a summary below.

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NOTE: It is the responsibility of the healthcare provider to use disinfecting agents that are effective in controlling the virus responsible for causing COVID-19. Philips cannot make any statement about the efficacy of the product/disinfectant used to clean or disinfect devices exposed potentially to the COVID-19 virus.

NOTE: If the disinfecting agents listed in this document or the Instructions for Use are not effective in controlling the COVID-19 virus, then follow the latest Center for Disease Control (CDC) and the World Health Organization (WHO) guidance regarding effective disinfecting agents and all other aspects of infection control, even if those specific agents have not been approved for use with Philips Diagnostic X-Ray device equipment.

NOTE: The use of non-approved disinfectants as may be recommended by CDC/WHO may cause damage to the Diagnostic X-Ray device housing and other external surfaces with the potential risk of affecting functionality and safe use of the Diagnostic X-Ray device. Please refer to the IFU and the summary below for further details.

We hope that with the information provided, we have been able to address your concerns and needs. If you require further assistance, then please do not hesitate to contact us and be assured of our continued support in this matter.

Sincerely,

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Michael Mizrachi Senior Director Global Quality & Regulatory DXR and Mammography

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SUMMARY AND EXPLANATION: Cleaning and disinfecting a Philips Diagnostic X-Ray devices

Avoiding Contamination

During examinations, protect the equipment by covers and drapes as far as reasonably possible. When you avoid contamination, you will minimize the need for cleaning and disinfecting.

Cleaning

All parts should only be wiped clean with a damp cloth and a detergent, and then rubbed down with a dry soft cloth immediately. Never use corrosive cleaning agents, solvents, abrasive detergents or abrasive polishes. If you are not sure about the properties of a cleaning agent, do not use it.

Disinfecting

The disinfection method used must conform to the legal regulations and guidelines regarding disinfecting and explosion protection. Those parts of the product that are suitable for such treatment, including accessories and connecting cables, can be disinfected by wiping with a cloth dampened with a suitable disinfectant. Never use corrosive or solvent disinfectants or sterilizing agents.

Observe the warnings of the manufacturer of the disinfectant. If you are not sure about the properties of a disinfecting agent, do not use it.

Use a disinfectant that contains one of the following ingredients:

- Ethanol or Isopropanol (70 %)
- Chlorohexidine or chloride (0.5%) in ethanol (70%)
- Chlorine upto 250ppm in water
- Quaternary ammonia compounds (QATs) for all surfaces except screens, displays and plastic surfaces
- Amines on all surfaces except plastic surfaces
- Combination of QAT and Amines except on plastic surfaces
- Active Oxygen e.g. Accelerated Hydrogen Peroxide (0.5%), Peracetic acid (1-2%) except on metal surfaces

You can find restrictions and special instructions for certain components in the IfU. Please follow all the warnings, cautions and notices mentioned in the Instructions for Use.

WARNING

Do not use flammable or potentially explosive disinfecting sprays. Such sprays create vapors, which can ignite, causing fatal or other serious personal injury

WARNING

Switch off the system before cleaning or disinfecting to prevent electric shocks. Never allow water or other liquids to enter the product, since this may cause electrical short circuits or metal corrosion.

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CAUTION

Disinfecting a medical product room by means of sprays is not recommended, since the vapor could penetrate the product, causing electrical short circuits, metal corrosion or other damage to the product.

If you nevertheless perform disinfecting a medical product room by means of sprays, the product must first be switched off and allowed to cool down. This prevents convection currents drawing spray mist into the product. Plastic sheeting must be used to cover the product thoroughly, after which spraying can begin. Once all traces of the vapor have dispersed, the plastic sheeting can be removed and the product itself can be disinfected in the way recommended above. If a spray was used, you must be sure that all traces of the vapor have dispersed before switching the product on again.

NOTICE: If WPD bags are not used, clean the detector after each patient.

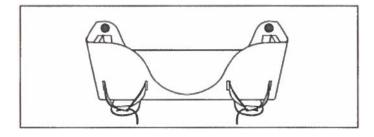
Cleaning the Touch Screen

Any standard glass cleaner can be used to clean the touch screen. Do not use products containing ammonia. Do not apply the glass cleaner directly on the touch screen. Spray the glass cleaner on the cloth or towel and then clean the touch screen.

2 NOTICE

Glass cleaner sprayed directly on the screen could possibly leak inside and cause damage. If liquid drops are somewhere on the touch-screen, the input could be blocked. To proceed working, clean the screen. Minor dirt and fingerprints do not affect the operation of the touch screen.

Cleaning the Grid Storage – tray of MobileDiagnost wDR



For cleaning, you can detach the grid storage-tray. Use the screws to attach/detach the grid storage-tray.

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