

April 9, 2020

Page: 1

April 9, 2020

Dear valued Philips customer,

Today, as the spread of SARS-CoV-2 (Coronavirus) persists throughout the global community, Philips is steadfast in its commitment to support health systems and healthcare professionals who trust us to help them care for their patients. As a leading health technology company, Philips has a broad portfolio of products, services and solutions that can help address the preparation for, response to and recovery needs resulting from an outbreak of this type of virus.

We realize the impact that our patient monitoring solutions are having in supporting health systems and care providers in dealing with this outbreak. However, we also recognize that our customers have significant concerns around the cleaning and disinfection of our solutions.

In this document, we provide guidance on our cleaning and disinfection procedures as they relate to the Coronavirus for Philips IntelliVue patient monitoring solutions and reusable accessories.

General Recommendations

The cleaning and disinfection agents that we recommend in our patient monitoring (and related accessories) products' Instructions for Use (IFU) have been tested for material compatibility. As of the date of this letter, recommendations for infection control in hospitals for the Coronavirus that are made by the Centers for Disease Control (CDC) and the World Health Organization (WHO), including for disinfection of medical devices, can be found on their websites.

You might also want to refer to 'List N: Products with Emerging Viral Pathogens AND Human Coronavirus claims for use against SARS-CoV-2,' which lists disinfectant products that meet EPA's criteria for use against SARS-CoV-2, the cause of COVID-19.

https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

If you use disinfectants other than the ones listed in the Philips Instructions for use, contact your disinfectant manufacturer for information about efficacy and compatibility. Please also consider the disinfectant vendor's recommendation in terms of usage and concentration by the principle "as little as possible, as much as necessary."

Be aware that individual ingredients of disinfectants may cause discoloration or damage to the monitor housing and may lead to reduced product lifetime. For example, specific ingredients could cause cracks in surfaces. If you notice significant changes to your monitor housing after disinfection, see your service guide for troubleshooting information or contact your service personnel. Damage is more likely to occur the more often a disinfection is performed.





April 9, 2020

Page: 2

Philips IntelliVue monitoring products and reusable accessories: cleaning and disinfection recommendations

Cleaning Instructions

The cleaning procedure described below has been validated using an enzymatic solution. Before cleaning, visually inspect the monitor for moderate to severe soiling. If the monitor is severely soiled, use swabs to clear soil before cleaning.

To clean the monitor and reusable accessories

- 1. Prepare an enzymatic detergent solution (using for example, Prolystica® Manual 2X Enzymatic Presoak and Cleaner, Cidezyme® or Enzol®) per the instructions provided by the cleaning agent manufacturer.
- 2. Using non-linting wipe(s) wetted (but not dripping) with the prepared detergent solution, thoroughly wipe the exterior surfaces of the device for a minimum of one (1) minute (for monitors), and three (3) minutes (for accessories) until visibly clean. Pay attention to irregular surfaces such as seams and ridges.
- 3. Remove the cleaner residue by wiping the device surfaces a minimum of one (1) time with non-linting wipe(s) wetted (but not dripping) with tap water.
- 4. Thoroughly dry the device using non-linting wipe(s).
- 5. Inspect the device in a well-lit area to ensure all surfaces are clean.

Disinfection Instructions for monitors and reusable accessories

- 1. Clean equipment before disinfecting.
- 2. Thoroughly wipe all exterior surfaces of the device using non-linting wipe(s) wetted (but not dripping) with 70% Isopropyl Alcohol (IPA).
- 3. Allow all surfaces to remain visibly wet for a minimum of ten (10) minutes. If needed, use additional wipes to ensure the surfaces remain wet for the full duration.
- 4. Thoroughly dry the device using non-linting wipe(s).

Material Compatibility with Disinfectants

The disinfectants listed on the following page were tested for material compatibility during product development. Philips IntelliVue patient monitors are made of damage resistant materials and designed for easy cleaning and disinfection. Philips recommends using one of the agents/disinfectants listed in the tables below. These contain the most common ingredients and have been tested by Philips for compatibility.



PHILIPS

#	Disinfectant	Manufacturer	IntelliVue MX750 (866470), MX850 (866471) and FMX-4 (866468)	IntelliVue MMX (867030), X3 (867030), MX100 (867033) and Measurement Extensions (867039, 867040, 867041)	IntelliVue MX400 (866060), MX450 (866062), MX500 (866064), MX550 (866066), MX700 (865241), MX 800 (865240)		IntelliVue Plug-In Measurement Modules, MMS (M3001A), X2	IntelliVue
					Disinfectants for Standard Use	Disinfectants for the Monitor Front	(M3002A) and previous generation Measurement Extensions (M3012A, M3014A, M3015A, M3015B)	MX40
1	Bacillol® 30	BODE Chemie GmbH	X (2)	X	X	X	X	
	Caviwipes	Metrex	X (2)					
3	Clinell Universal Sanitizing Wipes	Gama Healthcare	Х					
4	Descogen® Liquid r.f.u	Antiseptica Dr. Hans-Joachim Molitor GmbH	Х	X	X	X	X	X
	DESCOSEPT pur	Dr. Schumacher GmbH	X	X	X	X	X	X
6	Dismozon® plus, 0.4%	BODE Chemie GmbH		X	X	X	X	X
7	Hydrogen Peroxide, 3%		X	X	X	X	X	X
8	Incidin Active	Ecolab Inc.	X (2)					
9	Incidin® Foam	Ecolab Inc.		X	X	X	X	
10	Incidin® Plus 0,5%	Ecolab Inc.		X (5)		X		
11	Isopropanol, 80%		X (2)	X	X	X	X	X
12	Lysoformin®, 6%	Lysoform Dr. Hans Rosemann GmbH		X	Χ	Х	Χ	Х
13	Meliseptol®	B. Braun Melsungen AG		X	X	X	X	X
14	Mikrozid® PAA Wipes	Schülke & Mayr GmbH		X	X	Х	X	
15	Mikrozid® Sensitive Wipes	Schülke & Mayr GmbH	Х	X	X	X	X	
16	Oxivir® Tb Cleaner Disinfectant	Diversey Inc.	Х	X	Х	Х	X	Х
17	Rapid multi enzyme (3M)	3M	Х					
18	Sani-Cloth® AF3	PDI Inc.		X (3,5)		X		
19	Sani-Cloth® Bleach	PDI Inc.		X (3,5)		X		Х
	Super Sani-Cloth® Germicidal		v		V			.,
20	Disposable Wipes	PDI Inc.	X	X	Х	X	X	Х
	Sani-Cloth® PLUS Germicidal			V	V		V	.,
21	Disposable Wipes	PDI Inc.		X	Х	X	X	Х
22	Sodium Hypochlorite, bleach, 1%		X (2)	X (1,3)	Х	X	X	Х
	Virex tb Disinfectant Cleaner	Diversey Inc.		X (3,4,5)				

Note (1) up to 2% is approved

Note (2) Regular use of this disinfectant increases material stress and may lead to slightly reduced lifetime of the FMX-4 housing.

Note (3) Do not use these disinfectants on the Bedhanger Mount or the Rotatable Quick Claw Mount.

Note (4) Regular use of this disinfectant increases material stress and may lead to a slightly reduced lifetime of the monitor housing.

Note (5) Do not use these disinfectants on the Bedhanger Mount or the Rotatable Quick Claw Mount





COVID-19 Patient Monitoring & Accessories Customer FAQ

- Q1: How should Philips patient monitors and their reusable accessories be cleaned and disinfected?
- A1: Follow the "Cleaning Instructions and Disinfecting Instructions" in the device's Instructions for Use. Only agents listed in the Instructions for Use have been approved for compatibility with the device's material.
- Q2: Will there be any new recommendations for monitoring devices and accessories used on patients with COVID-19 infections?
- A2: No new recommendations are planned at this time.
- Q3: What should be done if my hospital's infection control protocols require the use of cleaning and disinfecting agents that are not on the Philips recommended lists?
- A3: Please share the recommended lists of cleaning and disinfecting agents from the Philips Instructions for use with the hospital infection control department. Inform healthcare providers that the use of agents not on the Philips recommended lists may cause discoloration or damage to the monitor housing and may lead to reduced product lifetime. For example, specific ingredients could cause cracks in surfaces. If you notice significant changes on your monitor housing after disinfection, see your service guide for troubleshooting information or contact your service personnel.
- Q4: What are your recommendations for cleaning and disinfecting single use only, or disposable, accessories?
- A4: Philips recommends that a single-patient-use product be discarded after each use and not be used on multiple patients. Philips has not analyzed the safety or effectiveness of reused Philips single-patient-use devices, and therefore cannot provide recommendations on such reuse

