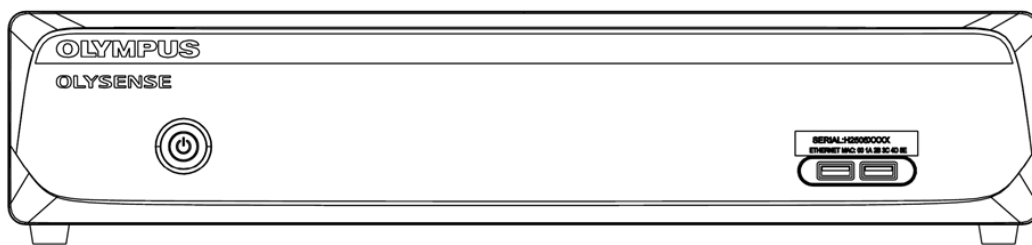




INSTRUCTIONS FOR USE

OLYSENSE Hub

IFU Revision 1.0 – 2025 August



REF

OS-HUB0001-G

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Please contact your Olympus representative in case you are interested in a printed version of this IFU.

For access to the e-IFU please visit: <https://www.onyxhealthcareusa.com/olysense-hub-ifu>

2. Acknowledgments

- Intel® Core i7 is registered trademarks of Intel® Corporation.
- IBM, PC/AT, PS/2 are trademarks of International Business Machines Corporation.
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- SiS is a trademark of Silicon Integrated Systems Corp.
- VIA is a trademark of VIA Technology, Inc.

All other product names or trademarks are properties of their respective owners.

3. Packing List

The PC Hardware which is contained in this package is manufactured by Onyx and identified on the type plate as Model ACCEL-VM300. It is branded and marketed as OLYSENSE Hub. For traceability, OLYSENSE Hub and Onyx VM300 refer to the same device.

Prior to installing your OLYSENSE Hub, please make sure the following items are in the package:

- Onyx VM300 / OLYSENSE Hub (PC)
- RJ-45 network isolator
- WiFi Antenna (2)

If any items are missing or damaged, please contact your local distributor or sales representative immediately. Please note that additional items beyond those specified in the packing list, such as adapters, cables, and accessories, may be included in the main package or an outer box.

4. Symbol Definitions

Symbol	Definition
	NOTE: Provides a comment that alerts the operator to particularly important information.
	CAUTION: Provides a notification that alerts the operator to the possibility of a problem with the device associated with its use or misuse. These types of problems may include device malfunction, device failure, and damage to the device or other property. The cautionary includes the precaution that should be taken to avoid the hazard.
	WARNING: Provides a notification that alerts the operator to the possibility of injury, serious adverse reactions or death associated with the use or misuse of device.
	The OLYSENSE Hub has been developed to be suitable for the UL60601-1 requirement
	Follow operating instructions
	Ground wire Protective Ground wire.
	Alternating current
	Equipotentiality To identify the terminals, when connected together, bring the various parts of an equipment or of a system to the same potential.
	Stand-by switch (PC power button)
I/O	Power Supply Switch (on/off)

5. Safety Information



Read these safety instructions carefully and keep this user's manual for later reference.

-  • **WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective ground.
-  • **CAUTION:** The OLYSENSE Hub is intended for use in highly sensitive medical environments. Access to these environments should be limited to individuals qualified and authorized by the healthcare facility. The device should be installed in a suitable and safe location to avoid unauthorized contact. The top cover of device is allowed to be opened by manufacturer-authorized personnel for professional service purposes only
-  • **CAUTION:** The OLYSENSE Hub should be installed and serviced only by qualified OLYMPUS personnel.
-  • **CAUTION:** All cautions and warnings on the equipment should be noted.
-  • **CAUTION:** Disconnect this equipment from any AC outlet before cleaning. Refer to section A.2 for proper use of cleaning solutions and reprocessing instructions.
-  • **CAUTION:** For pluggable equipment, the socket outlet must be installed near the equipment and must be easily accessible,
-  • **CAUTION:** Keep this equipment away from humidity.
-  • **CAUTION:** Keep all system components out of the reach of patients.
-  • **CAUTION:** Place this equipment on a reliable surface during installation. Dropping it or allowing it to fall could cause damage.
-  • **CAUTION:** The openings on the enclosure are for air convection, ensure that sufficient space is available around the device. Protect the equipment from overheating. **DO NOT COVER THE OPENINGS.**
-  • **CAUTION:** Make sure the voltage of the power source is correct before connecting the equipment to the power outlet.
-  • **CAUTION:** Ensure that all interconnecting cables, including the power cord, are well managed and positioned to minimize the risks of tripping persons, damaging or interfering with equipment, and damaging the cables themselves.
-  • **CAUTION:** If the equipment is not to be used for an extended time, unplug the power cord to disconnect it from the power source to avoid damage by transient over-voltage.
-  • **CAUTION:** Never pour liquid into any opening. This could cause fire or electrical shock. Do not store liquid on or near the equipment.
-  • **CAUTION:** To avoid the risk of electric shock, never open the equipment without the authorization of the manufacturer.
-  • **CAUTION:** Do not modify this equipment without authorization of the manufacturer.
-  • **CAUTION:** The OLYSENSE Hub system components are Magnetic Resonance Unsafe and shall not be used in MRI environments.
-  • **CAUTION:** If any of the following situations arise, have the equipment checked by service personnel:
 - The power cord or plug is damaged.
 - Liquid has penetrated the equipment.
 - The equipment has been exposed to moisture in excess of the exposure during normal cleaning according to the cleaning instructions.

-
- The equipment does not work well, or you cannot get it to work according to the user manual.
 - The equipment has been dropped and/or damaged.
 - The equipment has obvious signs of breakage.

- ⚠ • **CAUTION:** Do not leave this equipment in an environment where the storage temperature is below -20° c (-4°f) or above 60° c (140° f). It may damage the equipment.
- ⚠ • **CAUTION:** External equipment intended for connection to signal input/output or other connectors, shall comply with relevant UL / IEC standard (e.g. UL 62368/60950 for IT equipment, ANSI/AAMI ES 60601-1, and EN 60601-1-2:2015/A1:2021; IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1:2005+A1:2012+A2:2020; EN60601-1:2006+A1:2013+A2:2021+A13:2024).
- ⚠ • **CAUTION:** Any person who connects external equipment to signal input, signal output, or other connectors has formed a system and is therefore responsible for the system to comply with the standard IEC 60601-1, safety requirements for medical electrical systems.
- ⚠ • **CAUTION:** The OLYSENSE Hub is not a medical device providing therapeutic, diagnostic, or monitoring capabilities.
- ⚠ • **CAUTION:** The operator shall not touch any part of the and the patient at the same time.
- ⚠ • **CAUTION:** Please contact your assigned regional Olympus support representative to report any issues and to receive troubleshooting assistance.

6. Classification

- Degree of protection against electric shock: not classified
- Mode of operation: Continuous
- Type of protection against electric shock: Class I equipment
- No Applied Part, No AP/APG

7. FCC

Warning!  This device complies with Part 18 FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received including interference that may cause undesired operation.

8. UL Description



The OLYSENSE Hub is developed to be suitable for the Component Mark requirement:

Medical equipment with respect to electric shock, fire and mechanical hazards only in accordance with AAMI ES60601- 1:2005+AMD1:2012+AMD2:2021

9. General Information

9.1 Introduction

The OLYSENSE Hub is a medical grade, compact and slim general-use computer designed for computer-aided medical detection applications. To facilitate use of the applications, the OLYSENSE Hub is powered by an Intel Core i7 Processor, NVIDIA RTX 4000 Ada graphics card, and a configurable I/O capture card.

9.2 Specifications

Hardware Specifications

CPU	Intel® i7-13700TE 4.8GHz (TDP=35W)
Disk Drive Space	Main 2.5" 1TB Solid State Drive x 1
System Memory	2 x SO-DIMM DDR4 16GB (Total: 32GB)
Rear I/O	4 x USB 3.2 Type A Gen 2 (5V/900mA) 2 x USB 2.0 Type A 2 x RJ-45 2.5G LAN, 1 x RJ-45 isolate cable to achieve 2MOPP isolation 1 x HDMI 2.0b/ 2. x DP 1.4a/ 1 x VGA (on board) 2 x COM 1 x AC input 1 x Equipotentiality Pin Sound: 1 x Line-out 1 x Mic-in 2 x SMA WiFi Antenna Connector
Speaker (Optional)	2 x 5W Built-in Speaker
Security	TPM 2.0 onboard
Front I/O	1 x Power Button 2 x USB 3.0 (5V/900mA)
VGA	Up to 1920 x 1200 @60Hz
HDMI	Up to 4096 x 2160 @24Hz/2560 x 1600@60Hz, with Digital Audio
Display Port	Up to 4096 x 2160 @24Hz/3840 x 2160@60Hz, with Digital Audio
Expansion Slot	Capture card: 4x 12G SDI port (2 in / 2 out)
Graphic card	NVIDIA RTX 4000 Ada with 4 x DP 1.4a
Power Supply	100-240V~, 50-60Hz, 8-4A, 500W Medical ATX PSU

9.3 Mechanical Specifications

Construction	Metal chassis
Dimension	419.5 x 370.3 x 87 mm (without silicone feet) 419.5 x 370.3 x 94.8 mm (with silicone feet)
Carton Dimension	500 x 228 x 632 mm
Net Weight	8.87 kg Max.
Gross Weight	11 kg Max.
Packing Filler	PE foam

9.4 Environment Specifications

Operating Environment	0°C to 35°C (32 °F ~95°F) 30% ~ 75% @ 40°C, Non-Condensing 700~1060 hPa
Storage / Transport Environment	-20°C to 60°C (-4°F ~140°F) 10% ~ 90% @ 40°C, Non-Condensing 700~1060 hPa
EMI / Safety	CE: EMC: EN 60601-1-2:2015/A1:2021; IEC 60601-1-2:2014+AMD1:2020 RED: EN 300 328 V2.2.2; EN 301 893 V2.1.1; EN300 440 V2.2.1 EN303 687 V1.1.1 Safety: IEC 60601-1:2005+A1:2012+A2:2020; EN60601-1:2006+A1:2013+A2:2021+A13:2024 FCC: • EMI: Part 18 • RF: Part 15C, Part 15E UL: ANSI/AAMI ES60601-1:2005 & A1:2012 & A2:2021 (consolidated version) – revision date: 2022/02/01 CAN/CSA-C22.2 No. 60601-1:14 (IEC 60601-1:2005+A1:2012+A2:2020, MOD) (consolidated version) – revision date: 2022/July

9.5 Power Cord Specifications

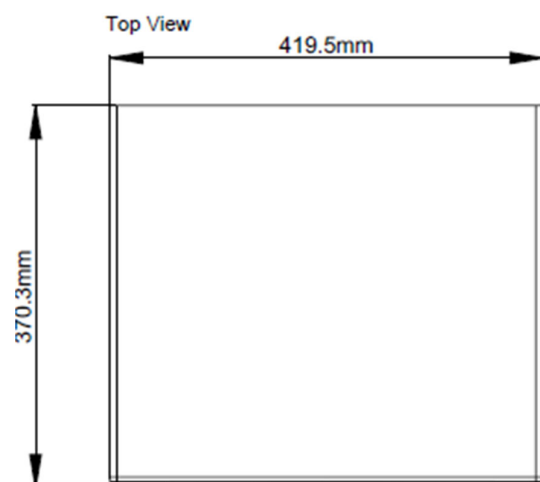
Ensure the power cord used with the OLYSENSE Hub matches the following specifications:

USA: Max 6ft(1.8m), 10A/125V min, Connectors: IEC 60320-C13 to Nema 5-15P, Cord: SJT or SVT, 18 AWG/3C min, UL 817, UL Listed, Hospital Grade.

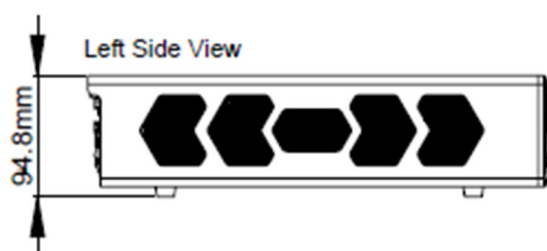
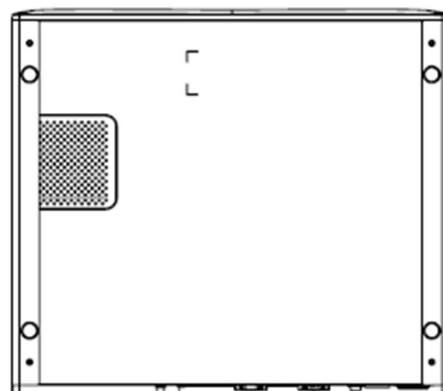
EU: Max 6ft(1.8m), 10A/250V min, Connectors: IEC 60320-C13 to Shuko, Cord: H05VV-F, 3G0.75 mm² min, CE Compliant.

UK: Max 6ft(1.8m), 10A/250V min, Connectors: IEC 60320-C13 to BS1363A, Cord: H05VV-F, 3G0.75 mm² min, CE or UKCA Compliant.

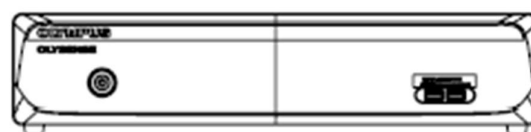
9.6 Dimensions



Bottom View



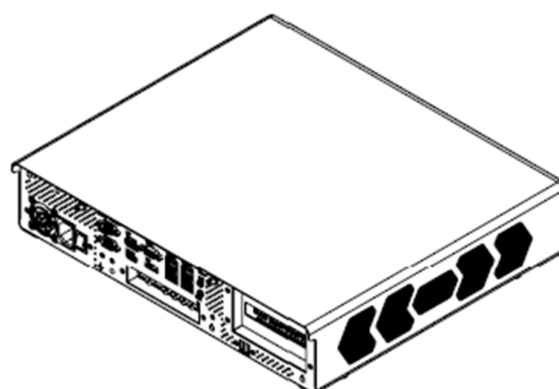
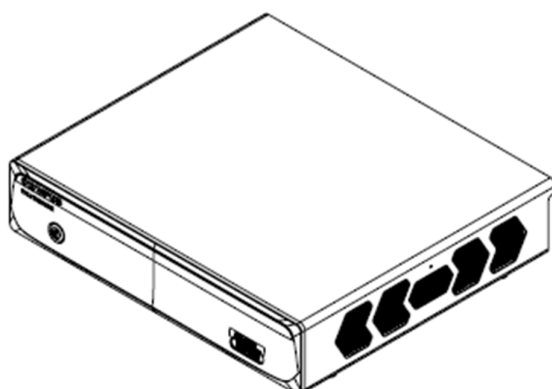
Front View



Right Side View



Back View



10. Hardware Introduction

10.1 Installation

The OLYSENSE Hub should be installed and configured only by Olympus personnel.

10.2 A Quick Tour of the OLYSENSE Hub

Before setting up the OLYSENSE Hub, take a moment to become familiar with the locations and purposes of the controls, connections, and ports illustrated in the figures below.

The OLYSENSE Hub should be placed upright with its feet resting on a level surface capable of supporting its weight.

The front side of the OLYSENSE Hub appears as shown in Figure 2.1.

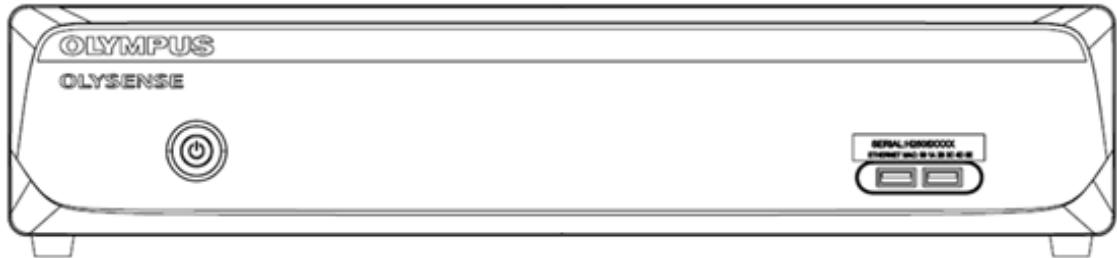


Figure 2.1: Front View of the OLYSENSE Hub

The rear side of the OLYSENSE Hub appears as shown in Figure 2.2.

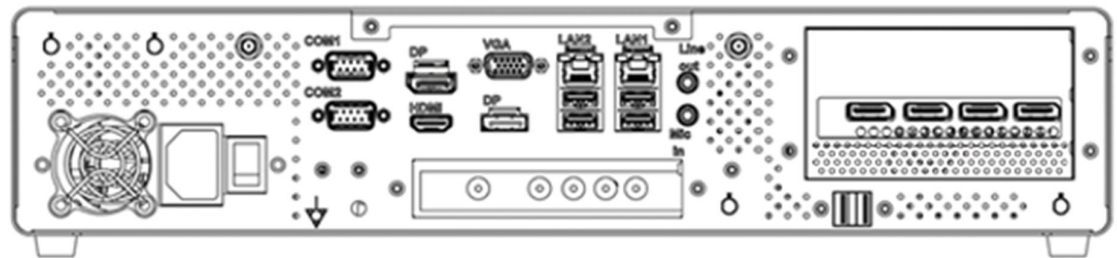


Figure 2.2: Rear view of the OLYSENSE Hub

10.3 Turn On the OLYSENSE Hub

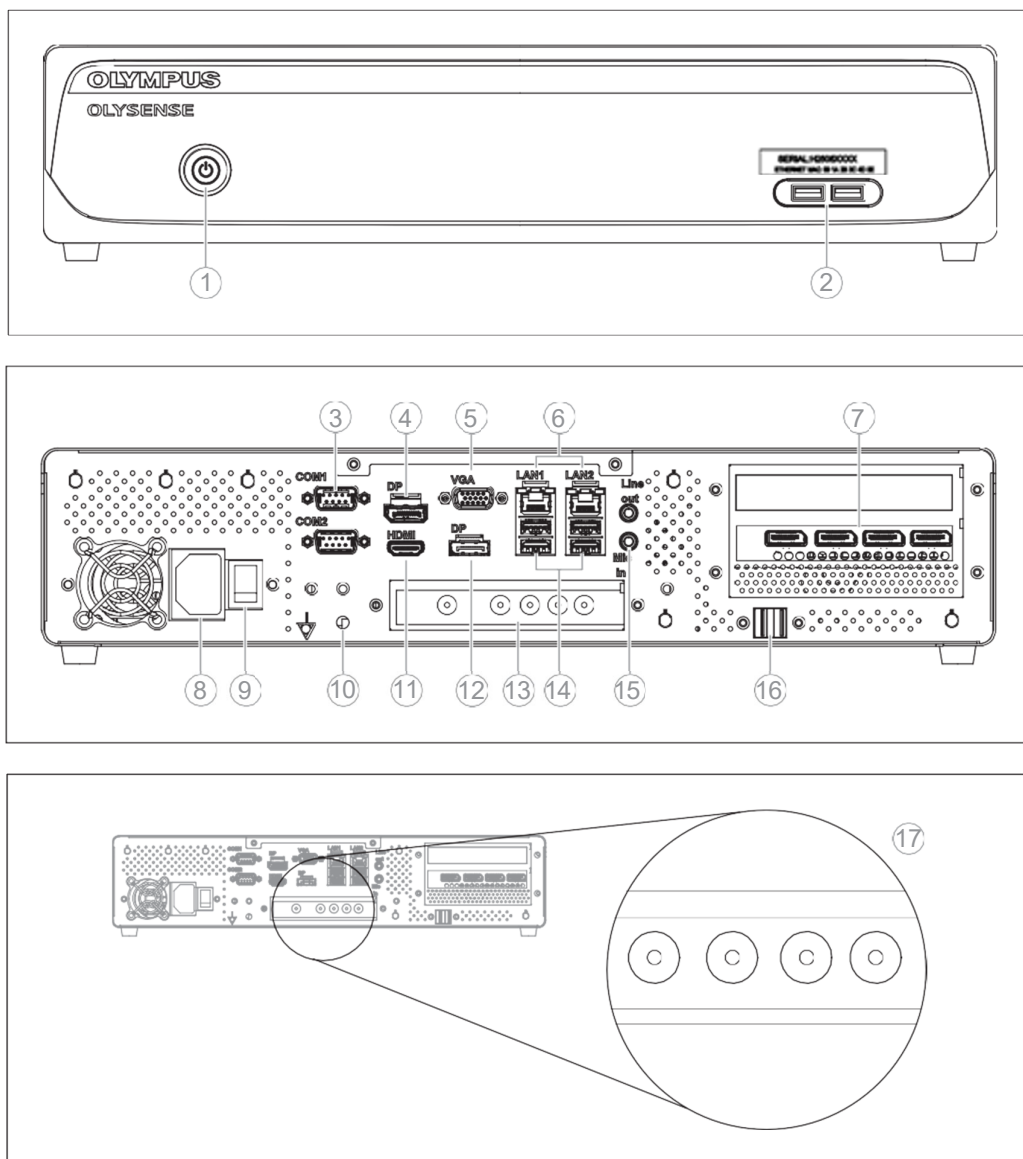
To turn on the OLYSENSE Hub, press the power button on the front of the OLYSENSE Hub. The LED indicator will illuminate in green.

10.4 Turn off the OLYSENSE Hub

Turning off the OLYSENSE Hub properly is important for system reliability.

To turn off the OLYSENSE Hub, quickly press and release the power button. The system will shut down and the LED indicator will turn off.

10.5 I/O Connectors



- | | |
|----------------------------------|---------------------------------|
| 1. Power Button | 10. Equipotential Terminal |
| 2. USB 3.0 x 2 | 11. HDMI x 1 |
| 3. COM Port x 2 | 12. DP x 1 |
| 4. DP x 1 | 13. Capture Card with SDI x 4 |
| 5. VGA x 1 | 14. USB 3.2 x 4 |
| 6. LAN x 2 | 15. Line Out x 1 and Mic In x 1 |
| 7. Graphics Card with DP1.4a x 4 | 16. USB 2.0 x 2 |
| 8. AC input | 17. SDI I/O x 4 |
| 9. Power Button | |

Appendix A Cleaning (Reprocessing) Instructions

A.1 General Cleaning Tips

Please read the following precautions before you begin to clean the computer. When you clean any single part or component for the computer, please read and understand the details below.

1. Turn the system off before you start to clean the unit or any components, and disconnect the power cord from the healthcare facility grade wall mains outlet.
2. Never spray or squirt the liquids directly onto any computer component. If you need to clean the device, please rub it with a piece of dry cloth.
3. Be cautious of small removable components when vacuuming around the device.
4. Never drop any components inside the computer.
5. Never get the circuit board damp or wet.
6. Be cautious of all kinds of cleaning solvents or chemicals when you use it for the sake of cleaning. Some individuals may be allergic to the ingredients.
7. Do not allow any food or drinks around the device.

A.2 Cleaning Warnings and Cautions



WARNING: When reprocessing the OLYSENSE Hub, follow the policies at your institution, national or local guidelines, and the chemical manufacturer's instructions.



WARNING: Insufficiently reprocessing this computer may pose an infection control risk to the patients and/or operators who touch it.

- Always wear appropriate personal protection equipment such as eyewear, a face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly.
- Blood, mucus, and other potentially infectious material adhering to the OLYSENSE Hub could pose an infection control risk.
- Use a disinfectant solution approved by your national or local regulatory agencies. Furthermore, disinfectant solution manufacturers should use antiseptic solution that is approved to be applied to medical products. Using an unauthorized disinfectant solution may result in insufficient disinfecting effect.



NOTE: Medical-grade 70% ethyl alcohol, 70% isopropyl alcohol, or not greater than 0.65% (6500ppm) sodium hypochlorite are the only recommended solutions for reprocessing the OLYSENSE Hub.)

- If patient debris directly or indirectly adhere to the outside of this instrument, disinfection must be performed within 1 hour of the patient procedure. Patient debris will begin to dry and solidify, hindering effective removal and reprocessing efficacy.



CAUTION: When patient debris enters a hole or gap of the device, DO NOT disinfect the unit, and contact Olympus directly.



CAUTION: Do not apply spray-type medical agents directly to the OLYSENSE Hub. Medical agents will get inside the connector sockets, causing malfunction of this computer.



CAUTION: Do not reprocess the I/O connectors and the AC mains power inlet. Reprocessing them can deform or corrode the contacts, which could damage the OLYSENSE Hub.



CAUTION: Do not soak the device in water, use an autoclave, or use gas sterilization to sterilize the OLYSENSE Hub. These methods will damage this instrument.



CAUTION: Clean and vacuum dust from the ventilation grilles using a vacuum cleaner, when necessary. Otherwise, the OLYSENSE Hub may break down and get damaged from overheating.

A.3 Detergent solution and disinfectant solution

Use a medical-grade neutral detergent solution and disinfectant solution (medical-grade 70% ethyl alcohol, 70% isopropyl alcohol or not greater than 0.65% (6500ppm) sodium hypochlorite).

Use the detergent solution and disinfectant solution cleared/approved by your national regulatory agency.

Follow the detergent solution and disinfectant solution manufacturer's instructions regarding concentration, drying, temperature, contact time, use life, and expiration date.

A.4 Signs of degradation from reprocessing

 **CAUTION:** Improper reprocessing may significantly reduce the service life of the OLYSENSE Hub. Always observe the manufacturer's instructions.

A.5 Preparing equipment for reprocessing

Equipment needed

The following equipment is prepared to perform the reprocessing steps described in this chapter.

Personal protective equipment (examples)



Eyewear



Face mask



**Moisture-resistant
clothing**



**Chemical-resistant
gloves^{*1}**

^{*1} Long sleeve gloves are recommended to prevent skin exposure.

Chemicals used for reprocessing

- Detergent solution and disinfectant solution (Refer to “Detergent solution and disinfectant solution”)

Other

- Clean lint-free cloths are recommended for reprocessing to prevent lint or cloth fibers from lodging or being trapped in the instrument's components. If gauze is used to reprocess the container, ensure that fibers do not get caught within on the instrument.

A.6 Reprocessing procedure

Reprocessing workflow for the OLYSENSE Hub

This section describes the workflow for reprocessing the OLYSENSE Hub.

1. Confirm the appearance of the OLYSENSE Hub.
2. If patient debris directly or indirectly adhere to the device, or if disinfection is necessary according to national, local, or facility standards, refer to the instructions in this document titled ‘Disinfection.’
3. If disinfection is not necessary, refer to the instructions in the document for “Cleaning.”

Disinfection



WARNING: Follow the usage (temperature, contact time, use life) and amount (concentration) provided by detergent solution manufacturer and disinfectant solution manufacturer. Failure to follow manufacturer's instructions may result in improper disinfection.



CAUTION: Wipe any remaining detergent solution and disinfectant solution from the unit according to the instructions of the detergent solution manufacturer or the disinfectant solution manufacturer. Failure to do so may adversely affect the human body or the device.

1. Turn OFF the OLYSENSE Hub and ensure the power cord is disconnected from the healthcare-facility grade wall mains outlet.
2. Prepare a lint-free cloth moistened with neutral detergent solution (Figure A1-1).



Figure A1-1

3. Wipe off all patient debris from the OLYSENSE Hub using the moistened lint-free cloth.
4. Prepare another lint-free cloth moistened with disinfectant solution (medical-grade 70% ethyl alcohol, 70% isopropyl alcohol or not greater than 0.65% (6500ppm) sodium hypochlorite) (Figure A1-2).



Figure A1-2

5. Disinfect the surfaces that previously contained patient debris (refer to Step 3) by wiping with the moistened lint-free cloth.

-
6. Ensure that the surfaces remain wet for the contact time instructed by the disinfectant solution manufacturer.
 7. If any surface of the OLYSENSE Hub remains wet, wipe it with a dry lint-free cloth and let it dry thoroughly.

Cleaning

1. Turn the OLYSENSE Hub OFF and disconnect the power cord from the healthcare facility grade wall mains outlet.
2. Wipe the device with a dry lint-free cloth or a lint-free cloth moistened with water until dust and dirt are removed.
3. If any surface of the OLYSENSE Hub remains wet, wipe it with a dry lint-free cloth and let it dry thoroughly.

Appendix B Scrap Computer Recycling

If the OLYSENSE Hub requires maintenance or is beyond repair, contact your local distributor or sales representative immediately.

If the OLYSENSE Hub is no longer useful, please contact your local distributor for assistance with disposal of the unit.



Follow local regulations for proper disposal of retired units.

Appendix C Distributed by

USA

Olympus America Inc.
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034-0610, U.S.A.
F +1 484 896 7128
T +1 484 896 5000
<https://medical.olympusamerica.com/>

UK

Olympus UK & Ireland
KeyMed House
Stock Road
SS2 5QH Southend-on-Sea
<https://www.olympus.co.uk/>

Europe

Olympus Europa SE & CO. KG
Wendenstraße 20, 20097 Hamburg, Germany
Postfach 10 49 08, 20034 Hamburg, Germany
F +40 23773 4656
T +40 23773 0
<http://www.olympus-europa.com>

Switzerland

Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
F +41 44 947 66 62
<http://www.olympus.ch>

Appendix D Legal Manufacturer

USA

Onyx Healthcare USA Inc.
324 W. Bluebridge Ave
Orange, CA 92865, U.S.A.
Office: +1 (714) 792-0774
FAX: +1 (714) 792-0481
<http://www.onyxhealthcareusa.com/>

Taiwan (Manufacture location)

Onyx Healthcare Inc.
4F., No. 135, Ln. 235, Baoqiao Rd. Xindian Dist.
New Taipei City, Taiwan
Office: +886 2 8919-2188
FAX: +886 2 8919-1699
<http://www.onyx-healthcare.com/>

PN: 200NOYP301

2025-08-18

OLYMPUS