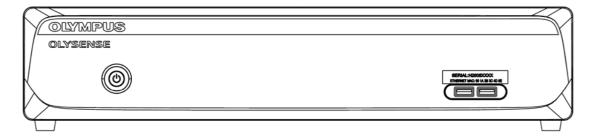
# **OLYMPUS**

## INSTRUCTIONS FOR USE

### **OLYSENSE** Hub

1.0 Ed 2025 August



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### 3. Packing List

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

- OLYSENSE Hub (PC)
- RJ-45 network isolator
- WiFi Antenna (2)
- Instructions for Use

\* Use power cord should follow then specification below:

Detachable power cord, using cable type SJT, SVT, or H05VV-F (or equivalent) rated for 125/250 V minimum, 18 AWG/3C minimum. Maximum length 15 FT (4.5M). One end shall terminate in a plug rated for 10 A minimum at 125 V or 250 V, grounding type, including but not limited to NEMA 5-15P, NEMA 6-15P, Schuko, BS1363A, or IEC 60320 C14. The other end shall terminate in an appliance coupler, such as IEC 60320 C13. Cords must be UL Listed, CE Compliant, or UKCA Compliant as applicable.

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. Safety Information

- 1. Read these safety instructions carefully.
- 2. Keep this user's manual for later reference.
- 3. Disconnect this equipment from any AC outlet before cleaning. Refer to section A.2 for proper use of cleaning solutions and reprocessing instructions.
- 4. For pluggable equipment, the power outlet must be installed near the equipment and must be easily accessible.



- 5. Keep this equipment away from humidity.
- 6. Put this equipment on a reliable surface during installation. Dropping it or allowing it to fall could cause damage.
- 7. The openings on the enclosure are for air convection. Protect the equipment from overheating. DO NOT COVER THE OPENINGS.
- 8. Make sure the voltage of the power source is correct before connecting the equipment to the power outlet.
- 9. AWARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective ground.
- Position the power cord so that people cannot step on it. Do not place anything over the power cord.
- 11. All cautions and warnings on the equipment should be noted.
- 12. If the equipment is not to be used for a long time, unplug the power cord to disconnect it from the power source to avoid damage by transient over-voltage.
- 13. Never pour any liquid into an opening. This could cause fire or electrical shock.
- 14. For safety reasons, never open the equipment without the authorization of the manufacturer.
- 15. Warning: Do not modify this equipment without authorization of the manufacturer.
- 16. If any of the following situations arise, get the equipment checked by service personnel:
  - a. The power cord or plug is damaged.
  - b. Liquid has penetrated into the equipment.
  - c. The equipment has been exposed to moisture in excess of the exposure during normal cleaning according to the cleaning instructions.
  - d. The equipment does not work well, or you cannot get it to work according to the user manual.
  - e. The equipment has been dropped and damaged.
  - f. The equipment has obvious signs of breakage.
- 17. DO NOT LEAVE THIS EQUIPMENT IN AN UNCONTROLLED ENVIRONMENT WHERE THE STORAGE TEMPERATURE IS BELOW -20° C (-4°F) OR ABOVE 60° C (140° F). IT MAY DAMAGE THE EQUIPMENT.
- 18. 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 [ADD EU and UK Standards]).
- 19. 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.
- 20. Warning: The device intends to be used in the highly sensitive medical environments. These environments should be prevented from access by general hospital staff, and 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.
- 21. The OLYSENSE Hub is not a medical device providing therapeutic, diagnostic, or monitoring capabilities..
- 22. Patient is not the intended operator, do not touch the device and patient at the same times.



### 5. Classification

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

### 6. FCC



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.



### 7. 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

### 8. Safety Symbol Description

The following safety symbols are the further explanations for your reference.

c <b>SN</b> °us	The OLYSENSE Hub is developed to be suitable for the UL60601-1 requirement
	Follow operating instructions.
	Ground wire Protective Ground wire.
$\sim$	Alternating current
4	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)



### 9. General Information

### 9.1 Introduction

The OLYSENSE Hub is a general-use, medical-grade computer intended to enable the use of software separately provided by OLYMPUS. To facilitate use of the software, the OLYSENSE Hub is powered by an Intel Core i7 Processor, a powerful 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" 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 foot)
	419.5 x 370.3 x 94.8 mm (with silicone foot)
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

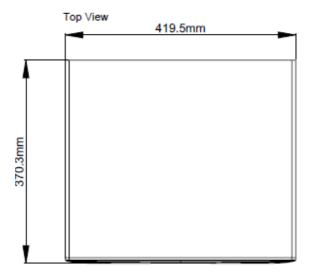
Operating	0°C to 35°C (32 °F ~95°F )
Environment	30% ~ 75% @ 40°C, Non-Condensing
	700~1060 hPa
Storage / Transport	-20°C to 60°C (-4°F ~140°F)
Environment	10% ~ 90% @ 40°C, Non-Condensing
	700~1060 hPa
EMI / Safety	CE:
	EMC: EN 60601-1-2:2015/A1:2021;IEC 60601-1-
	2:2014+AMD1:2020
	RED: EN 300 328 V2.2.2;EN 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
	• IXI . Fait 130, Fait 13L
	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

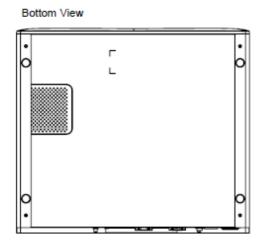
### 9.5 Power Cord Specifications

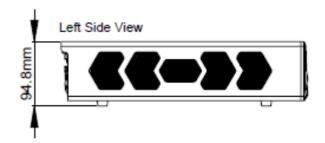
Ensure any power cords used with the OLYSENSE Hub match the following specifications:

- Max 6 ft (1.8 m), Connectors: IEC 60320 C13, IEC 60320 C14, 18 AWG/3C min, 10A/250V min, SJT or SVT and H05VV-F, UL Listed, CE Compliant, UKCA Compliant
- Max 15 ft (4.5m), Connectors: IEC 60320 C13, Nema 5-15P, 16 AWG/3C min, 10A/125V min, SJT or SVT, UL 817, UL Listed, Hospital Grade
- Max 15 ft (4.5m), Connectors: IEC 60320 C13, Shuko, 16 AWG/3C min, 10A/250V min, H05VV-F, LVD compliant, CE Compliant
- Max 15 ft (4.5m), Connectors: IEC 60320 C13, BS1363A, 16 AWG/3C min, 10A/250V min, H05VV-F, Fused, UKCA Compliant

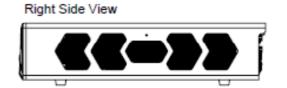
### 9.6 Dimensions



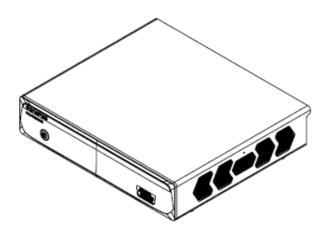


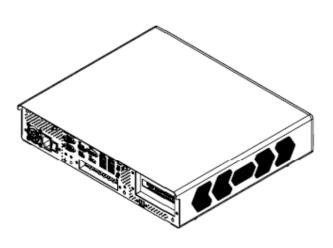












### 10. Hardware Introduction

### 10.1 Installation

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

### 10.2 System Servicing

### 10.3 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.

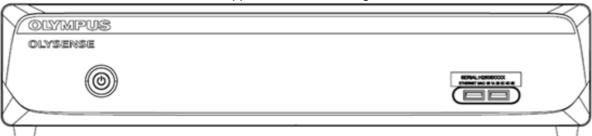


Figure 2.1: Front View of the OLYSENSE Hub

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

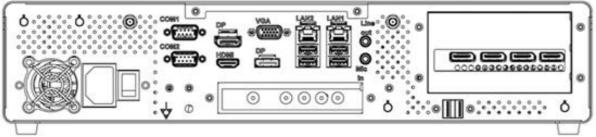


Figure 2.2: Rear view of the OLYSENSE Hub

### 10.4 Turn On the OLYSENSE Hub

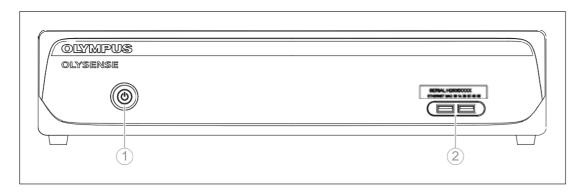
To turn on the OLYSENSE Hub, press the power button on the front of the OLYSENSE Hub. The LED indicator will illuminate in green.

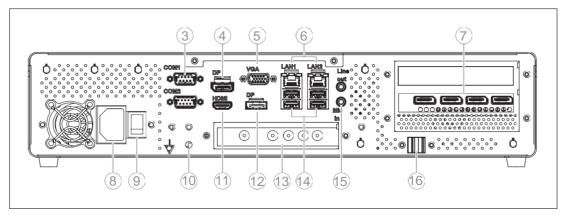
### 10.5 Turn off the OLYSENSE Hub

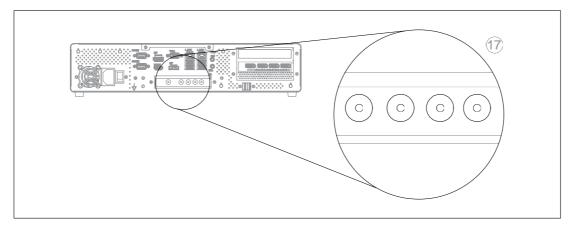
Turning off the OLYSENSE Hub properly is important for system reliability.

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

### 10.6 I/O Connectors







- 1. Power Button
- 2. USB 3.0 x 2
- 3. COM Port x 2
- 4. DP x 1
- 5. VGA x 1
- 6. LAN x 2
- 7. Graphics Card with DP1.4a x 4
- 8. AC input
- 9. Power Button

- 10. Equipotential Terminal
- 11. HDMI x 1
- 12. DP x 1
- 13. Capture Card with SDI x 4
- 14. USB 3.2 x 4
- 15. Line Out x 1 and Mic In x 1
- 16. USB 2.0 x 2
- 17. SDI I/O x 4

### 11. Distributed by

### Olympus America Inc.

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https://medical.olympusamerica.com/

### Olympus UK & Ireland

KeyMed House Stock Road SS2 5QH Southend-on-Sea https://www.olympus.co.uk/

#### Europe

### Olympus Europa SE & CO. KG

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### 12. Legal Manufacturer

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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/

## 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.
- 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, always wear appropriate personal protection equipment such as eyewear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. 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 that 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 this instrument, disinfection has to be performed within 1 hour after the patient procedure. Patient debris will begin to dry and solidify, hindering effective removal and reprocessing efficacy.

### **WARNING**

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

### CAUTION

- When patient debris enters a hole or gap of this computer, contact Olympus without disinfecting it. If you try to disinfect by force, the disinfectant solution will get inside this computer, causing fire and malfunction of this computer.
- 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.

#### NOTE

- 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.
- Do not soak in water, autoclave, or gas sterilize the OLYSENSE Hub. These methods will damage this instrument.
- 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).

#### NOTE

- 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. Avoid the following.

- Reprocessing without observing the instructions of the manufacturer.

### 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)







Face mask



Moisture-resistant clothing



Chemical-resistant gloves\*1

#### Chemicals used for reprocessing

 Detergent solution and disinfectant solution (Refer to "Detergent solution and disinfectant solution")

### Other

• Clean lint-free cloths. 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 on.

### A.6 Reprocessing procedure

### Reprocessing workflow for the OLYSENSE Hub

This section describes the workflow for reprocessing the OLYSENS Hub.

- 1. Confirm the appearance of the OLYSENSE Hub.
- 2. If patient debris directly or indirectly adheres to this computer, refer to the instructions in this document for "Disinfection". Otherwise, be sure to follow the next step.
- 3. If disinfection is necessary according to national, local, or facility standards, refer to the instructions in this document for "Disinfection". Otherwise, refer to the instructions in this document for "Cleaning".

#### Disinfection

<sup>\*1</sup> Long sleeve gloves are recommended to prevent skin exposure.

### 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 insufficient cleaning and disinfection effect.

### CAUTION

Wipe remaining detergent solution and disinfectant solution according to instructions of detergent solution manufacturer or disinfectant solution manufacturer. Failure to do so may adversely affect the human body or this computer.

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

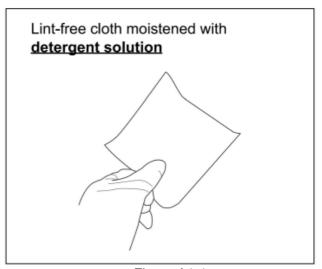


Figure A1-1

- 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).

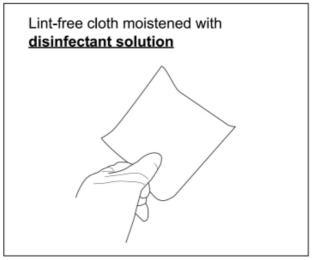


Figure A1-2

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 are completely wet for the contact time instructed by the disinfectant solution manufacture.
- 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 with a dry lint-free cloth or a lint-free cloth moistened with water until dust and dirt are removed.
- 3. If the surface of this instrument is 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 in disposing the unit.



Follow local regulations for proper disposal of retired units.

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