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User Manual | SnapshotGLO

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**General Instructions**

## Brand Names

The following are the Brand names owned by Adiuvo Diagnostics Pvt. Ltd. with respect to SnapshotGLO.

Type Reference: **SnapshotGLO**.

Model Number: **KB100**

FCC ID: **2BERUSNAP-V1**

## Publication Information

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## 1 Introduction

SnapshotGLO is a handheld rapid wound assessment device which is designed to help clinicians to:

- visualize the presence and distribution of potentially harmful bacteria present in the skin and wounds in the Realtime.
- Instantly track and record the dimensions of the region of interest, which includes the Length & Width.
- Critically record all image instances of patients for every visit to enable continuous
- monitoring of the region of interest

SnapshotGLO device is a handheld Point-of-care - Non-invasive device which is used at the time of delivering the healthcare service.

SnapshotGLO comprises of a high-resolution LCD display and touch screen with integrated microelectronic and optical components. The SnapshotGLO device uses its patented technology to enable multi-spectral imaging of the region of interest and processing the same to produce comprehensible reports, which will provide visual assessment of wounds for the clinicians

SnapshotGLO devices has the following two features:

- Bioburden imaging and visualization
- Wound imaging and wound analytics

The bioburden imager uses autofluorescence imaging combined with algorithms to infer and visualize regions of bioburden presence and detect bacteria in biofilms. In addition, the device also has a camera that captures the wound analytics, including wound dimensions, area & perimeter.

SnapshotGLO does not require any contrast reagents for the fluorescence imaging.

**Product:**

Name of the Product: **SnapshotGLO**

Model No: **KB100**

Generic name: **Autofluorescence detection device for general surgery and dermatological use**

**Regulatory Classification of the Device:**

The *SnapshotGLO* is a Class IIa medical device as per EU MDR 2017/745

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The *SnapshotGLO* is classified as class B, as per first schedule of part I, sub-paragraph (XIII) of Indian Medical device rules 2017.

The *SnapshotGLO* is classified as Autofluorescence detection device, 21 CFR 878.4550, Class II, QJF

## 2 Intended Use and Indication for Use

*The intended use of SnapshotGLO:*

Intended for surgical, trauma, wound care applications as an adjunct tool that uses autofluorescence to detect tissues or structures. This device is not intended to provide a diagnosis.

*The Indication for Use:*

*SnapshotGLO* is a handheld imaging tool that allows clinicians diagnosing and treating skin

wounds at the point of care,

- (i) View and digitally record images of a wound,
- (ii) Measure and digitally record the size of a wound, and
- (iii) View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light.

(v) Wound and bioburden progression documentation

The fluorescence image, when used in combination with clinical signs and symptoms, has been shown to increase the likelihood that clinicians can identify wounds containing high bacteria bioburden compared to clinical symptoms alone. *SnapshotGLO* should not be used to rule-out the presence of bacteria in a wound.

The *SnapshotGLO* does not diagnose or treat skin wounds

### Off-label Use

The *SnapshotGLO* device is intended only to be used through the *SnapshotGLO* app for the purpose of imaging and documentation. Using the device for any other purpose is considered off-label use.

*Intended medical indication:*

SnapshotGLO is intended to be used for patients with open wounds in upper torso and lower extremities of acute and chronic nature.

- Venous Ulcers
- Diabetic Foot Ulcers
- Burn Wounds
- Graft & Surgical Site Wounds
- Pressure Ulcers
- Bed Sores

Intended medical population:

SnapshotGLO is intended to be used in both male and female Patients with chronic and new foot ulcers with non-intact Skin (Scars, surgical site, skin tear, Stasis ulcer both arterial and venous).

Intended User:

The SnapshotGLO is intended to be used by trained health care professionals in wound care legally certified medical experts (such as a physician, nurse and therapist), healthcare personnel or a patient and / or caregiver under the guidance of qualified medical experts

Intended user environment:

The SnapshotGLO is intended to be used in the hospitals/ clinical settings or home healthcare environment. Avoid exposure to magnetic fields, electrostatic discharge, and thermal ignition sources during use of the device. And the Snapshot device requires the dark environment for imaging to avoid external light contamination.

### 3 Warnings, Cautions and Notes

The following symbols are used to describe serious and non-serious safety conditions of the device.

*Table 1 Warning, Caution and Notes*

Symbol	Symbol Name	Description
	<b>Warning</b>	Messages with this heading indicate serious adverse reactions, potential safety hazards, and limitations in use imposed by a condition labelled with a warning. The warning identifies steps that should be taken if the incident occurs.

	<b>Caution</b>	Messages with this heading indicate information regarding any special care to be exercised by the user and/or patient for the safe and effective use of the device. All caution statements should be followed to ensure data and device integrity.
	<b>Note</b>	Messages with this heading provide additional information that increase the user's understanding of the operation of the device.

### 3.1 General Warning Messages

*Table 2 General Warning Messages*

 <b>Warning</b>	 To avoid the risk of electric shock, SnapshotGLO equipment must only be connected to a supply main with protective earth.
	1. The use of an accessory or cable with the device other than those specified in this manual may result in increased emissions or decreased immunity of the device or improper report generation.
	2. The device comes fully assembled and ready for use. No modification of this equipment is allowed. Modification of the device will void the terms of the warranty.
	3. Do not attempt to insert any other USB cables other than specified in the user manual USB will not be recognized.
	4. Ensure to keep the device in its resting position, when not in use.
	5. The device is intended to be used in a hospital/clinic by trained health care professionals Legally certified medical experts (such as a physician, nurse and therapist), healthcare personnel or a patient and / or caregiver under the guidance of qualified medical experts Avoid exposure to magnetic fields, electrostatic discharge, and thermal ignition sources during use of the device.
	6. Do not charge or use the device in areas with potentially explosive atmospheres such as fuelling areas or in areas where the air contains chemicals or particles
	7. Do not point the optical unit directly into eyes
	8. The device is not suitable for use in the presence of flammable aesthetic mixtures with air, oxygen or nitrous oxide.
	9. Protect the device against dust and moisture by restoring the optical unit cap (when not in use) and storing it in the box (provided with the device) overnight or when not in use for prolonged periods of time.
	10. Avoid strong physical shocks and dropping.
	11. Any damage to the device (crack or other visible deformity) may affect the functional, intended use and/or safety of the device. Contact Adiuvo Diagnostics Pvt. Ltd. for guidance at <a href="mailto:contact@adiuvodiagnostics.com">contact@adiuvodiagnostics.com</a> , <a href="mailto:Support@adiuvodiagnostic.com">Support@adiuvodiagnostic.com</a>
	12. Do not soak or immerse the device in water or other liquids. Device is not water proof
	13. The limit of imaging wound should be approximately 12 cm sq. less than 12 cm imaging will result in erroneous results.
	14. Be aware of surroundings when operating the device in a dark environment. The environment should be safe to prevent tripping or bumping into any objects during imaging procedures.
	15. This device is not to be used in the vicinity of electrosurgery units because use may interrupt or interfere with the transmission of signals from the transmitter Do Not use the device while examining by MRI or CT, as the induced current may cause burn

	<p>16. The maintenance to the device or replacement of the battery can only be performed by qualified service personnel specified by manufacturer, dangers (such as over-temperature, fire or explosion) may occur when replacing the battery by the personnel not fully trained. Users are not permitted to maintain or refit the device by themselves.</p> <p>17. Do not use the device, when the charging status in display is less than 10% battery charge. Device will not allow to operate and will indicate in display "connect to the charger message" in the screen if the device is at 10% battery status until the device is connected to the charger.</p>
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## 3.2 General Caution Messages

*Table 3 General Caution Messages*

 <b>Caution</b>	<ol style="list-style-type: none"> <li>1. Keep the optical unit clean and avoid covering with your fingers, as this may affect illumination and image quality</li> <li>2. Do not image without using the SnapshotGLO Consumables to avoid light contamination</li> <li>3. Do not image the wound without cleaning the wound treated with antibiotic cream/disinfectant agents.</li> <li>4. Do not attempt to use the device while it is charging. The device will not function.</li> <li>5. Prior to charging the device, ensure the device Power Cable is undamaged before plugging into a wall outlet. Use of an extension cord or a power bank is discouraged.</li> <li>6. Use of controls, adjustments, or procedures other than those specified in this User Manual may result in erroneous results. Any controls or adjustments to the device should be carried out only through Adiuvo service personnel only, for servicing please contact <a href="mailto:contact@adiuvodiagnostics.com">contact@adiuvodiagnostics.com</a>, <a href="mailto:Support@adiuvodiagnostic.com">Support@adiuvodiagnostic.com</a></li> <li>7. Do not charge or use the device in areas with potentially explosive atmospheres such as fuelling areas or in areas where the air contains chemicals or particles</li> <li>8. The device is restricted to use by trained health care professionals &amp; caregivers only under the guidance of trained medical practitioners and should be protected from unauthorized use.</li> <li>9. The device may get warm after prolonged use. The device will shut down if temperature exceeds 46°C or 115°F</li> <li>10. Improper cleaning/disinfection of the device may result in distorted images</li> <li>11. Images/videos should be regularly downloaded and saved to avoid loss of patient information</li> <li>12. Do not perform any software updates on the device</li> <li>13. Handle the charging ports on the device with care. Do not push or pull hard the charging port header while inserting or removing the charging pin</li> <li>14. SnapshotGLO should not be used by individuals confirmed to be colour blind.</li> </ol>
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### 3.3 Risk of electrical shock:

Use only the AC cables plug & Adapter provided by the manufacturer the power

Supply requirement for the AC plug is 100–240V AC.



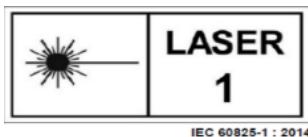
Do not overload power outlets. Plug the device into the appropriate voltage outlet



Do not plug or unplug the power cord into the electrical outlet with wet hands

### 3.4 Laser Safety:

1. In normal use, the laser containing sensors in SnapshotGLO is intended to be used for patients with open wounds in upper torso and lower extremities
2. As with the strong light source, do not shine the light source directly in to the eyes and do not stare into or at the light sources for extended periods.
3. SnapshotGLO employs FDA & IEC 60825 standard approved Low-level, Class 1 laser to assist with the wound measurements.
4. The device complies with FDA performance standard for laser products except for deviation pursuant to Laser notice No. 50



5. The sensor present in the SnapshotGLO device is a Class 1 laser product. The product fulfils the requirements of IEC 60825:2014 (safety of laser products) & complies with IEC 60601-2-22 standards.
6. In a medical context, this means that no special precautions are necessary providing users and patients have a normal blink reflex. User and patients are advised to wear safety glasses if they do not have a normal blink reflex.
7. There is no controls or adjustments on the sensors that are user accessible.
8. Never look directly at the transmitting laser through a magnifying device

### 3.5 Characteristics of emitting radiation:

Laser:	Low level, class 1, Safe beam laser
Emitted wavelength:	940nm
Standard compliance:	IEC 60825, IEC 60601-2-22, IEC 60601-2-57

Laser Radiation Output:

Ranging Sensor:

SnapshotGLO rapid wound assessment device uses a miniature pulsed laser-based range finder to determine the optimal distance between the device and the wound for superior image quality. The laser module in the range finder emits light at 940nm with max pulse width of 33ms with output power of 20mW max with laser output energy of  $2.66 \times 10^{-12}$ J which is invisible to the human eye. The laser complies with IEC 60601-2-22.

Depth Sensor:

SnapshotGLO rapid wound assessment device uses a miniature pulsed laser-based depth finder to determine the optimal depth of the wound for wound analysis. The laser module in the depth finder emits light at 940nm with max pulse width of 1,5ms with laser output energy  $5.05 \times 10^{-7}$ J which is invisible to the human eye. The laser complies with IEC 60601-2-22.

### 3.6 FCC Warning Statement:

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

#### FCC Radiation Exposure Statement

The antennas used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

This device complies with Part 15 of the 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.

FCC ID: 2BERUSNAP-V1

## 4 Symbols

This section describes the symbols used on the device.

### 4.1 Symbols Used –

#### Device Labelling

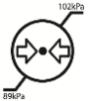
Table 4 Symbols Used – Device & Packaging Labelling

No.	Symbol	Source	Description
1) 1.		ISO 15223-1:2021	Maintain ambient temperature (10-30°C (50-86°F).)
2)		ISO 15223-1:2021	Non-sterile
3)		WEEE symbol, EU Directive 2012/19/EU	Dispose of the device in accordance with your country's legal requirements for the disposal of electrical and electronic waste
4)		ISO 15223-1:2021	Humidity range
5)		ISO 15223-1:2021	Maintain atmospheric pressure range
6)		ISO 15223-1:2021	Refer to instruction manual/booklet

7)		ISO 15223-1:2021	Consult instructions for use
8)		ISO 15223-1:2021	Manufacturer
9)		ISO 15223-1:2021	Date of Manufacturing
10)		ISO 15223-1:2021	Lot Number
11)		ISO 15223-1:2021	Serial Number
12)		ISO 15223-1:2021	Medical device
13)		IEC 60417-5010	Device- Power button
14)	<b>IP22</b>	IEC60529:1989/AMD2:2013/COR1:2019	Ingress Protection: Protected from touch by fingers and objects greater than 12 millimetres and protected from water spray less than 15 degrees from vertical.
15)		IEC 60417-5546	Battery status
16)		IEC 60417-5031	Charging port (Direct Current)
17)	<b>RX ONLY</b>	21 CFR 801.109	Prescription devices Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice

18)		SnapshotGLO symbol	MR unsafe
19)		SnapshotGLO symbol	Safety warning symbol to not look into the light source directly while operating
20)		IEC 60825-1	Class 1 laser product safe under all conditions of normal use.

### Packaging Labelling:

Symbol	Source	Description
	ISO 15223-1:2021	Maintain ambient temperature (10–30°C (50–86°F).)
	ISO 15223-1:2021	Non-sterile
	ISO 15223-1:2021	Fragile
	ISO 7000:2014	Face up
	WEEE symbol, EU Directive 2012/19/EU	Dispose of the device in accordance with your country's legal requirements for the disposal of electrical and electronic waste
	ISO 15223-1:2021	Humidity range
	ISO 15223-1:2021	Maintain atmospheric pressure range
	ISO 15223-1:2021	Keep away from rain

	ISO 15223-1:2021	Keep away from sunlight
	ISO 15223-1:2021	Refer to instruction manual/booklet
	ISO 15223-1:2021	Manufacturer
	ISO 15223-1:2021	Lot Number
	ISO 15223-1:2021	Serial Number
	ISO 15223-1:2021	Do not use if package is damaged
	ISO 15223-1:2021	Handle with Care
	ISO 15223-1:2021	Medical device

The *SnapshotGLO* is packaged after full assembly and is ready-to-use. The standard system configuration includes the following components.

Table 5 *SnapshotGLO* Package Contents

Number	Item	Description
1	<i>SnapshotGLO</i> imaging device	Device operates on Android OS
2	Power Cable and Adaptor	Cable to charge the Device
4	<i>GLODrape</i>	Sample hood for dark room setting imaging
5	Step-By-Step Guide (App and General)	Step-By-Step Guide for working on the device
6	<i>SnapshotGLO</i> Quick Guide	Quick Guide for usage



*SnapshotGLO* consumables are not part of the system configuration. They are the accessories that can be ordered separately.



For ordering and re-ordering, kindly mail Adiubo Diagnostics Pvt. Ltd. at [contact@adiuvodiagnostic.com](mailto:contact@adiuvodiagnostic.com), [Support@adiuvodiagnostic.com](mailto:Support@adiuvodiagnostic.com)

## 4.2 LED indicators provided in the SnapshotGLO device:

Number	LED Indicator	Status
1	Orange LED Indicator	Device charging status of Battery

## 4.3 Display Indicators for charging status in SnapshotGLO device:

Number	Display Indicators	Status
1	 <b>Green</b> Display power status Indicator-in Display	Device full charge status in display
2	 <b>Grey</b> Display charging status Indicator with lightning bolt	Device 75% charge status while charging in display
3	 <b>Grey</b> Display power status Indicator	Device 75% charge status in display
4	 <b>Yellow</b> Display charging status Indicator with lightning bolt.	Device 25% charge status while charging in display
5	 <b>Yellow</b> Display power status Indicator	Device 25% charge status in display
6	 <b>Red</b> Display Charging Indicator with lightning bolt	Device 15% charge status while charging in display
7	 <b>Red</b> Display power status Indicator	Device 15% charge status in display

## 5 SnapshotGLO Device Overview

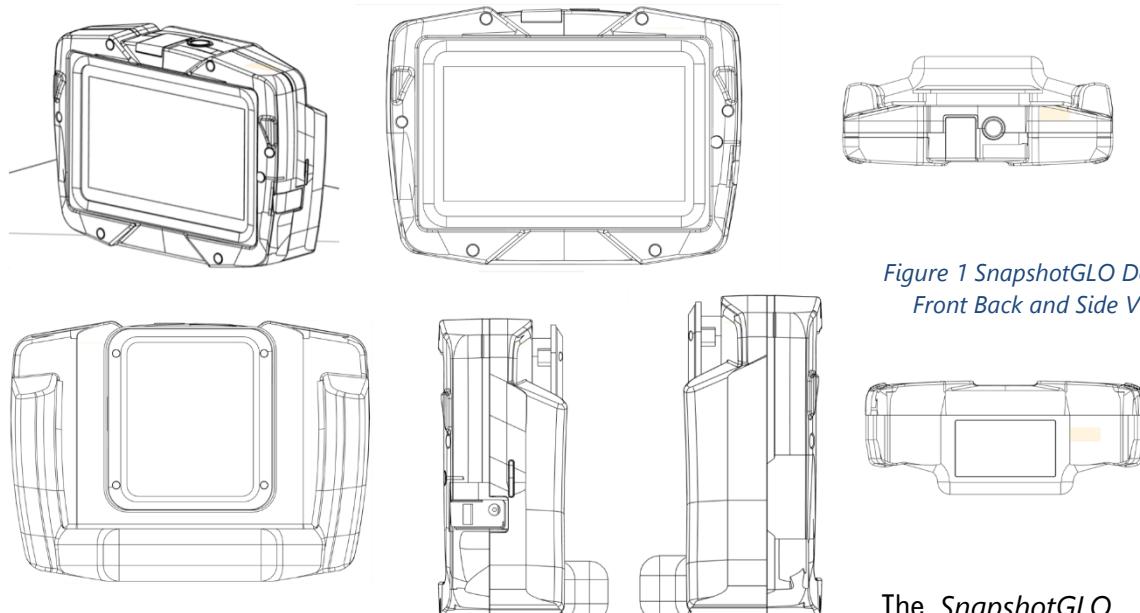


Figure 1 SnapshotGLO Device -  
Front Back and Side Views

device is designed to help clinicians to:

- Quickly visualize the presence and distribution of potentially harmful and clinically relevant bacteria on the skin and wounds in real-time
- Rapidly identify the bacteria if present on the skin and wound
- Effectively conduct clinical or surgical procedures like debridement and cleaning, including tissue sampling and swabbing with better accuracy and efficiency
- Instantly track and record the dimensions of the region of interest, which includes the length, width and depth
- Critically record all image instances of patients for every visit to enable continuous monitoring of the region of interest

The *SnapshotGLO* device is:

- *Handheld* - Device is used at the time delivering the healthcare service
- *Non-invasive* - Device does not come in direct contact with the patient at any point during the service however the accessories GLODrape will come in contact with patient while imaging (Note: Accessories GLODrape will have contact with patient and it is biocompatible with ISO 10993 standards)
- *Reagent-less* - No dyes or contrast are used on the patient

The *SnapshotGLO* comprises:

- 7-inch LCD touchscreen display
- Integrated optical and microelectronic components

The *SnapshotGLO* device uses its patented technology to enable multi-spectral imaging of the region of interest and processing the same to produce comprehensible reports, which will provide visual assessment of wounds for the clinicians.

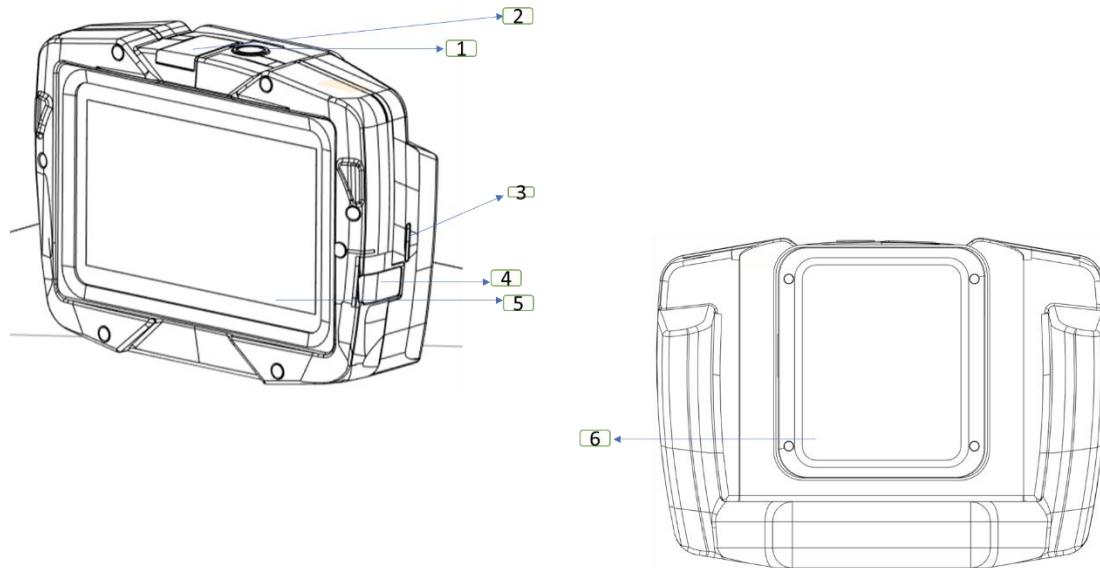


Figure 3 *SnapshotGLO - Components*

Table 6 *SnapshotGLO Components and Description*

Number	Name	Description
1	Power Button	To power ON/OFF the device display
2	Data Port	USB port for data transfer
3	Device Battery charging Indicator	Orange LED indicator for device battery charging status
4	Device Charging Port	USB port for charging the device
5	Display	Display unit for accessing <i>SnapshotGLO</i> app interface
6	Optics Frame	Protect the optics unit for the device

Table 7 *SnapshotGLO Accessories and Description*

Number	Name	Description
1	GLODrape	Consumable to isolate the wound being imaged from ambient light during imaging sessions.
2	Medical grade adapter	AC input: 100–240 V AC DC output: 12 V, up to 5A (up to 60 W)
3.	AC Cables	AC power cord terminating in a C13 termination that fits into the above medical grade adapter. The plug is of US/Canadian standard with a ground pin.
4	Type C USB cables	For data transfer

## 6 Device Cleaning & Disinfection instruction:

Clean and disinfect SnapshotGLO before and after it is used and between wound assessment procedures.

Failure to do so may result in cross-contamination, and patient or user exposure to bacterial contamination.

SnapshotGLO recommends using disinfecting wipes like cavi wipes for cleaning and disinfecting. The GLODrape accessories consumables is for single use only and must not be used more than once. The SnapshotGLO Adapter can be reused after being appropriately cleaned and disinfected.

 **Warning:** Do not reuse the GLODrapes. It is a single use only accessory.

**Pre-Clean the SnapshotGLO:** Wear impervious gloves such as latex gloves when handling disinfecting wipes. Use a disinfecting wipe to remove all debris from the SnapshotGLO by gently wiping ALL SIDES and surfaces including the Display Screen and optical components identified within the red perimeters in Figure 4.

**Disinfect the SnapshotGLO:** Use another disinfecting wipe to thoroughly wet ALL SIDES and surfaces (see Figure 4) of the SnapshotGLO, including the Display Screen and optical components identified within the red perimeters in Figure 4. Let the SnapshotGLO remain wet for 3 minutes at room temperature. Allow the SnapshotGLO to dry.

**Clean the SnapshotGLO:** Use a Lens Cleaning Towelette to thoroughly clean the Display Screen and optical components identified within the red perimeters in Figure 4. There should be no visible debris, fingerprints or material on the Display Screen or any of the optical components after cleaning. Allow the SnapshotGLO to dry. The SnapshotGLO is now clean, disinfected and ready for use

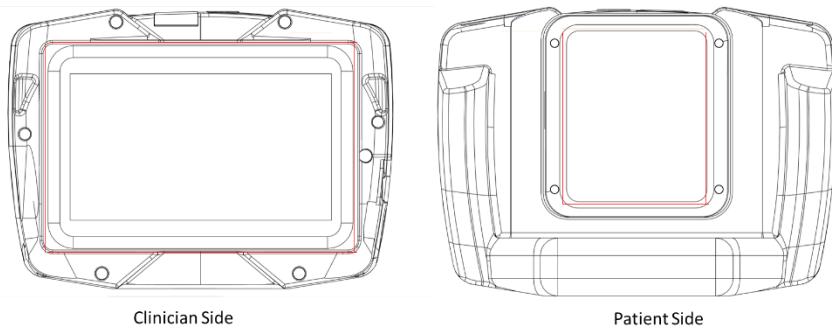


Figure 4 SnapshotGLO – Cleaning parts

## 7 Device technical specifications

### General

Weight	1-2 kg
Dimension	L-230mm x B-150mm x H-65mm
Power	100-240 V AC 50/60Hz
Battery	7.20 V Li-Ion battery, 6900mAh 49.68Wh (Rechargeable) - Not removable.

Specification for Operating Environment conditions:

Operating environment condition	Temperature	10° C to 30° C
	Relative humidity	10-70%
	Atmospheric Pressure:	89 - 102 kPa

Specification for Transport & Storage condition:

Transport & Storage environment	Temperature	-20° C to +50° C
	Relative humidity	10- 70 %
	Atmospheric Pressure:	89 - 102 kPa

## 8 Environmental Conditions That Affect Use

-  SnapshotGLO is not suitable for use in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxide.
-  Avoid exposure to magnetic fields, electrostatic discharge, and thermal ignition sources during use of the device.

### 8.1 Operating Temperature

The device is designed to operate in environment temperatures between 10-30°C (50-86°F).

### 8.2 Storage

Store SnapshotGLO at room temperature in a secure location between uses.

## 9 Maintenance of SnapshotGLO Device:

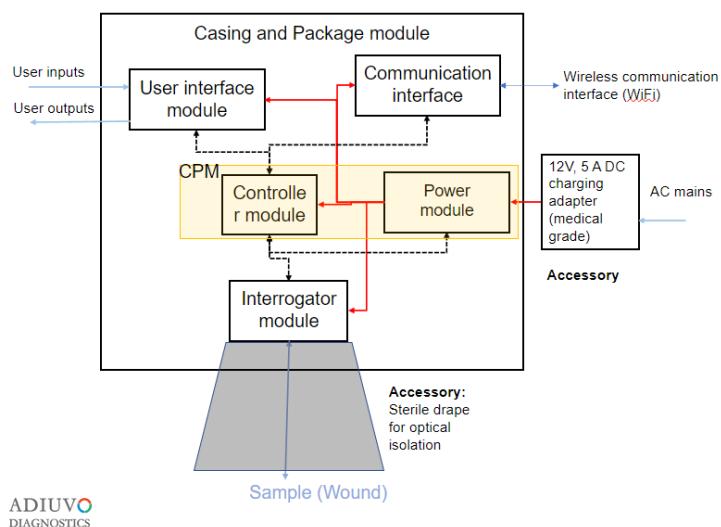
If the device imaging quality is distorted you may need to send the device to Adiuvo for servicing for details on service pricing, contact Adiuvo at [contact@adiuvodiagnostic.com](mailto:contact@adiuvodiagnostic.com) There are no maintenance or calibration activities that need to be performed. For more information and details on service pricing, contact Adiuvo at [contact@adiuvodiagnostic.com](mailto:contact@adiuvodiagnostic.com).

## 10 Appendix

1. User Manual - Snapshot App manual (with screenshots of App).
2. User Manual-User Quick start Operating Guide (with device operations screenshot)

## 11 Servicing Information: (For Adiuvo Service personnel's Purpose only)

- Remove the screws from the top enclosure with the help of tools.
- Place the display side of the casing at the table.
- Once after the screws are removed Slowly open the casings of optical unit side and place it on the side along with the connectors.



### Battery Check:

- Visually check any changes in battery shape and any liquid leakages from battery.
- Measure the 6900mAh 49.68Wh polymer battery charging and discharging voltage across the B+ and B- terminal using multimeter. Note the measured value.
- Ensure the Adapter rating 5V,2A

- While charging check the LED indication as Orange. Compare both the measured and Reference values.

#### **Battery Replacement:**

- Remove the SMB cable from the power board
- Remove the battery slowly from the foam tape
- Remove the old battery
- Place the new battery in the battery slot with the foam tape
- And connect the SMB cable to the power board.
- Ensure the SMB cable connected with power board.

Close the enclosure with the help of tools.