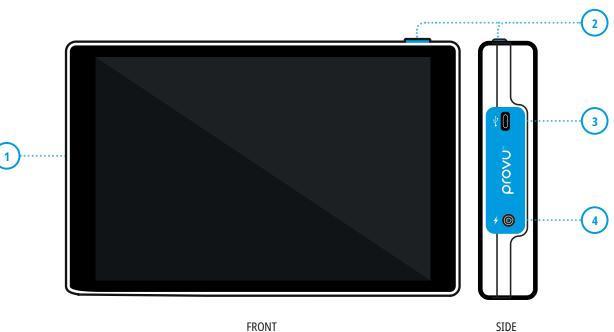
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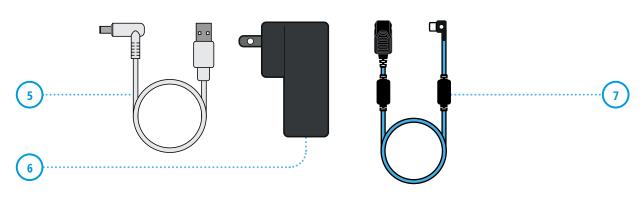


PROVU 8" DISPLAY

040-07-0080U



FRONT



- 1. ProVu 8" Display
- Power Button 2.
- Micro USB Port 3.
- 4. DC Power Port
- 5. DC USB Charging Cable
- 6. Wall Plug
- 7. Amplifier Cable



Technical Specifications

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DISPLAY		
RESOLUTION (PIXELS)	1280 x 800	
ORIENTATION	Landscape	
DISPLAY TYPE	8″	
START UP TIME (FROM STANDBY)	2 seconds	
START UP TIME (FROM BOOT MODE)	20 seconds	
SOFTWARE VERSION	Refer to device screen while charging	
CONNECTIONS		
USB CONNECTION	Micro USB	
POWER CONNECTION	DC Power	
STORAGE AND TRANSPORTATION		
TEMPERATURE	10°C TO 40°C (50°F TO 104°F)	
RELATIVE HUMIDITY	≤85%, non-condensing	
ATMOSPHERIC PRESSURE	700 to 1060 hPa	
OPERATING CONDITIONS		
TEMPERATURE	20°C +/- 10°C	
RELATIVE HUMIDITY	≤85%, non-condensing	
ATMOSPHERIC PRESSURE	700 to 1060 hPa	
DISPLAY ELECTRICAL POWER RATING		
POWER INPUT	Input: 5.0V 1.5A	
BATTERY TYPE	3.7V, 5000 mAh, Lithium-ion	
TYPICAL BATTERY RUN TIME	\approx 3.5 hours (of continuous use)	
TYPICAL BATTERY CHARGE TIME	pprox 3 hours (from 0 to 90% charge)	
WALL PLUG ELECTRICAL POWER RATING		
INPUT	100-240V AC - 0.5A 50-60Hz	
OUTPUT	Max 5.2V DC 3.0A	
DIMENSIONS		
WIDTH X HEIGHT X THICKNESS	205mm x 130mm x 25mm	
WEIGHT	396g	
PLUG		
PLUG TYPE	110-120V with NEMA 5-15P 3 Pin Plug	

Intended Use

The ProVu 8" Display is a digital display intended to show live images from the ProVu Video Laryngoscope (VL) via a micro-USB connection, as an aid to intubation for hospital use.

Product Description

The ProVu 8" Display is a non-sterile, reusable digital display intended to show live images from the ProVu Video Laryngoscope.

When connected to the ProVu device, a live video is shown on the display, which can be used to further aid intubation of the patient.

The display can be recharged with the ProVu charging cable or micro USB cable and, when fully charged, will provide up to 3.5 hours of continuous use.

Flexicare does not recommend the modification of the display. Any attempts to do so, will result in the failure of the display and voids warranty.

Precautions

- Ensure there is adequate room for easy operation.
- Inspect the ProVu 8" Display and all accessories for damage prior to each use. Do not use if it appears damaged.
- Charge the Display fully before use. For shipping requirements, ProVu 8" Displays are shipped with zero charge.
- Before charging, ensure that all components are completely dry, including the micro USB port.
 If using the Display Pole Stand, slide the Display securely onto the connector of the articulating
- arm, ensuring it is fully seated.
 If using the ProVu Display Table Stand, slide the Display securely onto the connector, ensuring
- If using the Provu Display lable stand, slide the Display securely onto the connector, ensurin it is fully seated.
- Always place the Display Table Stand on a stable, flat surface.

Warnings & Cautions

- ProVu 8" Display and Accessories should only be used by trained personnel.
- Do not use within Magnetic Resonance Imaging (MR/MRI) environments or with other high interference sources.
- Do not sterilize the device.
- The use of devices and other accessories which are not approved by Flexicare may result in suboptimal performance and place the patient at risk.
- The ProVu 8" Display is designed to fit on either the Display Pole Stand or the Display Table Stand.
 Use of another device may result in damage and/or loss of function to the ProVu 8" Display.
- The ProVu 8" Display should only be used with the ProVu VL and ProVu accessories.
 - Always disconnect the ProVu 8" Display from the charging cable before cleaning.
- Ensure the voltage recommendations of the Display are compatible with power supplies.
- Do not clean the Display or Display accessories using any abrasive agents or mineral acids.
- Do not use sterilants with caustic ingredients, such as surgical scrub solutions, peroxide solutions, bleaches, or povidone-iodine solutions.
- Do not disassemble device.
- Inadequate battery levels may result in sudden failure without warning. Check sufficient battery level before use.
- Do not modify the device.
- Device is not servicable.
- The battery is not removable. Do not open or remove battery. Warranty void if opened.
- Do not attempt maintenance of the device during use.
- Do not submerge.
- If the display screen does not illuminate from "sleep mode", it is likely the battery needs to be charged or the device needs to be reset. Follow Troubleshooting steps below for proper steps.

Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State of the user and/or patient.

Setting Up the ProVu Stands

Refer to instructions supplied with the ProVu Pole Stand (IP0000-030) or ProVu Display Table Stand (IP0000-021).

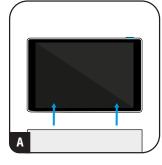
Charging

- 1. Connect the ProVu 8" Display to the DC charging cable, connected either to the plug socket on the Display Pole Stand or directly to an outlet.
- 2. When connected and turned on, an indication of charge is shown on the screen. If this screen does not display, check the security of the connections.
- 3. When fully charged, the Display will provide up to 3.5 hours of continuous use.
- For optimal performance, keep the Display connected to the charger while in use. If this is not suitable, re-charge between uses or when prompted on screen.

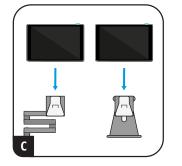
Using with ProVu VL

- 1. For more detailed instructions on the use of ProVu VL, refer to ProVu VL instructions (IP0000-018) supplied with the ProVu VL.
- Secure the ProVu 8" Display either on the ProVu Pole Stand or the Display Table Stand, according to user preference.
- 3. Press and hold the Power Button for 3 seconds. If charge capacity is more than 5%, a blue screen with a connection prompt image should appear.
- If charge capacity is 5% or less, a blue screen with the battery icon with strike out will appear. Please connect to charger; the Display can be charged while simultaneously in use with a ProVu VL.
- 5. Use currently accepted medical techniques to choose the correct size of ProVu VL blade.
- Securely connect the ProVu 8" Display to the ProVu VL, by connecting the elbow of the Amplifier Cable to the Display. Then connect the other end of the cable, to the USB connector on the ProVu VL.
- 7. Observe the Display screen to verify that a live image is being received from the ProVu VL.
- If no image is seen, briefly press the Power Button, a live image should be seen after 2 seconds.
- 9. Once a live image is seen, the device is ready to be used.
- 10. To put the ProVu 8" Display into standby mode, press the Power Button once quickly and the screen will turn black.
- To wake up from standby mode, press the Power Button once quickly and the screen image will resume.
- 12. To turn off the ProVu 8" Display, press and hold down the Power Button for 3 seconds and the screen will turn black.

Setting Up the ProVu 8" Display



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Connecting to ProVu VL





ProVu Software

The ProVu 8" Display has several on-screen prompts to assist use.



Software Version Software version is displayed in the bottom of the display when connected to power.



Connect Display Connect ProVu 8" Display to view camera image.



Error 1 Software error or crash. Reset ProVu 8" Display unit by holding Power Button for 5 seconds or more.

ProVu Battery Indicator



Display is Charging ProVu 8" Display battery is charging. Percentage charge is indicated in the circle.



Display Connected ProVu 8" Display is connected and camera image is loading.



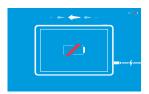
Error 2 Camera error or crash. Replace ProVu device.



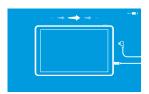
Charged ProVu 8" Display is fully charged.



Turn Off If Power Button is held for 3 seconds or more, this screen will show while the display shuts down.



Charge Display Display has insufficient battery. Please charge via the DC Charger or micro USB cable.



Disconnect Display If camera image fails to load, disconnect the ProVu 8" Display.

During use, the battery indicator appears on screen to show battery power remaining. The icon will change to flash on and off when battery charge is less than 20%. When the battery charge is 5% or less, the Charge Display screen will be shown. Please charge ProVu 8" Display.







Troubleshooting

No live image is seen			
POSSIBLE EXPLANATION	ACTION NEEDED		
ProVu 8" Display needs to be charged	Charge display via the DC Charger or micro USB cable. Note that the display can be charged while in use.		
ProVu 8" Display may be in sleep mode	Press the Power Button once to wake.		
ProVu 8" Display is damaged	Replace the ProVu 8" Display with a new device.		
ProVu 8" Display may be turned off	Press and hold the Power Button for 3 seconds.		
ProVu Amplifier Cable is damaged	Replace the ProVu Amplifier Cable.		
Incorrect connection to ProVu 8" Display and/or Amplifier Cable	Remove and reconnect the ProVu 8" Display to the device via the micro USB port as shown in the instructions for use section.		
ProVu device may be damaged	Replace with a new ProVu device.		
PROBLEM			
Low image quality			
POSSIBLE EXPLANATION	ACTION NEEDED		
Incorrect connection to ProVu 8" Display and/or Amplifier Cable	Remove and reconnect the ProVu 8" Display to the device via the micro USB port as shown in the instructions for use section.		
	the device via the micro USB port as shown in		
Amplifier Cable	the device via the micro USB port as shown in the instructions for use section.		
Amplifier Cable ProVu Amplifier Cable is damaged	the device via the micro USB port as shown in the instructions for use section. Replace the ProVu Amplifier Cable.		
Amplifier Cable ProVu Amplifier Cable is damaged Dirty screen	the device via the micro USB port as shown in the instructions for use section. Replace the ProVu Amplifier Cable. Wipe with an IPA cloth.		
Amplifier Cable ProVu Amplifier Cable is damaged Dirty screen Damp screen	the device via the micro USB port as shown in the instructions for use section. Replace the ProVu Amplifier Cable. Wipe with an IPA cloth. Wipe with a dry cloth. Clean camera lens with clean microfiber towel		
Amplifier Cable ProVu Amplifier Cable is damaged Dirty screen Damp screen Camera lens may have secretions on it	the device via the micro USB port as shown in the instructions for use section. Replace the ProVu Amplifier Cable. Wipe with an IPA cloth. Wipe with a dry cloth. Clean camera lens with clean microfiber towel or replace ProVu device.		

	POSSIBLE EXPLANATION	ACTION NEEDED
Software has malfunctioned	Software has malfunctioned	Hold down the Power Button for 5 seconds.
	Then wait for 10 seconds for software to reboot.	

List of Accessories

- Cables & Mounting Accessories
- Charging Cable -
- **Amplifier Cable**
- ProVu Pole Stand
- ProVu Display Table Stand

Symbols Glossary

After Use

- Disconnect the ProVu 8" Display from the power supply. 1.
- Disconnect the ProVu from the ProVu 8" Display, and from the Amplifier Cable. 2.
- 3 After use, dispose of all single-use components in accordance with local policies and / or as advised by your local healthcare provider.
- Clean and dry the ProVu 8" Display and Amplifier Cable referring to the cleaning instructions. 4.

ProVu 8" Display is suitable for cleaning or disinfection. Cleaning or disinfection should be carried out according to local hospital policies and cleaning/disinfector manufacturer's instructions.

Cleaning

- Wear gloves throughout the cleaning procedure. 1.
- After each use, clean the exterior of the ProVu 8" Display using a standard germicidal wipe 2. with at least 55% IPA (e.g. Super Sani-Cloth® Germicidal Disposable Wipe or equivalent).
- 3. Inspect the ProVu 8" Display and reusable accessories for contamination. If any is present repeat steps 1 & 2.
- Once the ProVu 8" Display and reusable accessories are free from contaminates, dry with a 4. clean, dry cloth.
- Check display for damage. If display does not function, refer to troubleshooting steps. 5.

Disinfection

Cleaning or disinfection may be done for the ProVu Display and reusable accessories. Cleaning or disinfection should be carried out according to local hospital policies and cleaning/disinfector manufacturer's instructions.

- ProVu 8" Display and reusable accessories disinfection should be carried out according to 1. local hospital policies and disinfector manufacturer's instructions and are compatible with the following solutions:
 - Chlorine or Bleach Wipes (Containing ≥ 5400ppm Sodium Hyperchlorite; e.g. Sani-Cloth® Chlor/Sani-Cloth® Bleach or equivalent).
- Clinell Universal Wipes (2 quaternary ammonium compounds and 1 polymeric biguanide). 2 Ensure that the device to be disinfected is free from any visible contaminants before
- disinfection. 3. Dry with a clean, dry cloth.
- Once dry, it is recommended that the display be placed on charge until next use.. 4.

Warranty Statement

Flexicare Medical Limited warrants that the product purchased meets the labelled specifications of the product and will be free from defects in materials and workmanship that occur within one (1) year from the date of purchase.

This warranty does not cover damage caused by:

- Handling during shipping.
- Use or maintenance contrary to labelling and instructions, including but not limited to incorrect disassembly, reprocessing and reassembly.
- Alteration or repair by anyone not authorized by Flexicare Medical Limited.

Abuse, Misuse or Accidental Damage

If a product covered by this warranty is determined to be defective materials, components, or workmanship, and the warrant claim is made within the warranty period described above, Flexicare Medical Limited will, at its discretion, repair or replace the defective product free of charge.

Written authorization must be obtained from Flexicare Medical Limited to return the product prior to sending it with postage paid to Flexicare Medical Limited's designated agent.

This warranty is in lieu of all other warranties, expressed or implied, including but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Flexicare Medical Limited's obligation under this warranty is limited to repair or replacement of products containing a defect.

Flexicare Medical Limited is not responsible for any indirect or consequential damages resulting from a product defect covered by the warranty.

This warranty shall be governed by and construed in accordance with Flexicare Medical Limited's Terms and Conditions

CE REF Rx Only SN Product Conforms Refer to Instruction Caution: US Federal Law Restricts this device Do Not Use Type BF Applied Class II Keep Away Catalog Number Serial Number with Directive Manufacturer Manufacturer Date Caution Manual/Booklet to sale by, or on the order of, a physician. Blade to Oper Part Equipment From Sunlight 93/42/EEC MADE IN: (⇔•⇔ 6 Atmospheric Pressure Alternating Current Direct Current DC Jack Polarity Separate Humidity USB/Amplifier Country of origin Temperature Keep Dry USB/Micro USB DC Power Port Recycle Collection Center-Positive Limit Limit Cable Box **Flexicare Medical Limited** Distributed by Flexicare, Inc. 15281 Barranca Pkwy, Unit D, Irvine, CA 92618

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