

CE **provu**<sup>®</sup>

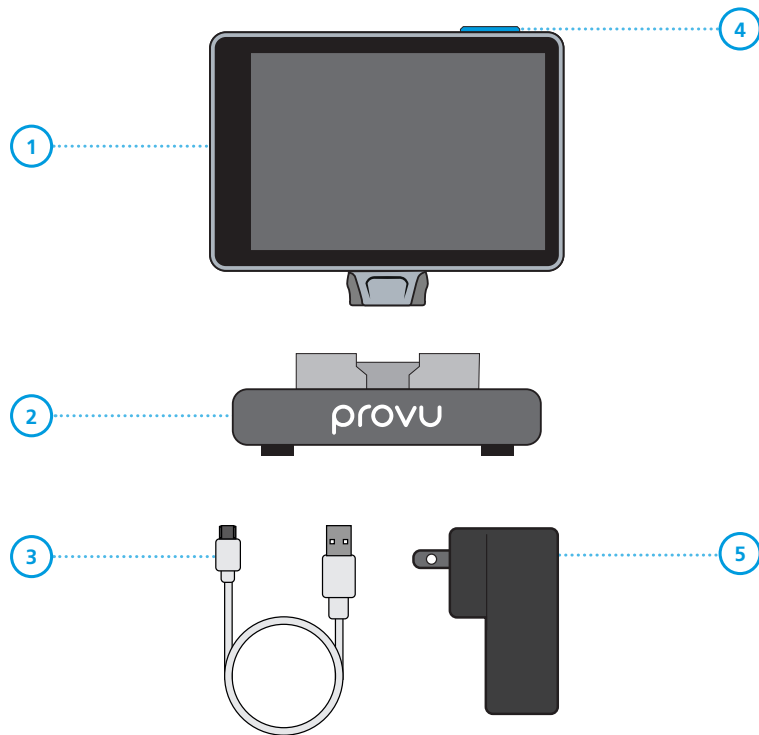


**PROVU 3.5" DISPLAY**

REF No. 040-07-0035U

**flexicare**<sup>®</sup>  
TOTAL QUALITY - TOTAL CARE

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#### PRODUCT KEY

1. Display
2. Charging Dock
3. USB Charging Cable
4. Power Button
5. Wall Plug

## Technical Specifications

DISPLAY ELECTRICAL POWER RATING	
POWER INPUT	Input: 5.0V --- 1.2A
BATTERY TYPE	3.7V, 1500mAh, Lithium-ion
TYPICAL BATTERY RUN TIME	Minimum of 60 minutes
TYPICAL BATTERY CHARGE TIME	90 minutes – 2 hours (from zero charge)
TYPICAL STANDBY TIME	Up to 48 hours
WALL PLUG ELECTRICAL POWER RATING	
INPUT	100-240V AC - 0.5A 50-60Hz
OUTPUT	Max 5.2V DC --- 1.2A
DIMENSIONS	
WIDTH X HEIGHT X THICKNESS	69mm x 89mm x 15mm
WEIGHT	90g
DISPLAY	
RESOLUTION (PIXELS)	480 x 320
ORIENTATION	Landscape
DISPLAY TYPE	3.5"
START UP TIME (FROM STANDBY)	2 seconds
START UP TIME (FROM BOOT MODE)	20 seconds
SOFTWARE VERSION	Refer to display screen while charging
IP RATING	IP64

CONNECTIONS	
USB CONNECTION	Micro USB
STORAGE AND TRANSPORTATION	
STORAGE TEMPERATURE	10°C to 40°C (50°F to 104°F)
TRANSPORT 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 ± 10°C
RELATIVE HUMIDITY	≤85%, non-condensing
ATMOSPHERIC PRESSURE	700 to 1060 hPa

## Intended Use

The ProVu 3.5" Display is a digital display intended to show live images from the ProVu Video Laryngoscope (VL) only, via a micro-USB connection, as an aid to intubation for the hospital use.

## Product Description

The ProVu 3.5" 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 on the charging dock provided or with the ProVu charging cable and, when fully charged, will provide a minimum of 1 hour of continuous use.

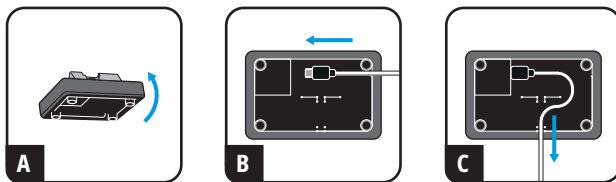
Flexicare does not recommend the modification of the display. Any attempts to do so, will result in the failure of the display and voids warranty.

## Precautions

- Ensure that you always have easy access to the power cord, plug or adapter to disconnect this display from the power.
- Inspect the ProVu 3.5" Display and all accessories for damage prior to each use. Do not use if it appears damaged.
- Charge the ProVu 3.5" Display fully before use. For shipping requirements, ProVu 3.5" Displays are shipped with zero charge.
- Before charging, ensure that all components are completely dry, including the micro-USB port.
- If not connected to ProVu VL and left unmoved for more than 5 minutes, the ProVu 3.5" Display will switch into "sleep mode" and the screen will go blank. This is normal. To reverse this, briefly press the Power Button. A prompt image should be seen after 2 seconds.

## Warnings & Cautions

- ProVu 3.5" Display and Accessories should only be used by trained medical professionals.
- Do not use within Magnetic Resonance Imaging (MR/MRI) environments or with other high interference sources.
- Do not sterilize the display.
- The use of devices and other accessories which are not approved by Flexicare may place the patient at risk. It is recommended that the ProVu 3.5" Display should only be used with the ProVu Video Laryngoscope and ProVu accessories.
- Always disconnect from ProVu 3.5" Display from the charging dock before cleaning.
- Ensure the voltage recommendations of the display wall plug 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.
- Inadequate battery levels may result in sudden failure without warning. Check sufficient battery level before use.
- Do not disassemble display.
- Do not modify the display.
- Battery is non-replaceable and non-removable.
- There are no user serviceable parts in the device. Any faulty device should be replaced or returned within warranty to the manufacturer.
- Do not attempt to charge while battery is in use.
- 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.

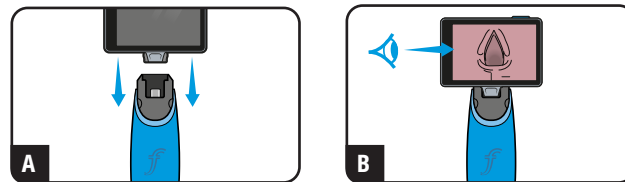


### Setting up the Charging Dock

1. Remove all components from the box.
2. Connect the USB cable to the charging dock.
3. Wrap the cable around the device in the dedicated path on the underside of the charging dock, leaving enough free cable outside the charging dock, to be able to reach the mains power.
4. Using the plug adaptor provided, plug into mains power source.
5. The charging dock is now ready to use.

### Charging

1. Connect the ProVu 3.5" Display to the charging dock or directly into the USB cable, if not using the charging dock.
2. Press the Power Button for 3 seconds.
3. After 3 seconds, an indication of charge is shown on the screen. If this screen does not display, check the security of the connections.
4. When fully charged, the display will provide a minimum of 1 hour of continuous use.
5. For optimal performance, re-charge after every use.



### Using with ProVu VL

For more detailed instructions on the use of the ProVu VL, refer to the ProVu VL instructions (IP0000- 018) supplied with the handles and blades.

1. Use currently accepted medical techniques to choose the correct size of ProVu VL blade.
2. Securely connect the ProVu VL handle and blade to the ProVu VL 3.5" Display (Fig. A).
3. Observe the Display screen to verify that a live image is being received from the ProVu VL blade (Fig. B).
4. If no image is seen, briefly press the power button, a live image should be seen after 2 seconds.
5. Observe the display screen to verify that a live image is being received from the ProVu VL blade.
6. Once a live image is seen, the device is ready to be used.
7. If necessary, when space is restricted, the display can be tilted, in order to show optimum view.

### After Use

1. Disconnect the ProVu VL handle and blade from the ProVu 3.5" Display.
2. Dispose of all single-use components in accordance with local policies and / or as advised by your local healthcare provider.
3. Clean and dry the ProVu 3.5" Display referring to the cleaning instructions.
4. Place the ProVu 3.5" Display onto the charging dock, when not in use.

## Device Disposal

When the ProVu 3.5" Display has reached the end of its product life, it should be disposed of in accordance to procedures set out in local guidelines.

ProVu 3.5" Display is suitable for cleaning or disinfection. Cleaning or disinfection should be carried out according to local hospital policies and cleaning/disinfectant manufacturer's instructions.

## Cleaning

1. Wear gloves throughout the cleaning procedure.
2. After each use, clean the exterior of the ProVu 3.5" Display using a standard germicidal wipe with at least 55% IPA (e.g. Super Sani-Cloth® Germicidal Disposable Wipe or equivalent).
3. Inspect the ProVu 3.5" Display and reusable accessories for contamination. If any is present repeat steps 1 & 2.
4. Once the ProVu 3.5" Display and reusable accessories are free from contaminants, dry with a clean, dry cloth.
5. Check display for damage. If display does not function, refer to troubleshooting steps.

## 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/disinfectant manufacturer's instructions.

1. ProVu 3.5" Display and reusable accessories disinfection should be carried out according to local hospital policies and disinfectant manufacturer's instructions and are compatible with the following solutions:
  - Chlorine or Bleach Wipes (Containing  $\geq 5400$ ppm Sodium Hypochlorite; 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.
4. Once dry, it is recommended that the display be placed on charge until next use.

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.

## 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 labeling and instructions, including but not limited to incorrect disassembly, reprocessing and reassembly.
- Modification 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 authorisation 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

## Troubleshooting

PROBLEM	
No live image is seen	
POSSIBLE EXPLANATION	ACTION NEEDED
Incorrect connection to ProVu 3.5" Display	Remove and reconnect the ProVu 3.5" Display to the handle and blade via the micro-USB ports as shown in the instructions for use section.
ProVu 3.5" Display needs to be charged	Charge display via the dock or USB cable. Note that the display cannot be charged while in use.
Display may be in sleep mode	Briefly press the power button, a live image should be seen after 2 seconds.
ProVu VL may be damaged	Replace with a new ProVu VL handle and blade. This is not a serviceable device.
ProVu 3.5" Display is damaged	Replace the ProVu VL Display with a new display.
PROBLEM	
Low Image Quality	
POSSIBLE EXPLANATION	ACTION NEEDED
Incorrect connection to ProVu 3.5" Display	Remove and reconnect the ProVu 3.5" Display to the device via the micro-USB ports as shown in the instructions for use section.
Dirty screen	Wipe with an IPA cloth.
Damp screen	Wipe with a dry cloth.
Camera lens may have secretions on it	Clean Camera lens with a clean microfiber towel or replace ProVu device.
Illumination failure	Replace with a new ProVu device.
Incorrectly inserted cable	Ensure all connections are secure.

PROBLEM	
Error screen is shown	
POSSIBLE EXPLANATION	ACTION NEEDED
Software has malfunctioned	Hold down the Power Button for 5 seconds to power off. Release power button. Press power button for 3 seconds to power on.



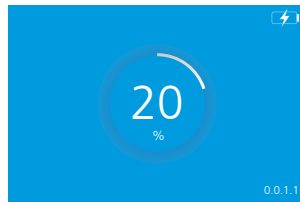
## Software

The ProVu 3.5" Display has several on-screen prompts to assist use.



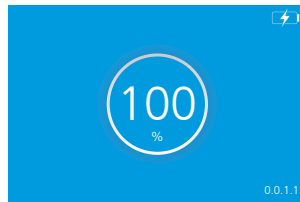
### Software Version

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



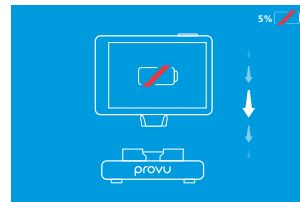
### Display is Charging

ProVu 3.5" Display battery is charging. Percentage charge is indicated in the circle.



### Charged

ProVu 3.5" Display is fully charged.



### Charge Display

ProVu 3.5" Display has insufficient battery. Please charge via USB or charging dock.



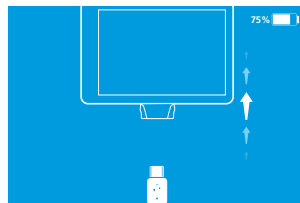
### Connect Display

Connect ProVu 3.5" Display to ProVu device to view camera image



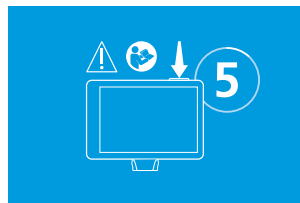
### Display Connected

ProVu 3.5" Display is connected and camera image is loading.



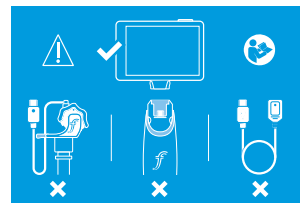
### Disconnect Display

If camera image fails to load, disconnect the ProVu 3.5" Display.



### Error 1

Software error or crash. Hold the power button down for 5 seconds. Release power button. Press power button for 3 seconds to power on.



### Error 2

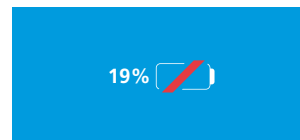
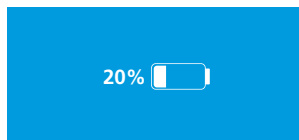
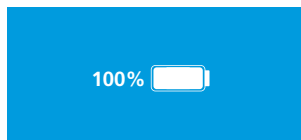
Camera error or crash. Replace ProVu device.

## Battery Indicator

During use, the battery indicator appears on screen to show battery power display 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 3.5" Display via USB or charging dock.



## Symbols Glossary



Catalogue Number



Serial Number



Product Conforms with Directive 93/42/EEC



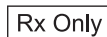
Refer to Instruction Manual/Booklet



Manufacturer



Caution



Caution: US Federal Law Restricts this device to sale by, or on the order of, a physician.



Do Not Use Blade to Open



Type BF Applied Part



Class II Equipment



Keep Away From Sunlight

MADE IN:

Country of origin



Keep Dry



Recycle



Separate Collection



Alternating Current



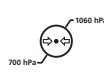
Direct Current



Temperature Limit



Humidity Limitation



Atmospheric Pressure Limitation



IP64



USB/Micro-USB



USB/Amplifier Cable Box



Date of Manufacture





**Flexicare Medical Limited**

Cynon Valley Business Park, Mountain Ash, CF45 4ER, UK.

☎ +44 (0)1443 474647

☎ +44 (0)1443 474222

@ enquiries@flexicare.com

🌐 www.flexicare.com

**Distributed by Flexicare, Inc.**

15281 Barranca Pkwy, Unit D, Irvine, CA 92618

☎ 949-450-9999

☎ 949-450-9902

@ inquiries@flexicare.com

🌐 www.flexicare.com

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