



Instructions For Use
























PROTECTSCOPE

DESCRIPTION – PROTECT VIDEO LARYNGOSCOPE

The **Protectscope** is a **video laryngoscope system** comprising a one piece blade and handle (Shell) available in various styles and sizes, an **HD Endoscope Camera** and a **bespoke Smartphone** with an installed **App** to display the camera video images. The blade is intended to be inserted into the oral cavity to manipulate the tongue and prevent obstruction of the oropharynx, allowing the Camera a clear view of the vocal cords which is displayed on the Smartphone to assist with the insertion of an endotracheal [ET] tube. The Shell is a **single use device**. The Smartphone, Phone Case and HD Endoscope Camera system are a **reusable device**.




























The **HD Endoscope Camera** with integrated LED light is installed at the distal end of the blade and connects to the **dedicated Smartphone** mounted on the handle of the **Shell**. The Smartphone is supplied with installed software (**Protectscope App**) and is fitted in a protective **Phone Case**. The Smartphone powers and receives video images from the **Camera**, displaying them to the user, but no clinical decisions or suggestions are made by the **Smartphone** or the **Protectscope App**.

WARNINGS: These indicate that injury, death, or other serious adverse reactions may result from use or misuse of the device.

	This product must only be used by qualified, trained medical personnel familiar with the Protectscope and the instructions for use.
	No attempt should be made to process, sterilise or reuse the single use handpiece (Shell) – due to potential for cross contamination.
	If the Protectscope is suspected of contacting Creutzfeldt-Jakob Disease (CJD) or variants, then no element of the Protectscope system (Camera/Smartphone) should be reused.
	Whilst still connected with the USB cable the Smartphone and Camera should be manually cleaned with sterile wipes in accordance with these instructions and local policy. The Smartphone and Camera should be handled with appropriate care before and after cleaning and MUST NOT be reused without appropriate disinfection.
	The user must prepare contingency plans in the event of difficult or emergency intubations.
	The user must confirm the Protectscope Camera light is illuminated before commencing clinical procedures.
	Do not use the Protectscope in strong magnetic fields such as MRI environments.
	The Protectscope Smartphone does not include a SIM card as it is not to be used as a mobile communications device.
	No part of the Protectscope laryngoscopy system (Smartphone, Camera and USB connector) contains user serviceable parts. No attempt should be made to open the Smartphone, Camera or USB Connector and doing so invalidates their use.
	Only the supplied power supply (Charger) for the Smartphone should be used. The Charger MUST NOT be used in a medical environment.
	The Protectscope Smartphone shall not be connected to a network, WIFI or otherwise except for the express purpose of installing its operating App from https://sanitas.uk/protectscope
	Protectscope should not come into contact with other electrical equipment during use.
	Protectscope should be removed if a defibrillator is applied.
	Direct contact with electrocautery and other electrosurgical devices may cause damage to the Protectscope.
	Protectscope should not be used with flammable anaesthetics.
	Protectscope should not be used in an oxygen rich environment, defined as a) greater than 25 % for ambient pressures up to 110 kPa; or b) the partial pressure of oxygen is greater than 27,5 kPa at ambient pressures exceeding 110 kPa.
	No data should be downloaded from the Protectscope Smartphone element.
	WARNING – No modification of this equipment is allowed.
	The Protectscope Shell, Camera and Smartphone should only be used together. No other equipment should be connected to any element of the Protectscope system. All parts are suitable for use in a Patient Environment.
	The Smartphone should ONLY be used when fitted with the Phone Case (supplied).
	Do not expose the Protectscope to electrostatic discharge.
	Do not use the Protectscope to take measurements. Images are for indication use only.
	Do not touch the Smartphone USB port and the patient at the same time.
	Do not drop the Protectscope system – as damage may occur! Do not use if any element of the Protectscope system is damaged.

For any specific information not contained in these Instructions for Use please contact Sanitas Healthcare Ltd using the contact details at the end of this document.

SYMBOL DEFINITIONS

	Warning		Catalogue Number
	Manufacturer		Batch Number
	Date of Manufacture		Made from Recycled material
	Not supplied Sterile		Conforms to applicable UK regulations
	Read Instructions before Use		Conforms to applicable EU regulations
	Do not reuse		Complies with Federal Communications Commission requirements
	Does not contain Latex		Contains no Restricted Hazardous substances
	Prescription only		Avoid listening at high volume levels for long periods
	Do not use if packaging is damaged		Recyclable
	Type B applied part		Must be disposed of as electrical equipment waste (WEEE)
	Use, Transport, and Storage temperature limits		Does not contain a SIM card
	Use, Transport, and Storage pressure limits		Use, Transport, and Storage humidity limits
	Duty Cycle		Refer to instruction manual
	IP rating		Use by Date

INDICATIONS FOR USE

The Protect video laryngoscope provides a direct and indirect view of the larynx to enable oral tracheal intubation by qualified medical personnel in a professional healthcare environment. It is intended to be used by trained and appropriately qualified individuals to gain a view of the vocal cords during medical procedures, typically laryngoscopy. The Protect video laryngoscope is a handheld device designed for single non-continuous use.

CONTRAINDICATIONS

There are no known specific contraindications for the Protect video laryngoscope, but the device may be contraindicated for specific patients if laryngoscopy in general is contraindicated in the opinion of a suitably qualified medical professional.

NOTICE TO USERS

Sanitas Healthcare recommends that all users read and understand these Instructions for Use before using the device with patients. The Protect video laryngoscope should not be used in domestic or non-medical settings or by users without medical qualifications recognised as appropriate within their jurisdiction.

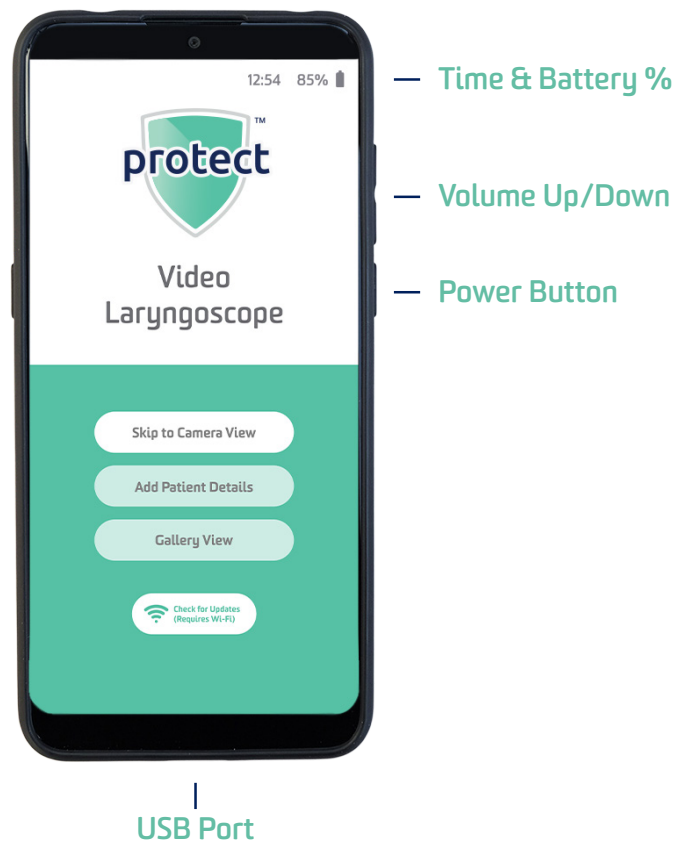
Inexperienced users should be trained in both video laryngoscopy and correct use of the Protectscope system, using a medical mannequin or similar approved technique, before using the device with patients.

Any serious incident that occurs in relation to the use or misuse of the device should be reported immediately to Sanitas Healthcare using the contact details at the end of these Instructions for Use.

PRE-USE CHECKS

The Protectscope components are supplied separately:

1. Protectscope Shell – Integrated handle and blade, supplied in two halves in various styles and sizes.
2. Smartphone with phone cover, charger and charging cable.
3. HD Endoscope Camera with integrated USB cable.



Ensure the packaging of the single use Shell is not damaged prior to opening. Do not use if the packaging or Shell is damaged.

Switch the Smartphone on by depressing the Power Button, as indicated, for approximately 4 seconds.

Confirm the Smartphone battery is **CHARGED TO A MINIMUM OF 50%**. If not the battery icon will turn **red** and the Smartphone should not be used with patients until it has been recharged. This should be done via the mains charger and USB charging cable supplied with the Smartphone.

Connect the Camera USB to the Smartphone port and confirm the camera light is illuminated. This represents the Essential Performance for the device.

Confirm the Protectscope App is running by pressing the 'Skip to Camera View' button and observing the image from the Camera. (If not present, please see the **Troubleshooting** section).

After this check, the camera should be disconnected from the phone prior to assembly into the Protectscope Shell.

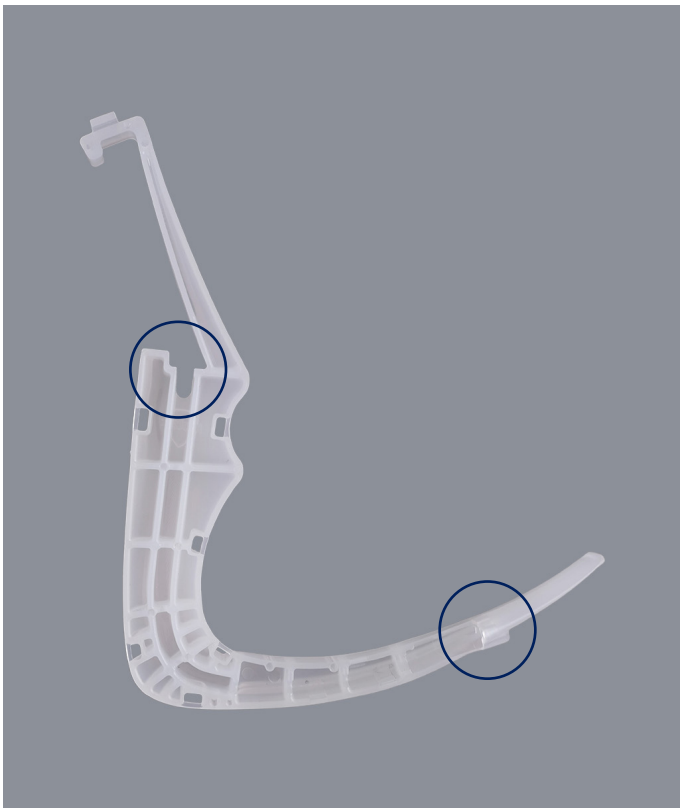
USING THE PROTECTSCOPE SYSTEM

The appropriate Shell for the patient should be selected by a medically qualified Healthcare Professional.

The options available are:

- Macintosh, Size 4 Blade (4)
- Macintosh, Size 3 Blade (3)
- J Blade – For difficult airways (J)
- Macintosh, Size 2 Blade (2)
- Macintosh, Size 1 Blade (1)

Remove the appropriate Shell from the packaging. Identify the left-hand half of the Protectscope Shell – assessed with the phone holder pointing upwards, blade pointing away from the user. The left-hand half also features the cable exit channel visible above the hand grip and the Camera location keyhole near the tip of the blade.



Left-hand half
(showing cable exit and Camera keyhole)



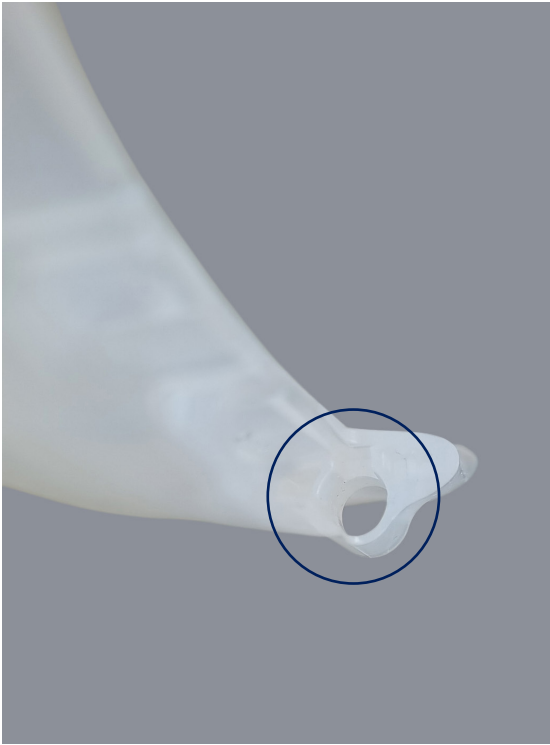
Right-hand half

Insert the Camera barrel into the location 'keyhole' near the tip of the left-hand half of the Protectscope Shell, with the Camera locator bar towards the top of the shell to match the 'keyhole'. Push the Camera firmly into place then insert the Camera Cable into the cable channel within the Protectscope Shell, ensuring the cable exits through the exit channel at the top of the Shell.

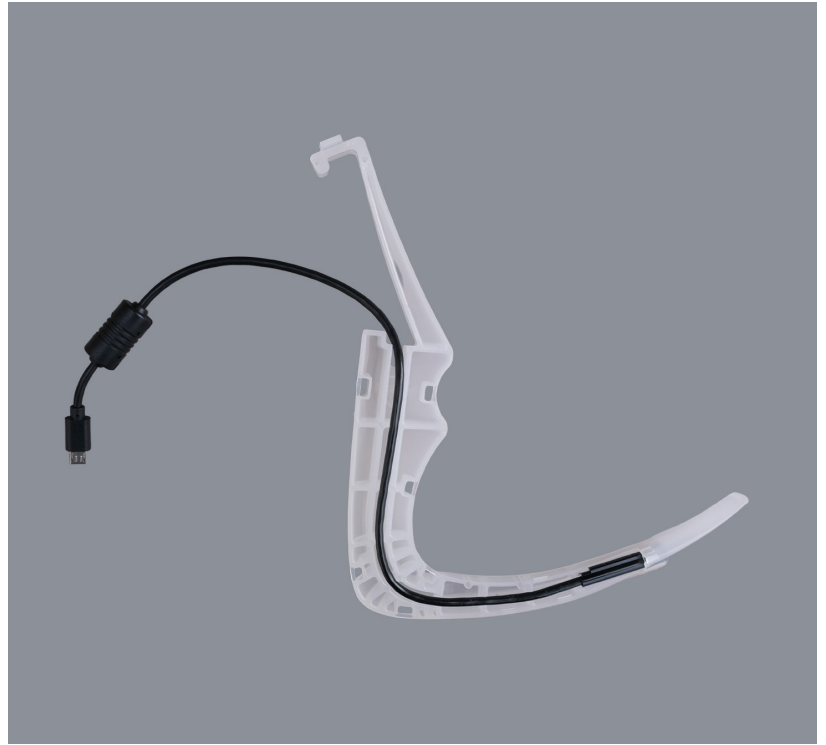
The camera bar features white arrows on the locator bar, to guide the insertion.



Insertion arrows on top of Camera locator bar



Camera keyhole in left hand Shell



Camera cable fitted to cable channel in Shell

The two halves of the Protectscope body are then firmly clipped together. Begin at the tip of the blade next to the camera, using the locator stud on the end of the left hand half to help alignment. Take care to ensure the Camera cable exits the Shell via the channel at the top of the cable guide so it is **NOT** trapped between the two halves during assembly.



Triangular Locator Stud on LH half



Docking LH Half to RH half and camera

Working backwards from the tip, push the shell together. The retaining clips will snap shut.



Snap the Shell together, starting from the tip



Finish with the top clip

Ensure the Camera Cable remains gripped and exits the Shell in the slot provided.

When the Shell is assembled correctly (with no significant gaps between the two halves) the Smartphone (previously powered on, as per the **Pre-Use Checks**) may be secured in the spring clip at the top of the handpiece. Grip the Smartphone approximately near the middle, and ensure the smartphone is held securely before continuing.

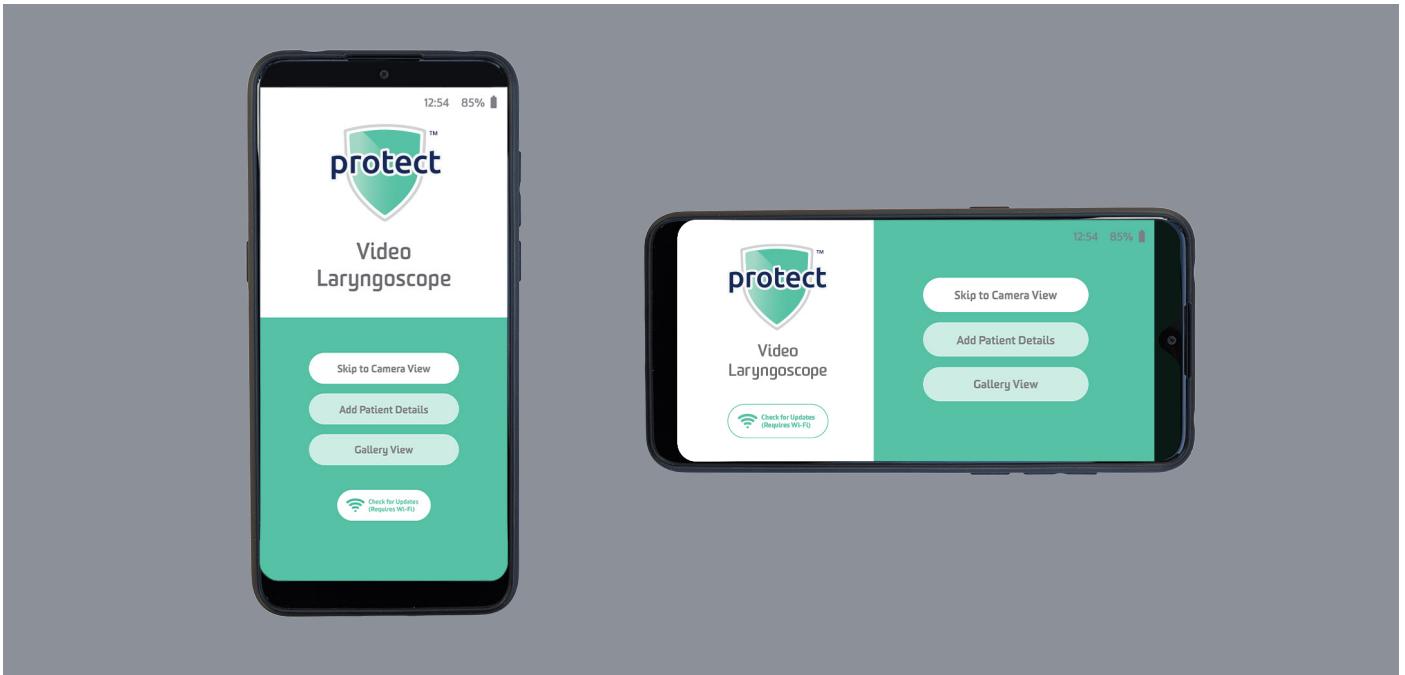


Protectscope system fully assembled

The camera USB connector should then be connected to the Smartphone.
This connection should **NOT** be made **UNTIL** the Smartphone is powered on.
The camera light should be illuminated – **DO NOT PROCEED IF NOT ILLUMINATED.**

The Protectscope system is now ready for use and should be showing the Main screen in either portrait or landscape depending on the orientation of the Smartphone.

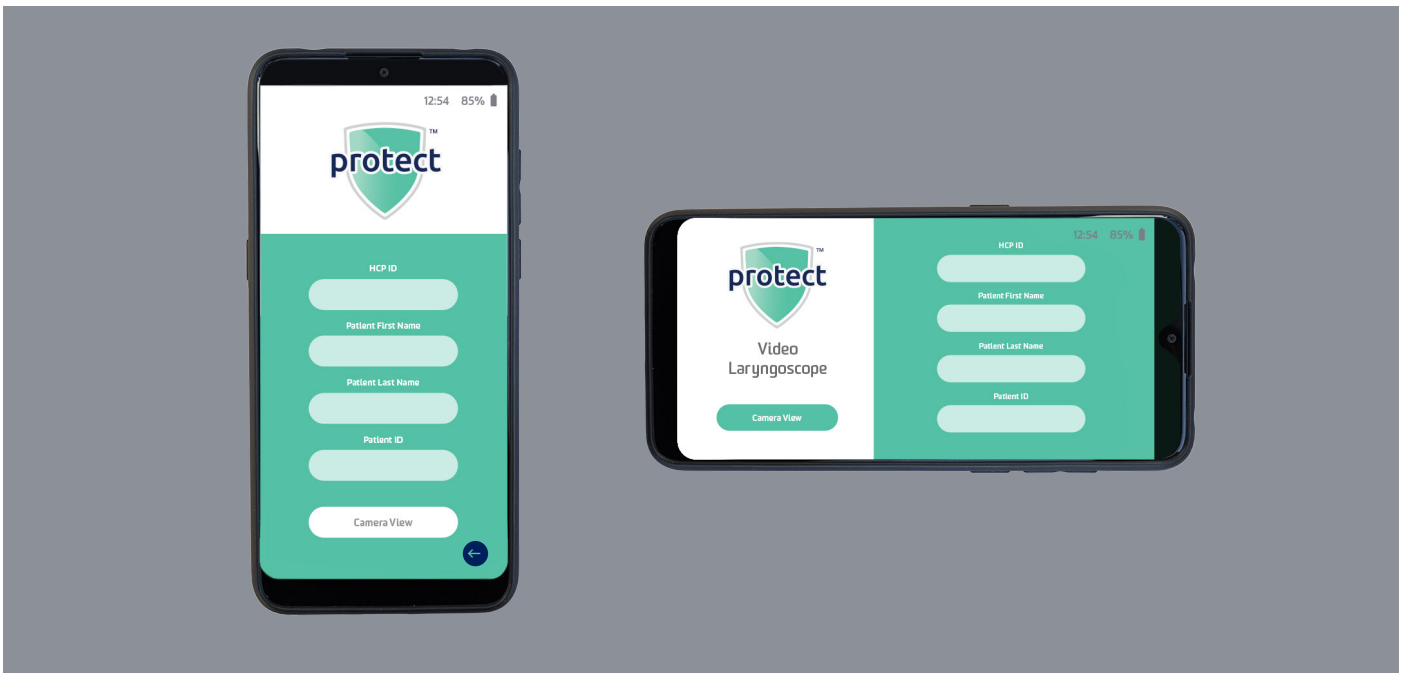
PROTECTSCOPE APP MAIN SCREEN SHOWING BOTH ORIENTATIONS



If no recordings are to be made, the user may go directly to real-time video imaging by selecting 'Skip to Camera View' at the bottom of the Main screen.

If images are to be recorded, then User and Patient details should be added. First select 'Add Patient Details' to move to the Patient Details screen then enter the Health Care Professional (HCP) ID in the first text box followed by the patient details and patient ID. This information is appended to the filename of any saved still image or video recording for subsequent ease of identification and retrieval.

PATIENT DETAILS SCREEN IN BOTH ORIENTATIONS






Select '**Camera View**' from the Patient Details screen to start the real-time video imaging, or '<' to return to the Main screen.

The Camera image is displayed, with options to **Capture a Still Image**, **Record Video with Sound**, or **Close the Camera View screen (x)**.

In use, the Protectscope is gently inserted into the patient's mouth to prevent damage to the teeth and soft tissue of the oral cavity. Once in place the device provides illumination and images of the vocal chords and larynx to assist with oral tracheal intubation. Once intubation has been achieved or if a decision is made to abort the process, the device is carefully removed from the patient's mouth.

RECORDING CAMERA IMAGES AND VIDEO

While the Protectscope is in use, still images and video (including sound) can be recorded on the device. Navigating to the Camera View screen either directly from the Main screen or via the Patient screen allows the Smartphone to display real-time Camera images. In addition to the image there are three button icons displayed on the right of the screen:

-  Close the Camera View and return to the Main screen after confirming end of the session
-  Start and stop video recording (turns red while recording)
-  Capture a still image (a confirmation message briefly appears on screen)

If images or video are recorded without first entering any user or patient information the images and video will be stored with a filename containing the date and time they were taken. If user and patient information has been entered this will be appended to the filename in addition to the date and time.

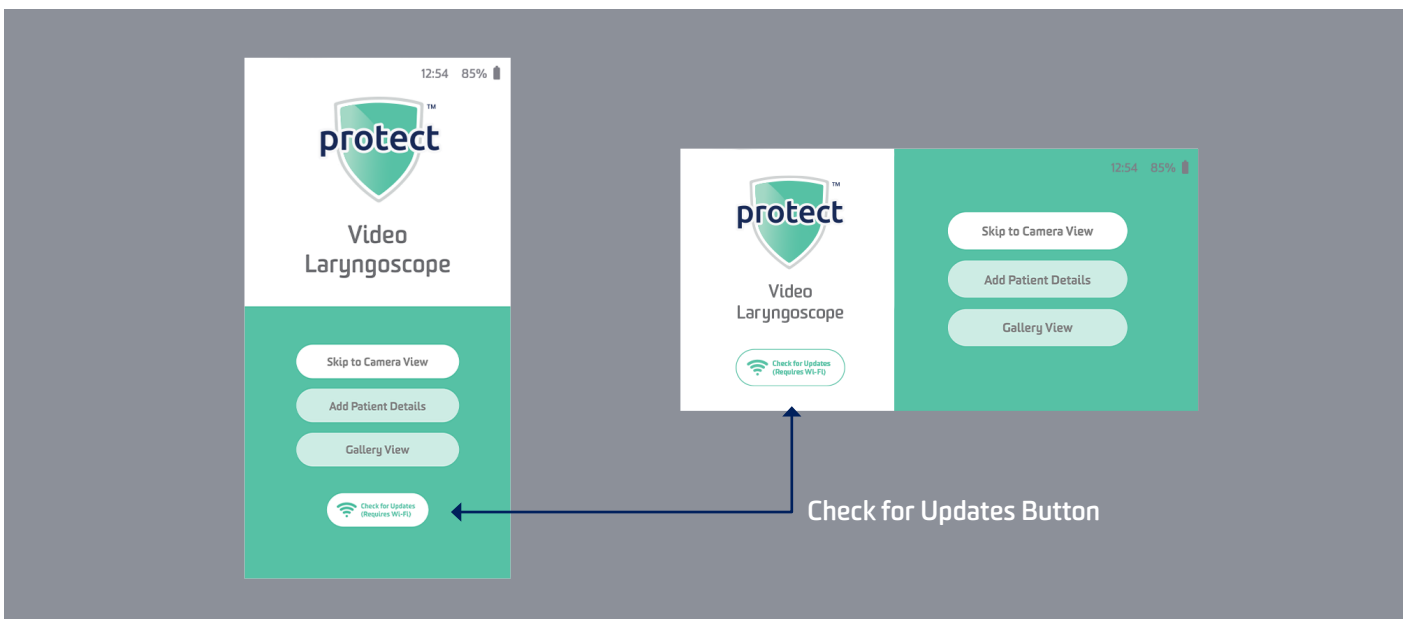
VIEWING RECORDED IMAGES AND VIDEO

On returning to the Main screen recorded images and video may be accessed by selecting 'Gallery View'. This opens the Gallery View screen with two tabs, 'Images' and 'Video', the 'Images' tab opens by default.

The recordings are stored as thumbnails and can be scrolled through using the filename to locate the desired image or video. Once located the image or video can be displayed full screen on the Smartphone allowing it to be viewed or deleted as required.

CHECK FOR UPDATES (REQUIRES WI-FI)

If required, and Wi-Fi access is available then the Protectscope App can be updated to the latest version: To do this, select the 'Check for Updates' button as below



A 'Please enable WiFi' pop-up will appear, then select '**ENABLE WIFI!**'. The Wi-Fi screen then appears with a list of available Wi-Fi networks.

If the network at the top of the list shows as '**Connected**' then a Wi-Fi connection has been made so press the return arrow to go back to the main screen. If there is no connected network, select the network to use and enter a password if prompted then press '**CONNECT!**' (This only needs doing the first time the network is used, the password is then stored securely for future use). The chosen network should then show as '**Connected**' at the top of the Wi-Fi list.

If the network shows any other message then either try connecting again or contact your IT Network Administrator for further assistance. Once the chosen network shows as '**Connected**' then a Wi-Fi connection has been made so press the return arrow to go back to the main screen. On returning to the main screen a pop-up will display either: '**No new updates available**' if the latest version is already installed, press '**OK**' to return to the main screen. Or '**Update available**', press '**OK**' to download and install the latest version of the app, or press Cancel to return to the main screen without updating.

DATE & TIME SETTINGS

The Smartphone ships with the date and time set but if these need to be updated then press the **'Displayed time'** shown in the top right of the display. This opens a **'Date & time'** screen that allows the date and time to be changed as needed.

The default setting is that **'Automatic date & time'** and **'Automatic time zone'** are turned on which greys out the manual date and time settings. Turning off these functions allows date, time and time zone to be set manually.

There is also an option to swap the time format between 24hr (default) and 12hr if preferred.

Once complete press the **'Back'** arrow (bottom left of the display) to return to the main screen.

DISASSEMBLING FOR DISPOSAL AND REPROCESSING



Removing Smartphone from phone grip



Top clip, partially opened

After use, the device is removed from the patient and the Smartphone should be removed from the grip and powered off (via the Power Button). The single-use Shell can then be opened to retrieve the camera – Lift the clip at the top of the phone holder and gently but firmly pull the halves apart with both hands.

The camera can then be removed from the Shell.

REPROCESSING THE PROTECTSCOPE SYSTEM

Once the Protectscope single-use Shell has been opened and the camera removed the Shell should be disposed of in line with local regulations. **The Shell is a single-use component and should never be reused under any circumstances.**

The Smartphone and camera assembly may be reprocessed for future re-use as described In the following cleaning and disinfection protocol.

CLEANING AND DISINFECTION MATERIALS

The required cleaning materials are Class IIb medical device wipes for high level disinfection of invasive medical devices, and medical iso-propanol wipes (ca. 70 %). Follow the manufacturer's instructions for use.

Disinfection wipes validated with Protectscope –

- **Virusolve+ High Level Disinfectant Wipes (Amity International)**

Disinfection wipes meeting the requirements for disinfection but not validated –

- **Tristel Trio Wipes System (Tristel)**
- **Bactryl Wipes (Cantel)**

CLEANING AND DISINFECTION INSTRUCTIONS

Take care handling the Protectscope system after use as it may be contaminated, and the camera may be warm. The **Smartphone should be turned off** during cleaning. The Smartphone and Camera are manually **cleaned whilst still connected**. **Cleaning the Smartphone and Camera separately has not been validated and should not be performed.**

Sanitas Healthcare recommend the VIRUSOLVE+ wipe (Amity International, UK) for high level disinfection. The VIRUSOLVE+ wipe has been validated for use with Protectscope. First, cleaning is conducted using a VIRUSOLVE+ wipe. The wipe is used to clean all surfaces of the Smartphone and camera thoroughly. Pay particular attention to the controls of the Smartphone, the edges of the Smartphone case, and the camera lens and barrel. Continue until the phone and camera are visually clean. Repeat the process with a new wipe if there is visible soiling, until the system is visually clean. Subsequent **disinfection is achieved by further wiping with a fresh VIRUSOLVE+ wipe.**

The Smartphone and Camera should be wiped for a **minimum contact time of 5 minutes** on all surfaces. Finally, the Smartphone and camera are wiped with a medical 70% iso-propanol wipe for a **minimum contact time of 2 minutes**. The device should be allowed to **dry for at least a further 2 minutes**, then returned to safe storage.

STORAGE

The Smartphone should be switched off after use, and the USB camera disconnected after the Smartphone Phone Case and Camera have all been cleaned, disinfected and dried, as above. After the cleaning process the Smartphone may be recharged if necessary, using the charger and charging cable supplied with the Smartphone. Alternative chargers or cables should not be used.

OPERATING AND STORAGE CONDITIONS

Temperature =	0 to 35°C,
Humidity =	0 to 95 % RH
Atmospheric Pressure =	70kPa to 106kPa

DISPOSAL

The single use Protectscope Shell may be contaminated, so it must be disposed of in a clinical waste stream according to local Infection Prevention policy. The Smartphone, Phone Case and Camera are reusable, and must be cleaned and disinfected as per 'Cleaning and Disinfection Instructions' above, post cleaning they should be stored for reuse in line with local Infection Prevention policy.

When the camera and smartphone reach the end of their operating life, they should be cleaned and disinfected as per 'Cleaning and Disinfection Instructions' above, then disposed of according to local procedures and compliance with Waste Electrical and Electronic Equipment regulations, and any similar future environmental regulation applicable (including but not limited to Directives 2011/65/EU and amended Directive 2015/863 and 2002/96/EC as implemented in the country of use). In the absence of suitable local provision, the user may contact Sanitas Healthcare. The Battery in the phone is compliant with 2006/66/EC and its amended directive 2013/56/EU.

MAINTENANCE

The Protectscope system contains no user serviceable parts. If any component fails to operate correctly, it should be disposed of directly according to the guidance above. No further technical information (e.g. circuit diagrams, internal components, etc) is provided as there are no user serviceable parts.

TROUBLESHOOTING

FAULT	ACTION
Any issue with Smartphone recognising the Protectscope Camera, Camera operation or associated permissions	Uninstall the Protectscope App from the smartphone, and reinstall over a Wi-Fi connection, as below.
Smartphone won't power on	Connect to the supplied USB charging cable and charger, wait 5 minutes then try again (whilst connected to the charger)
"Camera not connected" error	Check USB connection to the Camera. Remove and reconnect Camera USB Connector. Finally re-install App (as above).

UPDATING OR REINSTALLING THE APP OVER WI-FI

Navigate back to the Main screen from the Patient screen, the Gallery or the Camera view.

- Select 'Check for Updates (Requires Wi-Fi)'
- The Smartphone will turn on the Wi-Fi and scan for available networks.
- Select the network you wish to use.
- Enter the network password when prompted (you may need to contact your IT Dept for this)
- The Smartphone will then connect to Wi-Fi and download and install the latest version of the app.
- Once the app is installed the Smartphone will shut down the Wi-Fi and return to the main screen.
- In the event that the Smartphone cannot complete the process an error message will be displayed.

The Protectscope Smartphone is prevented from sending any signals, including Wi-Fi, while in use and under normal conditions. Wi-Fi is only activated during the update process.

PROPERTIES

	Protectscope Shell	Smartphone in Case	USB Camera
ID	Protectscope	Alcatel 1S	HY-008
Height	40 mm	10.5 mm	7 mm
Width	158 mm	77 mm	5.5 mm
Lenght	190 mm	160 mm	380 mm
Weight	57 g	188 g	18 g
Power Supply	n/a	5 V	5 V
IP Rating	IP20	IP20	IP67
Manufacturers	Sanitas Healthcare Ltd. Bateman House 82-88 Hills Road Cambridge CB2 1LQ United Kingdom	TCL Communication Ltd. 5/F, Building 22E 22 Science Park East Avenue Hong Kong Science Park Shatin, NT Hong Kong	Shenzhen Hong Yu Technology Co. Ltd. 503 5F, 1 Huaming Road, Yucui Community, Longhua Street, Longhua New district, Shenzhen City, Guangdong, China

REGULATORY STATEMENT

- The Protectscope system is a Class I Medical Device.
- The Protectscope is an internally powered Medical Electrical system.
- The Smartphone and Camera constitute a Class 2 Electrical Device.
- The Smartphone with Case, Shell and Camera is classed as a Medical Electrical system.
- The Shell, Camera and camera lens are considered to be the applied part of the Medical Electrical Device. It is a Type B Applied Part.
- The Smartphone power source is a 4000mAH Li-Ion battery. The Smartphone connection port is a USB port rated at 5V \pm 0.25v with a maximum current output of 100mA which is limited by the Smartphone. There is no mains electrical access from the device while in normal use.
- Protectscope contains no moving parts. The accessible parts are the Smartphone USB port and Camera USB connector.
- Protectscope has been tested to comply with EN60601-1:2006 + A12:2014.
- Protectscope has been tested to comply with EN60601-1-2:2015 for use in a professional healthcare facility environment.
- Protectscope electromagnetic emissions have been tested to Group 1 and Class A.
- Protectscope is a non-continuous use medical system. Maximum usage time is 5 minutes before being switched off for a minimum time of 55 minutes. The duty cycle is therefore declared as 1 hour.
- Maximum temperature of the applied part is 45.01°C.
- Anticipated User and Patient contact time is less than or equal to 5 minutes.
- The USB connector of the HY-008 Endoscope camera supplied with the Protectscope should ONLY be connected to the USB port of the Smartphone supplied as part of the Protectscope VL system.

KNOWN RF EXTERNAL INTERFERENCE TO PROTECTSCOPE (IMMUNITY)

Frequency (MHz)	Antenna Polarisation	Field Strength (V/m)	Modulation	Dwell Time(s)	Observation
385	Horizontal	27	18 Hz PM	10	Video stream interrupted. Protectscope light still illuminated. App restart required.
450	Horizontal	28	1 kHz FM	10	Video stream interrupted. Protectscope light still illuminated. App restart required.



PROTECTSCOPE BY SANITAS HEALTHCARE LIMITED

EU Registered Design Number 008307300-0001

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