Laryngoscope Supplement Guide

English

Part number: 42-2004EN-04

Document date: 2025-06-20

Tempus Pro

Patient Monitor

PHILIPS

Manufacturer's address

Tempus Pro is designed and manufactured by:

Remote Diagnostic Technologies Ltd.
Ascent 1
Farnborough Aerospace Centre
Aerospace Boulevard
Farnborough
Hampshire
GU14 6XW
United Kingdom

Tel: +44 (0) 1256 362 400
Email: rdt_info@philips.com
www.philips.com

CE
0413

EC REP Philips Medical Systems Nederland B.V.
Veenpluis 6
5684PC Best
The Netherlands

Australian TGA sponsor:
Philips Electronics Australia Ltd
65 Epping Road
North Ryde
NSW Australia 2113

The laryngoscope imager and blades are designed and manufactured by:

CE
Karl Storz SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

Tel +49 (0)7461 708-0
Fax +49 (0)7461 708-105
Email info@karlstorz.de
www.karlstorz.com

Table of Contents

Blank page

About this guide

This guide is to support the user in utilising the Tempus Pro's video laryngoscope system. The video laryngoscope system includes a third party imager and single-use blade accessories, details of which are as follows:

- 01-2044 – Tempus Pro C-MAC® S Imager Video Laryngoscope (Karl Storz Reference Number: 8403 XSB)
- 01-2010 – Video Laryngoscope Single Use Size 3 Macintosh blade (pack of 10) (Karl Storz Reference Number: 051113-10)
- 01-2011 – Video Laryngoscope Single Use Size 4 Macintosh blade (pack of 10) (Karl Storz Reference Number: 051114-10)
- 01-2063 – Video Laryngoscope Single D Blade (pack of 10) (Karl Storz Reference Number: 051116-10)

These laryngoscope imagers can be used with Tempus Pro patient monitors. To be compatible with the laryngoscope imagers , the Tempus Pro must be installed with software version 4.02 or higher.

While the Tempus Pro has been designed as a good quality monitor, RDT reminds users that no monitor can replace good clinical judgement or the care and attention of a clinician.

Document library

Consult the instructions for use. These are provided in electronic format in the Philips Document Library.

Important
Please check the Philips Document Library regularly for new versions of this document.

A paper copy of this document may be requested from the Philips Document Library or by sending a request to RDT_Customerservice@philips.com.

Purpose of this manual

The purpose of this document, which is to be read in conjunction with the *Tempus Pro User Manual* by RDT and the *C-MAC® S USB Imager 8403 XSB Instruction Manual* by Karl Storz, is to provide the user with adequately detailed information to efficiently operate the Tempus Pro Video Laryngoscope system. It is not meant to provide information on cleaning and disinfection, or care and handling of the C-MAC® S Imager Video Laryngoscope; for this information you should refer to *C-MAC® S USB Imager 8403 XSB Instruction Manual*.

Failure to comply with the information contained in this guide, the *Tempus Pro User Manual* and the *C MAC® S USB imager 8403 XSB Instruction Manual*, such as warnings, precautions, instructions etc. will violate the safety standards of design, manufacture and intended use of the product. Remote Diagnostic Technologies Ltd. assumes no liability for customer failure to comply with the information contained in this guide and the applicable supporting manuals.

The C-MAC® S Imager Video Laryngoscope and accompanying single use blades are designed and manufactured by Karl Storz GmbH & Co. KG. Please refer to the *C-MAC® S USB imager 8403 XSB Instruction Manual* for all warnings and cautions in relation to the C-MAC® S Imager Video Laryngoscope.

1.1 Safety and note icons

The following icons are used to indicate safety, caution and warning messages (per ISO 3864-2):

DANGER
Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION
Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

The note icon is used for important and helpful information:

A point of particular interest or emphasis intended to provide more effective or convenient operation.

Proprietary notice

The purpose of this document is to provide the user with adequately detailed information to efficiently install, operate, maintain and order spare parts for the Tempus Pro. Every effort has been made to keep the information contained in this document current and accurate as of the date of publication or revision. However, no guarantee is given or implied that the document is error free or that it is accurate with regard to any specification. RDT reserves the right to change specifications without notice.

NO IMPLIED LICENSE: Possession or purchase of this device does not convey any expressed or implied license to use the device with unauthorized sensors or cables that would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

Tempus Pro, Tempus ALS, Tempus LS, Tempus LS-Manual, Tempus IC2, Tempus IC, IntelliSpace Corsium, IntelliSpace Corsium Crew, Smart Mount and EDS are trademarks of RDT.

The following trademarks are the property of Karl Storz GmbH & Co. KG: C-MAC®, Karl Storz®.

Restrictions on use

EMC statements

EMC compliance statements for the Tempus Pro and laryngoscope are available in the following documents:

- For the Tempus Pro, please refer to the *Tempus Pro User/Operator Manual*.
- For the C-MAC® S USB Laryngoscope, please refer to the *C-MAC® S USB Imager 8403 XSB Instruction Manual* from Karl Storz.

Indications and contraindications for use

For indications and contraindications for use of the Tempus Pro, refer to the *Tempus Pro User/Operator Manual*.

FDA prescription statement

Federal law (USA) restricts the use or sale of this device by, or on the order of, a physician.

Software ownership and licensing

With respect to Products containing software components, RDT and its customers/end users are granted a non-exclusive, limited, non-transferable license (the "License") to use the programmed logic, computer programs and/or software, including software developed by or on behalf of KARL STORZ ("KARL STORZ Software") and/or software (“Third Party Software”) developed by or on behalf of third parties (who are considered third party beneficiaries of this Section) embedded in, or for use in conjunction with, such Products, internally, but only in the form in which delivered to RDT and its customers/end users and for the sole purpose of operating in accordance with KARL STORZ's written instructions for the Products (and for no other product or purpose). (“KARL STORZ Software” and “Third Party Software” are referred to collectively as “Software”). The Software, and all modifications, enhancements and upgrades thereto, will, at all times, remain the property of KARL STORZ or the applicable third party. Neither RDT nor any customer/end user may duplicate, copy, reverse-engineer, de-compile or disassemble the Software or in any way modify the Software. Neither RDT nor any customer/end user has any right to, and may not, create derivatives of the Software, and neither RDT nor any customer/end user may attempt to copy, create or re-create the source code of the Software. Any and all such modifications or enhancements to the Software will immediately become the sole property of KARL STORZ. RDT hereby acknowledges and agrees, and shall inform its customers/end users that:

(a) the purchase, lease or other acquisition of Products does not constitute a transfer of the Software; (b) the Software is the property of KARL STORZ or the applicable third party; (c) neither RDT nor any of its customers/end users owns or acquires any interest in any copyright, patent or other intellectual property right in or to the Software as a result of such purchase, lease or other acquisition of Products; (d) KARL STORZ, or the applicable third party, retains and owns all right, title, and interest in and to the Software and the ownership rights therein, at all times, regardless of the form or media in or on which the original or other copies of the Software may exist; and (e) by using the Products, RDT and its customers/end users are subject to, and are bound by, the terms of any separate third-party license agreement relating to the Third Party Software. In the event of a failure of RDT or a customer/end user or its agents, employees or representatives to comply with any terms and conditions of the License herein granted, the License granted herein to such party will, without any further action by KARL STORZ or any other party, immediately end and terminate.

CE statement

Marking by the CE symbol indicates compliance of this medical device to the Medical Device Regulation (EU) 2017/745.

General warnings, cautions and notes

Remote Diagnostic Technologies Ltd. assumes no liability for customer failure to comply with the information contained in this manual and its supporting manuals.

The C-MAC® S USB Laryngoscope is designed and manufactured by Karl Storz. Please refer to the *C MAC® S USB imager 8403 XSB Instruction Manual* for all warnings and cautions in relation to the C MAC® S USB Laryngoscope.

WARNING
Failure to comply with the information contained in this manual, the *Tempus Pro User/Operator Manual* and the *C-MAC® S USB Imager 8403 XSB Instruction Manual* from Karl Storz (e.g. warnings, precautions, instructions etc.) will violate the safety standards of design, manufacture and intended use of the product.

WARNING
The Tempus is intended to be operated by clinically qualified personnel only. This supplement guide, the *Tempus Pro User/Operator Manual* and the *C-MAC® S USB Imager 8403 XSB Instruction Manual* from Karl Storz, as well as accessory directions for use and all precautionary information and specifications should be read before use.

WARNING
Always maintain a charge level of at least 10% in the Termpus Pro's battery. If the Tempus Pro's battery charge is below 10%, the USB interfaces (and therefore the laryngoscope) will not work.

WARNING
Inspect the C-MAC® S USB imager and blade prior to each use to ensure that they function correctly and are free from signs of damage.

WARNING
To ensure high quality images, all laryngoscope images must be obtained by users trained to use laryngoscopes.

WARNING
Only personnel trained in and licensed to perform intubation with a laryngoscope may use this device.

WARNING
To prevent misdiagnosis or harm to the patient, you must understand the Tempus Pro's Video Laryngoscope capabilities prior to use.

WARNING
RDT offers training in how to use the Tempus Pro Patient Monitor but not training in how to perform an intubation. Consult RDT or its authorized representative for information.

WARNING
Service and repair of RDT's Patient Monitor and/ or Karl Storz's C-MAC® S USB Imager must be carried out only by the manufacturer or its authorized representatives. RDT and Karl Storz reserve the right to disclaim all responsibility, including but not limited to responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties.

WARNING
Do not try to use any type of USB Video Laryngoscope other than the Karl Storz C MAC® S USB Imager with the Tempus Pro.

WARNING
DO NOT connect the video laryngoscope USB probe to the Tempus Pro during device boot-up. Once ‘Patient Details’ dialog appears, enter patient data then plug in the video laryngoscope USB probe

CAUTION
Do not repeatedly plug in and out the Video Laryngoscope in quick succession. Once the video laryngoscope is unplugged wait approximately 30 seconds before plugging it back in.

CAUTION
Follow all instructions from the manufacturer of the C-MAC® S USB imager and single use blades. Any deviation from the manufacturer’s instructions or use of agents may impact the performance or durability of the imager and single use blade.

CAUTION
You cannot use USB ultrasound at the same time as a video laryngoscope. If a USB device error is reported, unplug all USB devices before reconnecting the device you need.

The Tempus Pro automatically enables pulse tones when the laryngoscope is connected.

Blank page

1 Laryngoscopy with the Tempus Pro

1.1 Intended purpose

The Tempus Pro can be used to obtain, save and transmit video laryngoscope images through the use of a plug-in USB Imager with a range of disposable blades.

Video Laryngoscopy provides the ability to perform video assisted intubations. With all the relevant vital signs information on one display, including capnometry, waveform and SPO2 measurements, you can see all the key information in one place while performing the intubation.

1.1.1 Indications for use

The device is indicated for displaying images from a Karl Storz C-MAC S USB video laryngoscope. You can use the laryngoscope on all patients monitored by a Tempus Pro. You can only use it with the Tempus Pro.

Before attempting to work with this equipment, the user must read, understand, note and strictly observe all warnings, cautions and safety markings in this supplement guide, the *Tempus Pro User/Operator Manual* from RDT and the *C MAC® S USB Imager 8403 XSB Instruction Manual* (supplied with the imager).

1.1.2 Contraindications

The Tempus Pro laryngoscope is not intended to be used in strong magnetic or electro-magnetic fields which are generated for medical purposes e.g. MRI.

1.1.3 Patient target populations

The patient target groups for use of the Tempus Pro laryngoscope are adults, pediatrics and neonates.

1.1.4 Intended users

Tempus Pro laryngoscope users must be clinically trained in patient vital signs monitoring, vital signs interpretation and how to use a laryngoscope.

1.1.5 Clinical benefits

Clinical benefits are described in the the *Tempus Pro User/Operator Manual*.

1.1.6 Undesirable side-effects

Our reports show that no undesirable side-effects occur when the Tempus Pro laryngoscope user obeys the correct instructions. The user must follow the instructions in this manual.

1.2 Laryngoscope imager and blades

The laryngoscope system uses a USB C-MAC® S Karl Storz Imager:

The USB C-MAC® S Karl Storz Imager can be fitted with a range of disposable single use blades including:

- Size D blade
- Size 3 Macintosh blade
- Size 4 Macintosh blade

The laryngoscope allows airway management for patients from grade 1 to 4 in both male and female, children and adults.

1.3 Starting a laryngoscope examination

WARNING
DO NOT connect the video laryngoscope USB probe to the Tempus Pro during device boot-up. Once 'Patient Details' dialog appears, enter patient data then plug in the video laryngoscope USB probe

Before you start the examination:

1. Install a disposable blade in the imager.

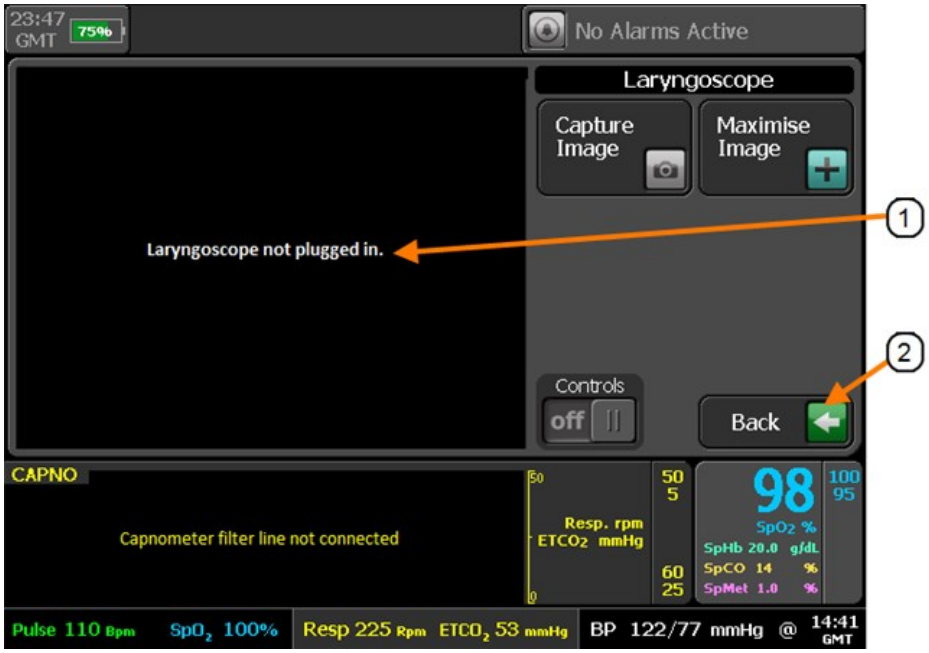
   The blade installation procedure is in *C-MAC® S USB imager 8403 XSB Instruction Manual*.

The easiest way to start a laryngoscope examination with Tempus Pro is:

1. Plug the laryngoscope into either of the two USB ports on the Tempus Pro after the boot-up sequence is complete.
2. Once plugged in, the laryngoscope screen will display automatically after a few seconds.
3. Do "1.3.1 Alignment and positioning".

Alternatively, you can open the laryngoscope screen before you plug in the laryngoscope:

1. Press the **Data Input / Output** button on the Tempus Pro and select **Laryngoscope** from the menu.
2. The laryngoscope screen displays automatically with: (1) message **Laryngoscope not plugged in**, and (2) **Back** button:



3. Plug in the laryngoscope and see "1.3.1 Alignment and positioning".

   The **Back** button text changes to **Stop** when you plug in the laryngoscope.

1.3.1 Alignment and positioning

> **CAUTION**
> If you do not press **Stop** before you unplug the laryngoscope, the Tempus Pro may reboot.

As you insert the blade into the larynx, you have a constant view of the video laryngoscope blade distal tip. This helps you to align the laryngoscope in the correct position.

- (1) Capnometer waveform and SpO_2 measurements.
- (2) **Maximize Image** button. This removes the Capnometer and SpO_2 waveforms to make the image full screen.
- (3) **Capture Image** button. This captures e a snapshot of current image from the laryngoscope.
- (4) **Control** switch. This switches on image control features for brightness etc.
- (5) **Stop** button. This stops the laryngoscope display before you unplug the laryngoscope from Tempus Pro.

1.3.2 Vital Signs Monitoring during Laryngoscopy

Tempus Pro continues monitoring vital signs data whilst it displays the laryngoscope screen. You can see the Tempus Pro status bar, alarm bar and medical summary bars above and below the laryngoscope screen. Alarms continue to sound and display in the alarm bar. The parameter in alarm flashes at the bottom and the alarm light illuminates on top of the Tempus Pro.

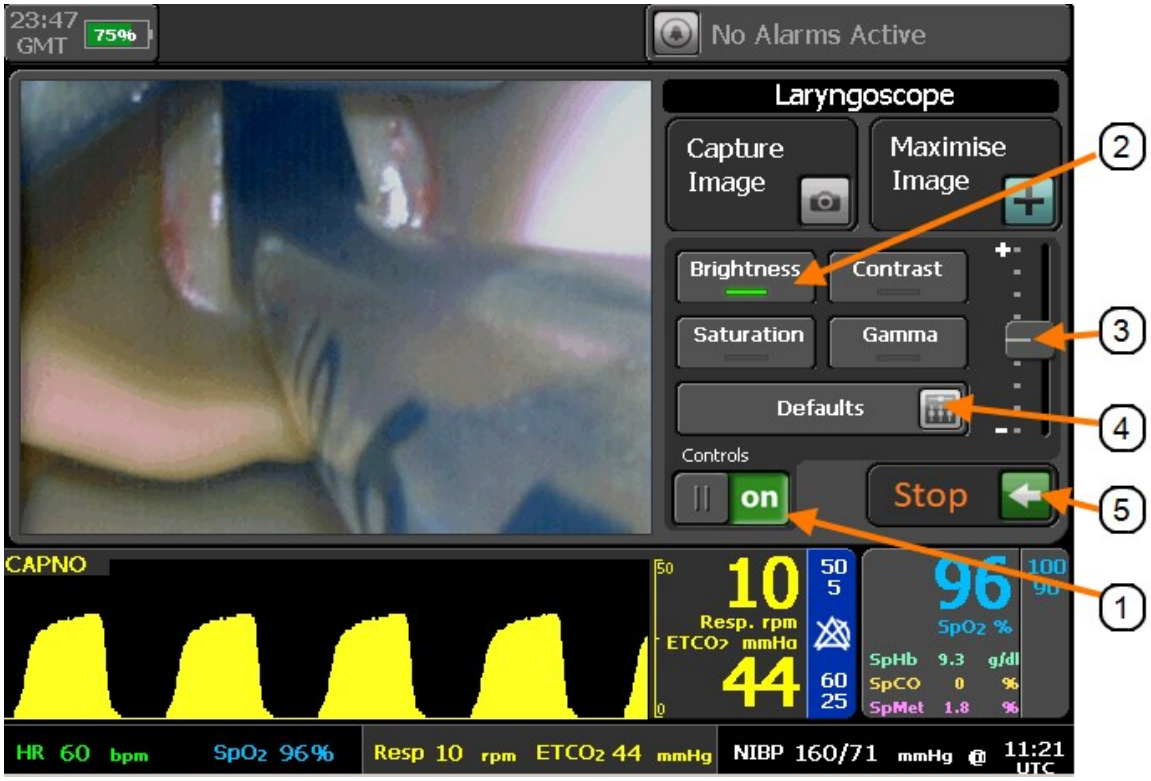
Tempus Pro displays the capnometer waveform and pulse oximetry measurements (except when you maximize the laryngoscopy image). Tempus Pro shows alarm indications in these medical readings in the normal manner. The *Tempus Pro User/Operator Manual* describes these functions.

1.4 Adjusting and capturing the laryngoscope image

> **CAUTION**
> If you do not press **Stop** before you unplug the laryngoscope, the Tempus Pro may reboot.

1.4.1 Controls switch

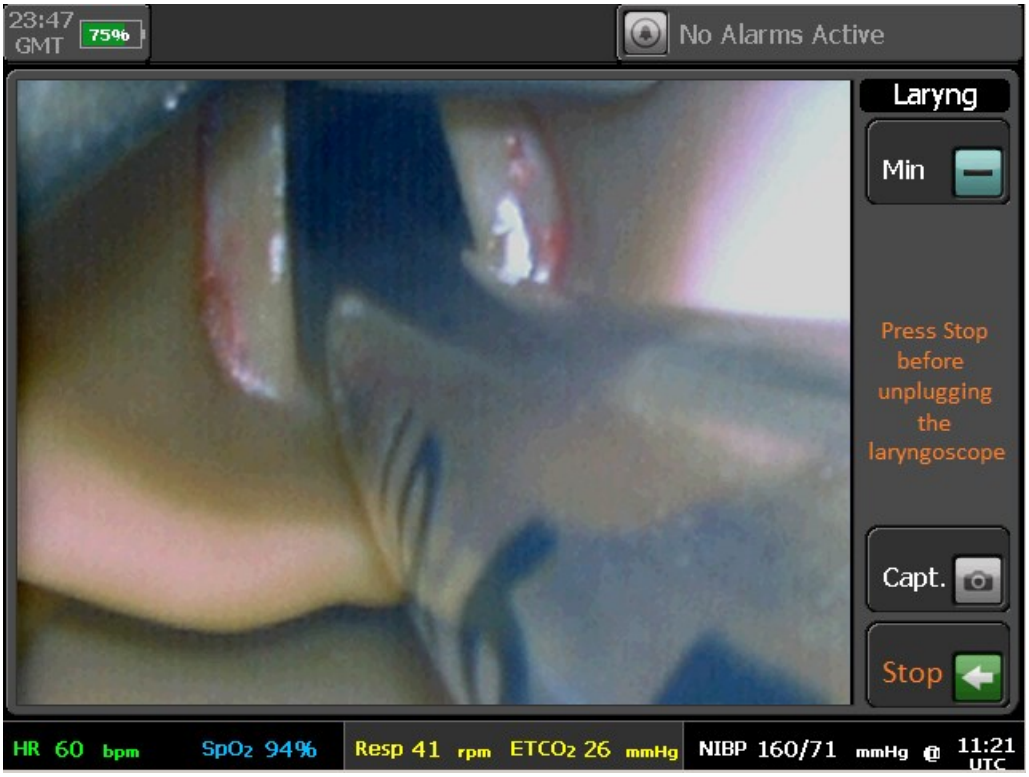
Turn the 'Controls' switch to **On** to display the image control options:



- (1) Controls switch. Use to display the **Brightness**, **Contrast**, **Saturation** and **Gamma** controls and the **Defaults** button.
- (2) **Brightness**, **Contrast**, **Saturation** and **Gamma** controls. Select one control for adjustment. The green bar indicates the selected control.
- (3) Slide bar. Use to adjust the selected control.
- (4) **Defaults** button. Use to return all four controls back to their defaults.
- (5) **Stop** button. Press this button before unplugging the laryngoscope from Tempus Pro.

1.4.2 Maximizing the image

Use the **Maximise Image** button to increase the image size. This will remove the capnography and large pulse oximetry display. However, all medical readings are still displayed at the bottom of the screen:



1.4.3 Capturing the image

Use the **Capture Image** or **Capt.** button to capture an image from the video laryngoscope. Captured images are part of the patient record and can be transferred to the i2i PC application or exported from the Tempus Pro. See the *Tempus Pro User/Operator Manual* for details of patient records.

Important
Laryngoscopy cannot be used while connected in ReachBak communications modes.

2 Removing and cleaning the laryngoscope

WARNING
Do not leave the video laryngoscope plugged into the Tempus Pro when not in use.

2.1 Removing

CAUTION
If you do not press **Stop** before you unplug the laryngoscope, the Tempus Pro may reboot.

When finished with the video laryngoscope:

1. Press the **Stop** button in the laryngoscope screen.
2. Unplug the video laryngoscope from the USB port and the Tempus Pro display will return to the currently configured home page (e.g. four waveform view). Alternatively press the **Home** button.
3. Remove the blade and dispose of appropriately.

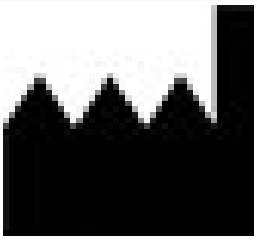
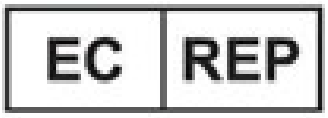
2.2 Cleaning

Please refer to *C-MAC® S USB imager 8403 XSB Instruction Manual* for information on cleaning the video laryngoscope imager.

Blank page

Annex A : Symbols Used

The following symbols are used either on this product or on the accessories and packaging providing with it:

	Consult the instructions for use. These are provided in electronic format in the Philips Document Library.
	Consult the Instructions for use.
	Signifies European technical conformity for a device/accessory, CE marked by notified body number 0413
	Indicates the medical device manufacturer
	Name and address of the European Union Authorized Representative.

Blank page

Blank page

Remote Diagnostic Technologies Limited
Ascent 1
Farnborough Aerospace Centre
Aerospace Boulevard
Farnborough
Hampshire
GU14 6XW
United Kingdom

Tel: +44 (0) 1256 362 400
www.philips.com

Part number: 42-2004EN-04