

Specificatie tehnica completata

Model: Strobolux III LED+HD Scope Producator: OPTOMIC Tara: Spania

Videoprocessor pentru investigații ORL				
Descriere	Sistem video pentru investigarea internă a organelor cavitare ale sistemului digestiv și respirator			
Parametrul		Specificarea tehnică deplină solicitată de către autoritatea contractantă		Specificarea tehnică deplină propusă de către autoritatea ofertantă
Videoprocessor	Camera	Intrări cameră	≥ 1	DA 1
		Lungimea cablul a camerei	$\geq 3\text{m}$	DA
		Butoane camera	≥ 2	DA
		Senzor de imagine	1/3"; CMOS	DA
		Lentilă de ajustare a imaginii	da, $\geq 13\text{-}19\text{ mm}$, autoclavabilă	Va fi prezenta Camera cu ajustare pe distanta focala 16-32 mm si la fel si ajustarea focusului
		Imaginea HDTV / HD	$\geq 1920 \times 1080$ pixeli	DA 1920x1080 pixel / 1080i
	Controale / caracteristici	Display	$\geq 7''$	5 "
		Touchscreen de control	da	NU prin intemrediuul butonelor cu membrana cu protectie
		Iluminare	auto	da
		Balans de alb	auto	da
		Acuitate	da	da
		Înghetarea imaginii	da	nu poate fi tranmisa direct la PC
		Reducerea zgomotului imaginii	da	da
		Zoom electronic	da	da
		Digital (DVI, SDI, HD-SDI)	da	HDMI, SDI
		Alte: PAL/SECAM	da	DA
	Posibilitatea de stocare a datelor prin cel puțin una din metode		DVD / SD-card / memory stick USB / HDD portabil	Este inclus soft cu pedala si convertor pentru conectarea la PC poate fi conectat la orice PCsau Nodbook cu port USB
Sursa de lumină	Tipul		încorporată sau separată	DA încorporat cu 2 intrari separte
	Tip lampă		LED sau xenon >250W	LED
	Temperatura de culoare		$\geq 5000\text{ K}$	DA controlabila
	Timpul de viață		≥ 50000 ore	DA 60.000 ore

Anexa 2

Accesorii	Endoscop	HD sau mai performant compatibil cu videoprocesorul	da	DA
		Autoclavabil, pentru ORL	da, 2 buc.	DA
		Grade	30°	DA 30°
		Lungimea de lucru	15 mm, ± 0,5 mm	DA 150 mm – <i>endoscop de 1,5 cm sau 15 mm nu exzistă</i>
		Diametrul	4mm	DA 3 mm
	Fibră optică		da, 2 buc.	da
	Lampă de rezervă		da, 2 buc.	Nu necesită este de tip LED

HD INTEGRATED ENDOSCOPY SYSTEM STROBOLUX III LED+HD

- HD endoscopy camera
- Stroboscope
- LED light source

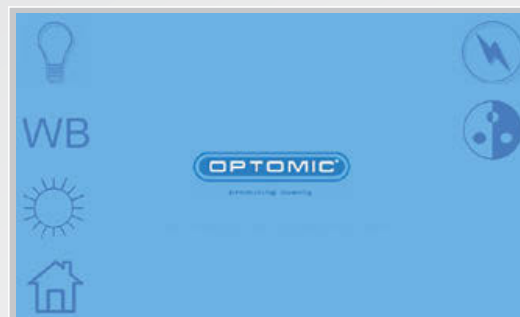


The Strobolux III LED + HD integrated endoscopy system is revolutionary in the ENT practice.
It allows the user to carry out stroboscopy and continuous light examination synchronized with the Optomic HD camera.

INTEGRATED SYSTEM STROBOLUX III LED+HD

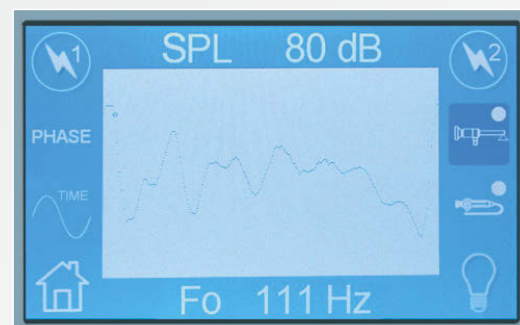
HD ENDOSCOPY CAMERA

- HD output, HDMI type.
- 1080i HD digital resolution.
- 2 outputs: S-Video and composite video.
- Shutter speed 1/100,000 sec.
- Manual and automatic white balance.
- Automatic synchronized ELC.
- Synchronization of camera and stroboscope to optimize the image quality.



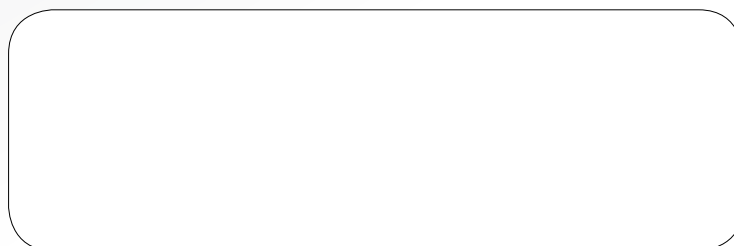
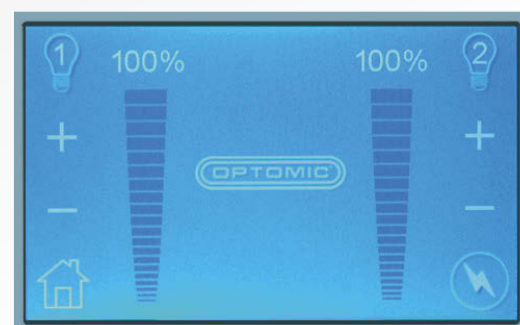
STROBOSCOPE

- LED stroboscopic system.
- 2 independent and simultaneous light outputs.
- Phase and slow movement function.
- Analysis frequency from 60 to 1,000Hz.
- Phase range variation from 0° to 400°.
- Voice analysis: spectrogram and waveform.
- Air and contact microphone.
- 5" TFT display.



LED COLD LIGHT SOURCE

- LED type illumination.
- 2 independent outputs.
- Alternating or simultaneous function of the outputs.
- Life of LED lamp: 60,000h.
- Intensity of use memory.
- Adaptors for all cable brands in the market.



Specifications are subject to change without notice



SOFTWARE DIGITALLY SOFT

PATIENT MANAGEMENT, IMAGE AND VIDEO CAPTURE SOFTWARE

- Video and image capture
- Medical record management
- Personalized reports

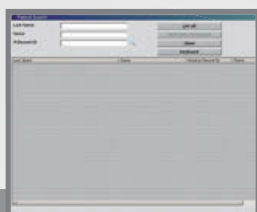


Digitally Soft is an integral patient management software, which allows to store and manage data from clinical records. It captures videos and photographs from any video source and quickly creates customized reports.

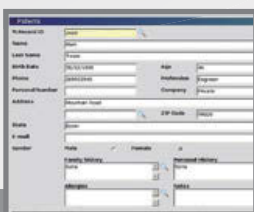
PATIENT MANAGEMENT SOFTWARE **DIGITALLY SOFT**



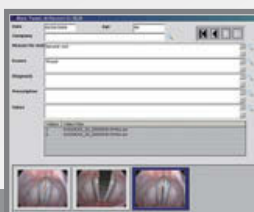
- Creation and modification of the patient's clinical records.
- Visits records.
- Quick search of patients.
- Still images and video capture.
- Control of main functions via a tactile screen (optional).
- User control via password.
- Works in a network, sharing a database.
- Predefined reports that can be personalized with images.
- Statistical tools.
- Image comparisons (before and after).



PATIENTS LIST



PATIENT RECORD



VISITS

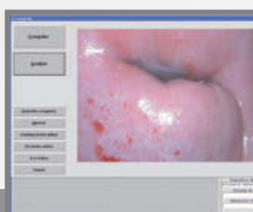
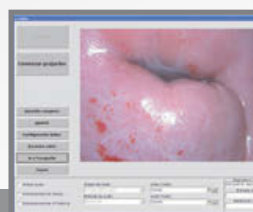


IMAGE CAPTURE



VIDEO CAPTURE



VISUALIZATION



IMAGE COMPARISON

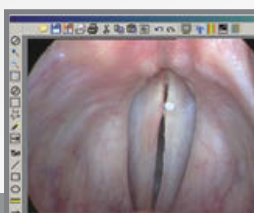
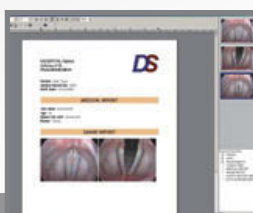
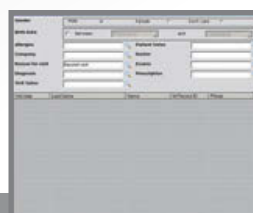


IMAGE EDITING



PERSONALIZED REPORTS



DATABASE QUERIES



Specifications are subject to change without notice



ENT RIGID ENDOSCOPES OTO-SINUS-LARYNGOSCOPES

OUTSTANDING QUALITY IN ENDOSCOPIC VISION

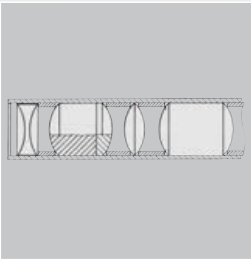
- High resolution
- Clear images
- High resistance



OPTOMIC offers a complete range of rigid otoscopes, sinusscopes and laryngoscopes for the inspection of the corresponding area. They allow for the diagnosis and serve as a method for minimal invasive surgical intervention. All the ENT OPTOMIC endoscopes are of proven quality and offer an exceptional image brightness to guarantee the satisfaction of the specialist.

ENT RIGID ENDOSCOPES

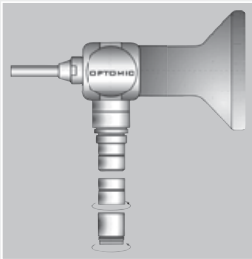
OTO-SINUS-LARYNGOSCOPIES



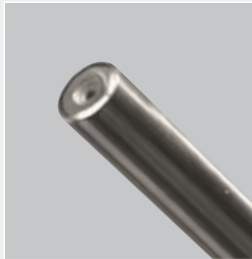
ROD LENSES SYSTEM



STAINLESS STEEL BODY



ADAPTERS



RESILIENT SAPPHIRE LENSES



PEEK EYEPIECE

			0°	30°	45°	70°	70°	90°
OTOSCOPE	1,9	100	● ●	● ●				
	2,7	75	● ●	● ●		● ●		
	4	50	●	●				
SINUSCOPE	2,7	140	● ●	● ●		● ●		
	2,7	195	● ●	● ●		● ●		
	3	150	●	●	●	●		
	4	185	● ●	● ●	● ●	● ●		
LARYNGOSCOPE	4	185					●	
	6	158					●	
	10	158					● ●	● ●

● Non-Autoclavables ● Autoclavables

- Rod lenses system and stainless steel sealed by laser welding.
- Adapters for connection to type *Storz/Olympus*, *Wolf* and *ACMI* fiber optic cables.
- Autoclavable endoscopes with lenses made of sapphire of high resistance to scratches.



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Declaration of Conformity *Declaración de Conformidad*

OPTOMIC ESPAÑA, S.A.
Madroño 4 F - P. Ind. La Mina
28770 Colmenar Viejo, Madrid
SPAIN

Declares under its solely responsibility that the Class I product:

Declara bajo su exclusiva responsabilidad que el producto de Clase I:

STROBOSCOPE (ANNEX I) ESTROBOSCOPIO (ANEXO I)

is in conformity with the legislation of Regulation 2017/745 concerning Medical Devices and complies with the standards included in the technical documentation.

es conforme a las disposiciones del Reglamento 2017/745 relativas a Productos Sanitarios y cumple con las normas incluidas en la documentación técnica.

Our Quality Management System, with its continuing certification, guarantees that our products meet the required quality demands.

Nuestro Sistema de Gestión de Calidad, con su certificación continua, garantiza que nuestros productos cumplen con las exigencias de calidad requeridas.

SRN: ES-MF-000003235

Basic UDI- DI/ UDI-DI básico: 843604158 0720 3A

Date of issue: 26/05/2021

Fecha de emisión:

Valid until: 28/07/2023

Válido hasta:

P.O.
JRF



Jorge Rial Ferrario
General Manager
In/En Colmenar Viejo, Spain

ANNEX I TO DECLARATION OF CONFORMITY: STROBOSCOPE

ANEXO I DE LA DECLARACIÓN DE CONFORMIDAD: ESTROBOSCOPIO

Reference / Referencia	OPTOMIC DESCRIPTION / DESCRIPCIÓN OPTOMIC
28503822	STROBOSCOPE STROBOLUX III LED / ESTROBOSCOPIO STROBOLUX III LED - 2 Salidas
28503843	STROBOSCOPE STROBOLUX III LED + HD PAL/ ESTROBOSCOPIO STROBOLUX III + CAMARA HD PAL
28503846	STROBOSCOPE STROBOLUX III LED + HD NTSC/ ESTROBOSCOPIO STROBOLUX III + CAMARA HD NTSC

Date of issue: 26/05/2021
Fecha de emisión:

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Válido hasta:

P.O.
JRF



Jorge Rial Ferrario
General Manager
In/En Colmenar Viejo, Spain



Certificate

No. Q5 034400 0015 Rev. 01

Holder of Certificate:



OPTOMIC ESPAÑA, S.A.

Madroño 4 F- P. Ind. La Mina
28770 Colmenar Viejo, Madrid
SPAIN

Facility(ies):

OPTOMIC ESPAÑA, S.A.
Madroño 4 F- P. Ind. La Mina, 28770 Colmenar Viejo, Madrid,
SPAIN

Certification Mark:



Scope of Certificate:

Design and Development, Production, Distribution, Sale and Technical Service of Microscopes, Colposcopes, Rigid and Flexible Endoscopes, Cold Light Sources, Camera Systems, Optic Systems, Diagnostic Workstations, Cameras for Endoscopy, Examination Chairs, Stroboscopes and Sale of Medical Equipment

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

713162857

Valid from:

2020-07-29

Valid until:

2023-07-28

Date,

2020-05-20

Christoph Dicks

Head of Certification/Notified Body