

CERTIFICATO CE

Certificato n. 1272/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

ARDET DENTAL & MEDICAL DEVICES SRL

20122 MILANO (MI) - VIA LARGA 8 (ITA) - Italy

mantiene negli stabilimenti di:

20090 ASSAGO (MI) - VIA GALVANI 15 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Apparecchi radiologici dentali

Sensori videoradiografici digitali

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II.

Riferimento pratiche IMQ:

10AJ00203; 10AL00077; DM14E0345293-01; COMEDCONMHDM110047919-01;
DM17-0008960-01; DM17-0009882-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.

Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2009-11-12
Data di Aggiornamento: 2017-05-29
Sostituisce: 2015-09-07
Data Scadenza: 2022-05-28

IMQ

 **IMQ** 
ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

CERTIFICATO CE

Certificato n. 1272/MDD

MOD. 1475A / 2

Allegato

Apparecchi radiologici dentali

Modd. ORIX 70 - Versioni come da documento allegato del 20/05/2017; valido solo se provvisto del timbro IMQ.

Marca ARDET

Modd. ORIX 70 New Edition - Versioni come da documento allegato del 20/05/2017; valido solo se provvisto del timbro IMQ.

Marca ARDET

Modd. ORIX 70 New Edition DG - Versioni come da documento allegato del 20/05/2017; valido solo se provvisto del timbro IMQ.

Marca ARDET

Modd. ORIX HF Advantage - Versioni come da documento allegato del 20/05/2017; valido solo se provvisto del timbro IMQ.

Marca ARDET

Modd. ORIX HF Plus - Versioni come da documento allegato del 20/05/2017; valido solo se provvisto del timbro IMQ.

Marca ARDET

Modd. x-on® tube - Versioni come da documento allegato del 20/05/2017; valido solo se provvisto del timbro IMQ.

Marca ORANGEDENTAL

Sensori videoradiografici digitali

Modd. IMAGE-1; IMAGE-2 - Versioni come da documento allegato del 20/05/2017; valido solo se provvisto del timbro IMQ.

Marca ARDET

Emesso il: 2009-11-12

Data di Aggiornamento: 2017-05-29

Sostituisce: 2015-09-07

Data Scadenza: 2022-05-28

IMQ



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EC CERTIFICATE

Certificate No 1272/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

ARDET DENTAL & MEDICAL DEVICES SRL

20122 MILANO (MI) - VIA LARGA 8 (ITA) - Italy

manages in the factories of:

20090 ASSAGO (MI) - VIA GALVANI 15 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Dental X-ray systems

Digitals videoradiographic sensors

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II.

Reference to IMQ files Nos:

10AJ00203; 10AL00077; DM14E0345293-01; COMEDCONMHDM110047919-01;
DM17-0008960-01; DM17-0009882-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.

Notified Body notified to European Commission under number: 0051.

Date: 2009-11-12
Updated: 2017-05-29
Substitution Date: 2015-09-07
Expiring Date: 2022-05-28

IMQ



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This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

EC CERTIFICATE

Certificate No 1272/MDD

Annex

Dental X-ray systems

Type ref. ORIX 70 - Versions as to annex document dated 2017/05/20; valid only if provided with IMQ stamp.

Trade mark ARDET

Type ref. ORIX 70 New Edition - Versions as to annex document dated /2017/05/20; valid only if provided with IMQ stamp.

Trade mark ARDET

Type ref. ORIX 70 New Edition DG - Versions as to annex document dated 2017/05/20; valid only if provided with IMQ stamp.

Trade mark ARDET

Type ref. ORIX HF Advantage - Versions as to annex document dated 2017/05/20; valid only if provided with IMQ stamp.

Trade mark ARDET

Type ref. ORIX HF Plus - Versions as to annex document dated 2017/05/20; valid only if provided with IMQ stamp.

Trade mark ARDET

Type ref. x-on® tube - Versions as to annex document dated 2017/05/20; valid only if provided with IMQ stamp.

Trade mark ORANGEDENTAL

Digital videoradiographic sensors

Type ref. IMAGE-1; IMAGE-2 - Versions as to annex document dated 2017/05/20; valid only if provided with IMQ stamp.

Trade mark ARDET

Date: 2009-11-12

Updated: 2017-05-29

Substitution Date: 2015-09-07

Expiring Date: 2022-05-28

IMQ



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**LISTA DEI PRODOTTI / PRODUCT LIST****-
1272/MDD**

Assago, 20/05/2017

Il fabbricante / *The manufacturer* : **ArdeT Dental & Medical Devices S.r.l.**Indirizzo / *Address* : Via Galvani 15, 20090 Assago (MI), ItalyDichiara sotto la propria responsabilità quanto segue / *Declares under its own responsibility as follows* :

Marca / <i>Trademark</i>	ArdeT	
Categoria di prodotto / <i>Product category</i>	Apparecchio radiologico dentale / <i>Dental X-ray system</i>	
Modello / <i>Model</i>	ORIX 70	
Versioni / <i>Versions</i>	Codice / <i>Code</i>	Descrizione / <i>Description</i>
	3000557	Murale / <i>Wall mount</i>
	3000558	Stativo mobile / <i>Stand mobile</i>
	3000559	Stativo fisso / <i>Stand fixed</i>

Marca / <i>Trademark</i>	ArdeT	
Categoria di prodotto / <i>Product category</i>	Apparecchio radiologico dentale / <i>Dental X-ray system</i>	
Modello / <i>Model</i>	ORIX 70 New Edition	
Versioni / <i>Versions</i>	Codice / <i>Code</i>	Descrizione / <i>Description</i>
	3500200	Murale / <i>Wall mount</i>
	3500300	Stativo mobile / <i>Stand mobile</i>
	3500400	Stativo fisso / <i>Stand fixed</i>

Marca / <i>Trademark</i>	ArdeT	
Categoria di prodotto / <i>Product category</i>	Apparecchio radiologico dentale / <i>Dental X-ray system</i>	
Modello / <i>Model</i>	ORIX 70 New Edition DG	
Versioni / <i>Versions</i>	Codice / <i>Code</i>	Descrizione / <i>Description</i>
	3500201	Murale / <i>Wall mount</i>
	3500301	Stativo mobile / <i>Stand mobile</i>
	3500401	Stativo fisso / <i>Stand fixed</i>

Marca / <i>Trademark</i>	ArdeT	
Categoria di prodotto / <i>Product category</i>	Apparecchio radiologico dentale / <i>Dental X-ray system</i>	
Modello / <i>Model</i>	ORIX HF Advantage	
Versioni / <i>Versions</i>	Codice / <i>Code</i>	Descrizione / <i>Description</i>
	3600201	Murale / <i>Wall mount</i>
	3600301	Stativo mobile / <i>Stand mobile</i>
	3600401	Stativo fisso / <i>Stand fixed</i>

Marca / <i>Trademark</i>	ArdeT Dental & Medical Devices Srl	
Categoria di prodotto / <i>Product category</i>	Apparecchio radiologico dentale / <i>Dental X-ray system</i>	
Modello / <i>Model</i>	ORIX HF Plus	
Versioni / <i>Versions</i>	Codice / <i>Code</i>	Descrizione / <i>Description</i>
	3600200	Murale / <i>Wall mount</i>
	3600300	Stativo mobile / <i>Stand mobile</i>
	3600400	Stativo fisso / <i>Stand fixed</i>



**LISTA DEI PRODOTTI / PRODUCT LIST**

-
1272/MDD

Marca / <i>Trademark</i>	Orangedental	
Categoria di prodotto / <i>Product category</i>	Apparecchio radiologico dentale / <i>Dental X-ray system</i>	
Modello / <i>Model</i>	x-on® tube	
Versioni / <i>Versions</i>	Codice / <i>Code</i>	Descrizione / <i>Description</i>
	xt0492000	Murale / <i>Wall mount</i>
	xt0493000	Stativo mobile / <i>Stand mobile</i>
	xt0494000	Stativo fisso / <i>Stand fixed</i>

Marca / <i>Trademark</i>	ArDET	
Categoria di prodotto / <i>Product category</i>	Sensore videoradiografico dentale / <i>Digital videoradiographic sensor</i>	
Modello / <i>Model</i>	IMAGE-1; IMAGE-2	
Versioni / <i>Versions</i>	Codice / <i>Code</i>	Descrizione / <i>Description</i>
	400601	Taglia 1 / <i>Size 1</i>
	400901	Taglia 2 / <i>Size 2</i>

In fede / *Your faithfully,*

ArDET Dental & Medical Devices S.r.l.

Luca Montagnana
Quality Assurance



2017-05-29

Technical Data

Electrical features

Power supply	110-240 V $\pm$ 10%
Frequency	50-60 Hz.
Current	2,1 A (@ 240 V) 5,2 A (@ 110 V)

Tubehead features

Total filtration	$\geq$ 2,5 mm Al eq.
Min. focus skin distance	200 mm
Irradiated area @ 200 mm	$\varnothing$ 55 mm
Leakage @ 1 m	$<$ 0,25 mGy/h

X-ray tube features

Tube	OCX 70-4
Focal spot	0,4 mm
Anodic material	Tungsten

Radiological features

High voltage	60-65-70 kVp
Anodic current	5 mA
Exposure time	0,01 - 2,00 s
Duty cycle	1:60
Control logic	Dead man

Mechanical features

Extension arm	500 - 900 mm
Max. extension	1980 mm



ORIX HF Plus

High frequency intraoral X-ray system



Best image quality ever



ARDET Dental & Medical Devices S.r.l. is an Italian company leader in the design, production and supply of high-tech dental and medical devices. Our quality management system in compliance with EN ISO 13485 standard, guarantees a careful control of the internal processes and the absolute reliability of our products, focusing our attention on the practical work of the doctor.



ARDET Dental & Medical Devices Srl

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Tel +39 02 944 35 294 - Fax +39 02 944 35 296
ardet@ardetsrl.com - www.ardetsrl.com



ARDET Dental & Medical Devices S.r.l. reserves the right to make technical changes and/or aesthetic changes to the product at any time and without prior notice.
PRO ORIX HF Plus rev. 3 - 26/02/2019

ORIX HF Plus

High frequency

Lower dose for the patient, higher definition for the doctor.

Design

A new design intended to speed up the workflow of the dental practice.

Ergonomic

Extremely easy, intuitive and safe.

Best image quality ever

Accurate, reliable and ergonomic **ORIX HF Plus** is the new high frequency X-ray system from Ardet, designed to provide user-friendly operational function, best performance and a longer lifetime.

Innovative design solutions and advanced technologies combine to provide dentistry professionals with an extremely accurate and reliable device.

Developed by the manufacturers of Orix 70, reference unit in terms of quality and reliability in conventional technology, **ORIX HF Plus** exploits the high frequency constant potential (DC) technology to ensure short exposures, a significant dose reduction for patients and detailed, repeatable, high quality radiographic images.

ORIX HF Plus is managed by the new Ardet control unit, which thanks to its simple and intuitive controls and its large screen, clearly displays all technical parameters providing valuable help in every situation with the highest standards for the health of patients.

With **ORIX HF Plus** X-ray system can be used either the short cone (20 cm) imaging technique or the long cone (30 cm) imaging technique.

Furthermore, it is possible to adjust the cone with an additional rectangular collimator to maximize radiation safety.

The mechanical parts of the system, in extruded aluminium are light and solid in order to make the unit extremely stable and safe, ensuring a precise linear movement that can reduce the risk of vibration of the head during image acquisition.

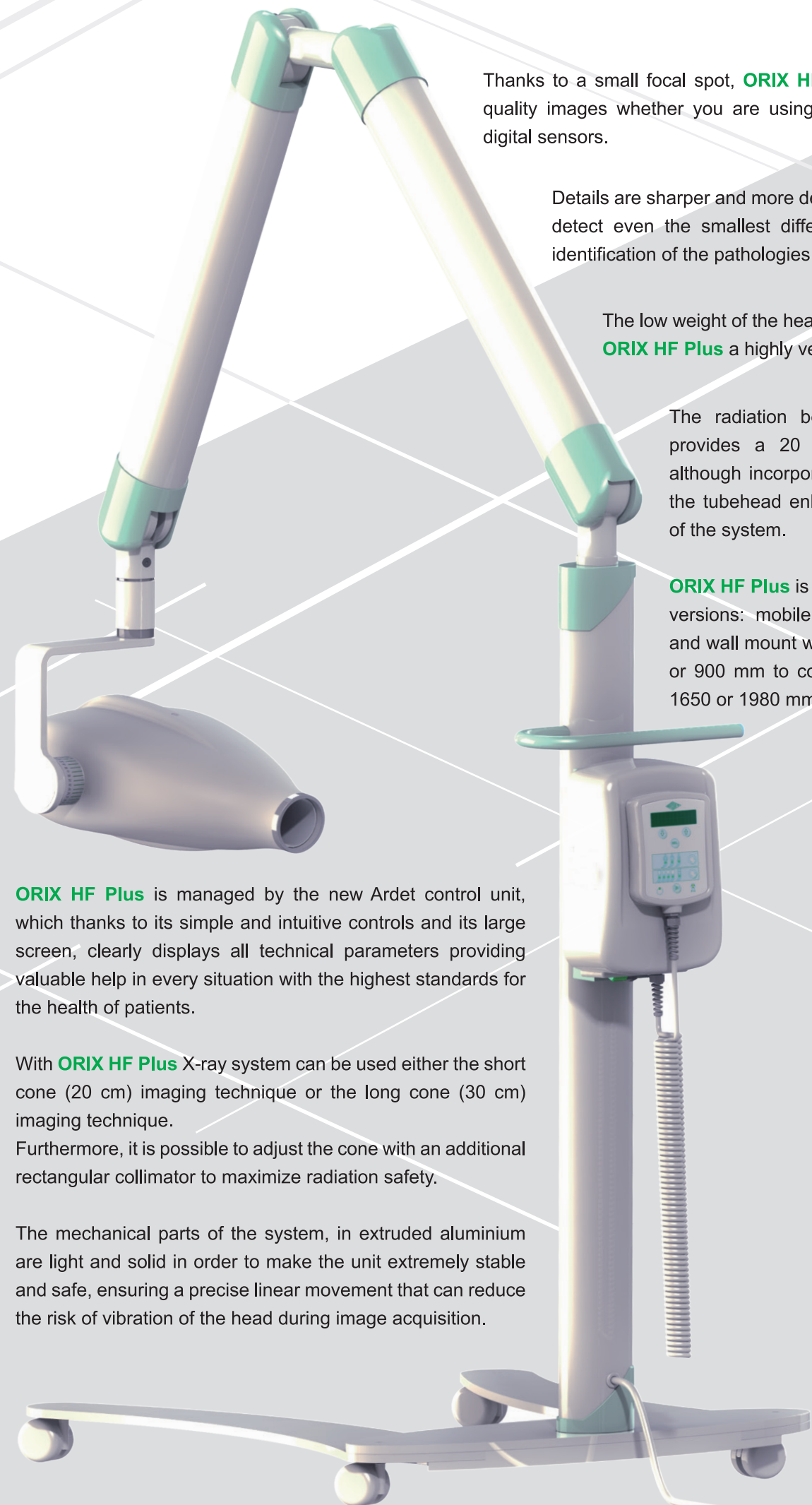
Thanks to a small focal spot, **ORIX HF Plus** produces superior quality images whether you are using film, phosphor plates or digital sensors.

Details are sharper and more defined so that it is easier to detect even the smallest differences for a more rapid identification of the pathologies.

The low weight of the head and its flexibility make of **ORIX HF Plus** a highly versatile X-ray machine.

The radiation beam delimitating system provides a 20 cm focus-skin distance, although incorporated into the structure of the tubehead enhancing the compactness of the system.

ORIX HF Plus is available in three different versions: mobile stand, floor fixed stand and wall mount with horizontal arms of 500 or 900 mm to cover variable distances of 1650 or 1980 mm.





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CISQ is a member of



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. 9124.AD02
CERTIFICATE N.

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

ARDET DENTAL & MEDICAL DEVICES SRL

VIA LARGA 8 - 20122 MILANO (MI)
UNITA' OPERATIVE / OPERATIVE UNITS

VIA GALVANI 15 - 20090 ASSAGO (MI)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, costruzione, riparazione e commercializzazione di apparecchi
per radiografie intra-orali e impianti per radiologia odontoiatrica
*Design, manufacturing, servicing and trading of intra-oral
dental X-ray units and dental X-ray units for dentistry*

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

*THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS*

DATE:	PRIMA CERTIFICAZIONE	EMISSIONE CORRENTE	SCADENZA
	<i>FIRST CERTIFICATION</i>	<i>CURRENT ISSUE</i>	<i>EXPIRY</i>
	2009-11-27	2018-10-30	2021-11-26

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



SGQ N° 005 A

Membro degli Accordi di Mutuo
Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo
del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment
of the entire Management System within three years



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale.
*CISQ is the Italian Federation of management
system Certification Bodies.*



2019

PRODUCT CATALOGUE

PROCAT Rev.3, ENG, 15/01/2019

IMAGE

CE
0051

IMAGE

Digital videoradiographic sensor



Let's enter into details

Description

IMAGE sensor 1,6 Mpixel
CMOS technology with optical fiber
External dimensions 24,35 mm x 36,73 mm
600 mm² active area
Theoretical resolution 26,3 lp/mm
Effective resolution > 20 lp/mm
Pixel dimension 19 µm
USB cable, 3 m length
Direct connection to the PC
Sensor holder support

IMAGE sensor 2,4 Mpixel
CMOS technology with optical fiber
External dimensions 30,49 mm x 42,80 mm
900 mm² active area
Theoretical resolution 26,3 lp/mm
Effective resolution > 20 lp/mm
Pixel dimension 19 µm
USB cable, 3 m length
Direct connection to the PC
Sensor holder support

IMAGE HD

CE 0051		
Description		
IMAGE HD sensor 1500x1000 pixel (1,5 Megapixels) CMOS technology with optical fiber Active area 20 mm x 30 mm (600 mm²) Effective resolution = 20 lp/mm Pixel dimension 20 µm USB cable, 2 m length Direct connection to the PC Scintillator type CSI	IMAGE HD sensor 1700x1300 pixel (2,1 Megapixels) CMOS technology with optical fiber Active area 26 mm x 34 mm (900mm²) Effective resolution = 20 lp/mm Pixel dimension 20 µm USB cable, 2 m length Direct connection to the PC Scintillator type CSI	



ORIXSCAN

CE
0123

ORIXSCAN

Phosphor plates scanner



Futuristic PSP technology

Description

Package:

ORIXSCAN unit

Ardes Software

Impaging plates (4x Size 2) with light protection covers

USB Cable

Power supply & power cable

Specifications:

Resolution: 12lp/mm

Scanning time: 6 sec

Cancellation of the plate: automatic

Interface with PC: USB 2.0 – USB 3.0

Power supply: 100-240 V, 50/60 Hz. , 1,5 A

Dimensions: 355 x 165 x 205 mm

Weight: 5,2 Kg

ORIX 70



Description

Low frequency
 Alternate current AC, single phase self-rectified.
 70 kV- 8mA
 Grid controlled x-ray tube.
 0,8 mm focal spot.
 SELEMATIC digital timer.
 Commands on the keyboard and remote x-ray push-button.
 Exposure times 0,03 – 1,32 sec.
 20 cm. focus – skin distance.
 Designed to work with X-ray film, digital sensors and phosphor plates.

ORIX 70 New Edition

CE
0051



ORIX 70
New Edition

Intraoral X-ray system

The classy choice

Low frequency
Alternate current AC, single phase self rectified.
70 kV- 8mA
Grid controlled x-ray tube.
0,8 mm focal spot.
TIMEX 70 digital timer
Commands on the keyboard and remote x-ray push-button.
Exposure times 0,04 – 2,00 sec.
20 cm. focus – skin distance.
Designed to work with X-ray film, digital sensors and phosphor plates.

ORIX 70 New Edition DG



Description

Low frequency
 Alternate current AC, single phase self rectified.
 70 kV- 3,5 mA
 Grid controlled x-ray tube.
 0,4 mm focal spot.
 TIMEX 70 digital timer
 Commands on the keyboard and remote x-ray push-button.
 Exposure times 0,04 – 2,00 sec.
 20 cm. focus – skin distance.
 Designed to work with X-ray film, digital sensors and phosphor plates.

ORIX HF Advantage

CE 0051	
Description	
High frequency Direct current DC, constant potential. 30% patient absorbed dose reduction. 60-65-70 kV - 7 mA. 0,8 mm focal spot. TIMEX HF digital timer. Commands on the keyboard and remote x-ray push-button. Exposure times 0,01 – 2,00 sec. 20 cm. focus – skin distance. Designed to work with X-ray film, digital sensors and phosphor plates.	

ORIX HF Plus

CE 0051		
Description		
High frequency Direct current DC, constant potential. 30% patient absorbed dose reduction. 60-65-70 kV - 5 mA. 0,4 mm focal spot. TIMEX HF digital timer. Commands on the keyboard and remote x-ray push-button. Exposure times 0,01 – 2,00 sec. 20 cm. focus – skin distance. Designed to work with X-ray film, digital sensors and phosphor plates.		



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Technical Data

Sensors

Film Size equivalent	Size 1 Size 2
External dimensions	24,35 mm x 36,73 mm (Size 1) 30,49 mm x 42,80 mm (Size 2)
Active area	600 mm ² (20 mm x 30 mm) (Size 1) 900 mm ² (26 mm x 36 mm) (Size 2)
Number of pixels	1,6 megapixels (1050 x 1580) (Size 1) 2,4 megapixels (1368 x 1896) (Size 2)
Pixel size	19 µm x 19 µm
Theoretical resolution	26,3 pl/mm
Real resolution	> 20 pl/mm or 0,05 mm image detail
Signal to noise ratio	40 dB (@130 µGy)
Cable length	3 m (maximum 20 m with USB hubs)



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IMAGE

Digital videoradiographic sensor



Let's enter into details

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PRO IMAGE rev.1 - 30/10/2015

IMAGE

Quality

Long acquired expertise to offer top diagnostic quality.

Simplicity

Easy, friendly, effective.

Flexibility

Image can be used with several X-ray intraoral units, without any hardware or software connections.

Image is a state of art digital radiovisiography system from Ardet.

With a direct USB 2.0 connectivity and drive electronics, **Image** simplifies the practice workflow and delivers superior quality images in a durable, patient friendly design.

The performance of **Image** sensor is crucial to helping detect the slightest dental disease and allowing for the best dental care. **Image** sensors are successful thanks to state-of-the-art image quality and features (integrated USB, advanced ergonomic) brought by the advanced CMOS-based technology and dedicated scintillating material.

Comfort

Image sensor has been designed to further appreciate the shape of the oral cavity of the patient. Thanks to its rounded corners, smooth edges and small thickness, the patient's comfort has been optimized while making the sensor positioning easier.

2 sizes available

Available in two sizes (size 1 and size 2), this sensor offers high resolution images.

With a theoretical resolution of 26.3 lp/mm associated with CMOS technology and a scintillator, the acquired image is exceptionally fine for an accurate diagnosis.

Acquisition rapidity

Image sensor works in USB 2.0 full speed mode. The high-resolution image will appear instantly on your computer screen.

Advanced technology

The embedded electronics of **Image** the Image system is so small that everything is within the sensor case. There is no need to find a place for the data box on your work space. With hot Plug & Play technology, you just need to plug the USB connector on your computer: You are now ready to take an X-ray.

Let's enter into details

