

**AeroDR3**  
1417HD2 / 1717HD2 / 1012HQ



KONICA MINOLTA, INC. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan  
<https://www.konicaminolta.com/global-en/healthcare/>



KONICA MINOLTA

WIRELESS DIGITAL RADIOGRAPHY SYSTEM

**AeroDR3**

1417HD2 / 1717HD2 / 1012HQ



Giving Shape to Ideas



***New generation,***

***High-Definition***

***High-Durability***

***Antibacterial***

Konica Minolta's next generation wireless FPD  
AeroDR 3 1417HD2 / 1717HD2 / 1012HQ exceeds  
the advantages of our current AeroDR® series and incorporates  
new features. It is the top-of-the-line model in the AeroDR series.

High Image Quality  
High-Definition, High DQE and Lower Radiation Doses

Lightweight, Rugged and Safety  
Antibacterial Carbon SMC Enclosure

Powerful and Reliable Workflow  
Rapid Cycle Time, Selectable Pixel Size,  
and Updated AeroSync® Automatic Exposure Detection.

# ***AeroDR 3 HD2***



**AeroDR 3 1417HD2**

Light weight at 2.6kg (5.7 lb)

Rapid cycle time of 4 s  
in wireless operation\*1

Antibacterial design



**AeroDR 3 1717HD2**

Light weight at 3.2kg (7.0 lb)

Rapid cycle time of 4 s  
in wireless operation\*1

Antibacterial design



**AeroDR 3 1012HQ**

Light weight at 1.5kg (3.3 lb)

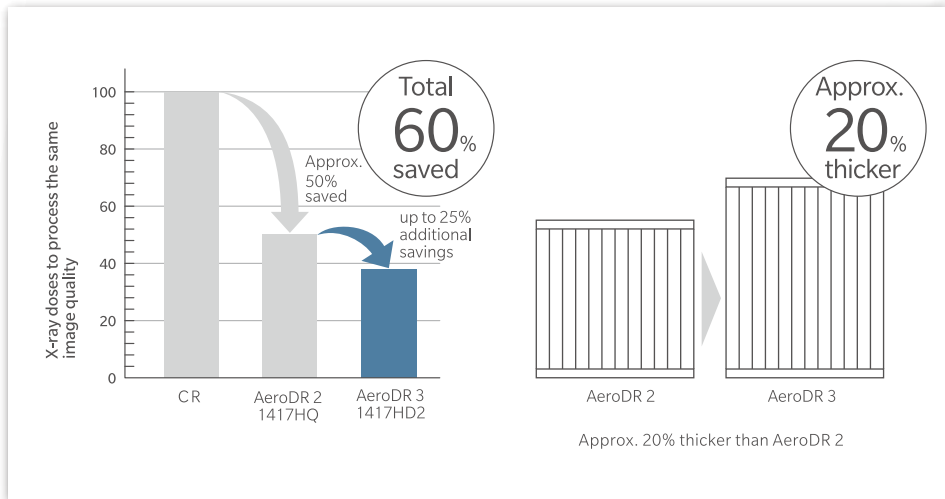
Rapid cycle time of 4 s  
in wireless operation\*1

\*1 Specifications may vary depending on system configuration or environment. The specifications described above assume that each AeroDR 3 panel (pixel size is selected 200µm) is connected to an X-ray generator.

# High Image Quality

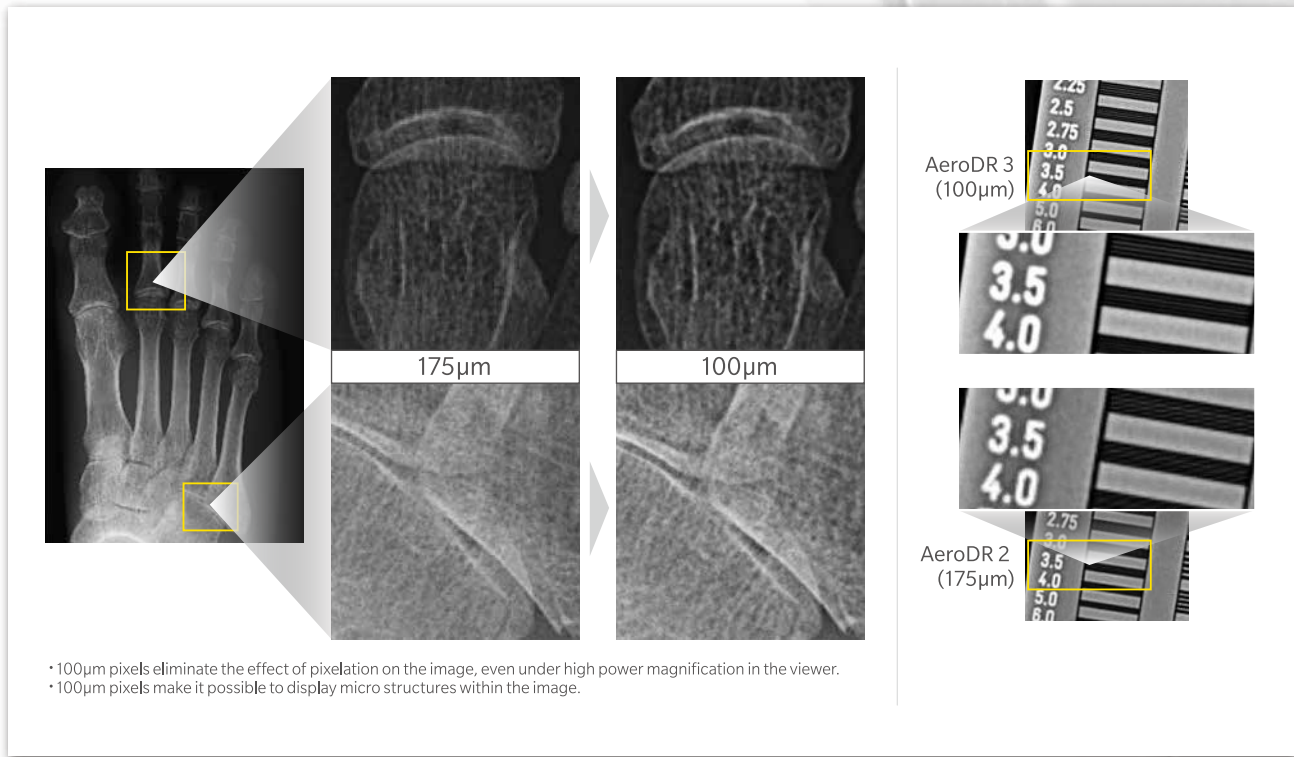
## High DQE and Lower Doses

Konica Minolta introduces the latest technological advances with the AeroDR 3 High sensitivity TFT panel. The thicker CsI scintillator and new ROIC can reduce the electrical noise level. Now we can provide patients and AeroDR users with high Detective Quantum Efficiency (DQE) and lesser doses with AeroDR 3 when compared with previous system.



## Thicker CsI Scintillator

The scintillator material is evenly distributed from the bottom to the top of the panel, it's more than 20% thicker than the AeroDR 2 1417HQ panel. This helps provide the high DQE.



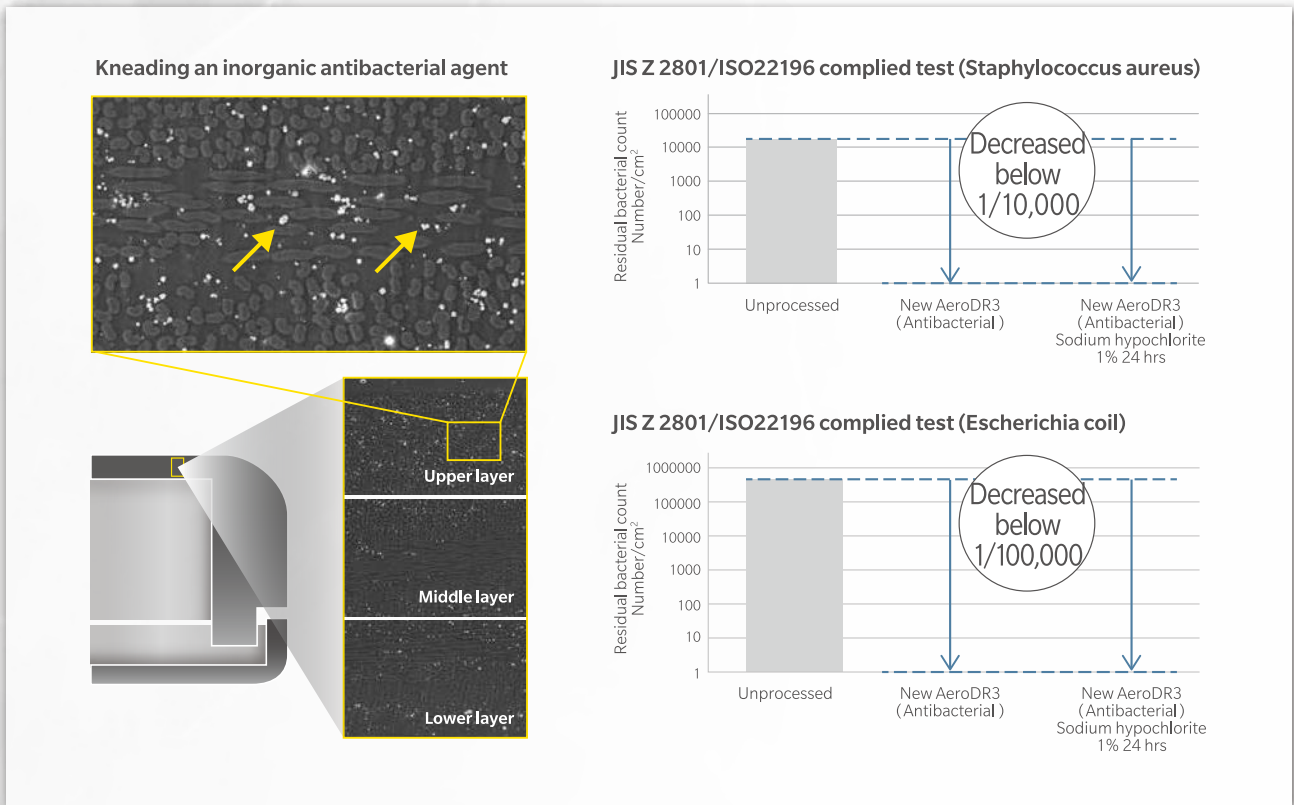
## Performance of 100µm pixels

The pixels are 100µm across, and this small size helps ensure clear images.

# Antibacterial Performance that Lasts.

## Antibacterial carbon enclosure that does not impact performance.\*2

AeroDR3 1417HD2/1717HD2 provides a permanent antibacterial performance that does not deteriorate over time by incorporating antimicrobial agents containing Ag in its enclosure materials. Since antibacterial performance is not lost due to scratches in daily use, it can be used with confidence due to the antibacterial properties required for preventing nosocomial infections.

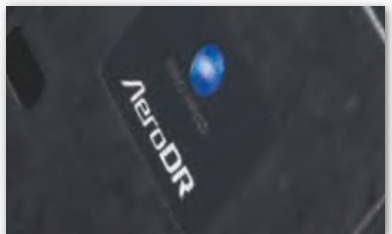


\*2 The antibacterial effect is not effective to all of bacteria. Although antibacterial treatment can suppress propagation of bacteria, it does not eliminate bacteria completely or help complete prevention of infection. Bacteria may propagate when the surface has fatand-oil or dirt adhered on it.

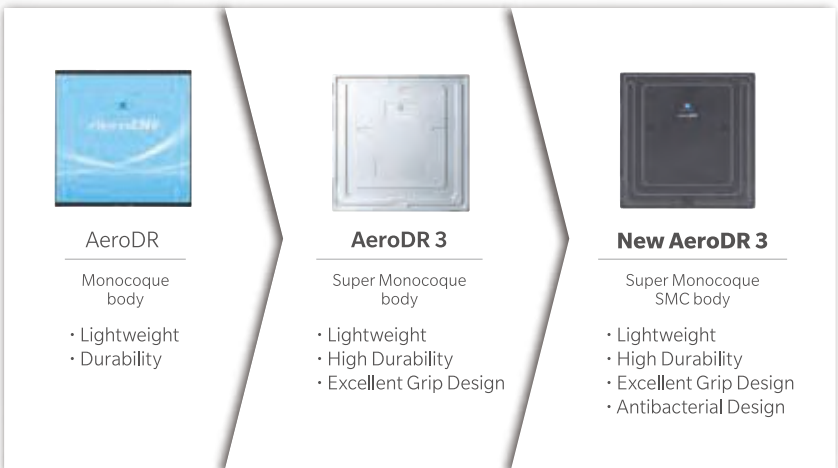
## An enclosure that is lightweight, rugged and safe.

Carbon SMC (Carbon Sheet Molding Compound) is used for the enclosure material for the first time as a medical device\*3. It is a material that is lightweight yet has excellent rigidity, and antibacterial agents can be kneaded into the material, achieving both high durability and safety required in the medical field.

\*3 As of Mar,2021, An internal investigation



AeroDR has evolved to meet the needs of healthcare workers.

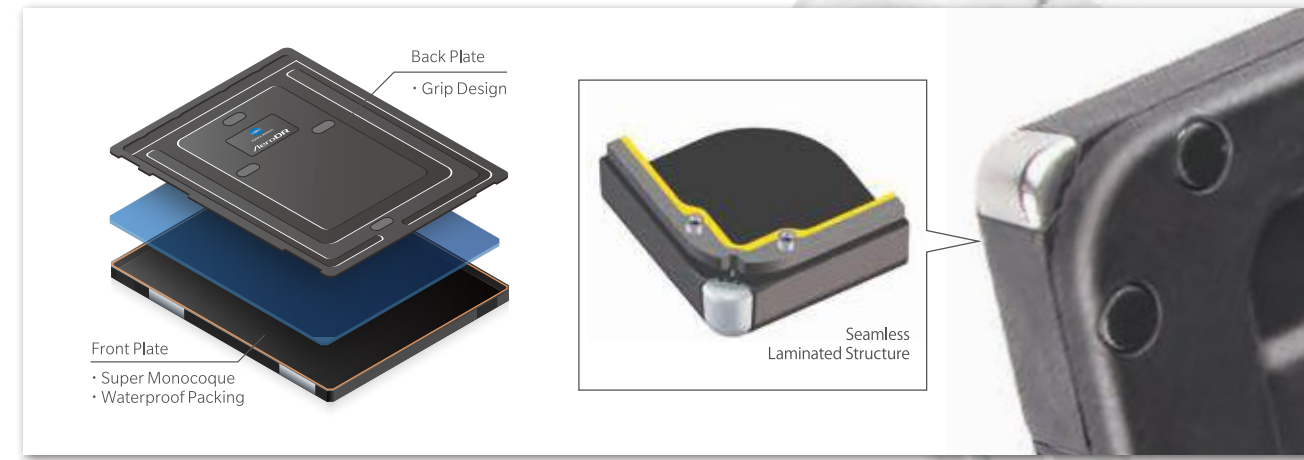




# Lightweight and Rugged Structure

## Super Monocoque Housing Structure

Konica Minolta has developed a new detector design to provide easy handling and high durability.



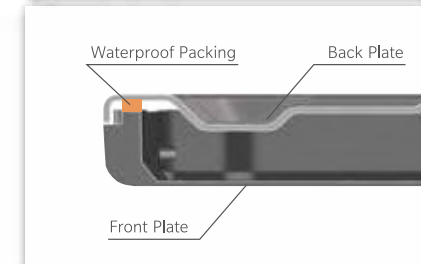
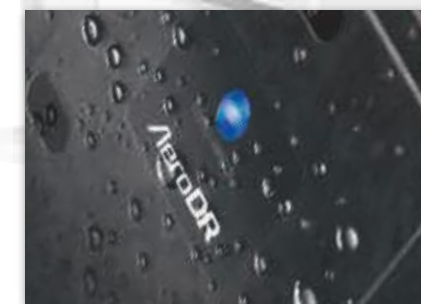
## Excellent Grip Design

The depression is on the backside panel surface, helping to prevent user fingers from being caught. This excellent design makes it easier and safer to handle in your daily routine.

## Sustains IPX6 waterproof compliance even after the panel was dropped from height of 1.0m.\*

The AeroDR 3 panel has cleared the durability test for water resistance after dropping it from a height of 1m. The structure of the AeroDR 3 panel does not allow liquids to penetrate or damage the main components.

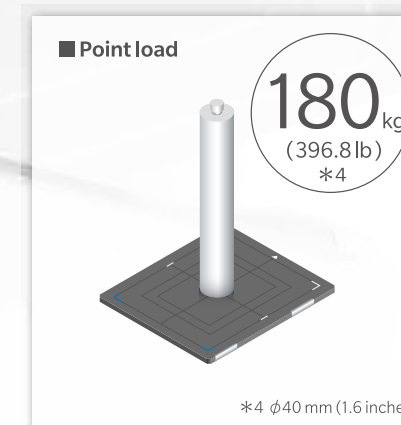
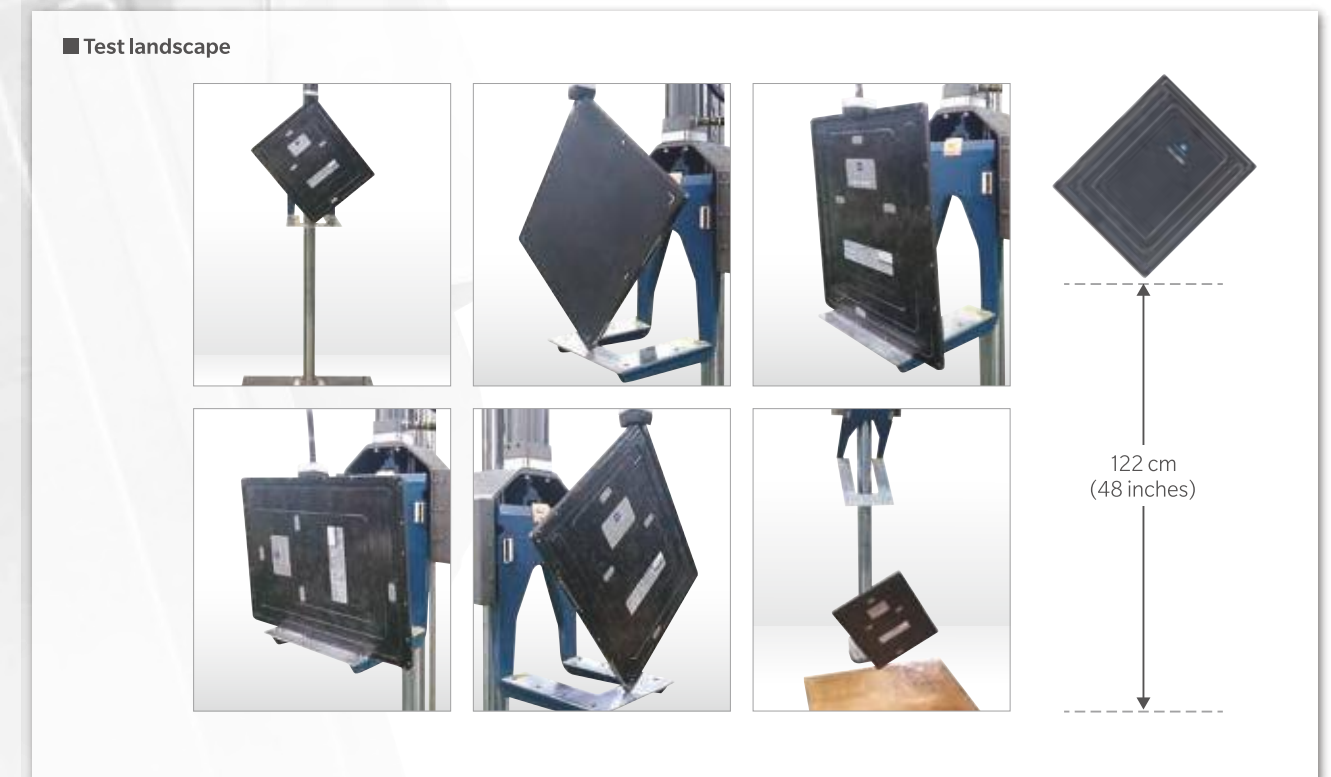
\* The internal test condition is that the AeroDR 3 1417HD2 main body is dropped once onto a concrete floor that has a 2mm-thick sheet laid on it, after which the water resistance test is conducted. Depending upon the operating conditions and detector status, the IPX6 water resistance may be lost.



Enhanced waterproof performance.

## AeroDR 3 panel has passed the US Department of Defense MIL-STD-810G drop strength test

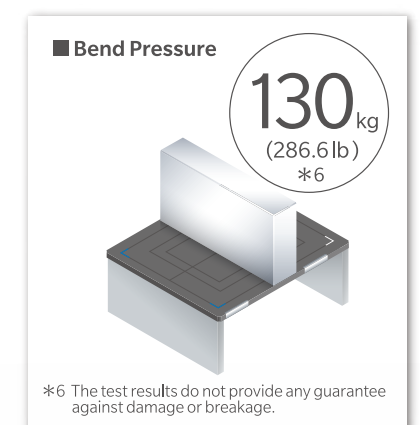
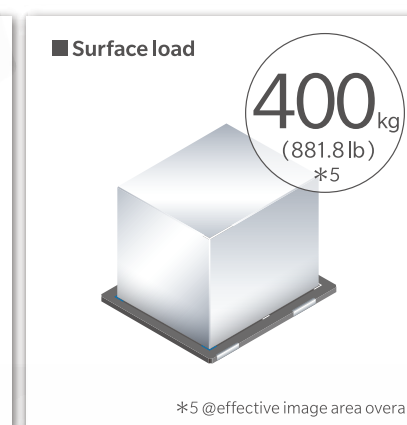
The test consists of drops from a total of 26 places once each from the height of 122 cm (48 inches). The 26 places are 6 planes above plywood, 12 ridgelines, and 8 vertices.



## Load Resistance\*

The AeroDR 3 panel has undergone a variety of internal tests based on some assumed extreme operating scenarios.

\* The test results do not provide any guarantee against damage or breakage.



## Bend Resistance

Konica Minolta assumed an operating scenario in which a 130 kg patient lies on the AeroDR 3 panel main body for a bed-side exposure, and designed the detector such that it would not affect the processed image or suffer internal damage.

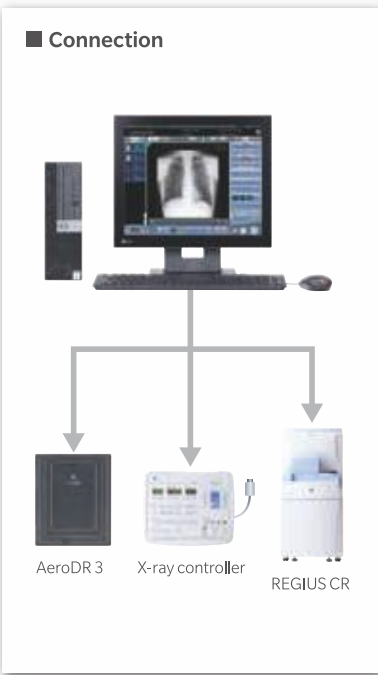


# Powerful and Reliable Workflow

## CS-7 Integrated control station

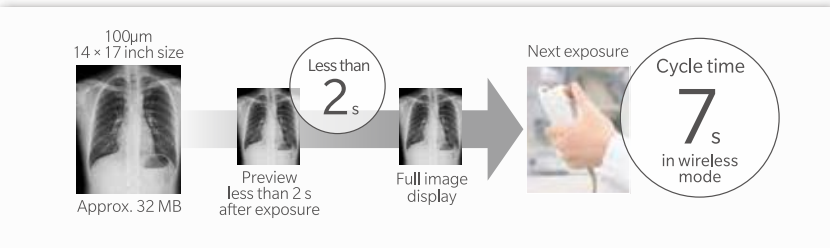
CS-7 can control multiple AeroDR panels and CR readers as a integrated console station.

(Please contact your Konica Minolta sales representative regarding which devices can connect to CS-7)



## Rapid Cycle Time

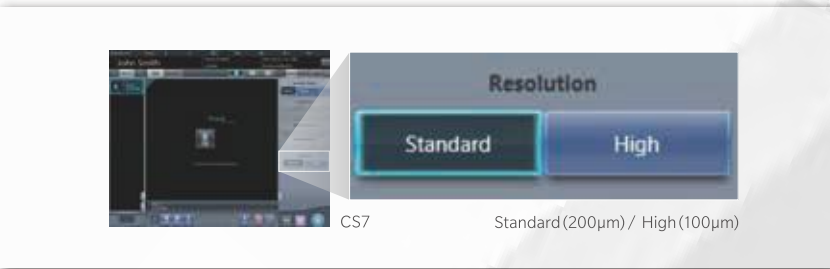
The AeroDR SYSTEM 3 can handle large image data and provide short cycle times even though the image data is taken at 100µm pixels.



With 200µm pixels and in wireless mode, the cycle time is 4 s.

## The pixel size is selectable between 100µm or 200µm.

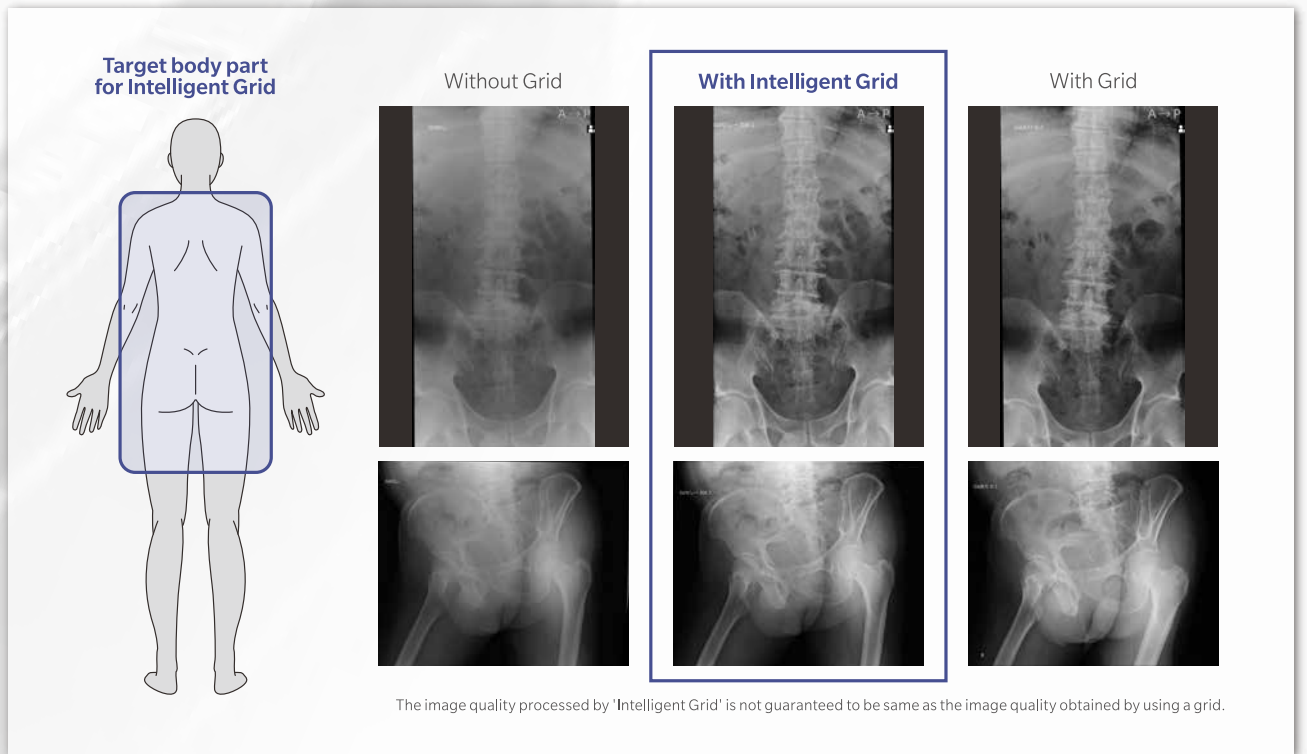
AeroDR 3 users can select a pixel size of 100µm or 200µm before taking an X-ray. This allows users to control the image data size if they need to save storage space. After taking the X-ray, the CS-7 image-processing workstation has options to output images to save data space.



# Its sophisticated functions will enrich your daily examination workflow.

## Intelligent Grid

Image processing that improves contrast which is affected by scattered radiation without a grid. This function provides easy workflow, and the operator need not carry it to perform an exam. Three types of parameters are available from comparable grid ratios;3:1/6:1/8:1/10:1/12:1.

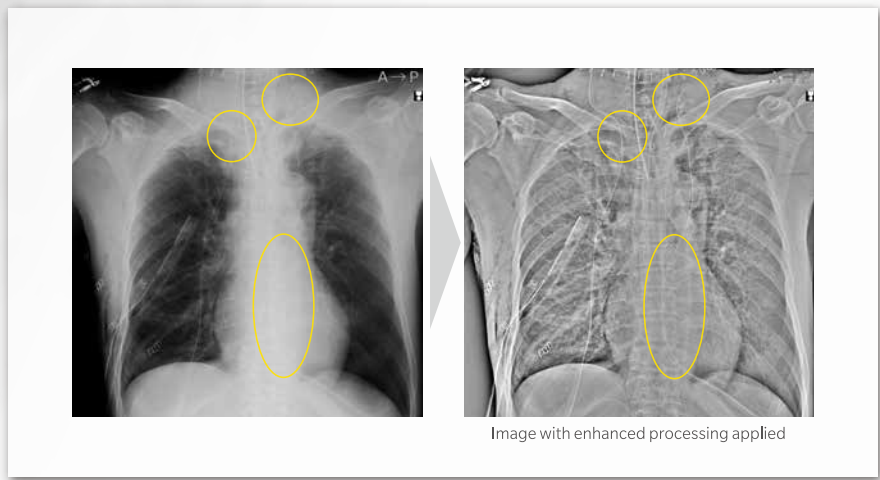


The image quality processed by 'Intelligent Grid' is not guaranteed to be same as the image quality obtained by using a grid.



## Aero Storage for bedside solution

AeroDR 3 is equipped with an "Aero Storage" function that allows you to exam with the panel alone. It can be stored up to 100 images, and it can switch from CR to DR easily at a bedside examination.



## Tube and gauze image enhancement

CS-7 can highlight tube and gauze images that are difficult to detect with normal images.

Optional license is necessary to use this function

# New image processing engine REALISM™ × AeroDR 3 1417HD2/1717HD2/1012HQ



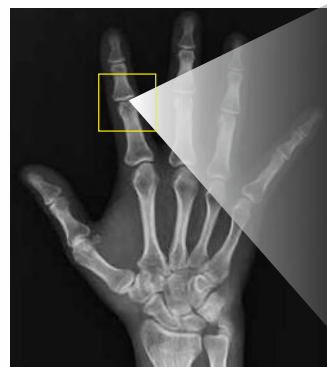
## X-ray images are stereoscopic and clearer

- 1 Depict whole image more clearly while maintaining contrast
- 2 Optimize high definition pixel size 100μm of AeroDR 3 series through sharpness enhancing technology
- 3 Control the granularity deterioration with updated HE/HF processing

### Increased sharpness maximizes panel resolution

RF processing (frequency processing of REALISM processing)

REALISM processing



Hybrid processing (Conventional)



### Technology to draw whole image + maintain contrast

RE processing (compression processing of REALISM processing), introducing New LUT



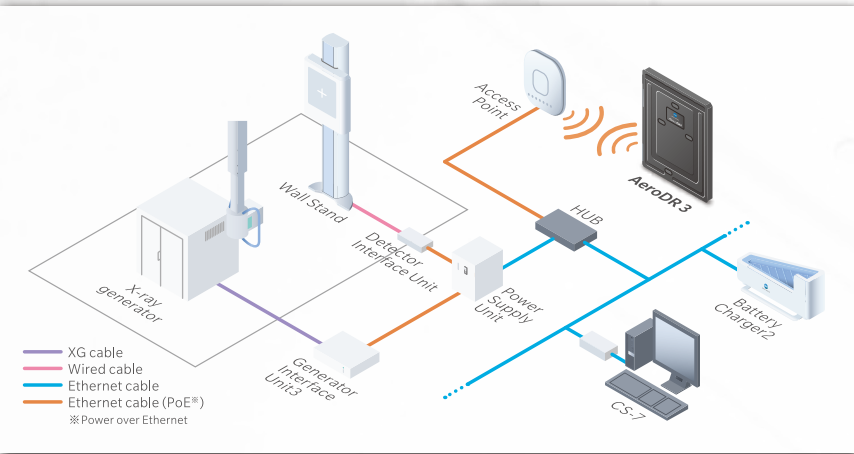


# AeroDR SYSTEM 3 Specifications

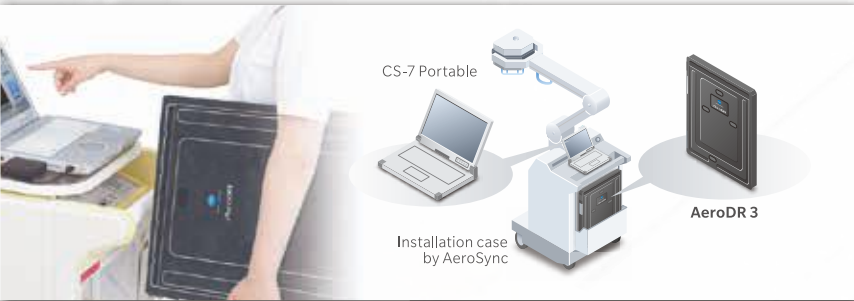
## AeroDR SYSTEM 3 \*7

AeroDR 3 1417HD2		AeroDR 3 1717HD2	AeroDR 3 1012HQ
Product name (model name)*8		AeroDR 3 1417HD2 (P-65)	AeroDR 3 1012HQ (P-81)
Detection method		Indirect conversion method	Indirect conversion method
Scintillator		CsI	CsI
External dimensions (W×D×H)		384×460×15mm (15.1×18.1×0.6 inches)	282×333×15mm (11.1×13.1×0.6 inches)
Weight		2.6kg (5.7lb)	1.5kg (3.3lb)
Pixel size		100 / 200 μm	100 / 200 μm
DQE 1mR,RQA5		56%(1cycle/mm) 72%(0cycle/mm)	56%(1cycle/mm) 72%(0cycle/mm)
MTF		62%(1cycle/mm)	62%(1cycle/mm)
Image area size		348.8×425.6mm (13.7×16.8 inches)	245.6×296.8mm (9.6×11.6 inches)
AD conversion		16 bit (65,536 gradients)	16 bit (65,536 gradients)
Usable grid frequency		60 / 40 / 34 lp/cm	60 / 40 / 34 lp/cm
Communication		Dedicated wired Ethernet connection / Wireless LAN (IEEE802.11a / 802.11n compliant)	Dedicated wired Ethernet connection / Wireless LAN (IEEE802.11a / 802.11n compliant)
W-LAN encryption		Wireless encryption method : AES / Authentication method : WPA2-PSK	Wireless encryption method : AES / Authentication method : WPA2-PSK
Antibacterial		An inorganic antibacterial agent kneaded into the exterior material (complied JIS Z 2801/ISO22196 test)	N/A
Auto Exposure Detection		Available (AeroSync)	Available (AeroSync)
Expected product life time		Same as the lifetime of AeroDR 3 1417HD2 main body	Same as the lifetime of AeroDR 3 1012HQ main body
Durability	Point load*9	180 kg @ ϕ 40 mm	180 kg @ ϕ 40 mm
	Face load	400 kg @ effective image area overall	400 kg @ effective image area overall
	MIL-STD	Acquisition	Acquisition
	Water resistance*10	IPX6 including power cell	IPX6 including power cell
Cycle time*11	100μm	Approx. 6s with dedicated wired connection Approx. 7s with wireless LAN connection	Approx. 5s with dedicated wired connection Approx. 5s with wireless LAN connection
	200μm	Approx. 4s with dedicated wired connection Approx. 4s with wireless LAN connection	Approx. 4s with dedicated wired connection Approx. 4s with wireless LAN connection
Battery performance	Operating time*12 (200μm with wireless LAN connection)	Approx. 309 images / 8.6 h	Approx. 165 images / 4.5 h
	Charging time empty to full	Within 30 min	Within 20 min
	Maximum stand by time*13	Approx. 13 h	Approx. 6 h

\*7 AeroDR SYSTEM 3 is the commercial product name of SKR 3000. \*8 AeroDR 3 1417HD2 / AeroDR 3 1717HD2 / AeroDR 3 1012HQ is the commercial name of P-65 / P-75 / P-81 of SKR3000. With regard to the tested values listed above, measurement methods follow KonicaMinolta standards. \*9 Dead loading does not affect the processed image or panel. Robustness against loading of the AeroDR 3 1417HD2 / AeroDR 3 1717HD2 / AeroDR 3 1012HQ does not provide any guarantees against damage or breakage. 1717HD2 / AeroDR 3 1012HQ does not provide any guarantees of perfect water resistance, nor that it cannot be damaged or broken. \*10 The water resistance performance of AeroDR 3 1417HD2 / AeroDR 3 specifications described above assume that AeroDR 3 1417HD2 / AeroDR 3 to position the patient. This also assumes that the AeroDR 3 1417HD2 / AeroDR 3 1012HQ is connected to an X-ray generator. \*11 Specifications may vary depending on system configuration or environment. The 1717HD2 / AeroDR 3 1012HQ is linked to an X-ray generator and is also connected to a CS-7 image processing workstation. \*12 The specifications assume that 3 exposures are taken within one study and that the time between studies is 5 min. They also assume that it takes 20s to position the patient. \*13 The specifications described above are based on a full battery charge and may vary depending on system configuration and environment.



■ **In-room solution :** One of KonicaMinolta’s proposals for an in-room solution is to retrofit DR systems which can utilize existing X-ray systems. We can provide high image quality and rapid cycle time and eliminate the need to handle CR cassettes. When a simple configuration is suitable for small X-ray rooms, KonicaMinolta can propose the AeroSync in-room system with a minimum configuration such as a panel, console, AP and battery charger.



■ **Portable system solution :** Konica Minolta has two several solutions to digitize analogue portable X-ray units. One is using Aero Storage function without console for small facilities. Another is using upgrade kit with AeroSync function which can be detect X-ray without cable. The customers can carry the DR system to the Portable X-ray unit easily.

Recommended storage and usage environment conditions	When operating :	(Temperature) 10 to 35°C (50 to 95°F) (Humidity) 35 to 80 % (ensure no water condensation) (Atmospheric pressure) 700 to 1060 hPa
	When not operating :	(Temperature) -10 to 40°C (14 to 104°F) (Humidity) 20 to 90 % (ensure no water condensation) (Atmospheric pressure) 700 to 1060 hPa
	In storage / transport :	(Temperature) -20 to 50°C (-4 to 122°F) (Humidity) 20 to 90 % (ensure no water condensation) (Atmospheric pressure) 700 to 1060 hPa
*Performance warranty period when storing at 50°C is 6 months after packing.		

# AeroDR SYSTEM 3 Specifications

## AeroDR Battery Charger2

Power	AC 100 / 110 / 115 / 120 / 200 / 220 / 230 / 240 V ± 10% Single Phase 50 / 60 Hz
External dimensions ( W×D×H )	474.2×200×206.7mm ( 18.7× 7.9× 8.1 inches )
Weight	6 kg ( 13.2 lb )



## Power Supply Unit

External dimensions ( W×D×H )	185×105×150mm ( 7.3×4.1×5.9 inches )
Weight	2.0kg ( 4.4 lb )
Power requirements	AC 100–240 V±10% Single phase 50/60 Hz
LAN interface	3 ports



## Detector Interface Unit

External dimensions ( W×D×H )	60×130×22mm ( 2.4×5.1×0.9 inches )
Weight	0.3 kg ( 0.7lb )
Power requirements	DC 24 V ( When dedicated AC adaptor is used ) DC 48 V ( When dedicated Power Supply Unit is used )
LAN interface	1 port



## Interface Cable 3

Length	8m ( 315 inches )
Weight	1.0 kg ( 2.2lb )

## AeroDR Generator Interface Unit3

Power requirement	When the AC adaptor is used : Supplied from the dedicated AC adaptor. When the Power Supply Unit is used : Supplied from the Power Supply Unit via the Ethernet cable.
Power Supply when using the dedicated AC adaptor	AC 100V–240V ± 10%, Single phase, 50/60 Hz
Power consumption when using the dedicated AC adaptor	Approx. 72VA (100–240V )
External dimensions ( W×D×H )	195×150×43 mm ( 7.7×5.9×1.7 inches )
Weight	1.0 kg ( 2.2 lb )
Dedicated AC adapter specifications	Dimensions : 78×50×35 mm ( 3.0×2.0×1.4 inches ) ※ excluding wall mount & cable Weight : 180g ( 0.4 lb ) Input : AC 100V - 240V 0.6A-0.3A, Single phase, 50Hz - 60 Hz Output : DC 5V, 3A Safety : IEC60601-1 Class II

## Control Station CS-7

Image processing	Auto-gradation processing, Frequency processing ( F processing ), Equalization processing ( E processing ), Hybrid processing ( HF processing - HE processing ), Hybrid smoothing processing ( HS processing ) REALISM processing, Grid removal processing, Automatic exposure field recognition processing, Tube and Gauze image enhancement ( option ), Intelligent Grid ( option )
Image output	Host : max 4 ch / Printer : max 2 ch
DICOM support	DICOM Storage SCU, DICOM basic Grayscale Print Management SCU, DICOM Modality Worklist Management SCU, DICOM Modality Performed Procedure Step SCU, DICOM X ray Radiation Dose SR Storage SCU, DICOM Storage Commitment SCU DICOM Grayscale Softcopy Presentation State Storage SCU, DICOM Verification SCU DICOM X-Ray Radiofluoroscopic Image Storage SCU
Readable devices	AeroDR detector REGIUS MODEL 170, REGIUS MODEL 190, REGIUS MODEL 210, REGIUS MODEL 110 REGIUS MODEL 110HQ, REGIUS SIGMA, REGIUS SIGMA2







**FABRICANTE:** Sociedad Española de Electromedicina y Calidad S.A. (SEDECAL)  
**MANUFACTURER:**

**DIRECCIÓN:** C/ Pelaya 9, Pol. Ind. Río de Janeiro, 28110 Algete (Madrid) Spain  
**ADDRESS**

**SRN:** ES-MF-000017998

**DECLARA BAJO SU EXCLUSIVA RESPONSABILIDAD QUE EL/LOS PRODUCTO(S) SANITARIO(S):**  
**DECLARE UNDER ITS SOLE RESPONSABILITY THAT THE MEDICAL DEVICE(S):**

**PRODUCTO SANITARIO:** Battery Mobile X-Ray Unit PHOENIX  
**MEDICAL DEVICE**

**REF:** AeroDR TX m01

**UDI-DI Básico:** 843604600MOBILECM  
**Basic UDI-DI**

**Código EMDN:** Z11039016  
**EMDN Code**

**CLASIFICACIÓN:** IIb (anexo VIII regla 10)  
**CLASSIFICATION** (annex VIII rule 10)

**Finalidad Prevista:** Radiología Convencional  
**Intended Purpose:** General Radiography

**CUMPLE LOS REQUISITOS GENERALES DE SEGURIDAD Y FUNCIONAMIENTO Y DISPOSICIONES DE:**  
**COMPLIES WITH THE GENERAL SAFETY AND PERFORMANCE REQUIREMENTS & PROVISION OF:**

**(EU) 2017/745**  
y sus modificaciones  
as amended

**Reglamento de Productos Sanitarios,**  
**Medical Devices Regulation,**  
y las legislaciones nacionales adicionales  
and the additional national laws

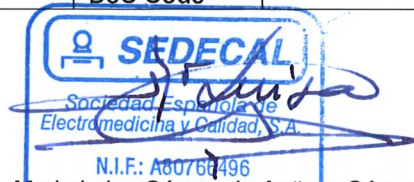
**Certificado CE por el ON:**  
**CE certified by NB**  
**Procedimiento de Evaluación de la Conformidad:**  
**Conformity Assessment Procedure:**

SGS Belgium NV, Notified Body nº 1639.

Anexo IX (Capítulos I y III)  
Annex IX (Chapters I and III)

**Certificado CE nº:** ES23/00000120  
**CE Certificate nº**

**Documentación Técnica:** TD117  
**Technical Documentation:**

<b>Lugar y Fecha:</b> <b>Place and Date</b>	Algete, 23/02/2023	<b>Validez hasta:</b> <b>Valid until</b>	06/02/2028	<b>Rev.: 01</b>	<b>Código DoC:</b> <b>DoC Code</b>	DoC117-1
<b>Nombre y Firma</b> <b>Name and Signature</b>	 N.I.F.: A80766496 Maria Luisa Gómez de Agüero Gómez Directora de Calidad y Reglamentación Quality and Regulatory Director					
<b>Función:</b> <b>Title:</b>						

Către Agenția Medicamentului  
și Dispozitivelor Medicale

**NOTIFICARE**

pentru înregistrarea dispozitivelor medicale în Registrul de stat  
al dispozitivelor medicale  
nr. 37 din 09.11.2023

Solicitantul „INTERMED” SRL, cu sediul în mun. Chișinău, str. Albisoara 64/2, tel./fax: 022 54 91 21, e-mail [office@intermed.md](mailto:office@intermed.md), solicit respectuos înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale ale producătorului **Sociedad Espanola de Electromedicina y Calidad, Sedecal S.A.**, pentru introducerea și punerea la dispoziție pe piață a următoarelor produse:

Denumirea Produs	Ref. Nr.	UDI-DI Basico
Battery Mobile X-Ray Unit PHOENIX	AeroDR TX m01	843604600MOBILECM

**Se anexează următoarele acte:**

Notificarea pentru înregistrarea dispozitivelor medicale;

Declarația pe proprie răspundere;

Declarația de conformitate;

Scrisoarea de Autorizare;

EC Certificat.

Data 09.11.2023

Semnătura



**Tabelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	Accept
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	No. 8050 din 13.11.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Clara Felici Director
Semnătura persoanei responsabile	CF



31<sup>st</sup> July, 2023

## DECLARATION LETTER

I hereby attest that the attached Letter of Authorization to be submitted in this application is true and correct copy of the original.

Legitimate representative of legal manufacturer/product owner



Guillermo Gómez  
Key Account Manager  
Date: August 1, 2023

## LETTER OF AUTHORIZATION

To Whom It May Concern

We, **Sociedad española de electromedicina y calidad S.A, Sedecal** located at c Calle de la Pelaya, 9 Pol. Ind. Río de Janeiro, 28119 Algete, Madrid, Spain do hereby authorize **Konica Minolta Business Solutions Europe GmbH**, having its address in Capellalaan 65, 2132 JL Hoofddorp, The Netherlands, to register, import and distribute **AeroDR TX m01** product listed below in the Market of the **European Union**.

**Please see below list of products in Annex A**

We commit to provide and support all information concerning product information, product quality and ensure the conditions of maintenance & provide consumables, accessories alternative for medical device mentioned above, through our authorized representative **Konica Minolta Business Solutions Europe GmbH**.

This authorization letter is valid until: July 31, 2024

Legitimate representative of legal manufacturer/product owner



**Guillermo J. Gomez de la Fuente**  
Position: Key Account Manager  
Date: August 1, 2023

### Annex A

Name of Products	Physical Manufacturer
AeroDR TX m01	<b>Sociedad española de electromedicina y calidad S.A, Sedecal</b> located at c Calle de la Pelaya, 9 Pol. Ind. Río de Janeiro, 28119 Algete, Madrid, Spain



Oficina Central: C/. Pelaya, 9  
Pol. Ind. "Río de Janeiro"  
28110 Algete (Madrid)  
Tel: (+34) 916 280 544  
Fax: (+34) 902 190 385  
Email: [guest@sedecal.com](mailto:guest@sedecal.com)



# Tracerco™

## Dozimetre electronice personale (PED)

### Măsurarea razelor X și gamma

PED-urile au fost concepute pentru a fi cele mai ușor de utilizat și de înțeles monitoare personale de radiații de pe piață. Totul de pe dispozitive a fost proiectat având în vedere utilizatorul. Ecranul de afișare prezintă măsurători grafice ale radiațiilor și o diagramă simplă a unei persoane care se colorează în funcție de doză de radiație primită. Toate PED-urile noastre au carcase rezistente la vreme, șocuri și căderi, un design curat și ușor de utilizat.

#### Beneficii

- Intervalul debitului dozei de până la 1Sv/h, 100 R/h (PED-ER și PED-ER+)
- Interval de energie de până la 3 MeV
- Siguranță intrinsecă - nu este nevoie de un permis de lucru (PED-IS)
- Afișaj mare, clar, ușor de citit, cu un singur buton
- Alarmer audio și vizuale cu funcționalitatea vibrațiilor
- Evaluat IP67
- Poate fi folosit ca un contor de supraveghere portabil cu funcții GPS și Bluetooth (PED+ și PED-ER+)
- Gestionarea ușoară a dozelor cu software-ul gratuit DoseVision

#### Piete

- Ulei și gaz
- Servicii de urgență
- Prim ajutor
- Militar
- NDT
- Minerit
- Energie nucleară
- Medical
- Controale la frontieră



PED-IS

PED Blue &  
PED-ER

PED+ &  
PED-ER+

#### Accesorii

- Carcasa pentru tranzit (PED-IS)
- Șnururi
- Dock portabil pentru desktop (PED-IS)
- Adaptoare pentru călătorie
- Suporturi din piele / material textil

# Specificațiile PED-urilor Tracerco™

Performanțe			
<b>Radiații detectate</b>	Raze X și raze gamma în interval (33 KeV până la 3 MeV PED-IS, PED Blue, PED+), (48 KeV până la 3 MeV PED-ER, PED-ER+)*	<b>Interval de doză acumulată</b>	Doza „Man” afișaj 0-10Sv, 0-1000 rem Afișaj numeric digital 0-10Sv, 0-1000 rem
<b>Detector</b>	Tub Geiger Muller cu o singură energie compensată	<b>Debitul maxim al dozei de radiație</b>	Afișaj numeric digital 0-100 mSv/h, 0-10 R/h (PED-IS, PED Blue, PED+) Afișaj numeric digital 0-1 Sv/h, 0-100 R/h (PED-ER, PED-ER+)
<b>Unități de măsură</b>	Sievert sau Rem (pot fi selectate în software-ul DoseVision™)		
<b>Memorie</b>	Capacitate de 125.000 de puncte de date. Memorie serială nevolatilă cu 10 ani păstrare a datelor	<b>Intervalul debitului dozei</b>	Afișare grafică cu bare 0-100 mSv/h, 0-10 R/h (PED-IS, PED Blue, PED+), 0-1 Sv/h, 0-100 R/h (PED-ER, PED-ER+)  Afișaj digital numeric 0-100 mSv/h, 0-10 R/h (PED-IS, PED Blue, PED+), 0-1 Sv/h, 0-100 R/h (PED-ER, PED-ER+)
Caracteristici electrice			
<b>Baterie</b>	Litiu Ion reîncărcabilă.  Reîncărcare prin conexiune micro USB standard de 5V.  Poate fi incarcat de la PC	<b>Indicație baterie descărcată</b>	La 8 ore de viață rămase a bateriei
<b>Durata de viata a bateriei</b>	300 de ore de obicei cu radiație de fond		
Caracteristici mecanice			
<b>Dimensiuni</b>	104mm x 64mm x 24mm	<b>Materialul carcasei</b>	Polimeri rezistenți la șocuri, vibrații și cădere Proprietăți antistatice ale suprafeței (numai PED-IS)
<b>Greutate</b>	190g inclusiv clema de curea		
Mediu			
<b>Gradul de protecție la pătrundere</b>	IP67 (etanș la praf și poate rezista la scufundarea în apă la adâncimea de 1 m)	<b>Interval umiditate</b>	Până la 95%
		<b>Interval temperatura de functionare</b>	-20°C până la 50°C
<b>Cod de clasificare a zonelor periculoase (numai PED-IS)</b> ATEX și IECEx: Zona 0, 1, 2 grup de gaz IIA, IIB, IIC FMC: Clasa I, Zona 0, Grupa IIA, IIB, IIC FMUS: Clasa I, Divizia 1, GPS A, B, C și D, Clasa I, Zona 0, Grupa IIA, IIB, IIC		<b>Cod de certificare pentru zone periculoase (numai PED-IS)</b> ATEX: Nr. Certificare Baseefa11ATEX0045 Marcare - II 1G Ex ia IIC T4 Ga (-20°C ≤ Ta ≤ +50°C) IECEx: Nr. Certificare IECEx BAS11.0027 Marcare - Ex ia IIC T4 Ga (-20°C ≤ Ta ≤ +50°C) FMC: Marcare - Cl I, ZONA 0, Ex ia IIC T3 (-20°C ≤ Ta ≤ +50°C) FMUS: Marcare - Cl I, ZONA 0, AEx ia IIC T3 (-20°C ≤ Ta ≤ +50°C) Marcare - IS Cl I, DIV 1, GPS ABCD T3 (-20°C ≤ Ta ≤ +50°C)	
<b>Conformitatea standardului</b> BSEN 61526, EN55011, IEC60079-0, IEC60079-11, IEC61010-1, FM clasa 3600, FM clasa 3610, FM clasa 3810, ANSI/IEC 60529, CSA-C22.2 Nr. 60079-0, CSA-C22.2 - E60079-11, CSA-C22.2 nr. 60529, CSA C22.2 nr. 1010.1			

\*Pentru curba de răspuns detaliată, consultați raportul Radiation Metrology Ltd.

\*\* Durata de viață a bateriei pe PED+ și PED-ER+ va fi redusă atunci când utilizați Bluetooth și GPS. Durata de viață tipică a bateriei se bazează pe utilizarea screensaver-ului.

# Tracerco™ Personal Electronic Dosimeters (PEDs)

## X-ray and gamma ray measurement

The PEDs have been designed to be the easiest personal radiation monitors on the market to use and understand. Everything on the devices has been designed with the user in mind. The display screen features radiation graph measurements and a simple diagram of a person who fills with colour, depending on the dose of radiation received. All of our PEDs have weather, shock and drop proof housings, a smooth clean design and simple to use software.

### Benefits

- Dose rate range of upto 1Sv/h, 100 R/h (PED-ER and PED-ER+)
- Energy range of up to 3 MeV
- Intrinsically safe - no need for a hot work permit (PED-IS)
- Large, clear, easy to read display with one button operation
- Audio and visual alarms with vibration functionality
- IP67 rated
- Can be used as a handheld survey meter with GPS and Bluetooth features (PED+ and PED-ER+)
- Easy dose management with free DoseVision software

### Markets

- |                      |                   |
|----------------------|-------------------|
| • Oil and Gas        | • Mining          |
| • Emergency services | • Nuclear Power   |
| • First responders   | • Medical         |
| • Military           | • Border Controls |
| • NDT                |                   |



PED-IS


PED Blue &  
PED-ERPED+ &  
PED-ER+

### Accessories

- Transit cases (PED-IS)
- Lanyards
- Desktop and portable dock (PED-IS)
- Travel adapters
- Leather / fabric holders



# Tracerco™ PEDs specification

Performance			
Radiation detected	X-rays and gamma rays in range (33 KeV to 3 MeV PED-IS, PED Blue, PED+), (48 KeV to 3 MeV PED-ER, PED-ER+)*	Accumulated dose range	Dose "Man" display 0-10Sv, 0-1000 rem Digital numeric display 0-10Sv, 0-1000 rem
Detector	Single energy compensated Geiger Muller tube	Peak radiation dose rate	Digital numeric display 0-100mSv/h, 0-10 R/h (PED-IS, PED Blue, PED+) Digital numeric display 0-1 Sv/h, 0-100 R/h (PED-ER, PED-ER+)
Units	Sieverts or Rem (may be selected in DoseVision™ software)		
Memory	125,000 data point capacity. Serial non-volatile memory 10 year data retention	Dose rate range	Bar graph display 0-100 mSv/h, 0-10 R/h (PED-IS, PED Blue, PED+), 0-1 Sv/h, 0-100 R/h (PED-ER, PED-ER+) Digital numeric display 0-100 mSv/h, 0-10 R/h (PED-IS, PED Blue, PED+), 0-1 Sv/h, 0-100 R/h (PED-ER, PED-ER+)
Electrical characteristics			
Battery	Rechargeable lithium Ion. Recharge via standard 5V micro USB connection. Can be charged from PC	Low battery indication	On 8 hours battery life remaining
Battery life	300 hours typically with background radiation**		
Mechanical characteristics			
Size	104mm x 64mm x 24mm	Case material	Shock, vibration and drop resistant polymers Antistatic surface properties (PED-IS only)
Weight	190g including belt clip		
Environmental			
Ingress protection rating	IP67 (dust tight and can withstand immersion in water at depth of 1m)	Humidity range	Up to 95%
		Operating temperature range	-20°C to 50°C
Hazardous area classification code (PED-IS only) ATEX & IECEx: Zone 0, 1, 2 gas group IIA, IIB, IIC FM <sub>C</sub> : Class I, Zone 0, Group IIA, IIB, IIC FM <sub>US</sub> : Class I, Division 1, Gps A, B, C and D, Class I, Zone 0, Group IIA, IIB, IIC		Hazardous area certification code (PED-IS only) ATEX: Certification No. Baseefa11ATEX0045 Marking -  II 1G Ex ia IIC T4 Ga (-20°C ≤ Ta ≤ +50°C) IECEx: Certification No. IECEx BAS11.0027 Marking - Ex ia IIC T4 Ga (-20°C ≤ Ta ≤ +50°C) FM <sub>C</sub> : Marking - CI I, ZONE 0, Ex ia IIC T3 (-20°C ≤ Ta ≤ +50°C) FM <sub>US</sub> : Marking - CI I, ZONE 0, AEx ia IIC T3 (-20°C ≤ Ta ≤ +50°C) Marking - IS CI I, DIV 1, GPS ABCD T3 (-20°C ≤ Ta ≤ +50°C)	
Standard compliance BSEN 61526, EN55011, IEC60079-0, IEC60079-11, IEC61010-1, FM Class 3600, FM Class 3610, FM Class 3810, ANSI/IEC 60529, CSA-C22.2 No. 60079-0, CSA-C22.2 - E60079-11, CSA-C22.2 No. 60529, CSA C22.2 No 1010.1			

\*For detailed response curve please see report by Radiation Metrology Ltd.

\*\* Battery life on the PED+ and PED-ER+ will be reduced when using Bluetooth and GPS. Typical battery life is based on the use of the screensaver.

Sistem Software si Hardware integrat  
**DICOM Workstation PixelData**

**Software DICOM Workstation 2D/3D(1 licenta)**

- Aplicatie software pentru procesare imagini medicale DICOM si inscriptionat CD/DVD-uri.
- Functionalitati:
  - Masuratori (distante, unghiuri, unghi Cobb, calcul raport intre doua distante);
  - Moduri de afisare: mod comparativ, mod cine, sincronizare automata intre mai multe serii din acelasi plan;
  - Linii de referinta intre plane;
  - 2D Window/Level, zoom, pan, lupa, inversare, rotire, oglindire;
  - Salvare imagini ca si DICOM, JPEG, BMP, TIFF.
  - Posibilitate de vizualizare documente PDF incapsulate DICOM;
  - Posibilitate de vizualizare rapoarte DICOM SR.
  - ROI (evaluare regiuni de interes si volum de interes), unitati Hounsfield;
  - Ferestre preformate (plaman, pelvis, sinus, laringe, cerebel, os, abdomen, mediastin, creier, etc.). Posibilitatea de a avea comenzi scurte (taste sau combinatii de taste) pentru fiecare fereasta.
  - Inscriptionare CD/DVD cu imagini pacient si cu viewer DICOM;
  - DICOM print;
  - Functii de cautare/filtrare dupa: ID Pacient, Nume Pacient, Prenume Pacient, Tipuri de echipamente, Efectiv echipamentele identificate dupa AE\_TITLE, Numar investigatie, ID studiu, Descriere Studiu, Descriere Serie, Interval de data efectuare studiu, interval de data cand s-a arhivat studiul.
  - Posibilitate de a se conecta simultan la mai multe servere de tip PACS.
  - Functie de alipire manuala a doua sau mai multe imagini de radiologie.
  - Posibilitate de redactare rezultat direct in interfata de la DICOM Viewer.
  - Posibilitatea de a selecta si incarca template de rezultat in functie de tipul examinarii.
  - Conversia rezultatului in PDF incapsulat DICOM.
  - Posibilitatea de a afisa istoricul imagistic (toate studiile anterioare) in momentul in care utilizatorul cheama spre vizualizare studiul curent.
  - Posibilitatea ca Viewer-ul DICOM sa lucreze multimonitor.
  - Posibilitatea de a selecta si deschide doar seriile selectate.
  - Posibilitatea de a importa imagini JPG si BMP si de a le trimite in PACS.
  - Fuziune PET/CT;
  - Spine labeling
  - Unealta tip Bagheta magica
  - Filtre procesare imagine: sharpness, blur, emboss
  - Vizualizare si procesare imagini DICOM comprimate JPEG
  - Functie de Stitching pentru imagini de tip RX pentru 2 sau mai multe imagini si obtinerea unei noi imagini DICOM
  - Baza de date pacienti, posibilitate de vizualizare si redactare a imaginilor primite de la locu de lucru 1 si retea DICOM
- Aplicatie de tip broker care preia mesaje DICOM trimise de fiecare modalitate, le transforma in mesaje HL7.
- Accepta urmatoarele comenzi DICOM: C-STORE, C-FIND, C-MOVE, C-GET.

- Posibilitatea de a redacta rezultate de la distanta fara a utilize VPN sau aplicatii de acces remote.
- Print pe imprimante DICOM (pe film sau hartie); Utilizeaza CD/DVD-ul de pe PC;
- 3D, MPR, MIP, Volume Rendering.
- Inscriptiuneaza CD/DVD cu imaginile DICOM ale pacientului impreuna cu un DICOM Viewer performant pentru vizualizarea automata a imaginilor DICOM de pe CD/DVD;
- Posibilitate de redactare rezultate direct din aplicatia software de vizualizare a imaginilor;
- Posibilitate diagnosticare, ajustare de la distanta;
- Posibilitate de scanare documente si incapsulare DICOM;
- Aplicatia de vizualizare a imaginilor DICOM de pe CD porneste automat dupa inserarea CD/DVD-ului in unitatea optica si are urmatoarele functionalitati:
  - Masuratori (distanțe, unghiuri, unghi Cobb);
  - Moduri de afisare: mod comparativ, mod cine, sincronizare automata contrast/fara contrast;
  - Linii de referinta intre plane;
  - 2D Window/Level, zoom;
  - ROI, unitati Hounsfield;
  - Ferestre preformatate (plaman, os, abdomen, etc.).
  -

#### **Hardware DICOM Workstation**

Desktop PC Intel i5, **16 GB RAM, SSD 512 GB, HDD 1TB**, placa video dedicata, DVD/RW, tastatura, mouse, Windows 11 Pro.

**Monitor DICOM** color: 1 x JVC **rezolutie 3 MP diagonala 21"** LED-TFT Color.

Monitor Office color: monitor LED min 23" color Full HD.

UPS min 750VA

**Standarde producator:** ISO9001:2015 si ISO13485:2016, declaratie de conformitate de la producator.

**Garantie:** 24 luni.



Certificate ES03/60071

The management system of

## SOCIEDAD ESPAÑOLA DE ELECTROMEDICINA Y CALIDAD, S.A. (SEDECAL)

Pol. Ind. Río de Janeiro, C/ Pelaya, 9-13  
28110 Algete (Madrid)

has been assessed and certified as meeting the requirements of

### ISO 9001:2015

For the following activities

- ✓ Design, manufacture, sales and technical support to customers for medical and veterinarian use, of: X-ray generators, X-ray systems (stationary, mobile, portable and monoblocks), X-ray tube starters, radiological positioners and ozone generators.
- ✓ Subcontracted design and manufacture of X-ray systems and components.
- ✓ Design and manufacture of electronic, mechanical and electromechanical modules for industrial applications.

in/ from the following sites

Headquarters and factory: Pol. Ind. Río de Janeiro, C/ Pelaya, 9-13  
28110 Algete (Madrid)

This certificate is valid from  
19 July 2021 until 19 July 2024.  
Issue 6. Company certified since January 1997.  
Certified with SGS since 6 April 2018.



Authorized by

*Esueta*

Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.  
C/Trespaderne, 29. 28042 Madrid. España.  
t 34 91 313 8115 www.sgs.com

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# SGS

Certificate ES19/85998

The management system of

## Sociedad Española de Electromedicina y Calidad, S.A. (SEDECAL)

Polígono Industrial Rio de Janeiro.  
C/ Pelaya, 9-13  
28110 ALGETE (Madrid). Spain

has been assessed and certified as meeting the requirements of

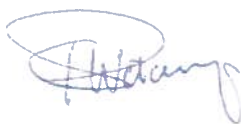
### ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Design, manufacture, sales and technical support to customers  
of X-ray generators and X-ray systems (stationary, mobile,  
portable and monoblocks), X-ray tube starters,  
radiological positioners and ozone generators.**

This certificate is valid from 20 July 2021 until 19 July 2024  
and remains valid subject to satisfactory surveillance audits.  
Issue 3. Certified since 28 January 1997.  
Re certification audit due before 19 July 2024.

Authorised by



Pieter Weterings  
Certification Manager

SGS Belgium NV

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

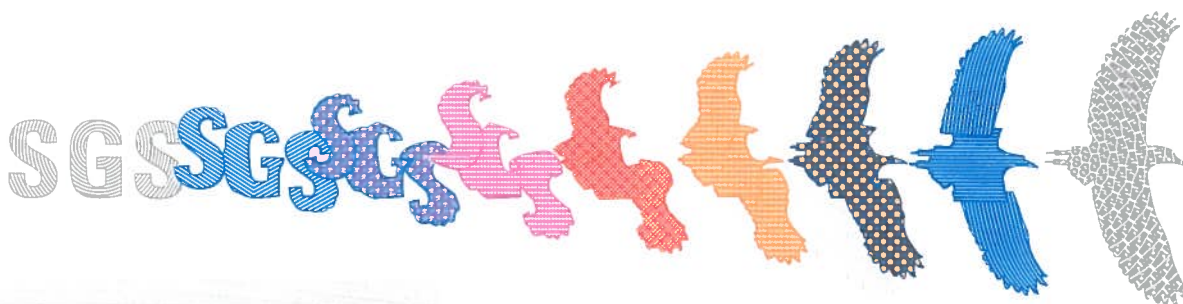
SGS Belgium 13485-2 0308



Accreditation Number

005-QMS  
EN ISO/IEC 17021-1:2015

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# EU Quality Management System Certificate ES23/00000120

The management system of



## Sociedad Española de Electromedicina y Calidad S.A. (SEDECAL)

C/ Pelaya 9, Polígono Industrial Rio de Janeiro, 28110 Algete (Madrid). Spain.

SRN: ES-MF-000017998

has been assessed and certified as meeting the requirements of

### MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

The Scope of Registration appears on page 2, 3, 4, and 5 of this certificate

This certificate is valid from 06 February 2023 until 06 February 2028 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 06 August 2027

Issue 1. Certified since 06 February 2023

Authorised by

Geoffrey De Visscher

Head of Notified Body 1639

SGS Belgium NV

SGS House Noorderlaan 87 2030 Antwerp Belgium

t +32 (0)3 545-48-48 - www.sgs.com

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## Sociedad Española de Electromedicina y Calidad S.A. (SEDECAL)

### MDR EU Quality Management System certificate (Annex IX QMS)

Class IIb devices:

Active non-implantable imaging devices utilising ionizing radiation (MDA0201, MDS1009);

#### X-Ray Generator SHF:

SHF-1010, SHF-1015, SHF-1020, SHF-1025, SHF-1030, SHF-1035,  
SHF-1610, SHF-1615, SHF-1620, SHF-1625, SHF-1630, SHF-1635,  
SHF-210, SHF-215, SHF-220, SHF-225, SHF-230, SHF-235,  
SHF-310, SHF-315, SHF-320, SHF-325, SHF-330, SHF-335,  
SHF-410, SHF-415, SHF-420, SHF-425, SHF-430, SHF-435,  
SHF-510, SHF-515, SHF-520, SHF-525, SHF-530, SHF-535,  
SHF-610, SHF-615, SHF-620, SHF-625, SHF-630, SHF-635, SHF-835,  
SHF-1610 PSU, SHF-1615 PSU,  
SHF-210 PSU, SHF-215 PSU,  
SHF-310 PSU, SHF-315 PSU,  
SHF-410 PSU, SHF-415 PSU, SHF-510 PSU, SHF-515 PSU  
SHF-1610-C, SHF-1615-C,  
SHF-210-C, SHF-215-C,  
SHF-310-C, SHF-315-C,  
SHF-410-C, SHF-415-C,  
SHF-510-C, SHF-515-C  
SHF-0510-M, SHF-0530-M, SHF-1010-M, SHF-1030-M,  
SHF-0510-MPSTA, SHF-1010-MPSTA  
(EMDN: Z11039011; Basic UDI-DI: 843604600GENERATORBD)

#### X-Ray Generator SHFR:

SHFR100, SHFR200, SHFR300, SHFR400, SHFR500, SHFR600, SHFR800  
(EMDN: Z11039011; Basic UDI-DI: 843604600GENERATORBD)

#### Mobile X-Ray Generator:

SM-IV  
SM-V  
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILEGENCG)

#### Battery Mobile X-Ray Unit PHOENIX:

PHOENIX  
AeroDR TX m01  
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

#### Battery Mobile X-Ray Unit EASY MOVING:

SM-20HF-Batt, SM-32HF-Batt, SM-40HF-Batt, SM-50HF-Batt  
SM-20HF-B-D-C, SM-32HF-B-D-C, SM-40HF-B-D-C, SM-50HF-B-D-C  
SM-20HF-B-D-TEZ, SM-32HF-B-D-TEZ, SM-40HF-B-D-TEZ, SM-50HF-B-D-TEZ  
SM-20HF-B-D-FDX, SM-32HF-B-D-FDX, SM-40HF-B-D-FDX, SM-50HF-B-D-FDX  
SM-20HF-B-D-FDXW, SM-32HF-B-D-FDXW, SM-40HF-B-D-FDXW,  
SM-50HF-B-D-FDXW  
SM-20HF-B-D-KM (AeroDR X30), SM-32HF-B-D-KM (AeroDR X30),  
SM-40HF-B-D-KM (AeroDR X30), SM-50HF-B-D-KM (AeroDR X30)  
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)



EU Quality Management System Certificate ES23/00000120, continued

# Sociedad Española de Electromedicina y Calidad S.A. (SEDECAL)

## MDR EU Quality Management System certificate (Annex IX QMS)

### Capacitor Mobile X-Ray Unit MOBIXRAY:

SMR-16, SMR-20, SMR-32  
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

### Portable X-Ray Unit SPL:

SPL-HF-2.0, SPL-HF-4.0, SPL-HF-8.0  
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

### Portable X-Ray Unit DRAGON X:

SPSL-HF-4.0, SPSL-HF-8.0,  
SPSL-HF-4.0-APR, SPSL-HF-8.0-APR,  
SPSLW4, SPSLW8, SPSL4HC, SPSL8HC  
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

### Radiographic System SEDECAL X:

SEDECAL X BRS, Composed of:  
Radiographic Positioner: SEDECAL X BRS  
(EMDN: Z11039005; Basic UDI-DI: 843604600UNIVERSALUF)

SEDECAL X URS, Composed of:

Radiographic Positioner: SEDECAL X URS  
Control Box: SEDECAL X URS  
(EMDN: Z11039005; Basic UDI-DI: 843604600UNIVERSALUF)

SEDECAL X PLUS LP PLUS, Composed of:

Radiographic Positioner: SEDECAL X PLUS LP PLUS  
Control Box: SEDECAL X PLUS LP PLUS  
(EMDN: Z11039005; Basic UDI-DI: 843604600UNIVERSALUF)

### Radiographic System MILLENNIUM:

MILLENNIUM, Composed of:  
Tube Stand MILLENNIUM: MILL-FMTS  
Tube Stand MILLENNIUM: MILL-FMTS-TS  
Tube Stand AD MILLENNIUM: MILL-FMTSAD  
Fixed Height Table MILLENNIUM: MILL-FWFTT-B  
Elevating Table MILLENNIUM: MILL-EL-B  
Wall Stand MILLENNIUM: MILL-WBS  
Wall Stand MILLENNIUM: MILL-WBS-TS  
Tomography MILLENNIUM: MILL-TOMO  
Power Supply: BRAKE BOX  
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

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# Sociedad Española de Electromedicina y Calidad S.A. (SEDECAL)

## MDR EU Quality Management System certificate (Annex IX QMS)

MILLENNIUM PLUS AT, Composed of:

Tube Stand MILLENNIUM PLUS AT: MILL-FMTSAT-PLUS  
Elevating Table MILLENNIUM PLUS AT: MILL-ELAT-PLUS  
Wall Stand MILLENNIUM PLUS AT: MILL-WBSAT-PLUS  
Wall Stand Manual Tilting: TWBS-TILT  
Tomography MILLENNIUM PLUS: MILL-TOMO-PLUS  
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

MILLENNIUM PLUS TPC, Composed of:

Tube Stand MILLENNIUM PLUS TPC: MILL-FMTSTPC-PLUS  
Elevating Table MILLENNIUM PLUS TPC: MILL-ELTPC-PLUS  
Wall Stand MILLENNIUM PLUS TPC: MILL-WBSTPC-PLUS  
Wall Stand Manual Tilting: TWBS-TILT  
Tomography MILLENNIUM PLUS: MILL-TOMO-PLUS  
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

### Radiographic System PROTEUS XR/f:

PROTEUS XR/f ET, Composed of:  
Tube Stand MULTIRAD: MULT-FMTS  
Elevating Table NET 4000: NET 4000-ST  
Wall Stand MILLENNIUM: MILL-WBS  
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

PROTEUS XR/f ST, Composed of:

Tube Stand MULTIRAD: MULT-FMTS  
Table MULTIRAD: MULT-FWFTTD  
Wall Stand MILLENNIUM: MILL-WBS  
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

### Radiographic System MULTIRAD:

MULTIRAD (Proteus), Composed of:  
Tube Stand MULTIRAD: MULT-FMTS  
Table MULTIRAD: MULT-FWFTT  
Wall Stand MULTIRAD: MULT-WBS  
Power Supply: BRAKE BOX  
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

MULTIRAD NET, Composed of:

Tube Stand MULTIRAD: MULT-FMTS  
Elevating Table NET 4000: NET 4000-ST  
Wall Stand MULTIRAD: MULT-WBS  
Wall Stand MILLENNIUM: MILL-WBS  
Power Supply: BRAKE BOX  
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)





EU Quality Management System Certificate ES23/00000120, continued

# Sociedad Española de Electromedicina y Calidad S.A. (SEDECAL)

## MDR EU Quality Management System certificate (Annex IX QMS)

### Radiographic System NOVA:

NOVA FA, Composed of:  
Elevating Table NET 4000: NET 4000-AU  
Moving Elevating Table: FLEXI-DT  
Wall Stand NBS 2100: NBS 2100-AU  
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

NOVA AT, Composed of:  
Ceiling Suspension NOVA: NOVA AT  
Elevating Table NET 4000: NET 4000-AT  
Moving Elevating Table: FLEXI-DT  
Wall Stand NBS 2100: NBS 2100-AT  
Wall Stand Manual Tilting: TWBS-TILT  
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

NOVA ST, Composed of:  
Ceiling Suspension NOVA: NOVA ST  
Elevating Table NET 4000: NET 4000-ST  
Moving Elevating Table: FLEXI-DT  
Wall Stand NBS 2100: NBS 2100-ST  
Wall Stand Manual Tilting: TWBS-TILT  
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

### Radiographic System CHALLENGE X:

CHALLENGEX AP, Composed of:  
Ceiling Suspension CHALLENGE X: CHAP  
Elevating Table NET400: NET400AP  
Elevating Table NET500: NET500AP  
Wall Stand CHALLENGE X: CHWSAP  
X-Ray Generator Console: STH  
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

### X-Ray Generator Console:

X Ray Generator Console: CTSC  
(EMDN: Z11039006; Basic UDI-DI: 843604600CONSOLEM9)

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on - ES/MAD/c300002079 - S2A 1.4


Previous certificate number: N/A

Change in between this certificate and previous one: N/A

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## AeroDR TX Premium Mobile - System Specifications v.2.1

WORKSTATION	CS-7	 <b>KONICA MINOLTA</b>
Operating system	Windows 10 IoT Enterprise (64bit)	
Processor	Intel Core i5-7500T	
Internal RAM	16 GB (2x8GB) DDR4 2133 MHz	
Hard drive	512GB SSD	
Image Storage	+10.000 images	
APR	+1.000 Exam Tags	
Ports	2xUSB, 1xRJ45	
DICOM Features	Dicom 3.0, Dicom Print, Dicom Storage, Dicom MWL, MPPS, Storage Commitment	

GENERATOR				
Output	20KW	32KW	40KW	50Kw
Generator Frequency	100-140 kHz			
Exposure Technics	3 point (kV/mA/sec) / 2 point (kV/mAs) selectable			
kVp Range	40 to 150kV			
mAs Range	0.1 mAs to 500 mAs			
mA Range	10 to 400 mA	10 to 500 mA		
Time Range	1 ms to 10000 ms			
High Speed Starter	Optional	Optional	Yes	Yes

X-RAY TUBE	
Tube Heat Capacity	300kHU
Anode Heat Capacity	210 kJ
Focal Spot	0.7/1.3
Target Angle	16

COLLIMATOR	
Filtration	0mm Al / 1mm Al + 0.1mm Cu / 1mm Al + 0.2mm Cu / 2mm Cu
Lamp	LED
Center marker	Center of the radiation field is indicated by a cross
SID indicator	Dual line laser for 1m distance

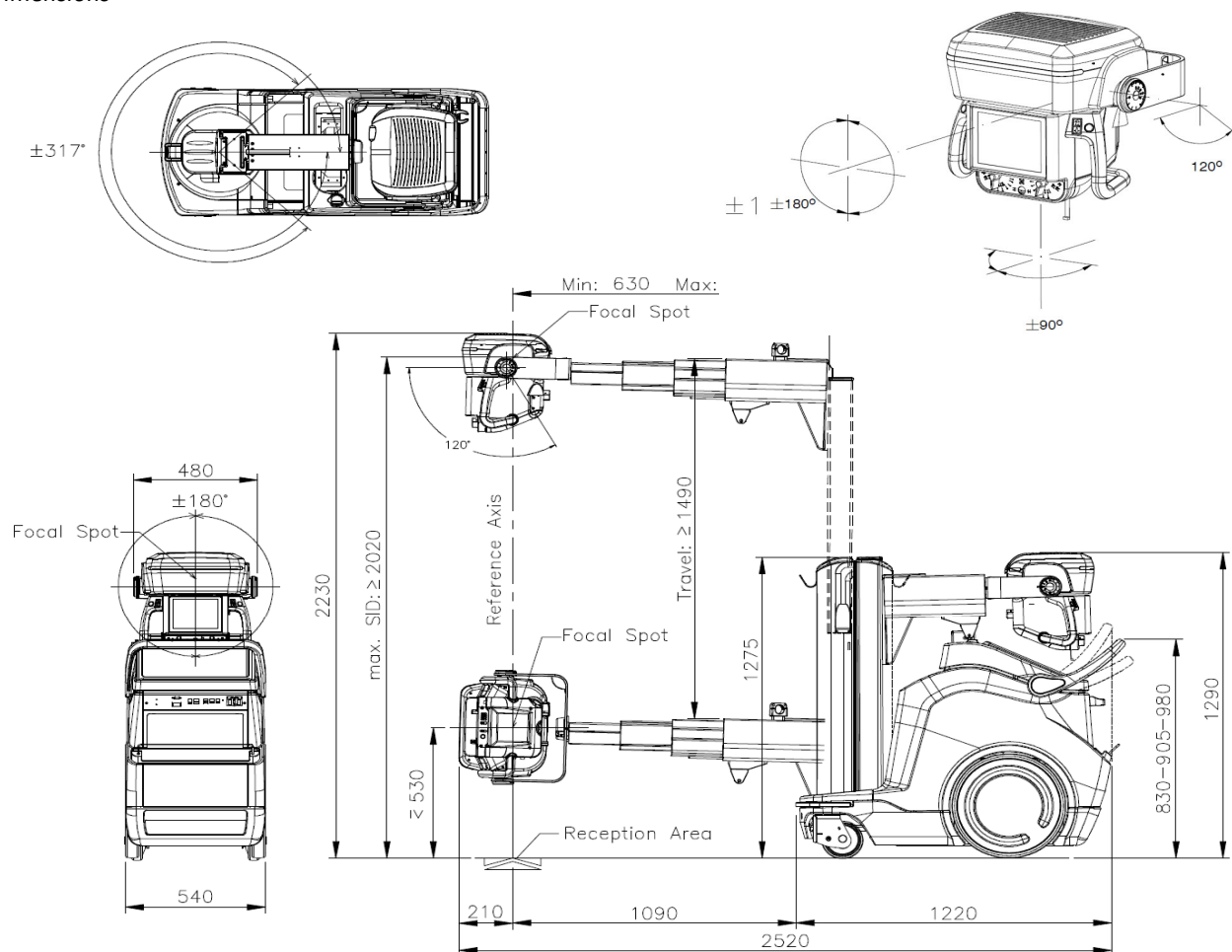
OPTIONS		
	Smart RFID Card (Secure ON/OFF)	DAP Chamber
	IR Remote Controller	E-DAP
	Anticollision Proximity Sensor	Focal to Skin Distance Measurement
	Backup Cable	Magnetic Support for gloves box
	Barcode Reader	Magnetic Support for gel bottle
	HSS (High Speed Starter) for 32/40 kW	

DETECTORS		
	AeroDR3 1417 HD2 (P-65)	
	AeroDR3 1717 HD2 (P-75)	
	AeroDR3 1012HQ (P-81)	

**KONICA MINOLTA Business Solutions Europe GmbH - Healthcare Division**  
 Capellalaan 65 2132 JL Hoofddorp  
 The Netherlands

CART		
System	Retractable column with telescopic tube arm	
Weight	520 kg	
Speed	max 5.5 km/h	
Battery System	Dual - Separate for driving and exposure with separate indicators	
Battery Charging	4 hrs (%80) / 8 hrs (%100)	
Battery Performance	11 hrs / 100 exposures / 25 km driving	
Main Monitor	19" (1280x1024) 178 degree viewing angle	
Tube Head Monitor	8.4" (1024x768) 170 degree viewing angle	
Power Line Operation	100-240 V AC - Single Phase 50/60Hz	
	Auto Line Compensation : %10	
Power Cable Length	5 m	
Access Point	Aruba- 303	
Tilting Slope	8°	
Built-in Features	Alignment Support (panels: HD2/HL/SL)	In-bin charging
	Inching on tube head	Front collision bumper
	Status indicator	Manual drive release button

#### Dimensions



**KONICA MINOLTA Business Solutions Europe GmbH**  
**Healthcare Division**

Capellalaan 65 2132 JL Hoofddorp  
The Netherlands





## SECTION 2 TECHNICAL SPECIFICATIONS

### 2.1 GENERATOR SPECIFICATIONS

#### 2.1.1 MINIMUM CURRENT TIME PRODUCT (mAs)

- Minimum Current Time Product obtained at 0.1 s is 1 mAs.
- Minimum Current Time Product within the specified ranges of compliance for linearity and constancy are as follows:
  - Static: 0.1 mAs
  - DDR: 0.0625 mAs

#### 2.1.2 ACCURACY OF RADIOGRAPHIC PARAMETERS

*Note* 

*Specified accuracy does not include test equipment accuracy. The tolerance of the accuracy of parameter values should be better than the values in the table below.*

PARAMETERS		ACCURACY
RAD	kV	$\pm (3\% + 1 \text{ kV})$
	mA	$\pm (4\% + 1 \text{ mA})$
	Exposure Time	$\pm (2\% + 0.1 \text{ ms})$

#### 2.1.3 HV FREQUENCY

The operating HV Frequency of this Generator is 100 kHz / 140 kHz.

## 2.2 FACTORS FOR RADIOGRAPHIC OPERATION

RAD FACTORS				
Maximum Power kW (Refer to Identification Label)	20 kW	32 kW	40 kW	50 kW
kVp Range	40 to 150			
	From 40 kVp to 150 kVp in 1 kVp steps			
mAs Range	Product of mA x Time values from 0.1 mAs to 500 mAs			
mA Range	10 to 400	10 to 500		
	From 10 mA to 400 mA or 500 mA, through the following mA stations: 10, 12.5, 16, 20, 25, 32, 40, 50, 63, 80, 100, 125, 160, 200, 250, 320, 400, 500. (Depending on the Generator model)			
Exposure Time Range	From 1 millisecond to 4 seconds through the following Time stations:  Milliseconds: 1, 1.25, 1.6, 2, 2.5, 3.2, 4, 5, 6.3, 8, 10, 12.5, 16, 20, 25, 32, 40, 50, 63, 80, 100, 125, 160, 200, 250, 320, 400, 500, 630, 800. Seconds: 1, 1.25, 1.6, 2, 2.5, 3.2, 4.  Maximum Exposure Time Range for DR: From 1 millisecond to 4 seconds.			
Focal Spot Size	Small / Large			
Power Output (@ 0,1s)	150 kVp @ 125 mA 125 kVp @ 160 mA 100 kVp @ 200 mA 80 kVp @ 250 mA 62 kVp @ 320 mA 50 kVp @ 400 mA	150 kVp @ 200 mA 128 kVp @ 250 mA 125 kVp @ 250 mA 100 kVp @ 320 mA 80 kVp @ 400 mA 64 kVp @ 500 mA	150 kVp @ 250 mA 125 kVp @ 320 mA 100 kVp @ 400 mA 80 kVp @ 500 mA	150 kVp @ 320 mA 125 kVp @ 400 mA 100 kVp @ 500 mA
Duty Cycle	18 exposures per hour at 100 kV, 200 mA, 320 ms (lapse time between exposure: 3 min.)	18 exposures per hour at 120 kV, 250 mA, 250 ms (lapse time between exposure: 3 min.)		
	Maximum leakage radiation depends on the type of X-ray Tube (<0.88 mGy/h)			
Ripple Factor	< 4% (constant voltage)			
Collimator	Manual Collimator with front and rear side Knobs, double Laser, Motorized Filters and ready for both Estimated Dose (EDAP) option and DAP Chamber option			
X-ray Tube	Refer to Section 2.4			

RAD FACTORS				
Maximum Power kW (Refer to Identification Label)	20 kW	32 kW	40 kW	50 kW
Power Line Operation (Depends on Region Configuration)	100-240 V~ - Single-Phase 50/60 Hz Automatic Line Compensation $\pm 10\%$ V~ Connection to standard outlets with GND that complies with local regulations			
	The Power Line Installation should be provided with a Differential of 30 mA Sensitivity  Power Line Impedance must be less than the maximum indicated value: 300 m $\Omega$ for 100 V~, 1 $\Omega$ for 110 V~, 2.5 $\Omega$ for 230 V~, 2.6 $\Omega$ for 240 V~			
Power Line Cable	Total Cable Length: 5 m Usable Cable Length: 4.75 m			
Maximum Input Power	1.2 kVA			
Operation independent from mains supply (Stand-Alone)	Standard			
Battery Capacity	Optimized Battery Management for extended Battery life. Charge Capacity: 15 Ah. The required time for the Batteries to be 100% charged is approximately: 8 hours, (80% of the total charge is available after 4 hours charging; approximately 20% per hour). Total Energy storage Capacity: 5760 Wh With the Batteries fully charged and disconnected from the mains, the Mobile system can be in continuous movement during approximately 25 km, at 5.5 km/h Once the exposure capacity is exhausted, the system motion is enabled for 1 km. The Mobile Unit in Stand-Alone (disconnected from the mains) will be 100% discharged from full charge in approximately: 11 hours.			
Radiation Output Accuracy (Reproducibility related to loading factors)	C.V. (Coefficient of variation) $\leq$ 0.05			
Maximum Symmetrical Radiation Field	Measured at 75 kV: 220 mm in "X" axis and 240 mm in "Y" axis. Measured at 125 kV: 210 mm in "X" axis and 250 mm in "Y" axis. (Test performed at a distance from the Focal Spot of 1200 mm, in accordance with IEC 60806:1984).			
Maximum Heat Output	260 W (1130 BTU/h)			
Storage / Transport Environmental Conditions	Temperature range of -10°C to 40°C Relative Humidity range of 20% to 90% Atmospheric Pressure range of 700 hPa to 1060 hPa			
Operating Environmental Conditions	Temperature range of 10°C to 35°C (the recommended temperature for a longer life cycle of batteries is around 22°C) Relative Humidity (no condensing) range of 30% to 75% Atmospheric Pressure range of 700 hPa to 1060 hPa			



## 2.3 FACTORS AND DUTY CYCLE FOR DDR FUNCTIONALITY

DDR FACTORS				
Maximum Power kW <i>(Refer to Identification Label)</i>	20 kW	32 kW	40 kW	50 kW
kVp Range	50 to 125			
	From 50 kVp to 125 kVp in 1 kVp steps			
mAs Range per Pulse	Product of mA x Time values from 0.0625 mAs to 2 mAs per pulse	Product of mA x Time values from 0.0625 mAs to 2.5 mAs per pulse		
mAs Range per Exam	Maximum 500 mAs / exam			
mA Range	12.5 to 400 mA	12.5 to 500 mA		
	From 12.5 mA to 400 mA or 500 mA, through the following mA stations: 12.5, 16, 20, 25, 32, 40, 50, 63, 80, 100, 125, 160, 200, 250, 320, 400, 500 mA <i>(Depending on the Generator model)</i>			
Focal Spot Size	Large			
Exposure Time Range per Pulse	5 milliseconds			
Pulse Rate	15 pulses per second			
Max. Exam Time	20 seconds			
Max. Number of Pulses per Exam	300 pulses			

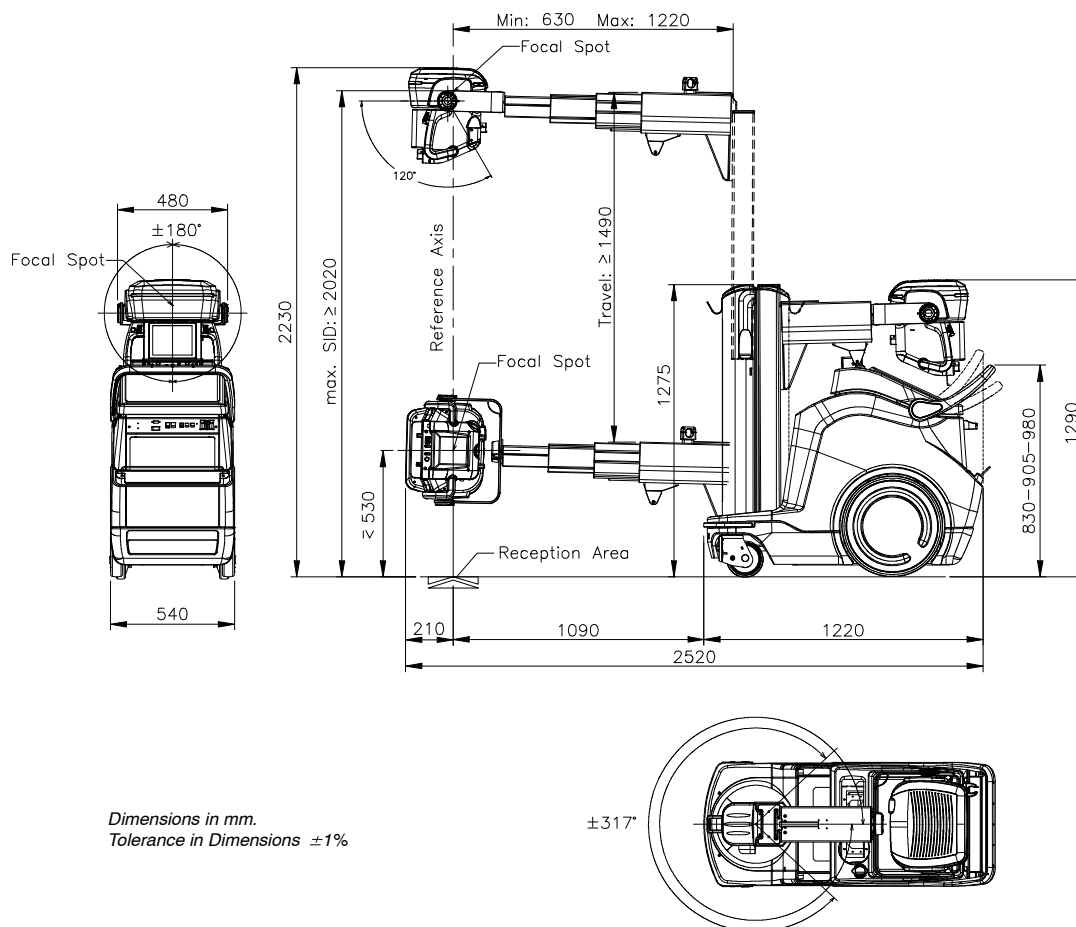
## 2.4 X-RAY TUBE INSERT

Maximum Power kW (Refer to Identification Label)	20 kW	32 kW	40 kW	50 kW
X-ray Tube Inserts	E7886 Low Speed / High Speed		E7886 High Speed	

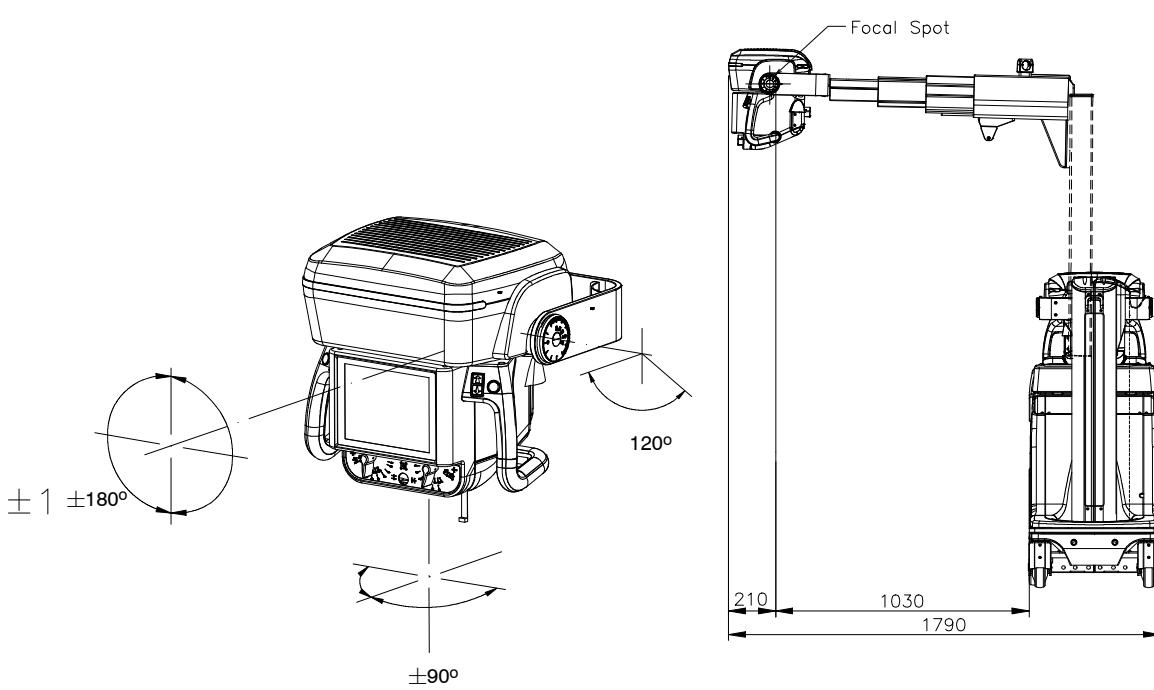
E7886	<p>Low Speed / High Speed – Rotating Anode  Focal Spots: 0.7 mm / 1.3 mm  Anode kHU / kVp: 300 kHU / 150 kVp  Target Angle: 16°</p> <p>Inherent Filtration of X-ray Source:  Tube + Collimator: 3.1 mm Al  Tube + Collimator + eDAP: 3.1 mm Al  Tube + Collimator + DAP: 3.4 mm Al</p>
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## 2.5 PHYSICAL CHARACTERISTICS

LENGTH	WIDTH	HEIGHT	WEIGHT
minimum 1220 mm (48") maximum 2520 mm (99.2")	540 mm (21.3")	minimum 1290 mm (50.8") maximum 2230 mm (87.8")	520 kg (1145 lbs) (without Detectors and/or Accessories)







Dimensions in mm.  
Tolerance in Dimensions  $\pm 1\%$