



C015

unico

TECHNICAL DATA





Intended Use ¹

The device is a digital system for the acquisition and display of RX images intended to be used and managed by: adequately trained, qualified and authorized healthcare professionals such as doctors, surgeons, cardiologists, radiologists and safety and emergency procedures, as well as the capabilities and functions of the device.

The device is used for radiological guidance and visualization during diagnostic, interventional (elective), and surgical procedures on all patients except new - borns (birth to one month), within the limitations of the device.

The typical intended use environment is in a hospital or clinical setting within a sterile operating room, operating room, or, in some situations, an emergency room. The device must be used in healthcare facilities both inside and outside the operating room, in sterile and non-sterile environments.

The mobile fluoroscopy device is designed to provide spot fluoroscopic and digital images during diagnostic, interventional and surgical procedures. The device can be used on all regions of the body.

Clinical applications include orthopedic, gastrointestinal, urological, neurological, vascular, thoracic, cardiac, critical care and emergency procedures. The various configurations available allow you to meet all special requirements for all procedures.

¹ Based on selected configuration

General Overview ²

The system is designed as an all-in-one solution, in which the radiological stand and the image processing workstation are fully integrated into one compact unit. The configuration includes:

- mobile **C-arm stand** with high-voltage generator and X-ray tube assembly, featuring the latest-generation of digital dynamic flat-panel detectors and an intuitive touch - screen control console
- **built-in workstation** equipped with dedicated full - touch screen monitor for high-quality live image display and advanced processing. It provides easy access to system settings and a fully integrated DICOM interface



C015 **unico** is a versatile, multi-purpose unit, engineered to adapt to different clinical needs through dedicated technical solutions that support a wide variety of procedures.

Main Features

- All- in- one compact, lightweight and ergonomic mechanical design with double - sided brakes and cable pushers on each wheel
- Equipped with the latest FPD technologies: aSi, CMOS & IGZO
- 10 kW high voltage generator PLANARIX™, in-house designed and produced
- X-Ray tube assembly to ensure high-end performance and system reliability
- 3.000 rpm automatic anode speed rotation for better heat distribution
- Optimized dose and image quality with automatic anatomy detection for acquiring detailed images in all conditions while reducing the learning curve for users
- Full touch – screen user interface on both control console and main monitor
- Perfectly counterbalanced C – Arm with wide depth and extended free space
- DICOM 3.0 integration

² UNICO is a commercial name and does not replace the original model name and code as registered in the EU MDR certificate



X-Ray Source

The X-ray section incorporates a dedicated in-house developed and produced high-voltage generator and a high-performance X-ray tube assembly with rotating anode, enhancing performances, heat dissipation and system reliability.

High Voltage Generator Micronica Planarix™

10 kW

Nominal power (IEC 60601-2-54)	10 kW @ 100kV @ 100mA
High frequency inverter	40 kHz
Minimum pulse width	4 ms
Max current	100 mA

Tube

Type (rotating anode)	X 20 P	RTM 70
Anode speed (rpm)	3.000 rpm	3.000 rpm
Max. nominal output	5 / 17 kW	10 / 34 kW
Anode heat storage capacity	150 kJ (200 kHU)	225 kJ (300 kHU)
Anode heat dissipation	300 W (24 kHU/min)	1300 W (104 kHU/min)
Focal spot	0.3 / 0.6 mm	0.3 / 0.5 (0.6) mm
Target angle	10°	10°

Automatic Anode Speed Control

Intelligent Speed Control (ISC)	3.000 rpm smart anode rotation management system specially designed by Micronica
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Housing

Type	C 30
Device heat capacity	1.2 million HU
Continuous heat dissipation (in clinical performance)	250 W
Total Filtration	≥ 3.2 mm Al equivalent + 0,1 mm Cu



Operational Modes

All X-ray acquisition modes operate in pulsed fluoroscopy, with each frame individually exposed to ensure continuous image visualization. Digital radiography is available in modality snapshots.

The internally developed image-processing software automatically selects the optimal X-ray parameters, exposure settings can also be adjusted manually or according to the targeted anatomical region, using specific anatomical tables available to the operator.

Fluoroscopy	
kV range	40 - 120 kV
mA range	5 - 30 mA
Pulse width	4 to 20 ms
Pulse rate	0.5 to 18 fps
BOOST	
(High current pulsed fluoroscopy)	
kV range	40 - 120 kV
mA range	up to 80 mA
Pulse width	4 to 20 ms
Pulse rate	0.5 to 18 fps
DS	
(Digital snapshots)	
kV range	40 - 120 kV
mA range	up to 100 mA
Pulse width	4 to 20 ms
Pulse rate	18 fps
CINE	
kV range	40 - 120 kV
mA range	up to 80 mA
Pulse width	4 to 20 ms
Pulse rate	0.5 to 18 fps



Flat Panel Detector

C015 supports all the latest generation of digital flat panel detectors, including aSi, CMOS and IGZO technologies, available in SMALL and X – LARGE format.

IGZO Flat Panel Detector

	VIVIX - D 2323 G	VIVIX - D 3131 G
Technology	IGZO with CsI scintillator	IGZO with CsI scintillator
Pixels size	148 µm	148 µm
Matrix	1536 x 1536 pixel	2048 x 2048 pixel
Flat-Panel dimensions	23 x 23 cm (9" x 9")	30 x 30 cm (11,8" x 11,8")
Digitization depth	16 bit	16 bit
MTF (RQA5, 2.5uGy, IEC 62220-1-3)	86% at 0,5 lp/mm 64% at 1 lp/mm 30% at 2 lp/mm 14% at 3 lp/mm	83% at 0,5 lp/mm 60% at 1 lp/mm 32% at 2 lp/mm 18% at 3 lp/mm
DQE (RQA5, 2.5uGy, IEC 62220-1-3)	68% at 0,5 lp/mm 61% at 1 lp/mm 49% at 2 lp/mm 27% at 3 lp/mm	72% at 0,5 lp/mm 61% at 1 lp/mm 46% at 2 lp/mm 30% at 3 lp/mm

aSi Flat Panel Detector

	VIVIX - D 0909 G	VIVIX - D 1212 G
Technology	aSi with CsI scintillator	aSi with CsI scintillator
Pixels size	179 µm	145 µm
Matrix	1280 x 1280 pixels	2048 x 2048 pixels
Flat-Panel dimensions	23 x 23 cm (9" x 9")	30 x 30 cm (11,8" x 11,8")
Digitization depth	16 bits	16 bits
MTF (RQA5, 2.5uGy, IEC 62220-1-3)	84 % at 0.5 lp/mm 60 % at 1 lp/mm 27 % at 2 lp/mm 12 % at 3 lp/mm	86 % at 0.5 lp/mm 64 % at 1 lp/mm 30 % at 2 lp/mm 15 % at 3 lp/mm
DQE (RQA5, 2.5uGy, IEC 62220-1-3)	68 % at 0.5 lp/mm 60 % at 1 lp/mm 41 % at 2 lp/mm 27% at 3 lp/mm	62 % at 0.5 lp/mm 56 % at 1 lp/mm 42 % at 2 lp/mm 26 % at 3 lp/mm

CMOS Flat Panel Detector

	Xineos – 2222 HS	Xineos – 3030 HS
Technology	aSi with CsI scintillator	aSi with CsI scintillator
Pixels size	179 µm	145 µm
Matrix	1280 x 1280 pixels	2048 x 2048 pixels
Flat-Panel dimensions	23 x 23 cm (9" x 9")	30 x 30 cm (11,8" x 11,8")
Digitization depth	16 bits	16 bits
MTF (RQA5, 2.5uGy, IEC 62220-1-3)	84 % at 0.5 lp/mm 60 % at 1 lp/mm 27 % at 2 lp/mm 12 % at 3 lp/mm	86 % at 0.5 lp/mm 64 % at 1 lp/mm 30 % at 2 lp/mm 15 % at 3 lp/mm
DQE (RQA5, 2.5uGy, IEC 62220-1-3)	68 % at 0.5 lp/mm 60 % at 1 lp/mm 41 % at 2 lp/mm 27% at 3 lp/mm	62 % at 0.5 lp/mm 56 % at 1 lp/mm 42 % at 2 lp/mm 26 % at 3 lp/mm



Collimator System

In-house designed and manufactured square collimator, to match the edges of the detector, with symmetric or asymmetric shutters and unlimited rotation, featuring a radiation-free collimation mode for precise field positioning without exposure.

Collimator movement is controlled via the touch-screen console, with automatic positioning based on the selected field of view.



Square diaphragm (lead) with Parallel (copper) shutter	Default
Square diaphragm (lead) with Parallel (lead) shutter	Optional (not after sale)
Square diaphragm (lead) with Asymmetric shutter (copper)	Optional (not after sale)
Square diaphragm (lead) with Asymmetric shutter (lead)	Optional (not after sale)



Digital Imaging System

The system provides local hard-disk storage for static images and dynamic sequences. Images are displayed as an infinite vertical mosaic, with the ability to delete individual images, dynamic sequences or entire examination sessions. Digital clips can be reviewed, managed and exported at any time using operator-selectable options.

Model

Surgical

(Examples of Clinical Use)

- Orthopedics
- General surgery
- Pain management
- Neurovascular surgery
- General applications

Digital Processor

Hardware	Intel microprocessor, RAM $\geq$ 4 GB, SSD main drive, USB 3.0
Operative system	Windows 10 - 64 bit
Storage Hard-disk capacity	$\geq$ 500 GB

Acquisition

Full detector resolution @ 16 bit – 65535 grey levels

Image acquisition: 0.5 f/s to 18 f/s

Image storage: 200.000 img

Image Display & Processing

Last-image hold	Gamma correction
Digital image rotation	Gray scale inversion
Horizontal and vertical image reversal	Recursive filter
Zoom and pan image	Digital Density Analysis (DDA) optimized gray-scale visualization based on image analysis
Window & level, brightness tool	Preview collimator
Edge enhancement	A.I.R.E. - Automatic Intelligent Radiographic Engine

Main Monitor

C015 **unico** is equipped with a single wide touch-screen monitor installed on articulated support. The user interface is full touch – screen with icon-based layout and guided workflow.

User interface available in different languages: **EN, IT, FR, ES, DE**.



27" Full HD Touchscreen Display

Type	Color TFT LCD Edge-to-edge design with integrated touch
Backlight	White LEDs
Diagonal Size	68.58 cm / 27"
Display Colors	8-bit colors: 16.77 million colors
Resolution	1920 x 1080 Full HD (16:9 aspect ratio)
Contrast Ratio (typical)	1000:1
Brightness (typical)	250 cd/m ²
Viewing Angles (H / V, typical)	Horizontal 89/89° or 178° total / Vertical 89/89° or 178° total
Regulatory approvals and declarations	CUL, IC / CCC / CE / KCC / BSMI / FCC, UL / VCCI / CB / RCM / EAC / CoC
Conformance	DICOM 14, AAPM-TG18 secondary medical display criteria Optional LCD Medical grade

32" UHD 4k Touchscreen Display

Type	IPS Touch
Backlight	White LEDs
Display Colors	10 bit - 1.07 billion colors
Resolution	UHD 4K (3840x2160)
Contrast Ratio (typical)	1000:1
Brightness (typical)	350 cd/m ²
Viewing Angles (H / V, typical)	178° / 178°
Regulatory approvals and declarations	CB, UL (cUL), FCC – B, CE, ErP

Touch Screen Control Console

Touch – screen control console with intuitive icons for maximum operational simplicity in the operating room and real-time image display with pinch – to – zoom function.



Main functions

- Selection / Indicator of exposure parameters
- Interactive icons for system status and alarms
- Live visualization of Air Kerma (mGy) and AK rate (mGy/min)
- F.O.V. and recursive filter selection
- Real – time and post – processing image controls
- Up & Down motorized vertical movement control
- Collimator adjustment
- Detector's laser aimer activation
- System settings

10"

Touch – Screen Console

Type	Touch screen Color, TFT (IPS)
Active area (W x L)	21.6 x 13.5 cm
Size	10.1"
Resolution	1280 x 800 pixel
Rotation Angle	270°

13"

Touch – Screen Console

Type	Touch screen Color, IPS-LCD
Active area (W x L)	29.3 x 16.7 cm
Size	13.3 "
Resolution	1920 x 1080 pixel
Rotation Angle	270°



Utilities & Optional

Connectivity

USB export	Digital image storage to USB device in BMP and AVI format	
LAN	Ethernet module for DICOM services	
Wireless Printer interface	Wireless connection with a compatible digital printer	Optional
Single HDMI output	Video splitter output for connecting an external Live Monitor	Optional
Remote Assistance Module	For remote technical service connection	Optional

Measure & Marker Tool

Annotations, comments, angle and distance measurements on the image	Optional
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DICOM Services

DICOM Store	
DICOM Storage Commitment	
DICOM Modality Worklist	
DICOM Print	Optional
DICOM Modality Performed Procedure Step (MPPS)	Optional
DICOM Query/Retrieve	Optional
DICOM Radiation Dose Structured Report (RDSR)	Only with DAP

Medical Grade Printer

Sony UP-971AD / UP-991AD	Optional
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Image Export

BMP/AVI image storage on USB memory	
DICOM image storage on USB memory	Optional

Dose Optimization

System-integrated FPD laser aimer	
Stitching – asynchronous image fusion	Optional
System-integrated tube-side laser targeting device	Optional
Dose Area Product (DAP) meter with automatic creation of radiation dose report and RDSR	Optional
Removable grid, e.g. for pediatric applications	Optional

Accessories

Hand switch	
Two-pedal foot switch	
Source skin spacer	
Semi-rigid cable pusher on wheels	
Wireless two - pedal foot switch	Optional
Sterile covers for C-arm, X-ray assembly and flat detector	Optional



System Specifications ³

Double-sided wheel brakes and ergonomic handles allow smooth and controlled movements. On-wheel cable pushers help avoid floor obstacles, improving safety and maneuverability. Color coded handles to identify each movement available.

C- Arm Stand Mechanical Data

Source Image Distance (SID)	111.2 cm (43.7")
Free space	91.2 cm (35.9")
C-arm depth	71.6 cm (28.18")
Orbital rotation	147° (-90° / +57°)
Horizontal travel	22.5 cm (8.8")
Vertical travel	45 cm (17.7")
Lowest lateral position	106.4 (41.8")
Swivel range	± 10.5°
Pivot rotation	±240°
Reverse position	Yes
H x W x D of C-arm frame	156.5 x 78 x 219 cm (61.6" x 30.7" x 86.2")
Weight	330 kg

Electrical Specifications

Power requirements⁴	230 V (±10%) 50/60Hz Line impedance ≤ 0.6 Ω
Standby current	1.5 A
Magneto Thermic Switch	32 A (230 Vac) Curve C
Emergency Stop Button	Yes

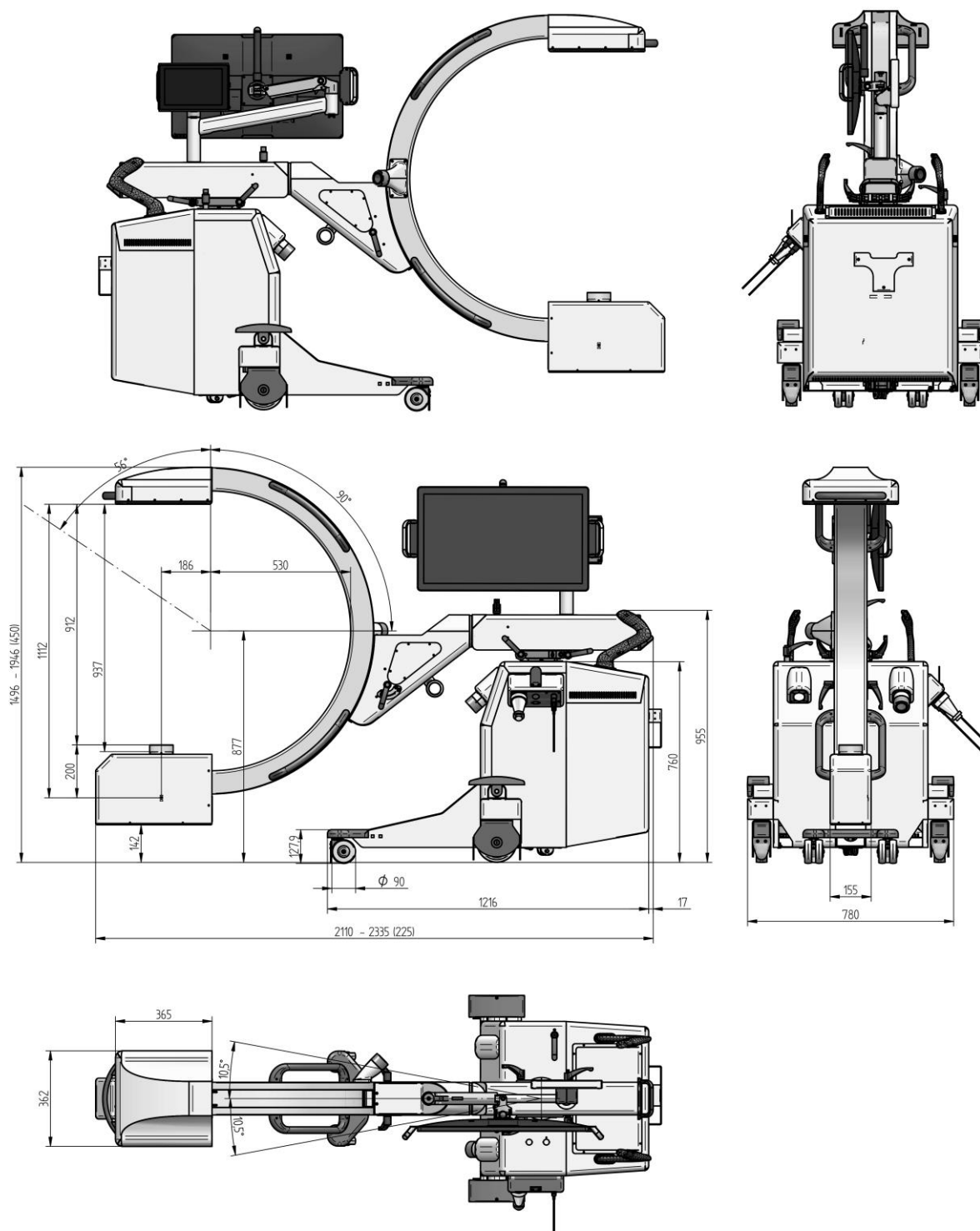
Environmental Specifications

Operating temperature	+10°C / +40°C
Storage temperature	0°C / +40°C
Operating humidity	20% / 80% non-condensing
Storage humidity	10% / 80%
Pressure	70/110 kPa (Operating) - 57/110 kPa (Storage)
Vibration	10 – 150 Hz, 0.35 mm peak

³ The manufacturer reserves the right to change specifications without prior notice

⁴ The electrical installation on the site where the device is installed the system shall comply with the requirements of VDE 0107/IEC 60364-7-710

FP S





Approvals

This device complies with IEC and 60601-1 is classified as a class I device B type (class)

The device complies with EU Regulation 2017/745 and following updates and is classified as a class IIb (annex VIII, rule 10 active device intended to emit ionizing radiation)

The device is an active medical device with no applied part

The device complies with the requirements of the EMC regulations and in particular is in class A

Certifications

Product	Certificate EU according MDR n° ITH 2456456 1
Management System	Certificate UNI CEI EN ISO 13485:2021 n° 39 05 1152210
	Certificate UNI EN ISO 9001:2015 n° 39 00 1152210

Model Identification

MODEL	CODE	CONFIGURATION
C015	1 130 0104	FP S C015, Planarix
	1 130 0105	FP L C015, Planarix
	1 130 0106	FP XL C015, Planarix