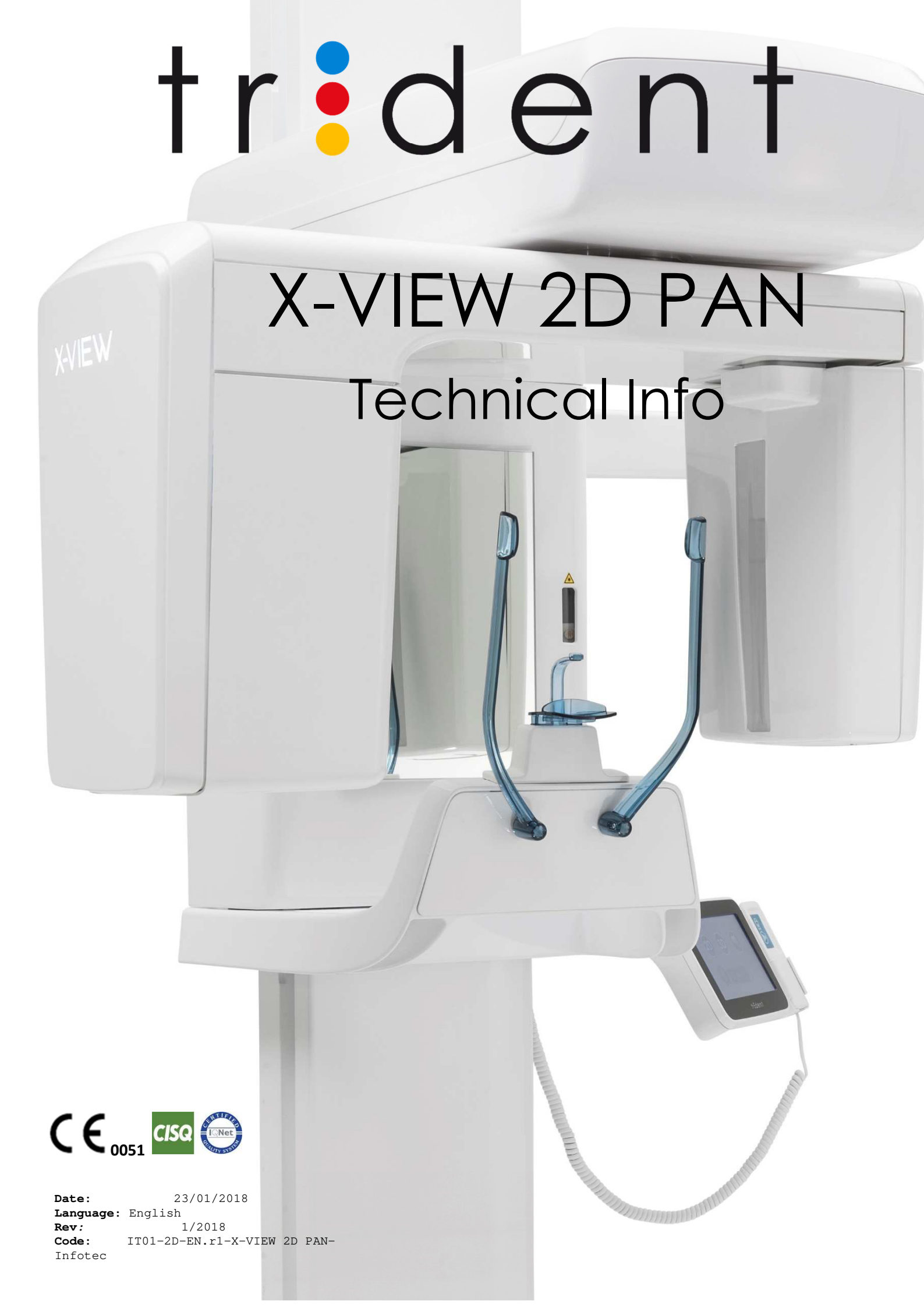


A large, white, modern dental X-ray machine with a central column and two large, white, rectangular detector arms extending horizontally. The machine is mounted on a white pedestal. The brand name 'trident' is visible at the top, with the 'i' represented by three colored dots (blue, red, yellow). The model name 'X-VIEW' is printed on the left detector arm. The text 'X-VIEW 2D PAN' and 'Technical Info' are prominently displayed in the center. A control panel with a screen is attached to the right side of the machine, connected by a coiled cable.

trident

X-VIEW 2D PAN

Technical Info

CE 0051



Date: 23/01/2018

Language: English

Rev: 1/2018

Code: IT01-2D-EN.r1-X-VIEW 2D PAN-
Infotec

DESCRIPTION AND INTENDED USE

X-VIEW 2D PAN, manufactured by Trident S.r.l., is a digital X-Ray system used to perform 2D panoramic and cephalometric radiographies of the maxillofacial complex. X-VIEW 2D PAN uses a CCD sensor with integrated TDI function and is composed by three main parts: an X-Ray generator mounted on one side, an X-Ray detector mounted on the opposite side and a mechanical system that supports the movement. During a panoramic X-Ray examination the X-Ray generator rotates around the patient's head, starting at one side of the jaw and ending at the other side.

The system must be connected to a dedicated PC, on which the software necessary for image acquisition, processing and visualization are installed. Digital images are stored in the software database and are easily accessible for diagnosis and disease management; this procedure allows the dentist to adjust and change the contrast, brightness and darkness of the image for better visualization of certain structures and tissues.

The system can be used on all kind of patients; it is possible to differentiate between adult and child, choose the size of the patient and, where applicable, the type of dentition. The device is intended to be used by qualified personnel, dentists, radiologists or legally qualified staff; therefore, it can be installed in dedicated places (hospitals and clinics) and in residential structures equipped with a shielding system.

The device allows an upgrade by adding the optional cephalometric arm.

GENERAL CHARACTERISTICS

Unit name	X-VIEW 2D PAN
Manufacturer	Trident Srl Via Artigiani 4, Castenedolo, 25014 (BS) Italy
Classification according to IEC 60601-2-63:2012	Medical Unit
Classification according to IEC 60601-1	Medical Unit Class I with type B applied parts
Classification according to Directive EC 93/42	Medical Unit Class II b
Working way	Continuous with adaptive duty cycle
Protection Rank	IPX0
Centering bite height	105 to 182 cm

SYSTEM SUPPLY	
Characteristic	Value
Line Voltage	115 V/230 V $\pm$ 10%
Frequency	50/60 Hz
Electric current	7.5 A @ 230V
Absorbed power	1720 VA @ 230V @ 50/60Hz
Apparent line resistance	0.5 Ω max
Main Power protection fuse (F1)	20 A T
Column actuator Protection fuse (F2)	5 A T
Rectifier Board protection fuse XRPSR	6,3 AT
Inverter Board protection fuse XRPSI	6,3 AT
Switching power supply protection fuse 24 V	2 x 3, 15AT
Switching power supply protection fuse 12 V	2 x 2, 15AT
High voltage	61 to 90 kVp, at steps of 3 kVp (9 steps)
Anodic current	4 to 15 mA, according to R'20 scale

X-RAY GENERATOR		
Characteristic	Value	
Model	P00-06-01	
Type	High frequency generator, DC	
Manufacturer	Trident S.r.l. Via Artigiani 4, Castenedolo, 25014 (BS) Italy	
Tube Voltage	90 kVp	
Precision kVp	± 8 %	
Maximum Anodic current	15 mA	
Anode current accuracy	± 10%	
Radiation Output linearity	< 0.2 IEC 60601-2-63 paragraph 203.6.3.1.101	
Duty cycle	Adaptive Duty cycle according to the exposure and dielectric oil temp. Minimum 1:8, average 1:16	
Transformer Isolation	Oil bath	
Nominal power	850 VA (85 kVp - 10 mA)	
Total filtration	2.5 mm Al eq. @ 70 kVp	
Half Value Layer (HVL)	> 2.0 mm Al eq. @ 61 kVp > 2.7 mm Al eq. @ 73 kVp > 3.5 mm Al eq. @ 85 kVp	
Cooling	As per convection	
Focal spot	0.5 mm (IEC 60336:2005)	
Leakage radiation at 1 m	< 0.5 mGy/h @ 85 kVp - 10 mA – 3s duty cycle	
Max thermal capacity of tube head	900 kJ	
Exposition parameters regulation	kVp	From 61 to 85 kVp, steps of 3 kVp
	mA	From 5 to 10 mA. R'20 scale

X-RAY TUBE		
Characteristic	Value	
Model	OPX 105	KL5A-0.5-105
Nominal Focus size	0.5 IEC 60336:2005	0.5 IEC 60336:2005
Inherent filtration	0.5 mm Al eq.	0.6 mm Al / 75 kV
Anode angle	5°	5°
Anode material	Tungsten	Tungsteno
Maximum Nominal voltage	105 kVp	105 kV
Nominal reverse tension	136 kVp	135 kVp
Maximum filament current	4 A	4.2 A
Maximum filament tension	8 V	7.8~8.2 V
Anode's thermal capacity	30 kJ	30 kJ (42 KHU)
Maximum anodic dissipation	250W	250 W

PAN SENSOR	
Characteristic	Value
Manufacturer	Teledyne Dalsa
Model	Argus PAN
Type of sensor	CCD-TDI Scanning X-Ray Detector
Sensitive area	151 x 6.9 mm
Pixel dimensions (L=H)	27 µm elementary, 81 µm in binning 3x3
Number of Pixel (H x L)	5580 x 256 1860 x 85 in binning 3 x 3
Data output format	16 bits
Scintillator	CsI
Dynamic range	> 80 dB
Operating temperature	10 to +40° C
Storage temperature	10 to + 55° C

CEPH SENSOR	
Characteristic	Value
Type of sensor	One Shot Phosphor Digital Sensor , (CR) with integrated reading and erasing for cephalometric images
Phosphor composition	BaSrFBr:Eu
Luminescence	400nm
Pixel dimensions	117 µm
Active Area Dimensions	30 x 24 cm
Image format	30 x 24cm and 24 x 24cm
Image dimensions (pixel)	2560 x 2048 for 30 x 24 cm image format

CENTERING LASER (Median-sagittal laser and Frankfurt plane laser)	
Characteristic	Value
Wavelength	650 nm ± 10 nm
Divergence	< 2.0 mRad
Optical power	< 1 mW
Classification	Class 1 according to IEC 60825-1

PROGRAMS	Standard Programs	Adult/Child Standard Panoramic
		Adult /Child Right Hemi Panoramic
		Adult/Child Left Hemi Panoramic
		Frontal Dentition
		TMJ closed mouth
		TMJ open mouth
		Sinus
	Ceph Programs	LL CEPH 30 x 24
		AP CEPH
		Carpus
		LL CEPH 24 x 24
	Optional Programs	Adult/Child Reduced Dose Panoramic
		Adult/Child Improved Orthogonality Panoramic
		Right Bitewing
		Left Bitewing
		Right and Left Bitewing

EXPOSURE TIME	
Program	Exposure Time (in seconds)
Adult Standard Panoramic	15.5
Child Standard Panoramic	14.8
Adult Right/Left Hemi Panoramic	8.4
Child Right/Left Hemi Panoramic	8
Adult Reduced dose Panoramic	12.1
Child Reduced dose Panoramic	12.1
Adult Improved Orthogonality Dentition	12.8
Child Improved Orthogonality Dentition	12.1
Adult Right/Left Bitewing	3.0
Frontal Dentition Adult/Child	4.4
Child Right/Left Bitewing	2.4
Adult Bitewing right left	6.0
Child Bitewing right left	4.8
TMJ open/close mouth	3.4 s for image right/left side joint in the open or closed condition
SINUS	12.1
Exposure times accuracy	± 10 %
Cephalometric (CEPH)	Variable exposure time as a function of the value of the current time * selected time. Minimum 2 mAs, maximum 30 mAs

IMAGES ENLARGEMENT	
Program	Value
Adult/Child Standard Panoramic	1 : 1.28
TMJ open/close mouth, 4 images	1 : 1.25 (nominal)
Sinus	1 : 1.27 (nominal)
CEPH	1: 1.10 on the median sagittal plane projection in LL (Latero-lateral) Not quantifiable in Projection AP (Antero-Posterior)
Carpus	Not quantifiable enlargement.

ENVIRONMENTAL CONDITIONS	
Condition	Value
Minimum room size	L x P x H: 120 x 120 x 240 (cm)
Maximum operating temperature ranges	+ 10° to + 40°
Operating relative humidity range	30% to 75%
Operating atmospheric pressure	80 to 106 Pa(maximum higher ≤ 2000 m)
Transport and storage temperature	- 20° to + 70°
Transport and storage Maximum relative humidity	< 95% not condensed
Transport and storage Atmospheric pressure	63 to 106 Pa

COMPUTER SPECIFICATIONS	
Model	Personal Computer Intel Core i5 3.2 GHz
RAM	4 GB DDR3
HDD	1TB SATA
OS	Windows 7 Pro/8.1 Pro
Graphic Card	ATI 5450 1GB
Monitor	1024x768 pixels at 65.000 colors (ideal 1280x1024 16 million of colors 32 bits)
Network Card	2 x Network card Intel Pro 1000 server (no ceph option) 3 x Network card Intel Pro 1000 server (with ceph option)

IMAGE ACQUISITION SOFTWARE

Name	DEEP-VIEW 2D
Type of license	FULL FIRST LICENCE USB KEY MONO-USER
Functions	The acquisition software DEEP-VIEW provides many image manipulation functions, including: • PAN and/or multi image visualization • Enlarging images with dynamic zoom and scroll • Flip and rotate images • Change of brightness and contrast • Application of median, logarithmic, noise reduction, dynamic and spatial filters • Edit of LUT (look up table) and range (greyscale compression) • Inversion of the gray scale (positive / negative) • Application of special filters such as exclusive harmonizer that optimizes the display of all the densities on the image • Display of histograms and representation of densitometric profiles • Insertion of anatomical references according to international numbering • Linear and angular dimensions measurement with the possibility of dedicated calibration • Printing of images with or without comments and measurements • Database • Dicom 3 compatibility

LABEL ID AND CLASSIFICATION

trident	
Unit type: X-VIEW 2D PAN	
REF	XXXXXXX
S/N	XXXXXXX
Voltage: 230V~ ± 10%	Nom. Power: 1720VA
Frequency: 50/60 Hz	
Trident s.r.l. via Artigiani 4 25014 Castenedolo (BS) Italy info@trident-dental.com	
 	

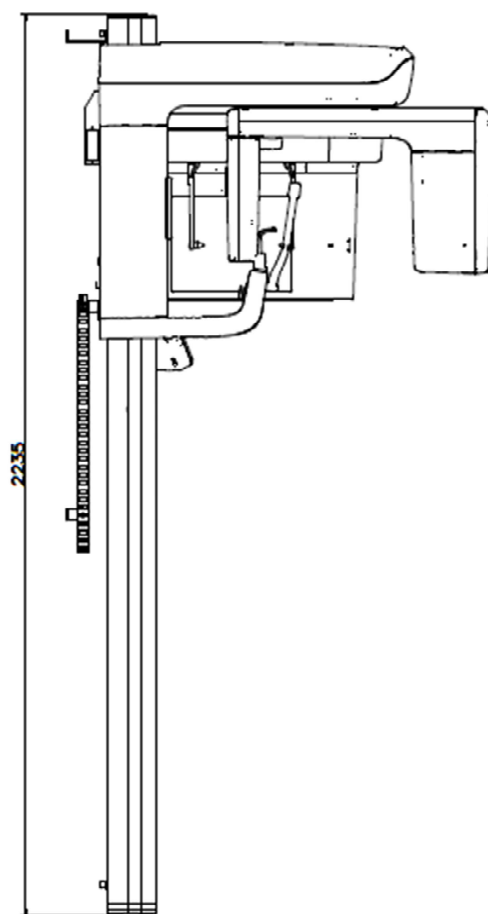
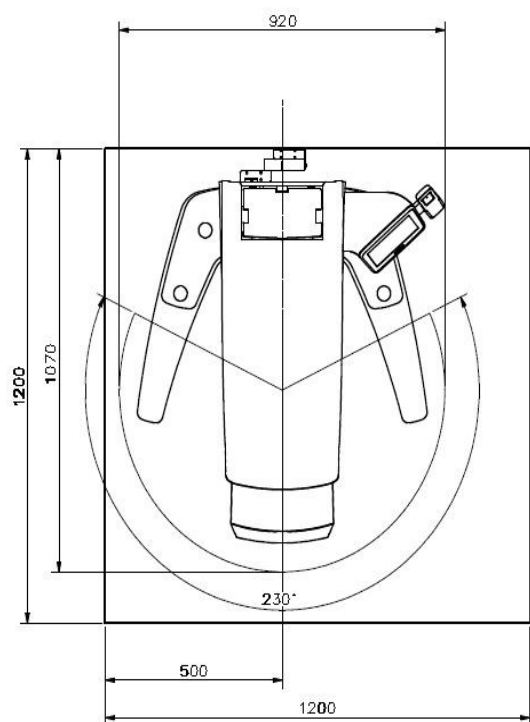
Classification CE directive
93/42: medical device class
IIB

Applicable Standards:

- IEC EN 60601-1:2005 / EN 60601-1
- EN 60601-1:2006 / IEC 60601-1:2005
- IEC 60601-2-63:2012
- IEC 60601-2-28 Ed. 2
- IEC 60336:2005
- EN 60601-1-2:2007
- IEC 60601-1-3 Ed.2
- IEC 60825-1:2007
- IEC 60601-1-6:2010 / EN 62366:2008
- EN ISO 15223-1:2012 / ISO 15223-1:2012
- EN ISO 780:2001
- IEC 60417-1: 2000

PACKAGING			
Box	Contents	W (Kg)	Size (cm)
Box No. 1 	• Carriage • Optional base, when required • PC if available • Ceph panel, when required The base is fixed to the floor of the pallet and the carriage is supported above a layer of polyethylene foam cushioning material. The display group, the front cover, and the accessories bag (chin support, bite, small parts, etc.), are housed in a special packaging.	100 Kg with standard base 120 Kg with big base Ceph: 18 Kg PC: 10 Kg	115 x 70 x 112
Box No. 2 	Column, with small base plate, when provided, alternatively to the bigger optional base. The bag of accessories (bracket, small parts, etc.), is placed inside the box.	43 Kg 50 Kg with Ceph	230 x 37 x 37

DIMENSIONS WITHOUT CEPH ARM



DIMENSIONS WITH CEPH ARM

