English

Owner´s Manual

Timex 70 E X-Rays

Cód. 300053312 Rev.01

GNATUS

PRESENTATION OF MANUAL

INSTRUCTIONS OF USE

EQUIPMENT:

Technical name: Odontological X -Ray
Trade name: Timex 70 E - X-Ray
Brand: GNATUS

Trade models:

- Timex 70 E X-Ray Mobile Column
- Timex 70 E X-Ray Wall
- Timex 70 E X-Ray Pantographic Mobile Column
- Timex 70 E X-Ray Pantographic Wall
- Timex 70 E X-Ray Pantographic Fixed Column

Manufacturer/ Distribuitor:
GNATUS - EQUIPAMENTOS MÉDICO-ODONTOLÓGICOS LTDA.
Rod. Abrão Assed , Km 53+450m - Cx. Postal 782 CEP 14097-500
Ribeirão Preto - S.P. - Brasil
Fone +55 (16) 2102-5000 - Fax +55 (16) 2102-5001
C.N.P.J. 48.015.119/0001-64 - Insc. Est. 582.329.957.115
www.gnatus.com.br - gnatus@gnatus.com.br
Technical Duties: Gilberto Henrique Canesin Nomelini
CREA-SP: 0600891412

Registration ANVISA nº: 10229030030

ATTENTION

For greater safety:

- Read and understand all the instructions contained in these Instructions for Use before installing or operating this Equipment.

Note: These Instructions for Use must be read by all the operators of this Equipment.

- This manual was originally written in Portuguese.
- Manual Review: 00

INDEX

INDEX

DESCRIPTION OF THE EQUIPMENT

Dear Customer

Congratulations. You have made a good choice when you decided to buy a GNATUS QUALITY product comparable to the best products available in the World. This manual is a general presentation of your product and it will give you important details to help you to solve possible problems.

Please, read it and keep this with you.

Identification

Technical name: Odontological X -Ray
Trade name: Timex 70 E - X-Ray

Trade models:
- Timex 70 E X-Ray Mobile Column
- Timex 70 E X-Ray Wall
- Timex 70 E X-Ray Pantographic Mobile Column
- Timex 70 E X-Ray Pantographic Wall
- Timex 70 E X-Ray Pantographic Fixed Column

Brand: GNATUS

DESCRIPTION OF THE EQUIPMENT

Principles and bases applied to the functioning of the product

Photomultipliers set, which are generated in X-rays tubes that transform light energy into electric energy, and then a circuit set forms the image, in order to diagnose or to guide evasive medical procedures and dental treatments.

Description of Equipment

This device is for intraoral radiography of patient's dentition with the purpose of making a diagnostic.

It is a unit of X- Ray for odontological use, with nominal tension of 70kVp and current in the tube of

7,0 mA. It has a centesimal digital timer, particularly developed for using with digital radiographic sensors, it reduces the time of radiation exposure and also it is indicated for conventional radiographic films.

Fixed column with the option of mobile column with 4-caster base; super steady columns, painted in epoxy at 250º C, and option of base for mounting on the wall built in steel, painted in epoxy and covered by a cover in polystyrene of high impact.

It is composed of type-pantographic arm (when pantographic model), which allows better reach and use in many positions.

Tube (ampoule), with focal point of 0,8 x 0,8mm, filtration with aluminum equivalence of 3,22 mm, cylindrical guide made in radiopaque polymer in order to avoid secondary radiations, wound completely immersed in special oil.

Manual trigger at a distance of 5m. Duly tested by legal body, respecting the rules in effect of radiological protection and elaborated by National Nuclear Energy Commission - CNEN.

The test method for measuring tension parameters of mean peak in the x- ray tube (kVp), mean current in the x-ray tube (mA), application time of load on x-ray tube(s) and product current X time in the x-ray time (mAs), adopted is the following:

It is used for measuring the device Dynalyzer III digital display, connected to a high tension unit. This unit consists of a resistive tension divisor of 1:20.000.

For odontological x-ray equipment it is used an adapter system in order to make a connection of the device Dynalyzer III. "In order to check the results obtained, it is connected to high tension unit The digital storage oscilloscope 2230 produced by Tektronix which gives the possibility to store an electrical signal to which is subject the x-ray tube, thus allowing an inspection of mean peak in the x-ray tube and the application time of load. Such results can be compared with those obtained from Dynalyzer III".

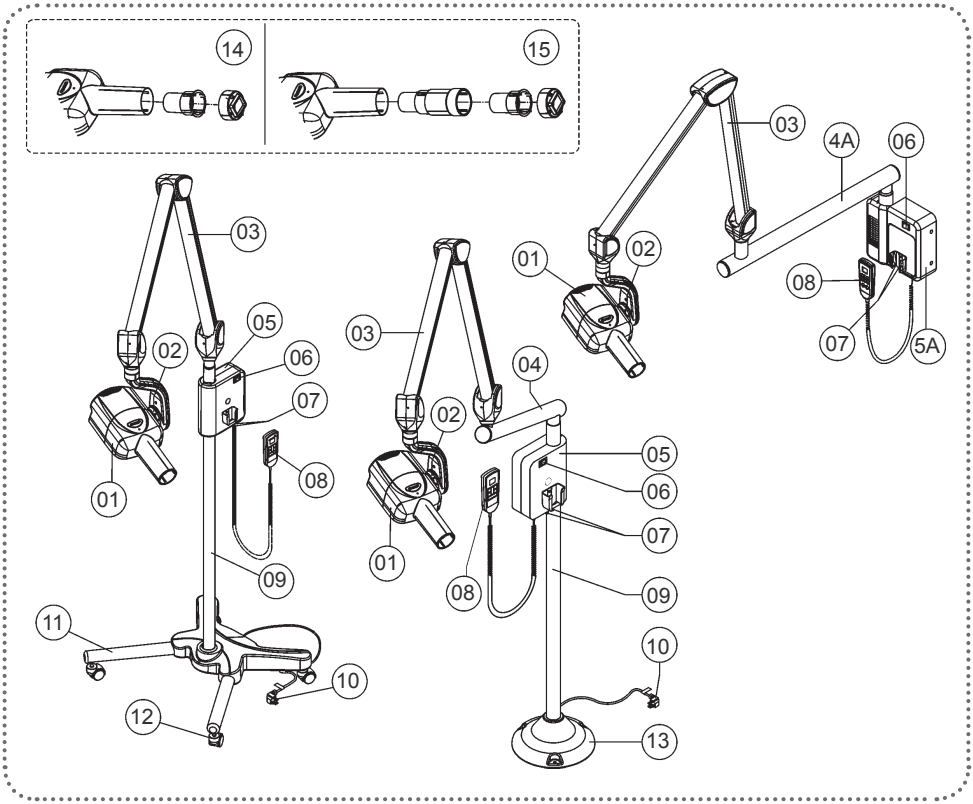
ISO 9001/2000 and ISO 13485/2003 Quality System, assuryng the products are manufactured under standart procedures.

Products manufactured in agreement with RDC-59 - ANVISA (Sanitary Surveillance National Agency).

Indication of Equipment

This equipment is for dental use use only. It must be operated and utilized by specialized professional (certified professional, according to the legislation of the country) and following the instructions of the manual. The operation of the equipment required, for the professional, the utilization of correct instruments and it should to be in perfect conditions of the use, and to protect the professional, the patients and others, in the eventual danger situation.

MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION

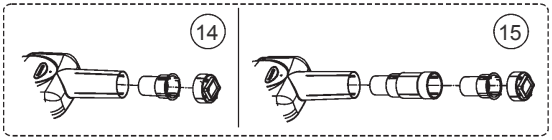


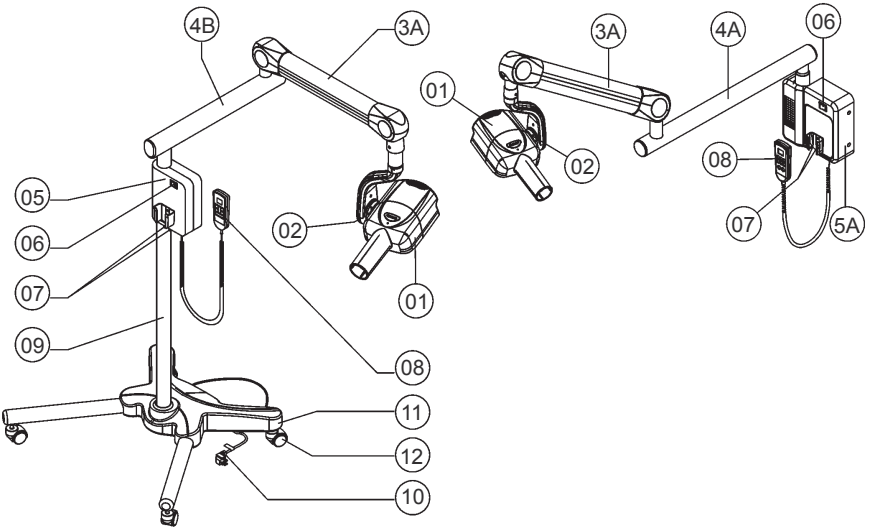
01 - Radiation transmitter Assembly x (cylinder head)
02 - Graduated scale
03 - Pantographic Arm
04 - Fixed arm (type Floor)
4A - Fixed arm (type Wall)
05 - Electronic command
5A - Electronic command (type Wall)
06 - Main switch - On / Off
07 - Fuse box
08 - Distance Control with cable
09 - Column
10 - Power - in cable
11 - Base (mobile type)
12 - Wheels
13 - Base (fixed type)
14 - Smaller colimator rectangular kit (optional)
15 - Extension with colimator cone kit (optional)

The contents of this page are of an informative nature, the equipment being able to differ from that illustrated. So, upon acquiring the product check the technical compatibilty between equipment, coupling and accessories.

Note: This equipment is designed for stationary use.

MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION





01 - Radiation transmitter Assembly x (cylinder head)
02 - Graduated scale
3A - Adjustable arm
4A - Fixed arm (type Wall)
4B - Fixed arm (type Mobile)
05 - Electronic command
5A - Electronic command (type Wall)
06 - Main switch - On / Off
07 - Fuse box
08 - Distance Control with cable
09 - Column
10 - Power - in cable
11 - Base (mobile type)
12 - Wheels
14 - Smaller colimator rectangular kit (optional)
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TECHNICAL SPECIFICATIONS

Technical features

General

Model
• Timex 70 E X-Ray Mobile Column • Timex 70 E X-Ray Wall • Timex 70 E X-Ray Pantographic Mobile Column • Timex 70 E X-Ray Pantographic Wall • Timex 70 E X-Ray Pantographic Fixed Column
Classification of Equipment as per ANVISA:
Class III
Classification of Equipment as per standard IEC 60601-1:
Protection against Electric Shock - Type B and Class I Equipment (IEC 60601-1)
Degree of safety of application in presence:
Equipment not suited to an anesthetic mixture inflammable with air, oxygen or nitrous oxide.
Mode of Operation
Continuous operation with intermittent load
Protection against Dangerous Ingress of water
Common device (Equip. Closed without protection against ingress o water)
Generator
Immersed in Oil
Transformer Oil
Lubrax Industrial AV-58-BR-Petrobras
Cylindrical Collimator
Totally armored
Target Material
Tungsten
Reference Axis
19o in relation to anode
Target Angle
19o
Nominal Focus Point Value
(0,8 x 0,8mm) positioned in relation to the reference axis of the XR tube in compliance with IEC336/1982)

TECHNICAL SPECIFICATIONS

Technical features
General

Tube Conditioning		
At iddle position the Cone should always be directed downwards		
kVp tube (average)		
70 kVp (for max. tube current 7.0 mA)		
kVp (average) beam peak		
70 kVp +/- 10%		
Net weight	**Gross weight**	Timex 70 E X-Ray Mobile Column
50 kg	64,5 kg	
Net weight	**Gross weight**	Timex 70 E X-Ray Wall
25 kg	29 kg	
Net weight	**Gross weight**	Timex 70 E X-Ray Pantographic Mobile Column
61,5 kg	75,5 kg	
Net weight	**Gross weight**	Timex 70 E X-Ray Pantographic Wall
31 kg	34,5 kg	
Net weight	**Gross weight**	Timex 70 E X-Ray Pantographic Fixed Column
35,6 kg	41 kg	

Power Supply

Model	Nominal Tension	Supply Rate	Freq	Consumption	Type Installation
Timex 70 E Mobile Column	127V~	125V~ + 4%	60Hz	10A	Mobile
	220V~	220V~ + 4%	60Hz	6A	Mobile
	220V~	220V~ + 4%	50Hz	6A	Mobile
	230V~	230V~ + 4%	50Hz	5,5A	Mobile
	240V~	240V~ + 4%	50Hz	5A	Mobile

TECHNICAL SPECIFICATIONS

Technical features
Power Supply

Model	Nominal Tension	Supply Rate	Freq	Consumption	Type Installation
Timex 70 E Wall	127V~	125V~ + 4%	60Hz	10A	Fixed
	220V~	220V~ + 4%	60Hz	6A	Fixed
	220V~	220V~ + 4%	50Hz	6A	Fixed
	230V~	230V~ + 4%	50Hz	5,5A	Fixed
	240V~	240V~ + 4%	50Hz	5A	Fixed

Model	Nominal Tension	Supply Rate	Freq	Consumption	Type Installation
Timex 70 E Pantographic Mobile Column	127V~	125V~ + 4%	60Hz	10A	Mobile
	220V~	220V~ + 4%	60Hz	6A	Mobile
	220V~	220V~ + 4%	50Hz	6A	Mobile
	230V~	230V~ + 4%	50Hz	5,5A	Mobile
	240V~	240V~ + 4%	50Hz	5A	Mobile

Model	Nominal Tension	Supply Rate	Freq	Consumption	Type Installation
Timex 70 E Pantographic Fixed Column / Wall	127V~	125V~ + 4%	60Hz	10A	Fixed
	220V~	220V~ + 4%	60Hz	6A	Fixed
	220V~	220V~ + 4%	50Hz	6A	Fixed
	230V~	230V~ + 4%	50Hz	5,5A	Fixed
	240V~	240V~ + 4%	50Hz	5A	Fixed

Power	**Power in stand by**
1200VA	15VA
No of phase:	
Single Phase / Biphasic	
Fuses: 127V~	**Fuses: 220 à 240V~**
F1 and F2 15A delayed action	F1 and F2 8A delayed action
F3 0,2A quick action	
Type of fuses	
Crystal 20 mm	

TECHNICAL SPECIFICATIONS

Technical features

Cooling - Sb

The device presents protection against excessive heating of the tube.

A new image can be performed only after a time equivalent of 30 times the trigger time, necessary time for natural cooling and return of normal functions.

Ex: Trigger time = 0,06 seconds.

Cooling time = 0,06seconds X 30 = 1,8 seconds.

Thermal protection

The device has a safety mechanism against temperature elevation of the transmitter assembly.

A thermal protection turn the device's functions off if the internal temperature of the transmitter assembly overpasses the allowed limit , damaging the internal components of the assembly.

Protection against acidental activation

The equipment has an electronic blocking mechanism against acidental activations, preventing consecutive activations, eliminating unecessary exposure to radiation and overheating of the emission set.

Under current protection

The equipment features a safety device for over-current by means of 3 fuses, being 2 of them for power supply and one for electronic circuit.

Overvoltage Protection

The device has a safety mechanism for overvoltage in device power supply that does not allow trigger when power supply overpasses approximately 3 Volts of specified limits.

Undervoltage Protection

The device has a safety mechanism for undervoltage in device power supply that does not allow trigger when power supply it goes inferior the 10 V~ of specified limits.

TECHNICAL SPECIFICATIONS

Technical features

Trigger

The button must be continuously pressed until the end of transmission, monitored by a sound signal (beep), that is, if the button activation is interrupted, the transmission will also be automatically interrupted , by indicating at display "A4".

Distance protection against parasite radiation

The operator must use the safety device of the equipment (distance activation cable), remaining at a minimum distance of 3 meters from the X-radiation beam during the charge application. The user must wear the protection clothes (lead apron and lead collar) they are not provided with the product

Lead apron and collar, (They are not provided with the product).

How to regulate arm tension

If the arm assembly/cylinder head loses its balance condition, a Technician authorized by Gnatus shall be called in order to make the adjustment.

TECHNICAL SPECIFICATIONS

Radiation quality

Ingress of quality equivalence

FILTERS Tube crystal
1,26 mm Al
Insulating oil, column 17mm
0,64 mm Al
Window
0,32 mm Al
Additional filter (aluminum)
1,00 mm Al
TOTAL FILTRATION = 3,22 mm Al

Parametes for charge exposure 0,32s

Tension
70 kVp ± 10%
Current
7 mA ± 1,5 mA
Power
0,49 kW
Product current time
2,24 mAs
Highest energy applied in intermittent mode during 1 h
170 KJ

Note:

Filtration with thickness equivalency of aluminum.

- Using as method an x-ray tube tension of 70 kVp and 2.5 mmAl of semiconducting reductor.

-The method using the measurement of the first semireductor layer was in narrow beam conditions, with the x-ray equipment operating with x-ray tube tension value of 70 kVp with anodic current of 7mA and exposure time of 1.0 second.

Timex 70E X-Ray
Mili Amper scale X Time

Set Time (seconds)	mA c/ Real Time	Set x Real KVp AVG	Set Time (seconds)	mA c/ Real Time	Set x Real KVp AVG
0,06	1,46	81,4	0,56	7,20	70,6
0,07	1,46	80,7	0,63	7,39	70,8
0,08	2,36	79,5	0,71	7,37	70,7
0,1	3,91	79,4	0,8	7,48	70,7
0,12	4,21	76,5	1	7,58	70,7
0,14	4,42	75,8	1,25	7,58	70,6
0,16	4,74	75,1	1,4	7,70	70,7
0,2	5,44	73,7	1,6	7,56	70,6
0,25	5,94	72,6	2	7,69	70,9
0,28	6,30	72,0	2,5	7,80	70,7
0,32	6 ,59	71,5	2,8	7,64	70,0
0,4	6,71	71,0	3,2	70,59	70,7
0,5	6,97	70,6	-----	-----	-----

OBS.:
The specified field for time irradiation compliance is comprehended within 0.06 and 3.2 seconds.

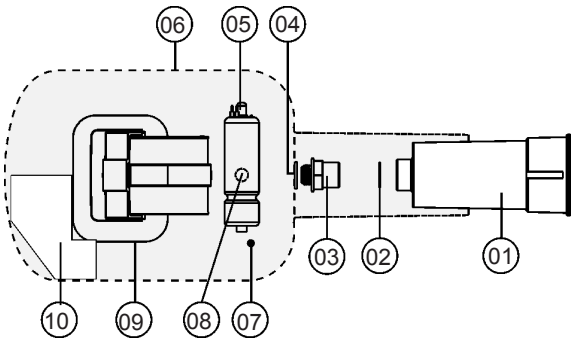
TECHNICAL SPECIFICATIONS

IMPORTANT: Information referring to x-ray dosage, radiation leak can be found in the conformity report attached to this manual.

NOTE:

- The serial number of the dome, beam limiter and radiation source is the same of the equipment, and it is stated in the product's label.

Transmitter assembly



01 - Complementary cone
02 - Aluminum filter (1mm a1)
03 - Collimator
04 - Collimator O-ring
05 - X-ray tube
06 - External cover
07 - Insulating oil
08 - Focal point
09 - High tension coil
10 - Electronic plate Assembly

Standards applied:

This product was tested and approved as per the standards:

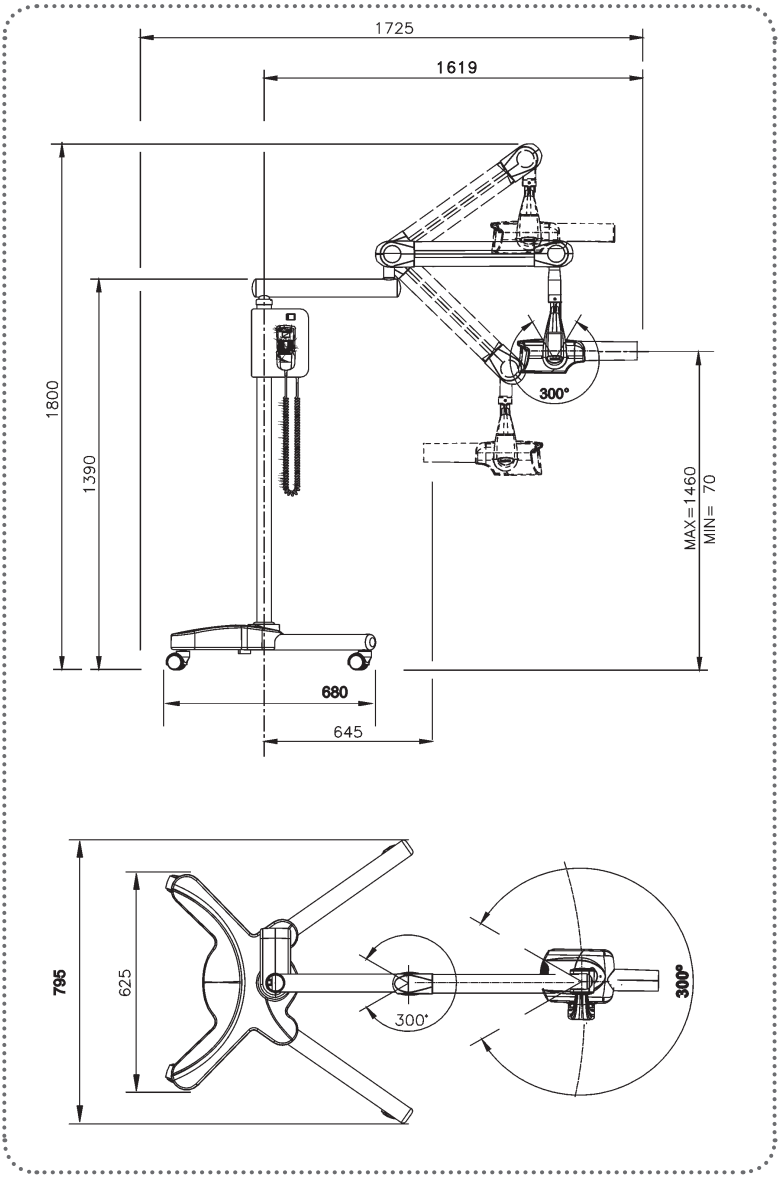
IEC 60601-1: (1988);	IEC 60601-2-7: (1998);	IEC 61000-4-3: (2006);
Amendment 1: (1993);	IEC 60601-2-28: (1993);	IEC 61000-4-4: (2004);
Amendment 2: (1995);	IEC 60601-2-32: (1994);	IEC 61000-4-5: (2005);
IEC 60601-1-2: (2001);	CISPR 11, edição 3.1 (1999);	IEC 61000-4-6: (2006);
IEC 60601-1-3: (1994);	IEC 61000-4-2: (2001);	IEC 61000-4-11: (2004);

NBR-IEC série 601-1 Equipamento Eletromédico - Parte 1: Prescrições gerais para segurança;
EN 980:2003 (Ed. 2) - Graphical symbols for use in the labelling of medical devices;
ISO 14971: 2007
ISO 9687: 1993 - Dental equipment - graphical symbols;
ISO 7494 - 1:2004 - Dental Units - Port 1: General requeriments and test methods
ISO 13485:2003
ISO 780:1997
ISO 11144:1995

TECHNICAL SPECIFICATIONS

Dimensions (mm)

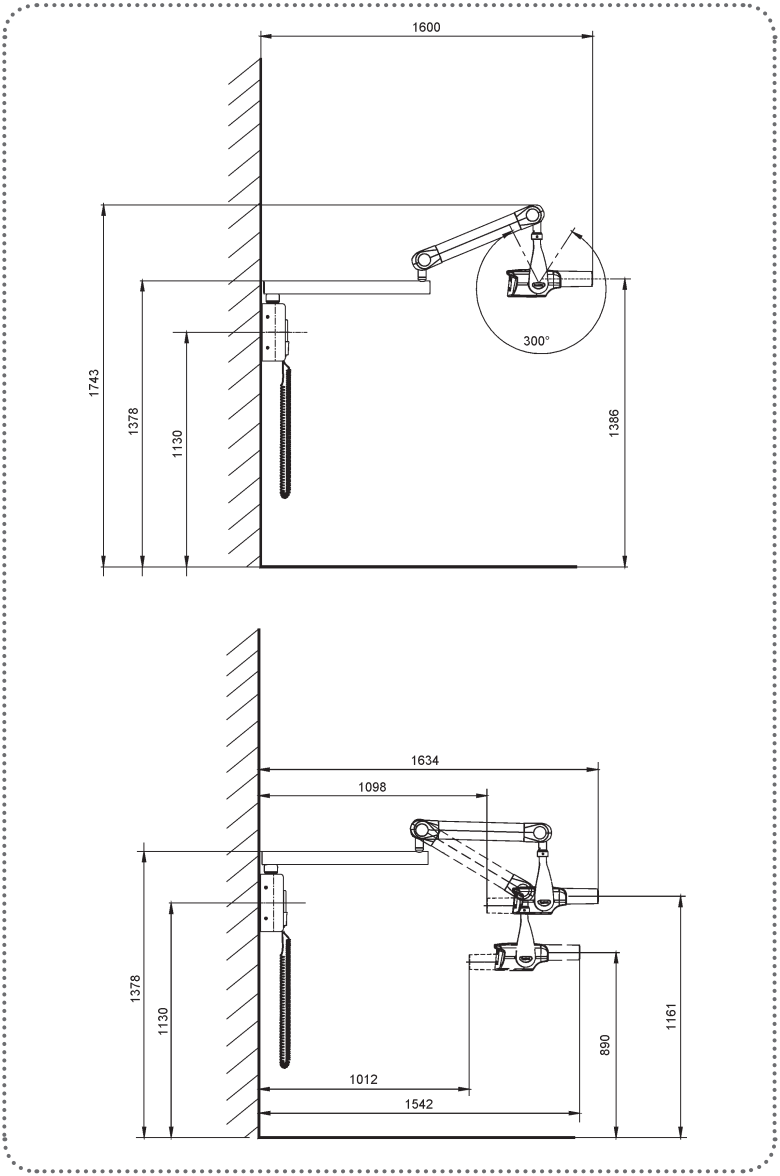
Model: Mobile Column



TECHNICAL SPECIFICATIONS

Dimensions (mm)

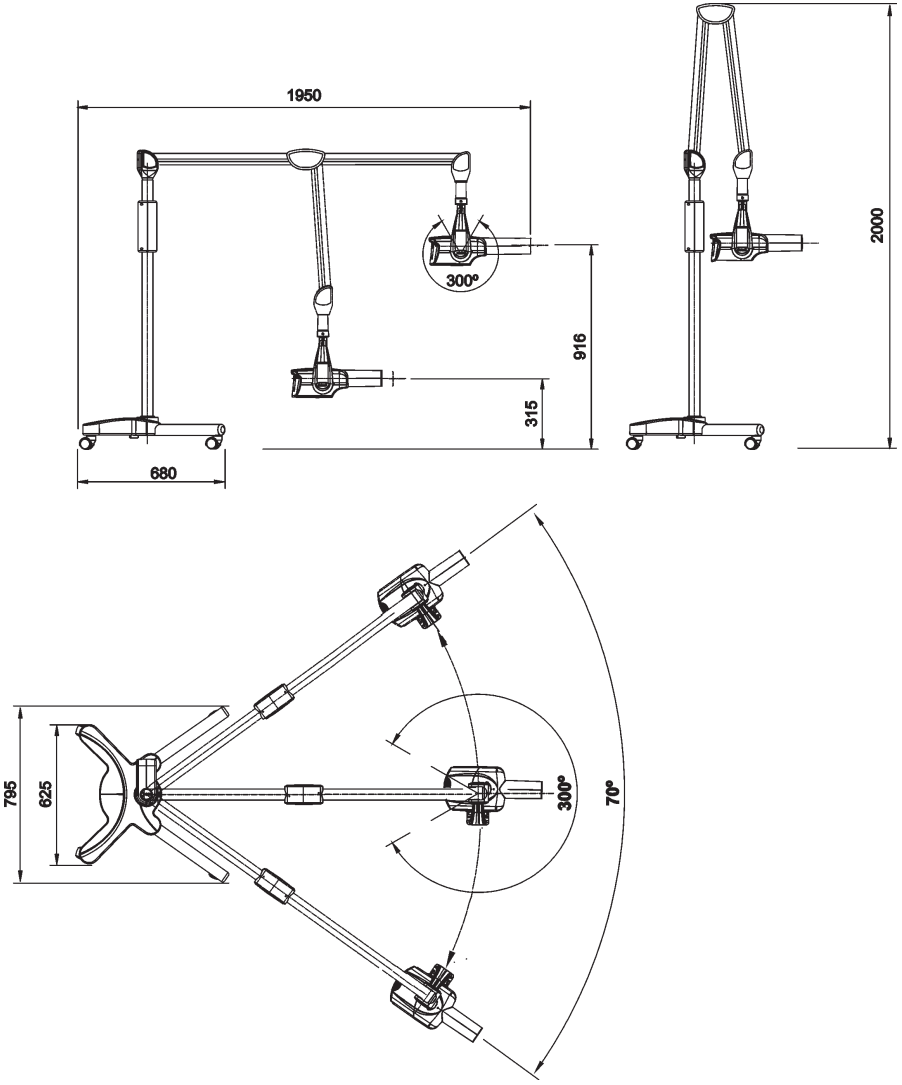
Model: Wall



TECHNICAL SPECIFICATIONS

Dimensions (mm)

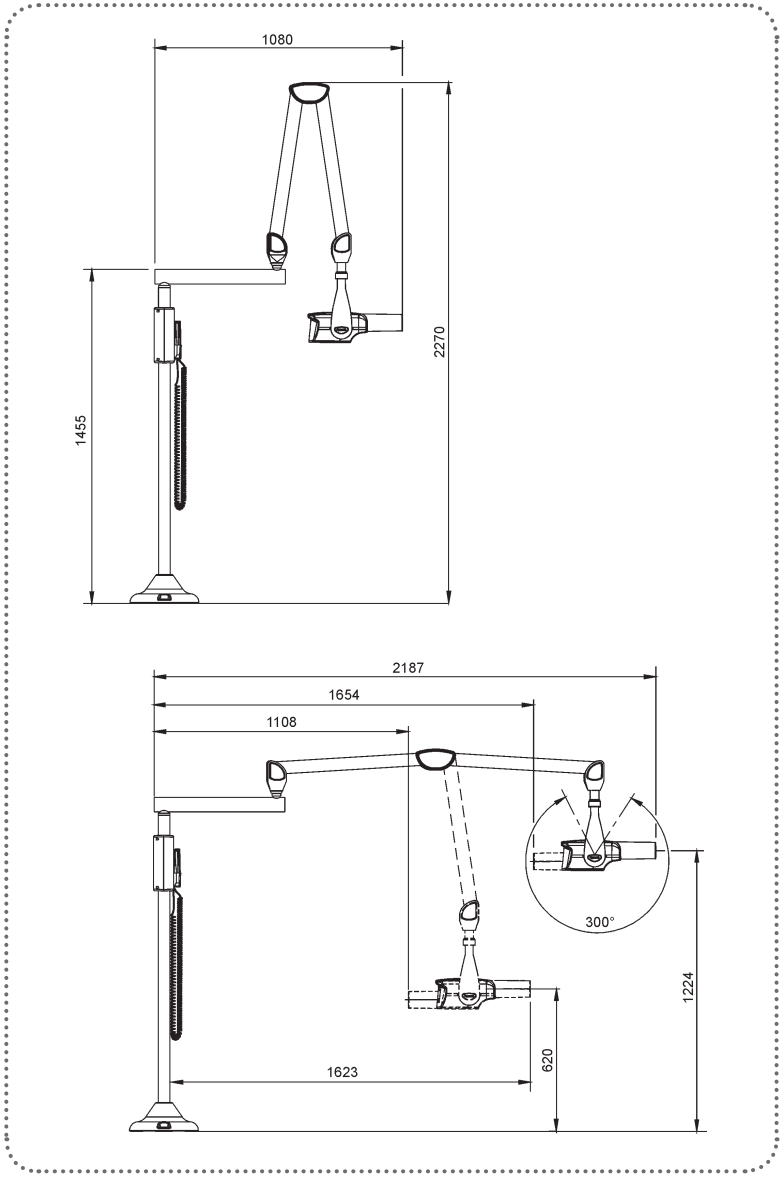
Model: Pantographic Mobile Column



TECHNICAL SPECIFICATIONS

Dimensions (mm)

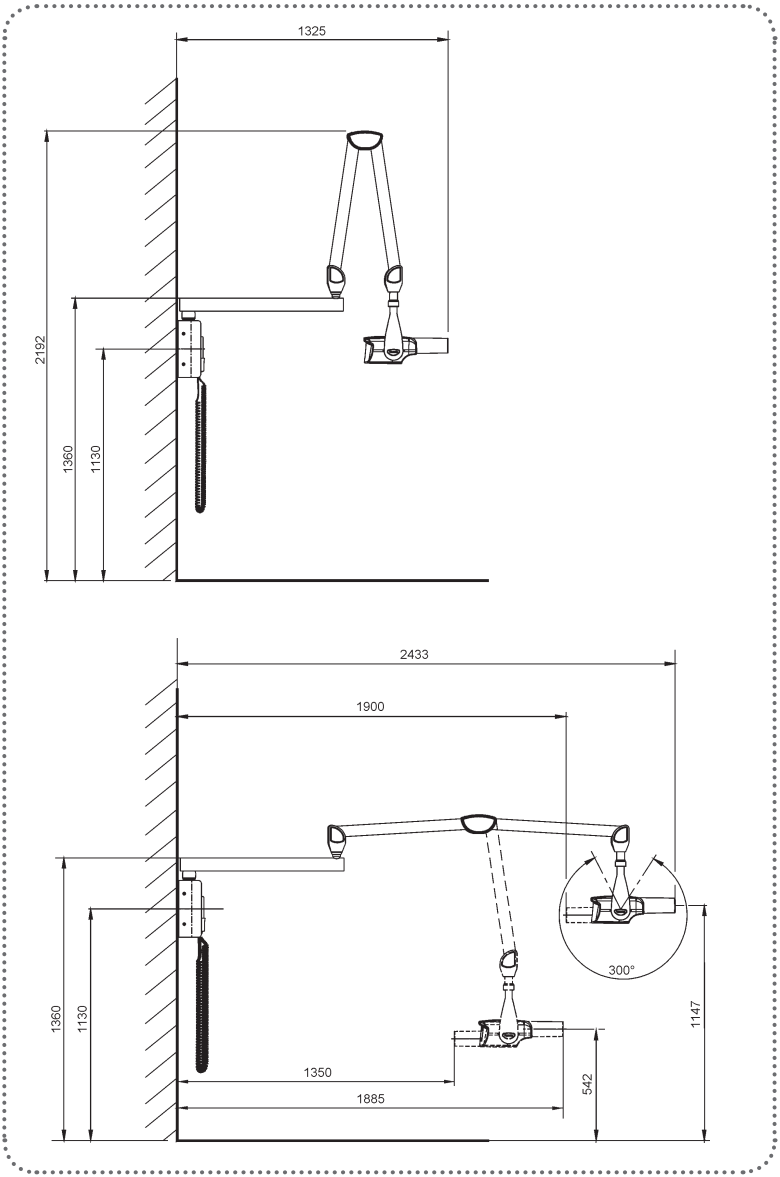
Model: Pantographic Fixed Column



TECHNICAL SPECIFICATIONS

Dimensions (mm)

Model: Pantographic Wall



TECHNICAL SPECIFICATIONS

Packing symbols

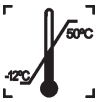
Maximum stacking:
It determines the maximum quantity of boxes which can be stacked during transportation and storage "as per packaging".

Packing to be transported and / or stored avoiding humidity, rains and wet floor.

Packing to be transported and / or stored with the harrows up.

The packing must be stored and transported away from direct sun light exposure.

Packing to be transported and / or stored with care (should not suffer drop and neither receive impact).



Temperature limit for the packing to be stored or transported.

Product symbols

Careful: It indicates an important instruction for the operation of the product. Not following it can cause dangerous malfunctioning.

Note: It indicates useful information for operation of the product.

Important: It indicates an instruction of safety for operation of the product. Not following it, can lead to serious danger to the patient.

Landing (in many parts of the equipment) indicates the condition of being landed.

"Focal Point"- indicates the exact position Of radiation transmitter center

Turned on

Turned off

B type equipment

Trigger Time Indicator Display and Many messages

x-ray transmission indicator LED (yellow)

"Radiation"- indicates that the device issues Ionizing radiation

TECHNICAL SPECIFICATIONS

Product symbols

Dangerous electrical tension

Trigger key

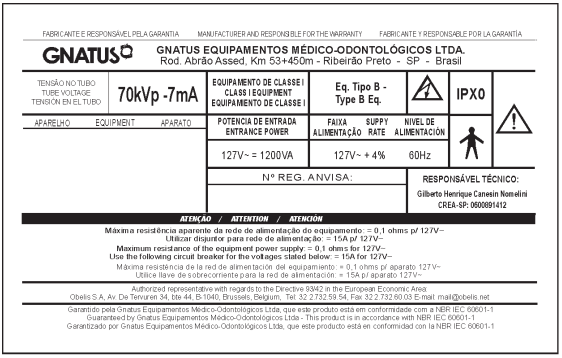
Button to reset the display indicator for x-ray emission time.

Time selector - decrease

Time selector - increase

Content of accessible and non-accessible demarcations

01



FABRICANTE E RESPONSÁVEL PELA GARANTIA MANUFACTURER AND RESPONSIBLE FOR THE WARRANTY FABRICANTE Y RESPONSABLE POR LA GARANTÍA

GNATUS

GNATUS EQUIPAMENTOS MÉDICO-ODONTOLÓGICOS LTDA.
Rod. Abrão Assed, Km 53+450m - Ribeirão Preto - SP - Brasil

TENSÃO NO TUBO / TUBE VOLTAGE / TENSIÓN EN EL TUBO	70kVp -7mA	EQUIPAMENTO DE CLASSE I / CLASS I EQUIPMENT / EQUIPAMIENTO DE CLASSE I	Eq. Tipo B - Type B Eq.		IPX0	
APARELHO / EQUIPMENT / APARATO		POTENCIA DE ENTRADA / ENTRANCE POWER	FAIXA ALIMENTAÇÃO / SUPPY RATE	NIVEL DE ALIMENTACIÓN		
		127V~ = 1200VA	127V~ + 4%	60Hz		
		Nº REG. ANVISA:			RESPONSÁVEL TÉCNICO: Gilberto Henrique Canesin Nomelini CREA-SP: 0600891412	

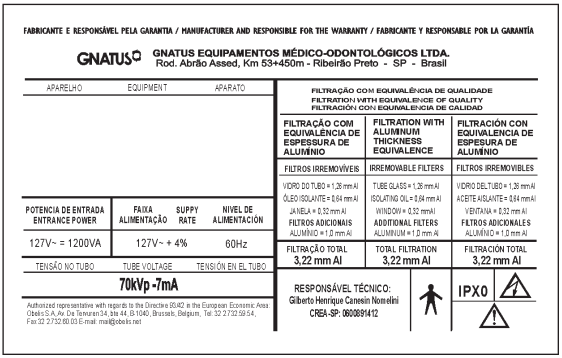
ATENÇÃO / ATTENTION / ATENCIÓN

Máxima resistência aparente da rede de alimentação do equipamento: = 0,1 ohms p/ 127V~
Utilizar disjuntor para rede de alimentação: = 15A p/ 127V~
Maximum resistance of the equipment power supply: = 0,1 ohms for 127V~
Use the following circuit breaker for the voltages stated below: = 15A for 127V~
Máxima resistência de la red de alimentación del equipamiento: = 0,1 ohms p/ aparato 127V~
Utilice llave de sobrecorriente para la red de alimentación: = 15A p/ aparato 127V~

Authorized representative with regards to the Directive 93/42 in the European Economic Area:
Obelis S.A, Av. De Tervuren 34, bte 44, B-1040, Brussels, Belgium, Tel: 32.2.732.59.54, Fax 32.2.732.60.03 E-mail: mail@obelis.net

Garantido pela Gnatus Equipamentos Médico-Odontológicos Ltda, que este produto está em conformidade com a NBR IEC 60601-1
Guaranteed by Gnatus Equipamentos Médico-Odontológicos Ltda - This product is in accordance with NBR IEC 60601-1
Garantizado por Gnatus Equipamentos Médico-Odontológicos Ltda, que este producto está en conformidad con la NBR IEC 60601-1

02



FABRICANTE E RESPONSÁVEL PELA GARANTIA / MANUFACTURER AND RESPONSIBLE FOR THE WARRANTY / FABRICANTE Y RESPONSABLE POR LA GARANTÍA

GNATUS

GNATUS EQUIPAMENTOS MÉDICO-ODONTOLÓGICOS LTDA.
Rod. Abrão Assed, Km 53+450m - Ribeirão Preto - SP - Brasil

APARELHO / EQUIPMENT / APARATO

POTENCIA DE ENTRADA / ENTRANCE POWER	FAIXA ALIMENTAÇÃO / SUPPY RATE	NIVEL DE ALIMENTACIÓN
127V~ = 1200VA	127V~ + 4%	60Hz

TENSÃO NO TUBO / TUBE VOLTAGE / TENSIÓN EN EL TUBO: 70kVp -7mA

Authorized representative with regards to the Directive 93/42 in the European Economic Area:
Obelis S.A, Av. De Tervuren 34, bte 44, B-1040, Brussels, Belgium, Tel: 32.2.732.59.54,
Fax 32.2.732.60.03 E-mail: mail@obelis.net

FILTRAÇÃO COM EQUIVALÊNCIA DE QUALIDADE / FILTRATION WITH EQUIVALENCE OF QUALITY / FILTRACIÓN CON EQUIVALENCIA DE CALIDAD

FILTRAÇÃO COM EQUIVALÊNCIA DE ESPESSURA DE ALUMÍNIO	FILTRATION WITH ALUMINUM THICKNESS EQUIVALENCE	FILTRACIÓN CON EQUIVALENCIA DE ESPESURA DE ALUMÍNIO
FILTROS IRREMOVÍVEIS	IRREMOVABLE FILTERS	FILTROS IRREMOVIBLES
VIDRO DO TUBO = 1,26 mm Al ÓLEO ISOLANTE = 0,64 mm Al JANELA = 0,32 mm Al FILTROS ADICIONAIS ALUMÍNIO = 1,0 mm Al	TUBE GLASS = 1,26 mm Al ISOLATING OIL = 0,64 mm Al WINDOW = 0,32 mm Al ADDITIONAL FILTERS ALUMINUM = 1,0 mm Al	VIDRIO DEL TUBO = 1,26 mm Al ACEITE AISLANTE = 0,64 mm Al VENTANA = 0,32 mm Al FILTROS ADICIONALES ALUMINIO = 1,0 mm Al
FILTRAÇÃO TOTAL 3,22 mm Al	TOTAL FILTRATION 3,22 mm Al	FILTRACIÓN TOTAL 3,22 mm Al

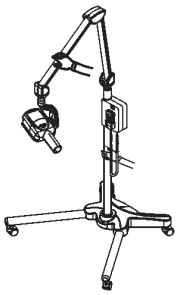
RESPONSÁVEL TÉCNICO:
Gilberto Henrique Canesin Nomelini
CREA-SP: 0600891412

IPX0

TECHNICAL SPECIFICATIONS

Content of accessible and non-accessible demarcations

03



ADVERTÊNCIA PARA TRANSPORTE E AUMENTO DE ESTABILIDADE

O equipamento deverá ser transportado com braços sobrepostos de acordo com a ilustração.
Desta forma terá sua estabilidade aumentada.

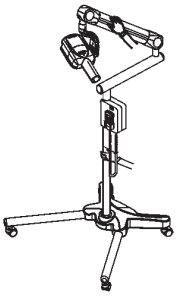
WARNING: TRANSPORTATION AND STABILITY

In order to increase the equipment´s stability, we recommend to keep the arms as shown in the picture.

ADVERTENCIA PARA TRANSPORTE Y AUMENTO DE ESTABILIDAD

El equipamiento deberá ser transportado con los brazos sobrepuestos de acuerdo con la ilustración.
De este modo tendrá mayor estabilidad.

04



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05

TECHNICAL SPECIFICATIONS

Content of accessible and non-accessible demarcations

06

GNATUS

07

Segurança

NCC OCP 0034 **Compulsório** INMETRO

08

GNATUS

GNATUS EQUIPAMENTOS
MÉDICO-ODONTOLÓGICOS LTDA.

Nº SÉRIE / SERIAL NUMBER

09

10

CUIDADO/CAUTION GNATUS

A remoção da fita de fixação acarreta risco de segurança se removida prematuramente. Para removê-la, deve-se pressionar o braço móvel tirando a pressão na fita. Após removida, solte o braço lentamente.

Removing the fixation tape could offer risk of safety if removed prematurely. To remove it, the mobile arm should be pressed removing the pressure in the tape. After it being removed, loosen the arm slowly.

El retiro de la cinta de fijación acarrea riesgo de seguridad si efectuado prematuramente, por lo tanto, debe presionarse el brazo móvil eliminan-do la presión en la cinta. Acto seguido, soltar el brazo lentamente.

CUIDADO/CAUTION GNATUS

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TECHNICAL SPECIFICATIONS

Content of accessible and non-accessible demarcations

Description	Fixation local
01 - Product identification tag	Cabinet cover
02 - Product identification tag	Cylinder head
03 - Ades. tag. Pantographic Arm	Cabinet cover
04 - Ades. tag. Adjustable arm	Cabinet cover
05 - Ades tag. radiation	Cylinder head
06 - Ades tag. identification Tension Cylinder head	Cylinder head
07 - Ades tag. electro medic safety seal	Packing and Cylinder head
08 - Product identification tag	X-Ray control
09 - Ades tag. - warning	Arm articulations and cabinet cover
10 - Ades tag. – tape removal	Arm

TECHNICAL SPECIFICATIONS

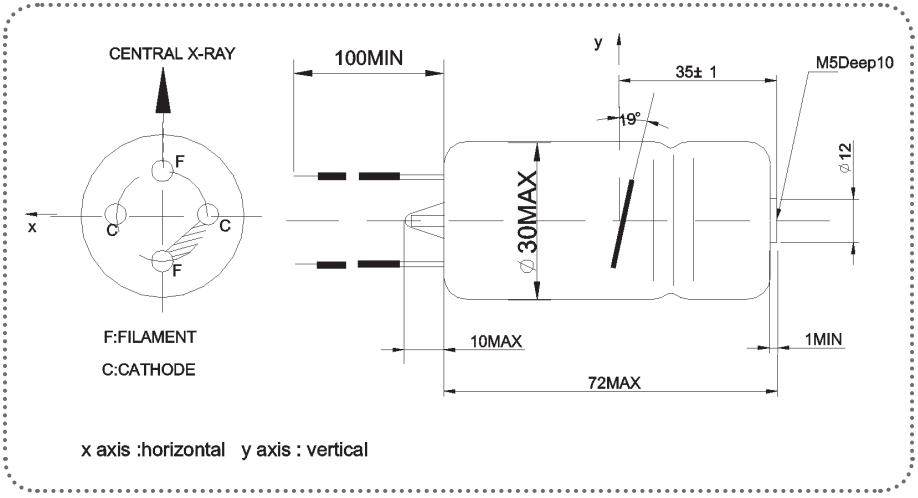
Tube letters with technical characteristics

KL27-0.8-70

TECHNICAL DATA

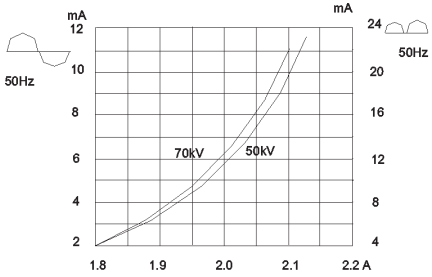
This tube is designated for intra-oral dental x-ray unit and available for nominal tube voltage with self-rectified circuit.

Nominal Tube Voltage……..70kV
Nominal Inverse Voltage……..85kV
Nominal Focal Spot……0.8 (IEC60336/1993)
Max. Anode Heat Content……7000J
Max. Current Continuous Service……2mA x 70kV
Max. Anode Cooling Rate……140W
Target Angle……19°
Filament Characteristics……1.8 – 2.2A, 2.5 – 3.6V
Permanent Filtration……Min. 0.8mmAl/50 kV(IEC60522/1999)
Target Material……Tungsten
Nominal Anode Input Power……840W

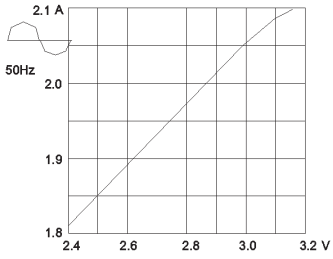


TECHNICAL SPECIFICATIONS

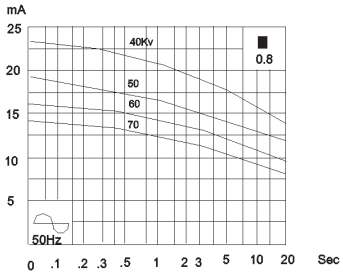
Tube letters with technical characteristics



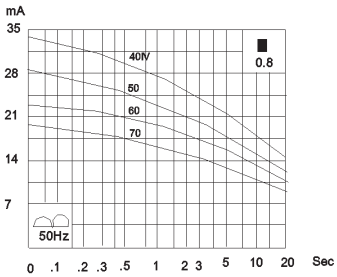
CATHODE EMISSION CHARACTERISTICS



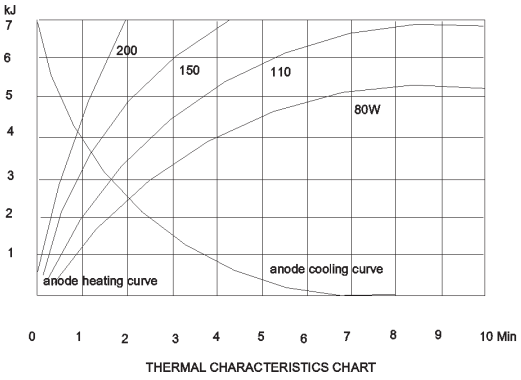
FILAMENT CHARACTERISTICS



RATING CHART



RATING CHART



THERMAL CHARACTERISTICS CHART

INSTALLATION OF EQUIPMENT

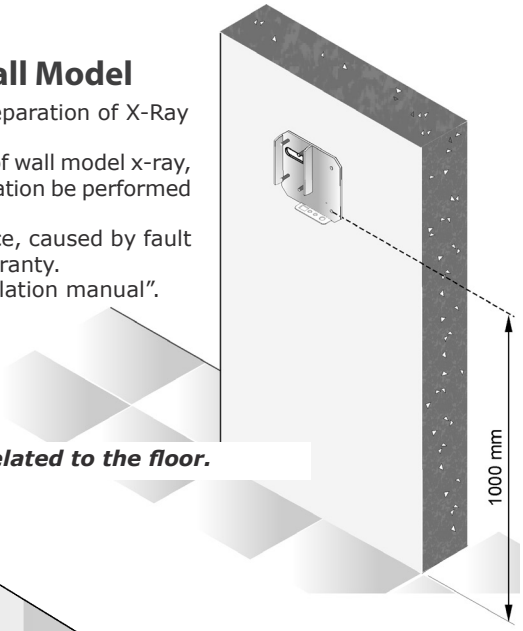
Dimensions and positioning
Chassis command box X-Ray Wall Model

Recommendations for pre-installation preparation of X-Ray Wall model:

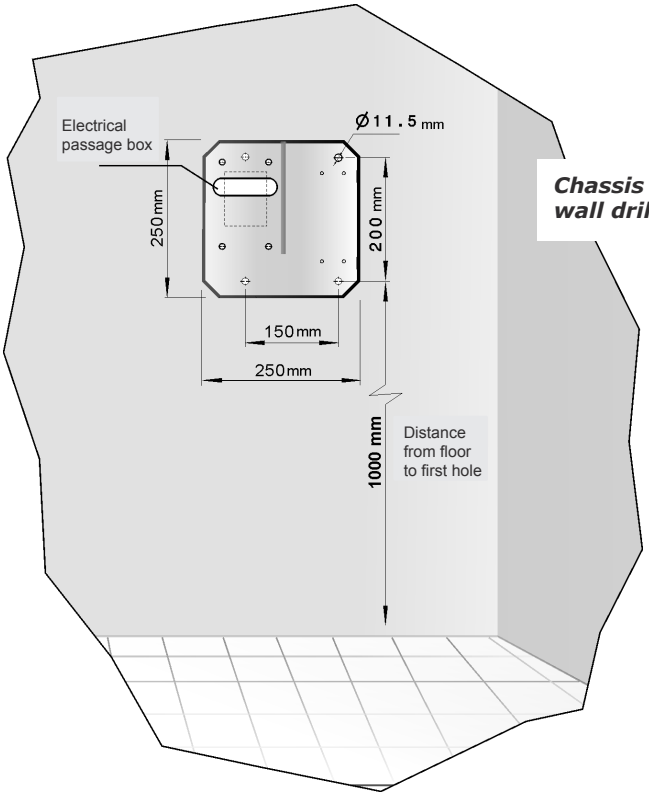
In order to assure the perfect functioning of wall model x-ray, we recommend that the services of pre-installation be performed by professionals duly qualified.

Any damages that may occur to the device, caused by fault at pre-installation will not be covered by warranty.

"For more information, refer to pre-installation manual".



Chassis positioning related to the floor.



Chassis Dimensional "template for wall drilling"

INSTALLATION OF EQUIPMENT

The installation of this equipment requires specialized technical assistance (Gnatus).

OBS: These information also make part of the Manual of Installation and Maintenance of the equipment that can be found with the authorized Gnatus technician.

- This equipment shall only be able to be unpacked and installed by a Gnatus authorized technician, under penalty of losing the warranty, as only (s)he has the information, suitable tools and training required to execute this task.
- Gnatus bears no responsibility for damages or accidents caused by poor installation executed by a technician not authorized by Gnatus.
- Only after the equipment has been installed and duly tested by the authorized technician representing Gnatus, will it be ready to start work operations.

OPERATION OF EQUIPMENT

Operating Instructions of Transmitter Assembly How to move the cylinder head

- When moving the cylinder head, grasp the cylinder (02) and back part (01) as shown in the picture.

Operating Instructions

Only after an authorized technician have properly installed and tested the equipment, it will be ready to work.

Verify if the equipment is connected to the main grid.

Turn on the general switch (09) and a green light will turn on.

Choose the time scale from 0 to 3.2 seconds according to the work to be performed. "See radiographic technique chart on page 33" and set it through the buttons (04 and 05) located on the control.

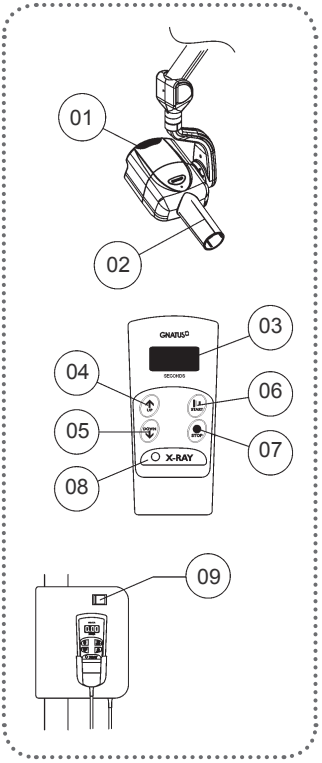
When the patient is properly prepared for the radiography:

Remove the support control, press the shutter-button (06) (Beep beeping) and keep it pressed.

The "yellow" LED must be lighted during radiation emission.

Note: Turn off the general key (09) whenever the equipment is not in use.

Always keep the remote control in its holder.



Note: If the messages appear on the display:

- A1 •A2
- A3 •A4
- Sb •A5

See page 40 "Unforeseen situations"

NOTE:

The value indicated on the digital command display refers to the exposure time. To obtain the charge application time, add 0.2 seconds (pre-warming) to any value indicated on the display.

- As it is a pulse device and depends on the wiring frequency, it is not possible to provide time of 0,063s belonging to geometric series within the range of ± 10%.

(IEC 60601-2-7 : 29.1.106 E)

OPERATION OF EQUIPMENT

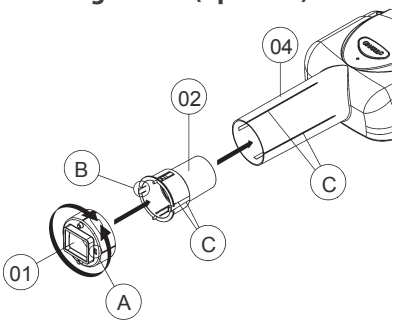
Operating Instructions “Smaller colimator rectangular kit and extension with colimator cone kit”

By applying a slight effort, press the cover (01) against the adapter (02) observing the alignment of openings (A) with catches (B) “click system”.

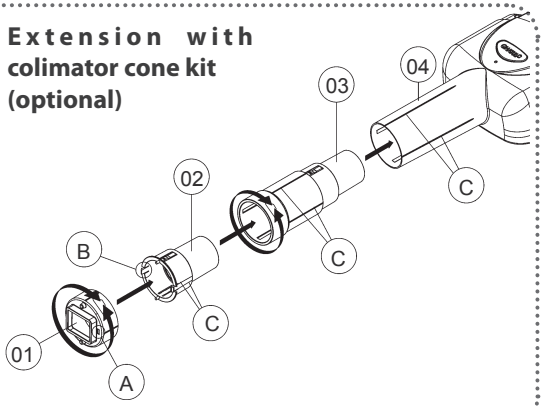
After assembling cover (01) and adaptor (02), attach the assembly mounted in the complementary cone (03), afterwards attach to the cylinder head (04).

The attachment between the couplings shall be performed with rotation movements, and the alignment between locking cams shall be observed (C).

Smaller colimator rectangular kit (optional)



Extension with colimator cone kit (optional)



WARNING

The operator shall keep a bigger distance between the distal extreme of limiting bunch device and patient’s surface.

Limit and x-ray beam extension recommendation

The X-Ray field is confined within the limits of opening of the Diaphragm (11,2mm - fixed).

Precautions to be observed before the 1st charge application

- Check that all the items from the instructions operations manual have been concluded.
- Place yourself behind the head (opposite the beam) at a minimum distance of 2.5m, to carry out the activation.

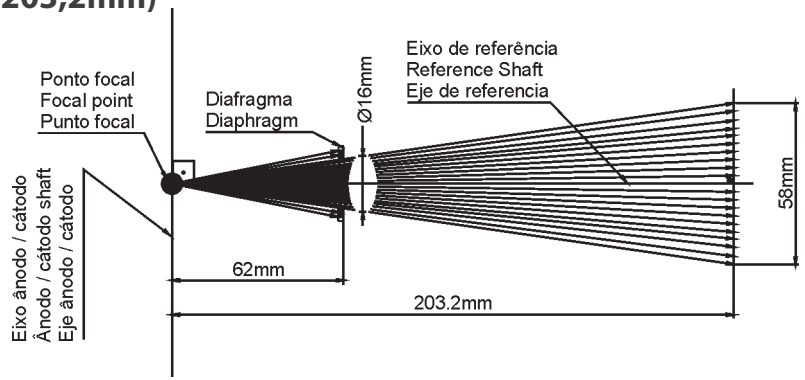
OPERATION OF EQUIPMENT

Radiation bunch characteristics

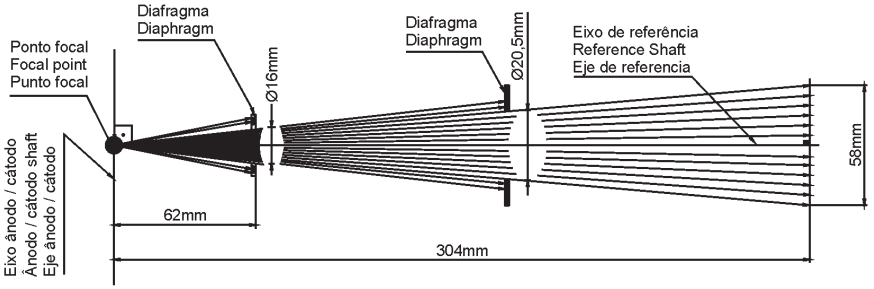
The pictures below present radiation bunch characteristics with and without the use of extension whit colimador cone.

The extension whit colimador cone is used to apply the parallelism technique which gives less distortion to the image generated due to x-ray from film/sensor presented less inclination related to reference axis.

Radiation bunch X without extension whit colimador cone (203,2mm)



Radiation bunch X with extension whit colimador cone (304mm)



NOTE: If the extension whit colimador cone is not used, it does not affect the safety level to patient during use of this device.

OPERATION OF EQUIPMENT

Radiography technical letter

Standard table for exposure time with type E film in adult individuals using the bisector periapical technique.

DEP - Skin penetration dose (mGy)

DEP - 3,5 mGy - Standard level established by ordinance 453 (D.O.U. 103 02/06/98) for a periapical exame of typical adult patient and film of group E. (Extaspeed/Agfa M-4)

Film D (Ultra-speed/Agfa M-2) double the time;

Children, con-sider 2/3 of time;

Angle with the vertical.

Region	Angle	Time (E group film)	DEP (mGy)	Time (Digital Sensor)	DEP (mGy)
Superior Jaw					
Incisor	+40º	0,32 - 0,40	1,1 - 1,5	0,06	0,10
Canine	+45º	0,40 - 0,50	1,5 - 2,0	0,08	0,16
Pre-molar	+30º	0,40 - 0,50	1,5 - 2,0	0,08	0,16
Molar	+20º	0,50 - 0,64	2,0 - 2,6	0,10	0,24
Lower Jaw					
Incisor	-15º	0,32 - 0,40	1,1 - 1,5	0,06	0,10
Canine	-20º	0,32 - 0,40	1,1 - 1,5	0,06	0,10
Pre-molar	-10º	0,32 - 0,40	1,1 - 1,5	0,06	0,10
Molar	-5º	0,40 - 0,50	1,5 - 2,0	0,08	0,16
Bitewing					
Anterior	+8º	0,32 - 0,40	1,1 - 1,5	0,06	0,10
Posterior	+8º	0,32 - 0,40	1,1 - 1,5	0,06	0,10
Oclusal					
Upper Jaw	+60º	0,50 - 0,63	2,0 - 2,6	---	---
Lower Jaw	-70º	0,40 - 0,50	1,5 - 2,0	---	---

Procedure for processing with recent chemical agents

Process Temperature (oC)	18 - 20	21 -22	23 - 25	26 - 28	29 - 31
Process Time (min)	5,0	4,0	3,0	2,0	1,0

OPERATION OF EQUIPMENT

Radiography test

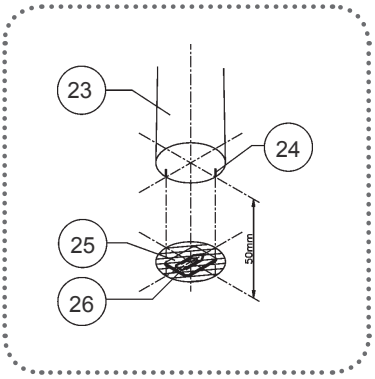
After the assembly of the equipment the authorized technician must carry out a radiography test, using the materials (film, dark room, processor and fixator) supplied by the client, following the instructions below:

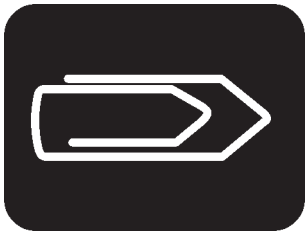
Place the head directed downwards (90o position) next to an horizontal surface (aprox. 50 mm).

Centralize the film (25) utilizing for such the auxilliary points (24) existing on the Collimator Cylinder (23), put over the film (25), a metallic object (26). (Ex.: clips or coin) as in the figure below:

Select a time scale of 0.32 seconds.

Activate the button "Start" (06) (see pg. 30).





Radiography carried out with
- Kodak Film.
- Ektaspeed Type

It is not provided with the product

NOTE:

The material (clips, coins, film, etc) will not be contaminated, and can be taken out after trigger.

Develop the film at Dark Room with the following times:

- 1 minute at development;
- 1 minute at fixation.

Afterwards, check if radiography is according to indicated standard.

In case of differences in comparison, see page 40 "fault".

If it is not possible to test by the authorized technician (because of lack of material) the proprietary will be responsible for it before initiating operations.

Caution:

Never test the device with the cylinder aimed to you, or people that are next to the place Always do the test with the cylinder aimed downwards, by keeping a minimum distance of 2m.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

Transportation and storage

This equipment must be transported and stored observing the following directions:

- Avoid falls and impacts;
- Keep it dry, do not expose it to rain, water drops or wet floor;
- Keep it away from water and direct sunlight, and in it original wrapping;
- Don't move it over irregular surfaces, protect it from rain and observe the maximum stack quantity specified in the packaging;
- Transportation and storage temperature range: -12°C to 50°C;
- Transportation and storage relative humidity range: 0°C to 90°C;
- Atmospheric pressure range: 500hPa to 1060hPa (375 mmHg to 795 mmHg).

Operation ambient conditions

- Ambient temperature range: +5°C to +45°C;
- Ambient temperature range recommended by Gnatus: +15°C to +30°C;
- Operation relative humidity range: 30% to 75% (non condensing);
- Atmospheric pressure range: 700 hPa to 1060 hPa (525 mmHg to 795 mmHg).

Sensitivity to environmental conditions in normal situations of use

- The equipment has been planned not to be sensitive to interference such as magnetic fields, external electrical factors, electrostatic discharge, pressure or variance of pressure, provided that the equipment is installed, maintained, clean, preserved, transported and operated as per this instruction for use.

Precautions and warnings "during the installation" of quipment

- The equipment should only be installed by Gnatus authorized technical assistance or technicians.
- Check that the socket in which the device will be connected has a ground connection. According to the ABNT standard, this is essential for the safe operation of the system;
- Position the unit in a place where it will not get wet.
- Install the unit in a place where it will not be damaged by the pressure, temperature, humidity, direct sunlight, dust, salts, or sulfur compounds.
- The unit should not be submitted to inclination, excessive vibrations, or blows (including during transportation and handling).

Removing the tape from the arm:

- If you early remove the adhesive tape, safety risk may occur. In order to remove it, please press the adjustable arm taking pressure off the tape. After removing it, slowly loose the arm.
- The equipment should be transported with the arms overlaid as illustrated. In this form it will have its stability enhanced.
- This equipment was not planned for use in an environment where vapors, anesthetic mixtures inflammable with air, or oxygen and nitrous oxide can be detected.
- Check the voltage of the equipment at the moment of executing the electrical installation.
- The equipment must be grounded correctly.
- Before the first use and/or after long interruptions from work such as vacations, clean and disinfect the equipment.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

These information also make part of the Manual of Installation and Maintenance of the equipment that can be found with the authorized Gnatus technician.

Recommendations for the dental equipment maintenance

Your Gnatus equipment has been designed and developed according to the standards of modern techology. Similarly to other kinds of equipment, it requires special care, which is many times neglected due to several reasons and circunstances.

Therefore, here are some important reminders for your daily routine. Try to follow these simple rules, which will save you a lot of time and will avoid unnecessary expenses once they start making part of your working procedure.

Precautions and warnings "during the use" of equipment

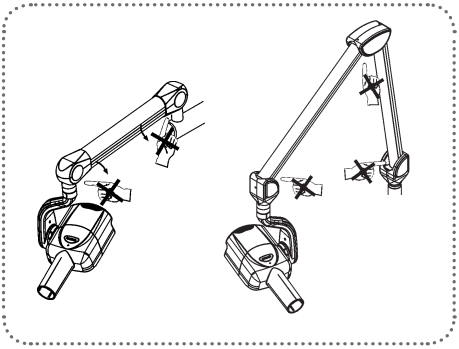
- The equipment should only be operated by duly enabled and trained technicians (Dental Surgeons, Capacitated Professionals)
- If any maintenance should be required, only use services of the Gnatus Authorized Technical Assistance.
- The equipment has been manufactured to handle both continuous and intermittent operation; so follow the cycles described in these Instructions for Use.
- Because of the emission of ionised radiation, this equipment can cause collateral effects in case users don't follow the protection requirements.
- In case of oil spilling in the Emission Set, the precautions below must be carried out:
- Avoid skin extended contact; wash the contaminated parts with soap and water.
- In case of skin or eyes irritation, visit a doctor.
- Do not throw it into water, soil or sewage. In case of spilling, absorb it with sawdust or similar material.
- The used oil is recyclable. For disposal, send the oil for re-refining according to the local law. Preserve the environment.
- Although this equipment has been planned in accordance with the standards of electromagnetic compatibility, it can, in very extreme conditions, cause interference with other equipment. Do not use this equipment together with other devices very sensitive to interference or with devices which create high electromagnetic disturbance.
- Do not expose the plastic parts to contact with chemical substances, use in the routines of dental treatment, such as: acids, mercury, acrylic liquids, amalgams, etc.

Gnatus shall not be responsible for:

- Use of the equipment differing from that for which it is intended.
- Damages caused to the equipment, the professional and/or the patient by the incorrect installation and erroneous procedures of maintenance, differing from those described in these Instructions for use which come with the equipment or by the incorrect operation of it.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

- When using the equipment, take care with the parts that can clamp your fingers as illustrated.



Precautions and warnings “after” the use of equipment

- Turn off the main switch of the dental set when it is not in use for an extended period of time.
- Always maintain the equipment clean for the next operation.
- Do not modify any part of the equipment. Do not disconnect the cable or other connections without need.
- After using the equipment, clean and disinfect all the parts which may be in contact with the patient.

Precautions and warnings during the “cleaning and disinfection” of equipment

- Before cleaning the equipment, turn off the main switch.
- Avoid spilling water, even accidentally, or other liquids inside the equipment, which could cause short circuits.
- Do not use microabrasive material or steel wool when cleaning, or employ organic solvents or detergents which contain solvents such as ether, stain remover, gasoline etc.

Precautions in case of alteration in the functioning of equipment

- If the equipment has any abnormality, check if the problem is related to any item listed in the topic of unforeseen events (failures, causes and solutions). If it is not possible to resolve the problem, turn off the equipment, remove the power supply cable from the socket and contact your representative (Gnatus).

Precautions to be adopted against foreseeable or uncommon risks, related to the deactivation and abandoning of equipment

In order to avoid environmental contamination or undue use of the Equipment after it has become useless, it should be discarded in the suitable place (as per the local legislation of the country).

- Pay attention to the local legislation of the country for the conditions of installation and disposal of residue.

CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

Additional procedures for reuse

The equipment can be reused in undetermined, i.e. unlimited, quantities, only needing to be cleaned and disinfected.

Disinfection

Use clean and soft cloth dampened in alcohol 70% to disinfection of the equipment. Never use corrosive disinfectants or solvents.

Cleaning

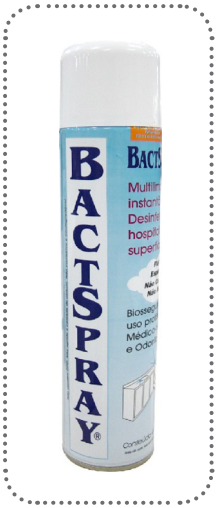
The cleaning procedure below should be executed at the start of the working day and after each patient.
Always turn off the main switch before executing the procedures of daily maintenance.

To clean the equipment, we recommend the use of "BactSpray **(Reg nº MS: 3.2079.0041.001-5)** or any other similar product:

Active component: Benzalkonium chloride (tri-quaternary ammonium)
Solution 50%..... 0.329%

Chemical composition: Butyl Glycol, Decyl polyglucose, Sodium Benzoate, Sodium Nitrate, Essence, Deodorized Propane / Butane, demineralized Water.

For more information concerning cleaning procedures, see manufacturer's instructions.



WARNING:

- In order to prevent risks and damages to equipment, make sure that the liquid does not enter into the unit.
- The application of other solvent-based cleaning products or sodium hypochloride isn't recommended, because they may damage the equipment.

NOTE: The registration at the Ministry of Health of the "BactSpray" is executed separately from the product described in this manual, as the "BactSpray" is not manufactured by Gnatus.

Note: Use gloves and other systems of protection, during the disinfection.

Attention: Do not use any disinfectant spray, as the vapor may be inflammable, or it may cause injury.

CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

Preventive Maintenance

The equipment should be calibrated routinely, as per the legislation in force in the country.

But never with a period exceeding 3 years.

In order to protect your equipment, seek Gnatus technical assistance for periodic revisions of preventive maintenance.

Corrective Maintenance

If the equipment has any abnormality, check if the problem is related to any of the items listed in the item Unforeseen Events (situation, cause and solution).

If it is not possible to solve the problem, turn off the equipment, and request Gnatus technical assistance.

UNFORESEEN EVENTS – SOLUTION OF PROBLEMS

⚠ Upon coming across any problem in operation, follow the instructions below to check and repair the problem, and/or get in touch with your representative.

Problem	Probable cause	Solution
- Not functioning properly.	-Damaged fuse. -Lack of power.	-Turn the device off and call a technician. -Check the wiring
-At radiography appears a semi circle.	-Wrong positioning of cylinder.	-Radiograph using the parallelism technique, using for that auxiliary lines of collimator cylinder.
-Radiography totally dark.	-Excess of XR time; -Development; -Developer with inadequate temperature. -Developer with inadequate mixture.	- Check if the time is well adjusted according to radiographic techniques table; -Check the development time. -AThe quicker is the developer action the bigger is the solution temperature. -Prepare the mixture again. NOTE: Kodak developer does not use mixture.
-Radiography with a dark targe.	-Development Camera with light penetration.	-Avoid light output.
Message in the Display -A1	-Invalid Voltage: Voltage higher than the equipment's limit.	-Check the supply voltage -See about overpotential protection on page 12.
-A2	-Invalid Voltage: Voltage lower than the equipment's limit.	-Check the supply voltage -See about overpotential protection on page 12.
-A3/A5	-Fault in electrical network	-Turn on the equipment. In case of failure lasts, request a technician service.
-A4	-Exposure error: Shutter button released before time.	-Turn on the equipment.
-Sb	-Protection against excessive tube heating.	-Wait for the correct cooling time to reestablish the normal functions – see page 12 – cooling item.

WARRANTY OF EQUIPMENT

This equipment is covered by the warranty terms counting from the date of installation, as specified below; provided that the defect has occurred in normal conditions of use and that the equipment has not remained stored for more than 06 months counting from the issue date of the sales document until the date of the actual installation.

- WARRANTY TERMS: Verify the guarantee certificate;
- LOSS OF THE WARRANTY:

A) Attempt to repair using an inadequate tool or by unauthorized technicians;
B) Installation of the equipment by an unauthorized technician;
C) Damage arising from inappropriate storage or signs of infringement;
D) Incorrect use of the equipment;
E) Use of a cleaning product not indicated by the factory;
F) Falls or blows which the equipment may undergo or lack of observation of an compliance with the guidelines of the Owner's Manual, which was delivered with the present document, together with the equipment. Repair or replacement of parts during the warranty period shall not extend the validity term of their warranty.

- This warranty doe snot exempt the customer from paying the service charge for the visit and the travel expenses of the technician, except when the customer sends the equipment to execute the maintenance inside the establishment of the technical assistance.

"Consumer Defense Code - art. 50, unique paragraph".

- The Warranty Certificate comes with the product and must be filled in upon the date of installation by the Gnatus Authorized Technician.
- Queries and information: GNATUS Help Desk (+55) 16 2102-5000.
- Check the warranty term attached to this manual.

FINAL CONSIDERATIONS

The most important aspect related to equipment care is that concerning spare parts.

To guarantee the life span of your equipment, use only ***original Gnatus spare parts***. They are sure to follow the technical specifications and standards required by Gnatus.

We must also point out to you our chain of authorized dealers. Only dealers that make part of this chain will be able to keep your equipment constantly new for they count on technical assistants who have been trained and on spedific tools for the correct maintenance of your equipment.

Doubts and information: GNATUS Call center (55-16) 2102-5000.

EC REP Obelis S.A, Boulevard Général Wahis 53, 1030 Brussels, Belgium,
Tel: +(32) 2 732-59-54 Fax: +(32) 2 732-60-03 E-mail: mail@obelis.net

NUM. REG. ANVISA: 10229030030

Manufacturer/ Distribuitor:

GNATUS

Technical Duties:
Gilberto Henrique Canesin Nomelini – CREA-SP: 0600891412

EQUIPAMENTOS MÉDICO-ODONTOLÓGICOS LTDA.
Rod. Abrão Assed , Km 53+450m - Cx. Postal 782
CEP 14097-500 - Ribeirão Preto - S.P. - Brasil
Fone (16) 2102-5000 - Fax (16) 2102-5001
C.N.P.J. 48.015.119/0001-64 - Insc. Est. 582.329.957.115
www.gnatus.com.br - gnatus@gnatus.com.br