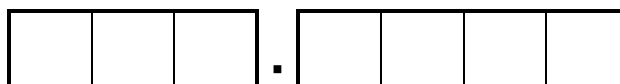


User's Manual

Control Console C306.36



n. 0077

Ver. ENG - Rev J5

While every care is taken to ensure the description and illustration accuracy in this publication, factory reserves itself the right to make any change in equipment design considered to be in the interest of our customers without noticing it.



NOTICE

The safety of both patient and operator was a major consideration in the design and manufacturing of this equipment.

The equipment will function reliably when operated, maintained, and repaired according to the instructions in this manual.

Misuse, however, could result in hazards to patient, operator and/or equipment.

CONFORMITY CERTIFICATION

Manufacturer certifies that X-ray generator series **R306.3x - R306.4x** is in accordance to European Medical Directive MDD 93/42/CEE, and it meets all the requirement asked by tubes or subassemblies that complies with this regulation, only if controls and requirement are strictly observed and tubes calibrated in the working range specified by tube

X-RAY DIAGNOSTIC SYSTEMS
MECHANICAL and ELECTRICAL SAFETY

All moveable assemblies and parts of the unit should be carefully operated and routinely inspected according to the Operator and Maintenance Manuals.

Only properly trained and qualified personnel should have access to any internal components; before opening any access door be sure that line disconnect witch is open.

DO NOT REMOVE the high tension cables from the X-ray tube housing or high tension generator until main and auxiliary power supplies have been disconnected.

Failure to comply with the above may result in hazard to operator, patient, and/or equipment.

Electrical Grounding Instruction

Equipment when installed must comply IEC 601-2-7 grounding requirements, it must have a protection ground using a specific separate ground cable.

The neutral side of the line is not to be considered the heart ground.

DIAGNOSTIC X-RAY DEVICES
IONIZING RADIATION WARNING

Ionizing radiation can be dangerous for both the patient and the operator if safety regulation are omitted.

Only specifically trained people can operate ionizing radiation equipments, following the on-site radiation directive according to general safety rules.



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1. GENERALS

1.1. Introduction

R306.3x microprocessors controlled series of X-Ray Generator have been developed according to conventional radio-diagnostics needs.

Repetitive operations have been reduced using a new concept of intuitive Anatomical Programming Techniques.

Designers always take in consideration the easy and intuitive interaction between man and device during the development process of this products

All X-ray parameters are freely changeable, and can be user-stored in memory associated with a strings of characters freely selectable for quick retrieve.

1.2. Technical Characteristics

R306.3x microprocessors controlled series of X-ray generator series includes several version of high frequency generators; the common characteristics are listed below.

- Microprocessors controlled, network connected modular units
- Intuitive Anatomic programming
- R306.3x power output 40 - 50 - 65kW (High frequency - High Voltage Rectification)
- Automatic Mains Voltage Drop Compensation
- Intermittent working modes:
 - Automatic Exposure Control
 - Anatomical (APR) including Automatic Exposure Control
 - Free technique, including Automatic Exposure Control
- Easy and Intuitive parameters change
- Touch View interface (Touch Screen panel)
- 1,2,3 points techniques
- X-Ray Time & mAs pre-indication in kV/mA/s technique.
- Actual Exposure Time display in Automatic Exposure Control mode (1 or 2 points).
- Tube thermal load indication in Relative and Absolute format

1.3. Configuration

R306.3x microprocessors controlled series of X-Ray Generator always includes the Power Rack (HV Transformer, Power Electronics and Control Electronics), and, as option, a Touch Screen Control Console for User Interaction.

1.3.1. User's Interface

User's Interface is realized using a Graphic Interface on Touch Screen industrial class computer.

All the information and selections are made through graphic virtual Selectors and Graphic Displays on the control console.

C306.36 Control Console permits all the working techniques (1-2-3 points) as well as the technique with automatic exposure control and prefixed anatomical programs.

The Control Console is connected to the microprocessor located in the power rack via Controlled Area Network Bus (CANBus) over a cable carrying all the necessary machine status information.

All the functions are controlled via the various microprocessors standing on the network during all the working phases, the operator is run time informed of the "**machine status**" in progress using icons and color lights.

1.4. Programmed Memory (Anatomical Technique)

The term “Program” stands for an series of values stored in a computer location in which it is described the way the generator have to be set for the specific job.

Every program is associated with two 12 characters strings for easy user recall.

In every program are stored all the useful parameters such as kV, mA, time, working stations, predisposition for AEC, X- Ray tube, continuous mode preset and so further.

These values can be adapted to three patient sizes according to its structure (normal, thin, obese) using the proper control.

At any time, the pre-programmed parameters can be corrected on the control console according to the operator decisions.

The programs available are as follows:

- 12 Programs per screen
- 2 banks per working station: 24 programs per working station
- 4 working station on R306.4x or 4 working station on R306.3x.

For a total of 96 memory location on 3 patients: 288 programmable working ways

1.5. User selection – Free Technique

Every single modification of a programmed value changes the generator status to “Free Technique”: the starting values are the ones memorized in an anatomic program, freely changeable.

1.6. Automatic Exposure Control Technique

Automatic exposure control chamber is automatically chosen when the associated working station is selected.

Up to three dominant zones are freely selectable.

Up to three different film/screen combination (Slow Speed High Resolution, Normal Speed Medium Resolution, High Speed Low Resolution, for example).

The Automatic Exposure calibration process is performed by technical service during generator installation, the calibrated darkness can be modified by user needs in seven different timing steps from 50% to 200% of the nominal timing value.

A user selectable mAs limit can be runtime selectable for special regulation requirements.

Exposure technique (1 or 2 points) are set during generator installation according to user’s specifications.

1.7. Working Place Selection

In Anatomic technique, the working station is automatically set according to the exam selected.

In free Technique or in Programmed technique, the working station is selected according to the user working way through on-keyboard virtual pushbuttons.

1.8. Technical Characteristics

| | R306.34 | R306.35 | R306.36 |
|--------------------------------------|---|---------------------|---------------------|
| NOMINAL MAXIMAL THROUGHPUT | 400mA @ 100kV | 500mA @ 100kV | 630mA @ 100kV |
| HIGH VOLTAGE WAVEFORM | Continuous: High Frequency | | |
| TUBE VOLTAGE | Continuous Adjust | | |
| IRRADIATION TIME | from 1ms to 6s in R'10 step scale | | |
| <i>FLUOROSCOPY (RF version only)</i> | <i>kV and mA chained from 50kV to 100/110/120kV up to 5 mA</i> | | |
| AUTOMATIC EXPOSURE CONTROL | AEC Semiconductor or Ionizing Chamber up to 2 chambers | | |
| X-RAY TUBE | The complete standard bifocal tube library already present on other products | | |
| WORKING STATION | 4 3 on Bucky Reply 1 Direct Radiography | | |
| HOSTING | On a standard PC using ODEL NAVIGATOR program | | |

1.9. Identification Data Sheet

| | | | |
|---|---|------------------|------------------|
| REFERENCE STANDARDS | CONFORMITY to GENERAL MD STANDARD MDD 93/42/CEE | | |
| | CONFORMITY to PARTICULAR STANDARD IEC 601-1:1988 + A1:1991 + A2:1995 IEC 60601-2-7:1998 | | |
| MANUFACTURER NAME | Odel S.p.A. Via Sartirana,12 Monza (MI) – Italia | | |
| MANUFACTURER' s PRODUCT TRADE NAME | <input type="checkbox"/> R306.34 (40HF) <input type="checkbox"/> R306.35 (50HF) <input type="checkbox"/> R306.36 (65HF) | | |
| Dealer's PRODUCT TRADE NAME | | | |
| USER CONTROL CONSOLE | <input type="checkbox"/> C306.36 <input type="checkbox"/> Other O-XRLink compatible device | | |
| MANUFACTURING DATE | | | |
| | R306.34 | R306.35 | R306.36 |
| NOMINAL MAINS VOLTAGE | 400 Vac Three-phase | | |
| NOMINAL MAINS FREQUENCY | 50-60 Hz | | |
| MAXIMUM POWER ABSORBED | 60 kVA 54 kW | 75 kVA 63 kW | 98 kVA 82 kW |
| MAXIMUM APPARENT NOMINAL RESISTENCE (SUPPLY IMPEDANCE) | 0,30 Ohm | 0,20 Ohm | |
| MAINS CURRENT FUSES OR DEVICE | 60 A delayed (fuses) or 63 A C-curve (magneto-thermal circuit breaker) | | |
| GROUND | COMPULSORY | | |
| MAINS DROP ADMITTED | -10% .. +10% | | |
| COMPENSATED MAIN DROP | AUTOMATIC on admitted mains drop interval | | |
| MAXIMUM POWER OUTPUT | 40 kW | 50 kW | 65 kW |
| MD CLASS and TYPE | Class I Type B | | |
| PROTECTION INDEX | IPX0 | | |
| INTERMITTENT MODE (nominal maximum power output) | 400mA @ 100kV | 500mA @ 100kV | 630mA @ 103kV |
| CONTINUOUS MODE (RF version) | 5mA @ 120kV | | |
| COOLING REQUIREMENT | CONTROL CONSOLE 95 kcal/h POWER RACK 930 kcal/h | | |
| NOMINAL TUBE VOLTAGE | 150 kV Intermittent Mode 120 kV Continuous Mode (RF Version) | | |

| | | | |
|------------------------------|------------------------------|------------------|------------------|
| NOMINAL MAXIMUM TUBE CURRENT | Intermittent Mode | | |
| | 400mA @ 100kV | 500mA @ 100kV | 630mA @ 103kV |
| | Continuous Mode (RF Version) | | |
| | 5mA | | |
| MAXIMUM CURRENT TIME PRODUCT | 600 mAs | | |
| MINIMUM CURRENT TIME PRODUCT | 0,4 mAs | | |
| SHORTEST IRRADIATION TIME | 0,001 s (1ms) | | |

CERTIFICATO CE

Certificato n. 605/MDD

Dichiarazione di approvazione del sistema qualità (Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, punto 3 del Decreto Legislativo 24 febbraio 1997, n. 46, attuazione della direttiva 93/42/CEE, si dichiara che la ditta:

ODEL SPA

mantiene negli stabilimenti di:

MONZA (MI) - VIA SARTIRANA, 12 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Generatori di alta tensione ad alta frequenza di gruppi radiogeni per diagnostica
Modd. R306.34; R306.35; R306.36; R306.40; R306.41; R306.42

Serie: PROGRAM HF US; ENDEAVOUR
Marca ODEL

ai requisiti essenziali ad essi applicabili del Decreto suddetto, in tutte le fasi dalla progettazione al controllo finale.

Riferimento pratiche IMQ: 10AC00267 ; 10AE00216.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2003-01-22

Data di Aggiornamento: 2004-11-04

Sostituisce: 2003-01-22




IMQ

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".
Essa non è comunque valida dopo il 2008-01-21 (articolo 11, comma 11 della direttiva).


2.Controls

2.1. Generator Switch ON/OFF


2.1.1. Control Electronics Switch ON

Press  key on control console to switch on the control electronics.
A welcome message will appear on the control console screen.

2.1.2. Power Electronics Switch ON



Switch on the Power Electronics on welcome screen, pressing  key .
Since the power part is switched on it is possible to modify the parameters and recall a stored program.


2.1.3. Generator Switch OFF


Press  key on control console to switch off the generator.
Immediately is switched off the power electronics, after a few seconds it is switched off also the control electronics including the control console.



2.1.4. Reload Installation Condition



If on initial screen (the welcome dialog box) appear the following key  and doesn't appear the  key the generator has lost the actual configuration.


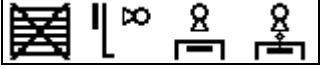
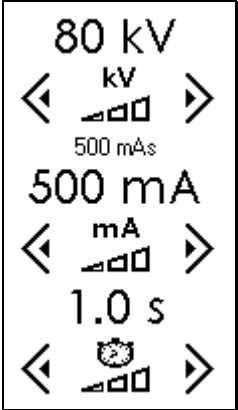
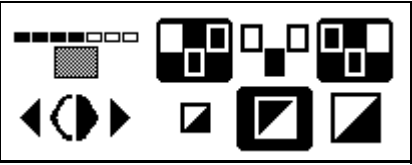



It is possible to reload the initial configuration pressing  key,

Then  key appear and have to be pressed to start the electronics and go on working.
Nevertheless call your Local Technical Service to inspect the causes of configuration lost.

If the  key appear within  key, the generator in Initial Setup Condition: call your Local Technical Service to switch the generator in Normal Working Condition before using it.








2.2. Main Screen


Several virtual gauges are present on the main screen.

| | |
|---|---|
| <p>GENERATOR STATUS ICON</p> |  |
| <p>WORKING PLACE WINDOW</p> |  |
| <p>RADIOGRAPHIC PARAMETERS WINDOW</p> |  |
| <p>AUTOMATIC EXPOSURE CONTROL ACTIVATED WINDOW</p> |  |
| <p>WORKING TECHNIQUE SELECTOR</p> |  |
| <p>ANATOMICAL PROGRAM SCREEN ACTIVATION KEY</p> |  |
| <p>ANATOMICAL PROGRAM STORE ACTIVATION KEY</p> |  |

2.3. Generator Status

Generator status is identified with several icons: the **GENERATOR STATUS ICON** display.

| | | |
|--------------------------------------|--|---|
| HANDSHAKE | Initial link try-out between control console and power rack |  |
| STAND-BY | Parameter modify status |  |
| RADIOGRAPHIC EXPOSURE REQUEST | Pressing the I Step discrete key on the control console or an optional hand switch the generator changes status from STAND-BY to this state |  |
| READY FOR EMISSION | When the II Step key is pressed within the I Step key pressed the new state is this. Now the generator is waiting for an external command to start exposure |  |
| IONIZING RADIATION EMISSION | The tube is emitting radiation. At the end of exposure will follow an acoustic signal (beep) |  |
| LAST RADIOGRAPY EXPOSURE DATA | Is a Stand-By state having data to be print from last exposure. Press the icon to learn more about the tube status |  |
| WARNING | There is an error in parameter setting Press the icon to learn more about the actual warning. Or simply look at the parameters display: the one in negative are the wrong parameters |  |
| ALARM | There was / there is an alarm Press the icon to learn more about the actual alarm. | |

| | | |
|--|--|---|
| | <p>Call the local technical service to ask for the possibility to keep on working</p> <p>Press <input checked="" type="checkbox"/> on the opened window to reset the alarm</p> |  |
|--|--|---|


2.4. Ionizing Radiation Emission Indication


























status shows an Ionizing Radiation Emission Indication in the upper left part of the screen, accompanied by a flashing yellow light indication on the control console.

2.5. Warning Messages


Warning messages are identified by  icon and described in the following table.


It is possible to have a description of the warning pressing the  icon.
Remove the warning cause to keep on working.











| COD | MESSAGE | ACTION |
|----------|--|---|
| 1 | Radiography: kV exceed the maximum | Use  kV to reduce the High Voltage value till  icon appear |
| 2 | Radiography: As exceed the maximum | In 3 points technique use  mA or, in 2 points technique use  mAs to reduce the High Voltage Current value till  icon appear |
| 3 | Radiography: mAs value under the minimum | In 3 points technique use  mA or, in 2 points technique use  mAs to increase the High Voltage Current value till  icon appear |
| 4 | Instantaneous Power Exceed the maximum | Use  mA or  kV to reduce the Instantaneous Power value till  icon appear |
| 5 | Radiography: Power Overload | Act on  mA or   to reduce the Power value till  icon appear |
| 6 | X-Ray Tube: Thermal Overload | Act on  mA or   to reduce the Thermal Power value till  icon appear or wait for tube cool down |
| 7 | Filament Lighting Computation not possible | Act on   to change the current focus. If the problem remains, call the technical service indicating the WARNING CODE "7" |










| | | |
|-----------|---|---|
| 8 | Back-Up Memory Corrupted | Act on  to reload the initial configuration. If the problem remains, call the technical service indicating the WARNING CODE "8" |
| 9 | Powering OFF the Generator in 30 seconds | No exposure made in 60 minutes: the generator will shut down automatically in 30 seconds. Press  to keep it alive |
| 10 | Powering OFF the Generator | Wait for the control console to switch off then press I key to switch the generator on again |
| 11 | O-XRL Protocol Transaction Error NO SJA1000 REPLY | Error in generator initialization. Call the technical service indicating the WARNING CODE "11". |
| 12 | O-XRL Protocol Transaction Error UNKNOWN COMMAND | Error in CANBus transmission. NOTE: retransmission is automatic. If the problem remains call the technical service indicating the WARNING CODE "12". |
| 13 | O-XRL Protocol Transaction Error COMMAND UNDONE | Error in CANBus transmission. NOTE: retransmission is automatic. If the problem remains call the technical service indicating the WARNING CODE "13". |
| 14 | O-XRL Protocol Transaction Error TX TIMEOUT | Error in CANBus transmission. NOTE: retransmission is automatic. If the problem remains call the technical service indicating the WARNING CODE "14". |
| 15 | O-XRL Protocol Transaction Error RX TIMEOUT | Error in CANBus transmission. NOTE: retransmission is automatic. If the problem remains call the technical service indicating the WARNING CODE "15". |
| 16 | Stop Emission Quick pre-release of Accessory Reply | Call the technical service indicating the WARNING CODE "16" |
| 17 | Stop Emission Quick pre-release of Emission Switch | Keep the hand switch or the key switch on the control console pressed till the emission is over.. If the problem remains call the technical service indicating the WARNING CODE "17" |
| 18 | Stop Emission Quick pre-release of Preparation Switch | Keep the hand switch or the key switch on the control console pressed till the emission is over.. If the problem remains call the technical service indicating the WARNING CODE "18" |
| 19 | Stop Emission Angiographic Sequence requested on Priority | Call the technical service indicating the WARNING CODE "19". |
| 20 | Stop Emission for Alarm | Verify the Alarm Message |












2.6. Alarm Messages













An alarm message which follows this status icon  are described in following table









It is possible to have a description of the alarm pressing the  icon.
Remove the alarm cause to keep on working.


| COD | MESSAGE | ACTION |
|------------|--|---|
| 127 | Ionizing Radiation can be dangerous for patient and operator | Welcome Message Press  key to go on |
| 128 | Anatomical Program Not Existent | Store a program in selected position. Press  key to go on |
| 129 | Potter Reply Time-out | Verify that the accessories are switched on and working well. Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "129". |
| 130 | Tomography Input Error | Verify that the accessories are switched on and working well. Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "130". |
| 131 | Error in Filament Lighting Computation | Press  key to go on. Act on  to change the current focus. If the problem remains call the technical service indicating the ALARM CODE "131". |
| 132 | IMA Signal Inactive | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "132". |
| 133 | IAR Anode Rotation Failure | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "133". |
| 134 | IPW Signal Inactive | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "134". |
| 135 | ICF Signal Inactive | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "135". |

| COD | MESSAGE | ACTION |
|------------|---|--|
| 136 | IKV Signal Inactive | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "136". |
| 137 | IFI Signal Inactive | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "137". |
| 138 | Tube Selection Error | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "138". |
| 139 | Door Opened During Emission | VERIFY THAT ROOM DOORS ARE CLOSED DURING PREPARATION AND EXPOSURE. Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "139". |
| 140 | IRM Signal Inactive | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "140". |
| 141 | Exposure Meter Dose Level Too Low | Press  key to go on. INCREASE RADIO kV and redo the exposure. Try several times, If the problem remains call the technical service indicating the ALARM CODE "141". |
| 142 | X-Ray Hand switch Released before Radiography End | Press  key to go on. KEEP THE HANDSWITCH PRESSED DURING ALL THE EXPOSITION If the problem remains call the technical service indicating the ALARM CODE "142". |
| 143 | Exposure Meter Stop Signal Inactive | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "143". |
| 144 | Tomography: First Step Released | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "144". |

| COD | MESSAGE | ACTION |
|------------|--|--|
| 145 | Tomography: Second Step Released | Press  key to go on. KEEP THE HANDSWITCH PRESSED DURING ALL THE EXPOSITION If the problem remains call the technical service indicating the ALARM CODE "145". |
| 146 | Tomography: Accessory Activity Time-out | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "146". |
| 147 | Tomography: Unable to rise High Voltage value | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "147". |
| 148 | Tomography: Unable to reduce High Voltage value | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "148". |
| 149 | Radiography: High Voltage Current outside Compliant Interval | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "149". |
| 150 | Radiography: High Voltage value outside Compliant Interval | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "150". |
| 151 | High Voltage Forced Extinction code: OAB | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "151". |
| 152 | Fluoroscopy: Tube Thermal Overload | Press  key to go on. WAIT A FEW MINUTES TO COOL DOWN THE TUBE ANODE BEFORE NEXT EXPOSURE. If the problem remains call the technical service indicating the ALARM CODE "152". |
| 153 | Fluoroscopy: Unable to Compute Filament lighting | Press  key to go on. Act on  to change the current focus. If the problem remains call the technical service indicating the ALARM CODE "153". |
| 154 | Fluoroscopy: High Voltage value outside Compliant Interval | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "154". |


| COD | MESSAGE | ACTION |
|------------|--|--|
| 155 | Fluoroscopy: High Voltage Current outside Compliant Interval | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "155" |
| 156 | Fluoroscopy: Single Patient Examination Time Limit | Release Fluoroscopy Footswitch. Press  key to go on. |
| 157 | Tube 1: Thermal Safety | Press  key to go on. WAIT A FEW MINUTES TO COOL DOWN THE TUBE ANODE BEFORE NEXT EXPOSURE. If the problem remains call the technical service indicating the ALARM CODE "157" |
| 158 | Tube 2: Thermal Safety | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "158" |
| 159 | Tube 3: Thermal Safety | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "159" |
| 160 | ADuC error in analogue coprocessor | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "160" |
| 161 | Alarm IXSA: External Request X-Ray Stop | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "161" |
| 162 | Time * Current Product outside Compliant Interval | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "162" |
| 163 | Cine/Angio Sequence: Tube Thermal Overload | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "163" |
| 164 | Alarm ISTP: High Voltage Transformer wrong connection | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "164" |
| 165 | Alarm IBLX: Unbalanced High Voltage | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "165" |
| 166 | Alarm IPO: Maximal Inverter Current | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "166" |

| COD | MESSAGE | ACTION |
|------------|---|---|
| 167 | Alarm IMAX: Maximal High Voltage Current | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "167" |
| 168 | Alarm IKVX: Maximal High Voltage Value | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "168" |
| 169 | Alarm ISCX: Inverter in Short Circuit | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "169" |
| 170 | Tube: Error in Computing Filament Lighting | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "170" |
| 171 | Dummy Alarm: Radiography OK during Calibration | Press  key to go on. If the problem remains call the technical service indicating the ALARM CODE "171" |
| 172 | Fluoroscopy or Radio switch ON during operations | Press and Release every control (Hand switches and Footswitches) to be sure that no-one is still pressed. Press  key to proceed. If the error window appear again and the generator do not evolve in Stand-By mode switch OFF the generator and ON again using the I and O keys on the control console. The same error can happen when the external accessory asserts a "ready" state before the generator's "state" question. In this case call the technical service for a system revision. If the problem remains call the technical service indicating the ALARM CODE "172". |
| 173 | Exposure Meter Dose Level Too Low | Press  key to go on. DECREASE RADIO kV and redo the exposure. If the problem remains call the technical service indicating the ALARM CODE "173". |
| 174 | Safety Supervisor Device in Alarm State | Press  key to proceed. Annotate the code written on the control console. Generally the error is related to main power supply failure, ask your electrical staff to check for line phases, fuses if present, ... If it happens call the technical service indicating the ALARM CODE "174". |

















| COD | MESSAGE | ACTION |
|------------|--|---|
| 175 | Alarm COMCONS: CANBus link Lost between Control Console and Power Rack | Release the hand switch at the end of the exposure / sequence of exposures and check that it is released. Press  key to proceed. If it happens call the technical service indicating the ALARM CODE "175". |























2.7. Working Station Selection





























Working Station identified with following icon  indicates the technique in direct exposure, without reply from anti scatter grid or other active devices between the tube and the film.

The other three working station are identified during installation, using the following symbols described in the table.

| WORKING STATION ACCESSORY | UNSELECTED | SELECTED |
|-------------------------------|--|---|
| Recorder |  |  |
| Main Control Panel |  |  |
| Vertical Radioscopic Stand |  |  |
| Vertical Radiographic Stand |  |  |
| Horizontal Radiographic Table |  |  |
| Photo Fluorographic Stand |  |  |
| Photo Fluorographic Camera |  |  |
| Tomograph |  |  |

| WORKING STATION ACCESSORY | UNSELECTED | SELECTED |
|-------------------------------|--|---|
| Tilting table with Tube Above |  |  |
| Tilting table with Tube Below |  |  |
| Fixed Antiscatter Grid |  |  |
| Moving Anti Scatter Grid |  |  |
| Direct Radiography |  |  |
| Seriograph |  |  |
| Film Changer |  |  |
| Biplane Film Changer |  |  |
| Simultaneous Biplane |  |  |
| Alternate Biplane |  |  |
| Standing Accessory |  |  |

| WORKING STATION ACCESSORY | UNSELECTED | SELECTED |
|--------------------------------------|--|---|
| Ceiling Accessory |  |  |
| Urologic Table |  |  |
| Craniostat |  |  |
| C – Arc |  |  |
| U – Arc |  |  |
| Mammography |  |  |
| Light Intensifier |  |  |
| Injector |  |  |
| No Radiation Tomography (simulation) |  |  |
| Tomography with Radiation |  |  |
| Spot |  |  |

| WORKING STATION ACCESSORY | UNSELECTED | SELECTED |
|---------------------------|--|---|
| Puck |  |  |
| Computer |  |  |

3. Intermittent Mode

Intermittent Mode is the default emission mode present on the panel and it is usually known as “Radiography Mode”.

There are various parameter that identify the single exposure, and several way to combine them.

Those “way” to identify the parameters are known as “radiological techniques”

Techniques can be:

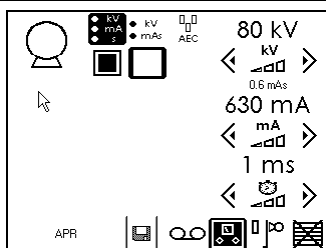
| | |
|-----------------------|--|
| Manual | 3 Points and 2 Points – All parameters are chosen manually |
| Semi Automatic | 2 Points AEC assisted, 1 Point AEC assisted – A few parameters are chosen manually, the rest is automated |
| Automatic | 0 Points, - The parameters are a function of the previous Continuous Mode steady state (Manually or Automatically set) |


Manual and Semi Automatic techniques are best known as “Radiographic Techniques”

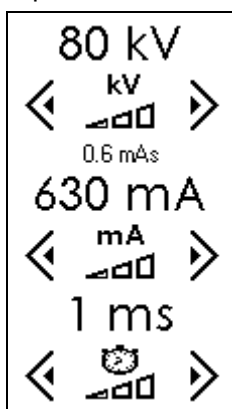
3.1. Radiographic Technique

Radiographic Technique is freely selectable for every accessory during installation phase.

3.1.1. Three Points Technique




Use  to select the 3 points technique:




It is possible to adjust every parameter relative to next emission in terms of:

High Voltage Tube Value




Using  keys it is possible to adjust the High Voltage Value for next exposure expressed in **kV** from a minimum of 40kV to the maximum value permitted by the Tube up to a generator maximum of 150kV in 1kV step value.

High Voltage Tube Current

Using  keys it is possible to adjust the High Voltage Tube Current Value for next exposure expressed in **mA** using permitted tube value in R10' step scale

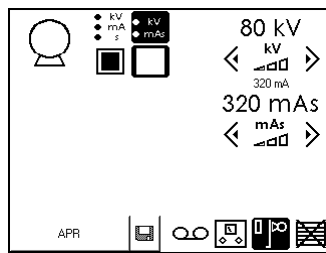
Significant values are the one which gives a value of Current Time product within interval 0.4 mAs .. 600mAs.


Emission Interval (Exposure Time)

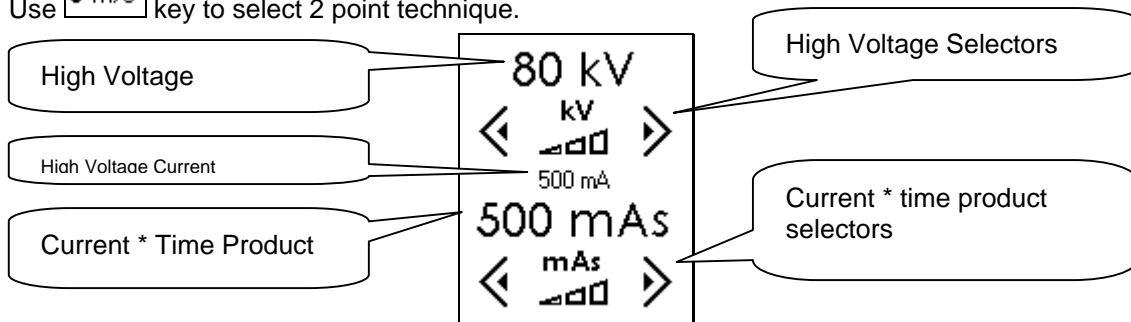
Using  keys it is possible to adjust the duration of the tube emission for next exposure expressed in **s** using permitted tube value in R10' step scale

Significant values are the one which gives a value of Current Time product within interval 0.4 mAs .. 600mAs.

3.1.2. Two Points Technique




Use  key to select 2 point technique.




It is possible to adjust every parameter relative to next emission in terms of:

High Voltage Tube Value

Using  keys it is possible to adjust the High Voltage Value for next exposure expressed in **kV** from a minimum of 40kV to the maximum value permitted by the Tube up to a generator maximum of 150kV in 1kV step value.

High Voltage Current * Emission Interval product

Using  keys it is possible to adjust the High Voltage Tube Current time product Value for next exposure expressed in **mAs** using permitted tube value in R10' step scale

3.2. Focal Spot Selection







Focus dimension depends on installed tube.

In standard bifocal tube the foci are identified in

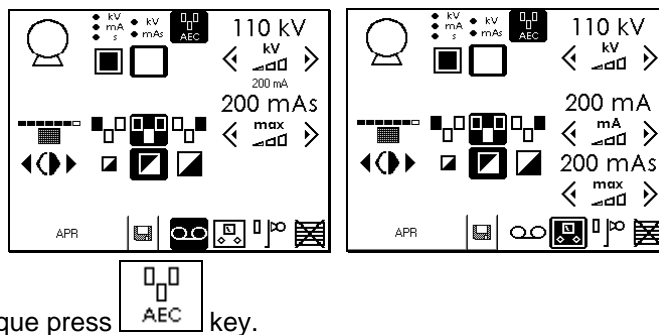
- SMALL (0.3mm ~ 1 mm)
- LARGE (1mm ~ 2mm):

According to international standard, the symbols chosen for the two categories are listed below:

| Focus | UNSELECTED | SELECTED |
|-------------|---|---|
| Small Focus |  |  |
| Large Focus |  |  |

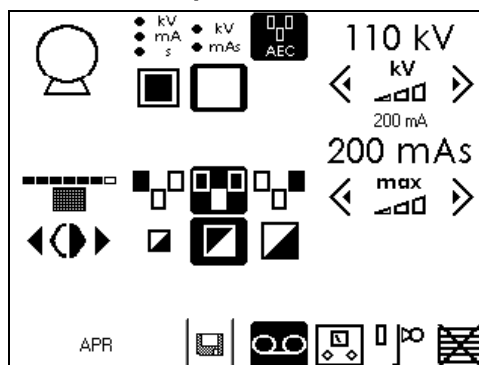
3.2.1. Automatic Exposure Control Technique

During installation phase, if Automatic Exposure Control Option is present, it is possible to select the technique between 1 or 2 points.






To use AEC technique press  key.

One Point Automatic Exposition Technique




It is possible to adjust every parameter relative to next emission in term of:

High Voltage Tube Value

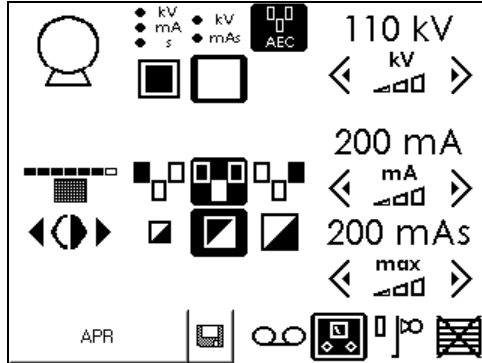
Using    keys it is possible to adjust the High Voltage Value for next exposure expressed in **kV** from a minimum of 40kV to the maximum value permitted by the Tube up to a generator maximum of 150kV in 1kV step value.

High voltage current value is calculated automatically according to tube characteristics.

High Voltage Current * Time Limit


Use  to fix a limit to mAs under AEC control; this will stop exposure automatically in AEC don't stops it after the imposed limit.

TWO POINTS AEC TECHNIQUE




It is possible to adjust every parameter relative to next emission in term of:


High Voltage Tube Value

Using  keys it is possible to adjust the High Voltage Value for next exposure expressed in **kV** from a minimum of 40kV to the maximum value permitted by the Tube up to a generator maximum of 150kV in 1kV step value.

High Voltage Tube Current

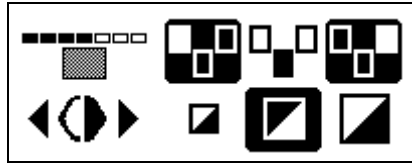
Using  keys it is possible to adjust the High Voltage Tube Current Value for next exposure expressed in **mA** using permitted tube value in R10' step scale
Significant values are the one which gives a value of Current Time product within the interval 0.4mAs .. 600mAs.

High Voltage Current * Time Limit

Use  to fix a limit to mAs under AEC control; this will stop exposure automatically in AEC don't stops it after the imposed limit.

3.3. Automatic Exposure Control Option

3.3.1. AEC controls



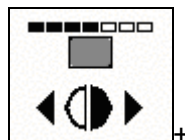
AEC control is divided into three parts:

Dominants Zone selection



| | UNACTIVE | ACTIVE |
|------------------|----------|--------|
| LEFT DOMINANT | | |
| CENTRAL DOMINANT | | |
| RIGHT DOMINANT | | |

Darkness Correction

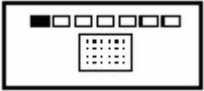
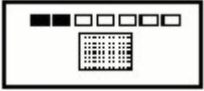







It is possible to correct the darkness in 7 different level.

The central position is the 100% of the darkness as it is programmed during installation process.

Variation can be made from 50% to 200% following the R10' progression using the following keys:









| Time Selection | Darkness index | Visualization |
|----------------|----------------|---|
| 50% | -3 Half |  |
| 63% | -2 |  |
| 80% | -1 |  |
| 100% | 0 Nominal |  |
| 125% | +1 |  |
| 160% | +2 |  |
| 200% | +3 Double |  |

Screen Speed Selection



Standard combination, listed below, can be overwrite during installation process according to site needs:

| Control Description | UNACTIVE | ACTIVE |
|--|---|---|
| Fast Combination (Low Definition – High Speed – Low Dose) |  |  |
| Intermediate Combination (Normal Definition – Normal Speed) |  |  |
| Slow Combination (High Definition – Low Speed – High Dose) |  |  |

3.4. LAST EXPOSURE DATA SUMMARY WINDOW

| | |
|-------------|-----------|
| 2002/04/16 | 120 kV |
| 08:25:015 | 250 mA |
| Tube | 80 mAs |
| 25 % | 5 s - run |
| 50 kJ | 3 exp |
| 5273 mG*cm2 | |

Last Exposure Data summary window following data are shown.

DATE and TIME of last exposure activity (hi, left side)

RADIOGRAPHYC PARAMETERS (on right): High Voltage, High Voltage Current, Current * time product, Global Run Time (time passed since I step where pressed), Number of Exposures in Run Time (number of exposures made keeping pressed the I step).

ANODE TUBE HEAT Expressed in RELATIVE (percentage of maximum thermal capacity) and ABSOLUTE expressed in kJ).

The keys:



Re-print last label



Print Data label



Start Automatic Data Window show after exposure


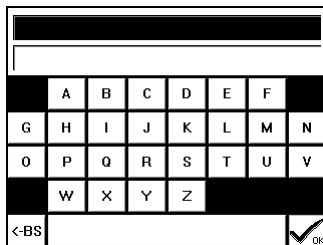


Stop Automatic Data Window show after exposure



Close Data window.




Pressing  Following window  is open.

Here is possible to write 2 lines of up to 40 characters printed in the top of the label.

| | | | | | | | | | | | | | |
|------|---|---|---|---|---|---|---|--|--|--|--|--|----|
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| A | B | C | D | E | F | | | | | | | | |
| G | H | I | J | K | L | M | N | | | | | | |
| O | P | Q | R | S | T | U | V | | | | | | |
| W | X | Y | Z | | | | | | | | | | |
| <-BS | | | | | | | | | | | | | OK |

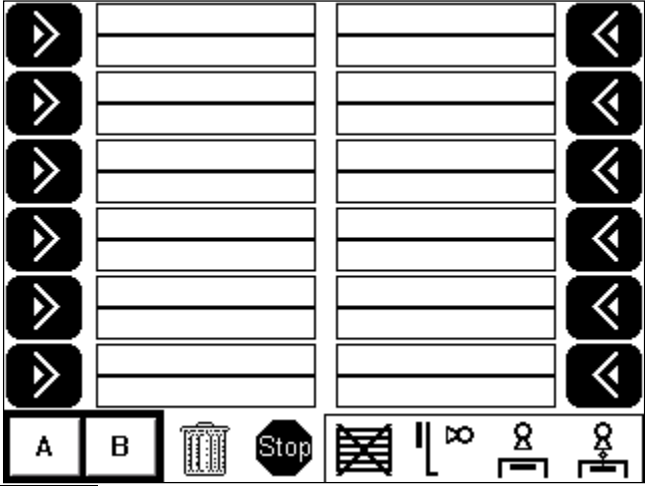
3.5. Intermittent Mode Data Programming

3.5.1. Programmed Memory Selection

Pressing  key on main Screen is activated the APR program selection screen.

The APR divided into 5 parts:
 The complete programs into:
 4 Working
 2 Memory bank station
 12 Programs for

WORKING MEMORY
 Pressing one of

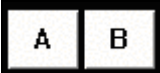


Selection screen is parts:
 memory is 98 divided respectively
 Station for every working
 every memory bank

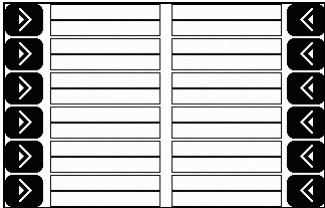
STATION BANK SELECTION

keys it is possible to select one specific working station's memory bank.



MEMORY BANK SELECTION

Pressing one of  keys it is possible to select one of the two memory banks for every working station memory bank as selected in previous paragraph.

ANATOMIC PROGRAM SELECTION

Pressing one of the  keys it is possible to recall a previously stored anatomic program.






If the program has been previously stored, in the centre of the screen appear the name with which the program was stored (12 upper character for organ identification and 12 lower characters for projection identification).

On the name side appears also a key ( or ) with which it is possible to select that particular program.


A not existing program is identified by the absence of both name and selector key (a blank space instead of a program).

ANATOMICAL PROGRAM DELETE







It is always possible to overwrite a program with a new one, or it is possible to delete a program from memory using following procedure:

Press  key, the key become  and the led indicator starts blinking red, in this condition it is possible to abort the operation pressing the  key, or delete a program pressing the relative  or  key.


APR PATIENT SIZE SELECTION

Patient size is selected using the    keys whenever an anatomical program is selected.

If a parameter is modified the keys disappears to indicate that no more APR program is running but a free selection.


| Patient Parametrization | UNACTIVE | ACTIVE |
|-------------------------|--|---|
| Thin Patient |  |  |
| Normal Patient |  |  |
| Large Patient |  |  |

3.5.2. APR Program Store in Memory


Pressing  key it is possible to save the actual contest into an anatomic program.


First thing is to associate the program to a descriptive name using the keyboard screen


| | | | | | |
|------------|---|---|---|---|----|
| ORGAN | 1 | 2 | 3 | 4 | 5 |
| PROJECTION | 6 | 7 | 8 | 9 | 0 |
| A | B | C | D | E | F |
| G | H | I | J | K | L |
| M | N | | | | |
| O | P | Q | R | S | T |
| U | V | | | | |
| W | X | Y | Z | * | - |
| <BS | | | | | OK |


which automatically appears as soon as the  key is pressed.

NOTE:

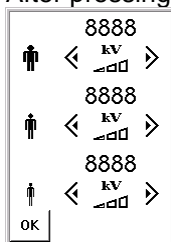
Pressing  key it is possible to associate an ORGAN description to the program up to 12 characters.

Pressing  key it is possible to associate a PROJECTION description to the program up to 12 characters.

 is BACK SPACE key, used to delete last character

 confirms the input names

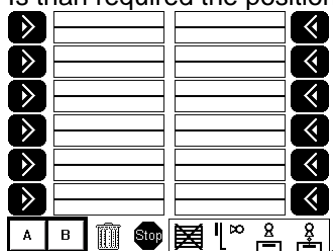
After pressing **OK**, is required the kV parameterization for patient thickness: act on up/down



key to modify the values.

Than press **OK** to go on.

Is than required the position in which the programs have to be saved using following screen

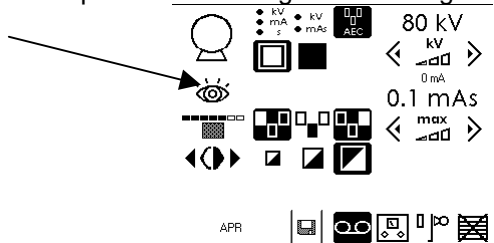


Pressing  or  in the desired position the program is stored in memory.

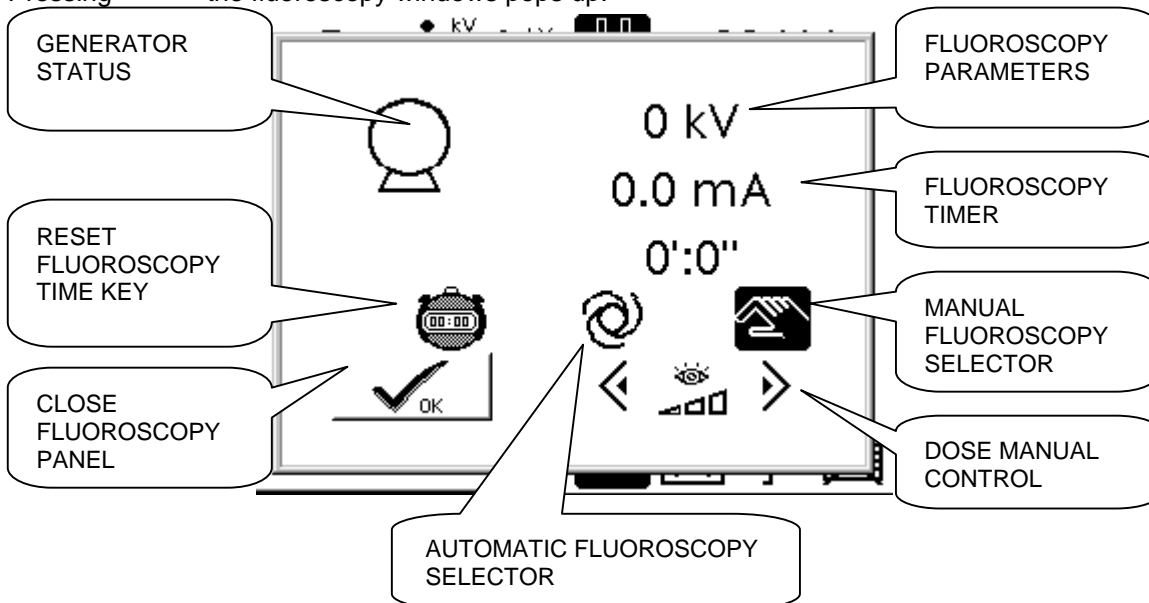
To abort saving a program press  key.

3.6. Continuous Mode (*RF version only)

On a RF generator it is possible to configure a working station to use the continuous mode.



Pressing  the fluoroscopy windows pops up:



The windows pops up also automatically when the fluoro footswitch is switched on, in this case when the fluoro footswitch is switche off, the window automatically hides.

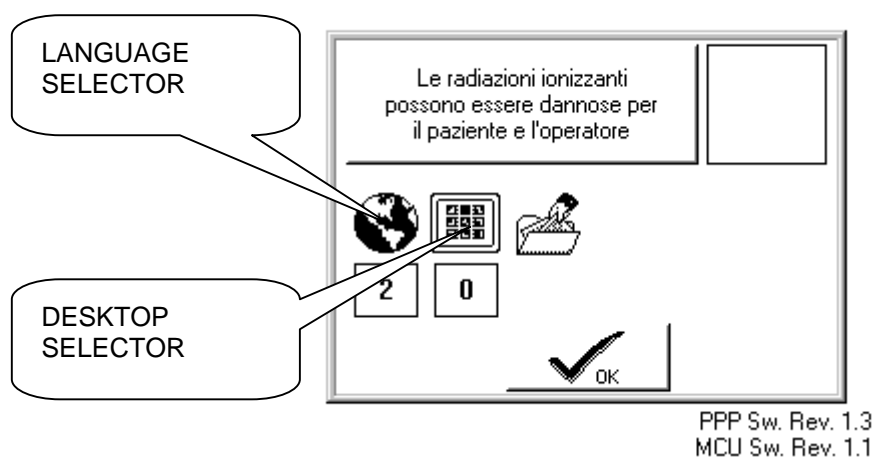


During emission, the Status Icon is the following:

Every fluoroscopy effective 5' an acoustic signal is emitted to advise the operator.











After 10' consecutive of continuos fluoroscopy the generator automatically stops emitting: the operator must release the footswitch and press again according to current regulation in matter of ionizing radiation generator

3.7. Auxiliary Functions



Language and Desktop Image are changeable during setup. Ask to Your local service to adjust language or desktop background (option available only for technical service).

3.8. Other Symbols

| | UNACTIVE CONTROL | ACTIVE CONTROL |
|---------------------------|--|---|
| CONFIRM an operation |  |  |
| PRINT a label |  |  |
| STORE a program in memory |  |  |
| ABORT current operation |  |  |
| CHANGE technique |  |  |

4. SAFETY NOTICE

4.1. General Information

Laws or regulations for both operating and/or services must be respected.

To assure patient, operator and people that could come in contact with the X- Ray system is better to make a preventive inspection service every 12 month.

The manufacturer (ODEL S.p.A.) directly train and qualify the technicians to service the generator, no responsibility is assumed if the generator is serviced by unqualified people.

More severe control must be done if generator is working out of the specified range of compliance or in condition that do not meet manufacturer specifications reported in the tables.

It is better to contact your local dealer to be informed regarding service policy and maintenance contract.

The installation parts that can be dangerous must be controlled every 12 months by qualified people and if necessary changed.

If local laws or regulations regarding maintenance are more restrictive and severe they must be complied and respected.

Before using the equipment, the operator has to check that all the functionality is guaranteed.

Pay attention to the leds, display and indicators in order to control that no faults occur.

The X- Ray lamp must be lighted in YELLOW flashing only during radiography or fluoroscopy exposure time.

If these indicators remain lit the equipment must be switched off and you the technical service has to be call.

Manufacturer and manufacturer's qualified local dealer disclaims all responsibility on any equipment malfunctioning if:

- Installations, functional extensions, calibration, maintenance, have not been done by people qualified by the manufacturer.
- Components, parts, subassembly or assembly, especially the ones directly involved in generator safety, are replaced non original one or modified with components not reported in schematics
- Electrical installation doesn't meet IEC 601 - 2 -7 regulation and requirements reported in Technical Manual code 1038.
- Destination or modality of use different from the one declared by manufacturer.

On reasonable request, the manufacturer permits technical documentation to be consulted in factory.

4.2. Safety

4.2.1. Safety against Explosion


This equipment was not designed to work in areas where explosion hazard can occur.

4.2.2. Safety against ionizing radiation

Operator must follow all the regulations and facilities on safety against radiation hazard.

4.2.3. Automated Procedures and Device periodic test

Caution!

 Before starting the tests, protective wear has to be put on, a safety distance must be respected, and, if necessary, use personal dosimeter during all the tests requiring X-Ray emission.

Automatic exposure functional test (AEC)

If Applicable

Close the beam collimator.

Be sure that A.E.C. is activated and make one exposure by constantly pushing the X- Ray button.

The X-ray lamp must blink yellow for all exposure time.

NOTE: the alarm that appears when exposure is blocked is normal if the collimator is closed and it means that A.E.C. is working in the right way.

Open the beam collimator.

Make another exposure. In this case the X-ray lamp will blink for the whole duration of the exposure, which will depends on the filtration. If no filtration is present, a direct radiography can saturate the A.E.C. giving a new alarm.

Put a phantom of at least 5 cm of water and redo the test.

Keep track on timing when the exposure regularly ends to have a reference for next tests

Automatic Brightness control test (where applicable in RF version)

Close the beam collimator.

Make a fluoroscopy, maintain constantly pushed the fluoroscopy footswitch and be sure that A.B.C. is activated.

The X-ray indicator must blink yellow during the fluoroscopy time.

NOTE: the dose, reported on the control console in terms of kV-mA, must go to the maximum (maximum value of kV-mA).

Open the beam collimator and remove any phantom.

Make a new fluoroscopy. In this case the dose has to go down to the minimum.

Release fluoroscopy footswitch.

4.2.4. Cleaning

Equipment has to be switched off before any keeping or cleaning action.

Clean it by using cotton cloth and don't use abrasive detergent.

Do not use organic solvent or any kind of detergent containing any kind of solvent.

Do not uses Spray, It can penetrate into the equipment and damage the electronics inside.

To disinfect equipment parts we recommend using a water solution based on aldeide. We recommend to not using aggressive detergent based on Al cool.

Do not use Spray disinfectant. Some of its components are harmful for the health

4.3. Performance and Safety Tests

4.3.1. Daily Tests

Before starting with live examinations make a visual inspection of the equipment.

During examinations look for the right functioning of the X- Ray yellow indicator.

Do not expose to high kV when the X-ray tube is cold

4.3.2. Monthly Tests

Make test reported in the page behind on good A.E.C. (option) and A.B.C. (option) working.

4.3.3. Annual Service

In order to maintain all the functions of the equipment we recommend an annual verification performed by manufacturer's qualified technicians of your local dealer.

If a malfunction occurs, call the technical service:

Ask to your local dealer for preventive maintenance program.

LOCAL DEALER