TOP-X

HIGH-FREQUENCY X-RAY GENERATOR

MODEL: TOP-X 100NR

USER MANUAL

Manufacturer:

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WARNING!

Innomed Medical Inc. states the following information according to operative European norms and related international standards.

Extensive preparedness in the field of X-ray diagnostics is required for the operation of the generator. There is dangerous voltage inside the generator and in the high-voltage cables connected to the X-ray tubes, even after it has been turned off. During the operation of the generator the X-ray source generates X-rays, so the device may only be used in a work area prepared according to X-ray safety regulations. During operation take all necessary precautions to protect the patient, yourself and the environment from the harmful effects of the generated X-ray radiation.

During the operation of the generator when selecting the applied examination, treatment or intervention, for the patient's protection and the accuracy of the diagnostic results, take into consideration the generated X-ray radiation's physical, chemical and physiological effects, their treatments, interventions and efficiency, and the effects and possible risks on the equipment.

The generator must be installed, checked and maintained according to the following document and references:

R-2622
TOP-X 100NR
HIGH FREQUENCY X-RAY GENERATORS
TECHNICAL MANUAL AND INSTALLATION GUIDE

Only personnel properly trained in X-ray technology may perform any servicing on the generator.

During normal operation the generator does not emit any environmentally dangerous substances. The oil in the generator's high-voltage transformer is dangerous to the environment so its disposal must be according to the environmental regulations in effect. When rolling out the generator or its parts the operative environmental regulations must be followed.

Not complying with the user manual and the installation related regulations might result in the generator not fulfilling manufacturer specified specifications and endanger the operator, the patient or the environment. The manufacturer is not responsible for results of not complying with the regulations.

Portable and mobile RF communication equipment may interfere with generator operation. The generator requires special precautions regarding EMC. Installation must be performed according to the EMC information in the technical data and installation manual.

For the safety of your patient and the reliable operation of the device please read the entire manual to become acquainted with it.

1. Introduction

We would like to welcome your decision to purchase the TOP-X 100NR high-frequency X-ray generator. We wish you success with its application!

This document contains all the information necessary for the operation of the TOP-X 100NR high-frequency X-ray generator.

1.1 General

The main feature of the TOP-X 100NR X-ray generator is the easy operation. The configuration containing the anatomical programs can contain up to 1700 pre-programmed automatic recording settings. The settings are grouped by body parts; selection of a body part menu allows the selection of sub body parts. If required the settings can be modified manually (3-point: kV, mA, time; and 2-point: kV, mAs).

The TOP-X 100NR X-ray generator has the following main parts:

- control panel
- power unit, which contains the high-voltage transformer, the power electronics, the generator controller and the device interface

X-ray diagnostic equipments are connected to the generator: X-ray tube, collimator, examination devices, etc. These are already connected during installation according to the installation manual; other devices do not have to be connected during operation.

In this manual we will detail the control panel's operation; the power unit does not contain any controls.

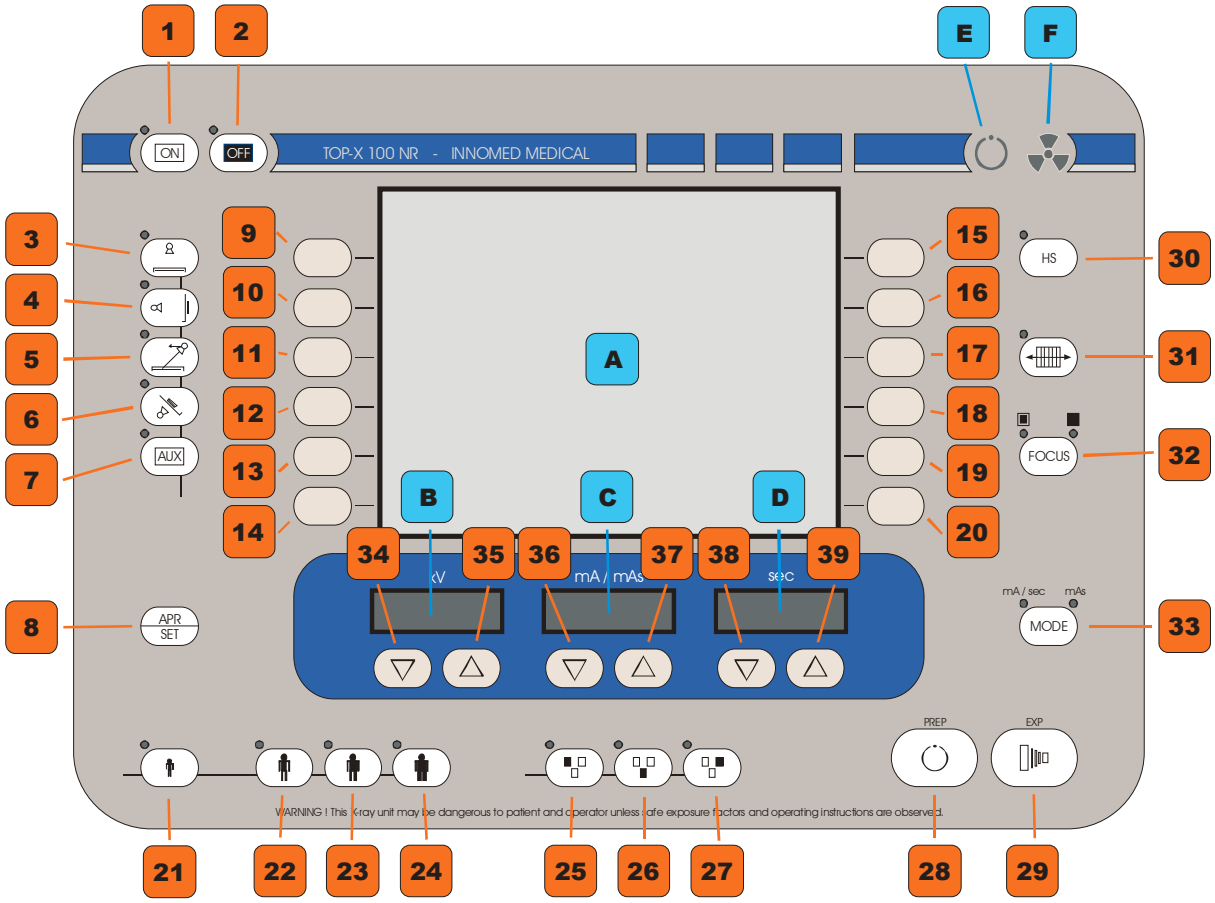
The appearance of the control panel (NRSRC) can be the following:

- Plastic frame, table-top version
- Glass frame with stainless-steel stand and exposure switch holder

The front panels of the above versions are identical, their operation are the same.

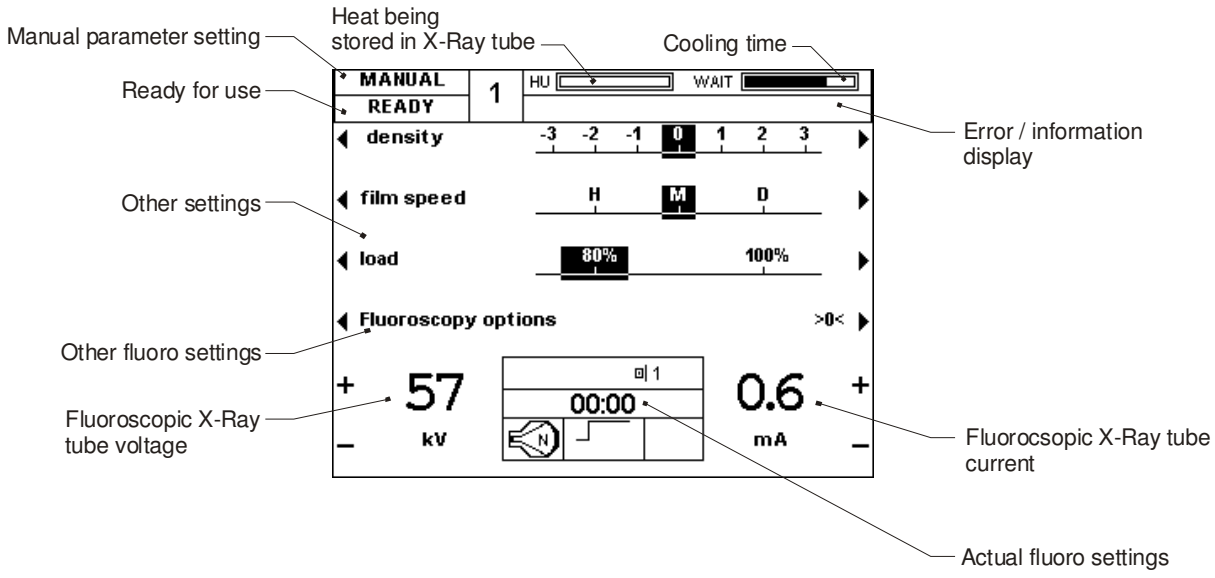
Make sure the generator and its parts (control panel) are always clean. For the proper cooling of the power unit the vent openings must be open at all times. Do not cover it with a tablecloth or place other items on it even temporarily. Make sure no liquid or foreign objects – especially metal – get inside the generator. Cleaning the generator is detailed in the Cleaning and maintenance section.

1.2 Control panel



In the rest of the manual the above image is referenced by the button and display identifying number or letter. For example (8), (B).

LCD display layout



2. Turning the generator on and off

Turn the generator on with the ON button (1) and off with the OFF button (2). The LED above the ON button indicates when the generator is on, and the LED above the OFF button indicates when it is off, but the input mains presented.

When turning the generator on a process starts during which the control panel, the X-ray controller, and the generator controlled parts are placed under voltage. As a first step the generator performs a self-test procedure.

Parameters may be set after the default settings (80kV, 100mA, 100ms) appear on the LED displays (B, C, D).

Exposure can be started when the main contactor is on and READY appears on the panel LCD (A).

3. Load limits, writing a log file

The generator takes the load-limit of the parts into consideration in all operating modes and does not allow the use of settings that can damage the generator or the X-ray tube.

The generator considers the following limits:

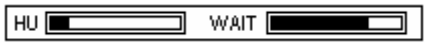
- The maximum allowed anode voltage (kV) value of the generator.
- The maximum allowed anode current (mA) value of the generator.
- The maximum allowed power (kW) value of the generator.
- The maximum allowed current – time product (mAs) value of the generator.
- The maximum allowed anode current (mA) value of the X-ray tube for both focal spots, considering anode rotation speed.
- The maximum allowed anode voltage (kV) of the X-ray tube.
- The maximum allowed power (kW) of the X-ray tube for both focal spots, considering the anode rotation speed and the set exposure time.
- The input heat from rotation and from exposures, and the cooling period, considering the thermal energy in the anode and in the housing. This is calculated exactly even if the generator is turned off and turned back on much later. This is called the “heat unit (HU) calculation”.
- The cooling period of the “track” – the anode’s most loaded part during exposure. This is called ”wait time”.

To prevent overload, the HU value is always displayed on the top right corner of the control panel’s LCD (A). It indicates the calculated amount of heat that would be stored in the tube, as a percentage of the total load-limit, if the exposure with the currently set parameters was made. As the tube cools, this value decreases.

Do not perform exposure as long as the HU value is over 100%, because it will overload the tube!

A slowly decreasing line will appear after every exposure next to the HU value with the word WAIT. This indicates the cooling period of the anode track.

Do not perform exposure until the word WAIT disappears, because it will overload the tube!



For both of the above cases exposure is not disabled.
It is the operator’s responsibility to decide whether to make exposure contrary to the warning. The generator records exposures made with overloading in a separate log-file!

The generator logs all exposures. All exposure data (date, time, set / measured values) are stored. Three logs are created:

Normal exposures:
This contains all perfect exposures. Its capacity is approximately 600 exposures.

Faulty exposures:
This contains the data of exposures that end with fault-message. Its capacity is approximately 300 exposures.

Overloaded exposures:
This contains the exposures that had HU value over 100% at the moment of exposure, or the WAIT time did not reach zero. Its capacity is approximately 300 exposures.

A PC based service program can be used to view the logs. If any of the logs are full, the oldest exposure's data is deleted, overwritten with the newest ones.

4. Errors

4.1 Error display

In case of an error a text is shown on the top right part of the console display to inform about the type of the error and a code which identifies the error more precise for a qualified person.

If the operational state of the generator changes the top left script of "READY" shows the new state.

4.2 Error acknowledgement

In case of any error it can be cleared by pushing any button on the console or on the fluoro remote controller. In case of an error causing “safe mode”, the error display can be cleared, but the exposure remains disabled. Another exposition can only be made after turning the generator off and on again.

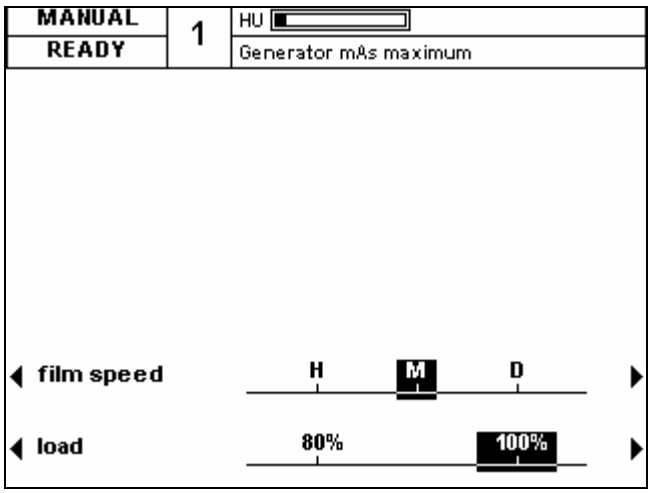
4.3 Types of errors

The errors are grouped by their fatality.

The "READY" script on the console display means that no error happened disabling the generator operation, so the generator is ready for use.

4.3.1 Limit control

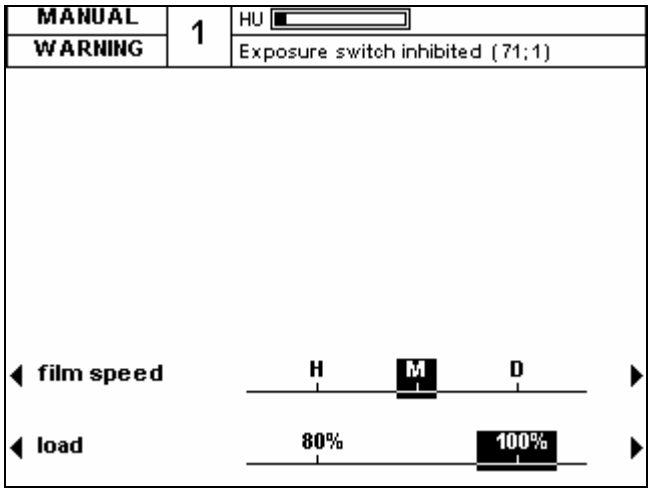
The warnings displayed when reaching the load limits of the X-Ray tube or the generator are only for information. E.g.: Reaching the current-time product (mAs) limit of the generator:



The generator remains ready for use, the "READY" script does not change.

4.3.2 Warnings

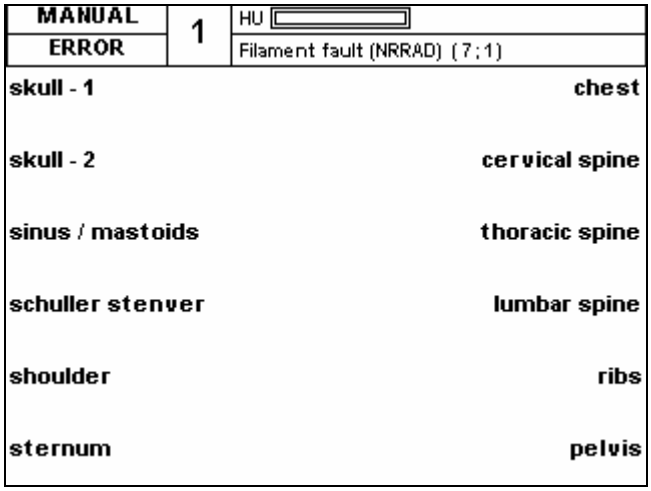
Warnings are errors detected by the generator that do not influence the operation from the standpoint of the user, but are logged. E.g.: Pushing an exposure button that is unusable according to the current configuration.



The "READY" script changes to "WARNING".

4.3.3 X-Ray interruption, inhibition

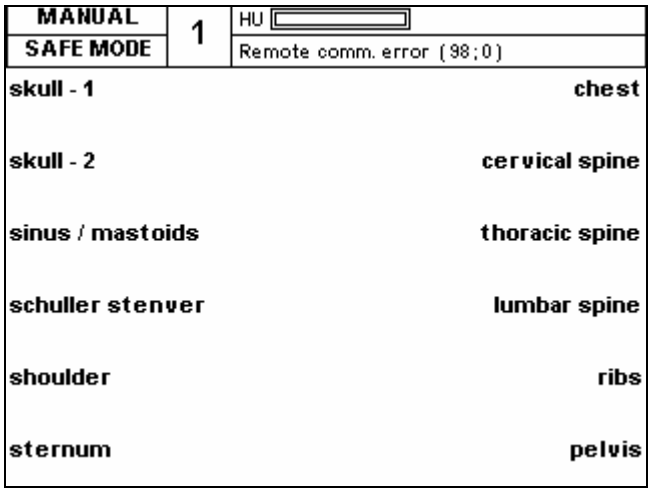
These error disable the exposure and preparation. In case of such an error the exposure in progress is interrupted. Mostly caused by a system state that is dangerous to the generator or the connected equipment or makes the further use impossible. E.g.: No current on the selected filament.



The "READY" script changes to "ERROR".

4.3.4 Safe mode

Gross errors, the high power parts of the generator must be deenergised in order to avoid damage. E.g.: Communication with the fluoro remote controller is interrupted



The "READY" script changes to "SAFE MODE".

4.3.5 Turn off

Gross errors, the high power parts and the control of the generator must be deenergised in order to avoid damage. In case of such an error the generator turns off, the error can not be displayed.

The error can only be read from the log file by a PC-based installation software.

4.4 Log file

All the errors are stored in a log file. The time of the error and its code is stored. The log file can be read by a PC based installation software.

4.5 Service contact

Please contact the nearest service in case of errors which make the use of the generator impossible, or are not caused by improper use.

Please inform the service person about the code of the error which is located after the name of the error in round brackets.

E.g.: Remote comm. error **(98;0)**

4.6 Basic errors

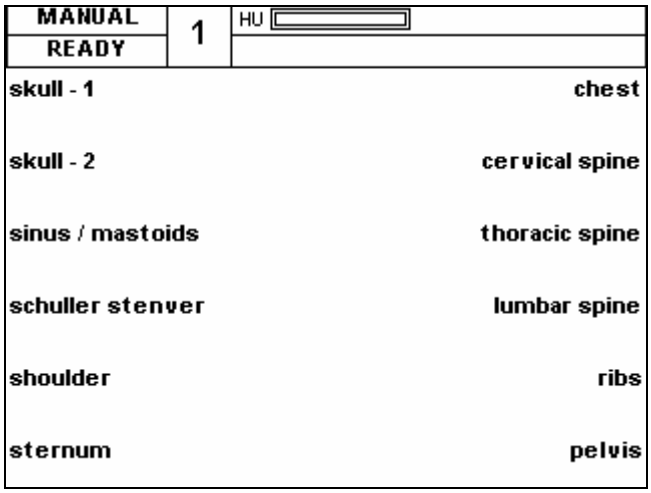
A list of errors that can appear during normal operation

Error code	Description
(1;1), (1;2)	The tube is overheated by load. Wait until it cools.
(2;1)	Preparation button pressed during tube change. Wait a few seconds with preparation after device change.
(3;1)	Check the tube positioning (Device interlock missing)
(4;1)	The examination room door is open.
(18;1)	The maximum fluoro time is reached. Reset the time counter.

(20;1)	The tube is overheated by load. Wait until it cools.
(25;1..512)	Error of the power unit during exposure. If regularly happens contact the service.
(37;0)	The set time for tomo exposure was too short.
(47;0)	The set mAs value for the AEC-controlled exposure was too little
(51;0)	Prep button released during preparation.
(55;0)	The generator is overheated by load. Wait until it cools.
(56;0)	Exp button released during exposure
(70;0)	The ionization chamber has not received sufficient amount of X-Ray. Check the X-Ray parameters set, and that the sensitive areas of the ionization chamber receive X-Ray properly.
(71;0)	The other exposure button must be used in the current configuration
(76;0)	Preparation longer than 10 seconds
(106;0)	Attempt to start a tomographic exposure, but the tomo mode was not selected on the device (there is no tomo-ready signal from the device)
(119;0)	Exp button not released 10 seconds after exposure
(122;0)	Too little mAs set for an AEC controlled exposure. Check the set X-Ray parameters.
(137;0)	The external device (image processor, PC) is not turned on or is not ready receiving X-Ray. (Waiting for ready signal on the serial line)

5. Anatomical program mode

After turning on, the generator starts with the **APR** operating mode – a low-power program.



In the APR operating mode of the **TOP-X 100NR** 12 buttons (9-20) are reserved in the APR field (A) for the anatomical programs. Each button is an arbitrary level, independent anatomical program. During installation it is possible to set each field's unique name.

When a body part button (9-20) is pushed, the selected body part's sub-menu is displayed. Here 12 body parts or sub-body parts selections are available.

When the anatomical program is displayed (sub body part selection including settings), all program-related settings appear on the control panel displays.

Selecting an anatomical program (APR) always means the automatic setting of the next parameters (in this example at the "SKULL AP").

kV:	70kV
mAs:	40mAs
Device (TECHNIQUE):	Vertical Bucky stand
Grid use (GRID):	Grid is used
High-speed starter (HS):	Not used
Tube (TUBE):	Tube 1
Focal spot (FOCUS):	Large focal spot
AEC ON/OFF:	On
Dominant field (FIELD):	2. (middle) is selected
Film type (SCREEN):	M medium film sensitivity
Density correction (DENSITY):	"0" (middle setting)
Patient thickness (PATIENT):	Normal (average) size
Load (LOAD 100%):	Allows max. 80% load

The parameter values retrieved in APR mode are preset to a patient with average height and weight, but the parameters can be changed anytime.

All changes (fatter/thinner patient, film sensitivity selection, etc.) that modify the default data are supervised by the generator's software. It is important to note that these modifications will set only correct values for the anatomical programs until one of the following buttons will be used:

kV up/down (34,35), **mA** up/down (36,37), **mAs** up/down (36,37), **sec** up/down (38,39)

Using these buttons will switch the generator into manual mode, in other words an operating mode with free parameter setting (see section 2.2). In this case all parameters can be changed freely within the limits of the tube and generator.

Use the APR/SET 

button (8) to return to the main APR menu.

After exposure the console returns to the last used sub-body part menu. If you would like to return to the upper body part selection, push the APR/SET 

button again.

6. Automatic exposure control (AEC)

6.1 The AEC operating mode

When using the AEC operating mode, the so-called ionization chamber placed between the patient and the film performs the in time exposure stoppage. The ionization chamber measures the dosage passing through it and stops exposure when the dosage required for the optimal darkening of the used film is reached.

AEC can be used in both APR and manual mode, but only if AEC mode is configured for the given examination device. In both cases the AEC function can be turned on or off according to user preference. In APR mode, depending on body part related programming the program starts either with or without AEC. The LEDs above the AEC field buttons (25-27) indicate which fields are used. If any of the three LEDs are on, the device is operating in AEC mode.

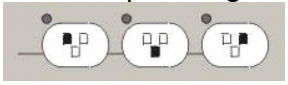
The AEC dominant field buttons (25-27) determine which part of the image is considered important; while the DENSITY (density correction) buttons (12, 18) let you set whether to make the image darker or lighter than usual.

In AEC mode the time (sec) or current-time product (mAs) parameters on the RAD parameter displays (C, D) only indicate the maximum value the generator will allow during exposure. If this exposure time value or the mAs value is reached during exposure, the generator will turn off exposure. These are the so-called backup values. These are protections in case the AEC function is not operational. This can happen, for example, if X-ray radiation does not reach the ionization chamber, because the collimator setting is not appropriate.

If the AEC function did not stop the exposure but reaching either the set time or the set mAs value, the generator displays an error message at the end of the exposure, warning that the film will most likely be too light. In this case the error message remains and exposure is disabled until the user pushes any of the buttons on the console to acknowledge it.

The two backup values have to be set according to the expected mAs value within the current conditions (FFD, patient size, etc.) and at the given tube voltage (kV).

6.2 AEC operating mode setting possibilities

You can access AEC operating mode by selecting one or more of the AEC dominant fields (25-27).  The LED over the selected field's button turns on and the DENSITY field appears on the LCD display (A). The mentioned field is not accessible in other operating modes. Setting the dominant fields does not affect the recording parameters.

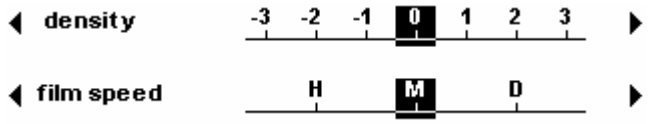
When using AEC, prior to the exposure mAs or sec backup values must be set on the LED displays (B, C, D) according to the examination. The measured values after exposure appear floating on the LCD display.

6.2.1 DENSITY – density correction

Density can be set in seven steps in the field (12, 18), which effects the darkening of the image on the film. The higher the density correction value, the darker the image will be. The seven values change the dosage value of terminating the exposure compared to the default value (0) reaching the film:

-3	50%
-2	63%
-1	80%
0	100%
+1	125%
+2	160%
+3	200%

6.2.2 SCREEN – screen selection



Three screen types are available (13, 19). These are usually the following:

- **H**igh speed high-sensitivity, but more coarse resolution
- **M**edium speed medium-sensitivity, medium resolution
- **D**etailed low-sensitivity, but high resolution, rich in detail

The high-sensitivity screen / film combination requires less dosage, but the resulting film resolution is lower. The lower sensitivity requires a higher dosage, but the film quality and resolution is very good.

The user decides what type of screen and film to use considering the examination characteristics and other conditions. H, M or D type is set accordingly on the console.

The generator automatically corrects the mAs value according to the selection of the film / screen combination sensitivity. Since there are numerous film and screen types available in the market, and their sensitivity is variable, the sensitivity values for H, M and D must be set during generator installation.

This is performed by the installing professional based on the cassettes used at the workstation. Based on the cassettes, i.e. the used screen / film systems the installing professional assigns sensitivity values to each of the H, M, D signs (based on the nominal sensitivity set at 80kV). This way it is easy to reconcile the H/M/D marking on the control panel with the type indicated on the cassettes.

Selecting the correct screen type on the control panel in AEC mode is extremely important, because when determining the required dosage, the generator takes into account the selected film / screen sensitivity as well.

6.3 Verifying the exact operation of the AEC

Make an exposure using AEC. Make sure the film has the same sensitivity as the film used for calibration during installation. Set 80kV and beam current that result in radiation period longer than 50ms and shorter than 1s. Place a 15cm water phantom in the radiation's path.

After development compare this film to the film made during calibration. The optical density can only deviate by 0.15 between the two films.

7. Parameter setting in manual operating mode

Free parameter setting means that any of the four parameters effecting X-ray quality, strength and duration can be set freely – within the operating limits of the tube and the generator, and the device's allowed accuracy.

The four parameters are the following:

- U_a (the voltage between the X-ray tube anode-cathode, kV)
- I_a (the current flowing through the X-ray tube, mA)
- T_e (the time until the tube current exists, ms or s)
- Q (I_a x T_e : the product of tube current and time, mAs)

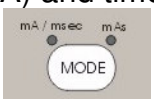
Pushing the APR/SET button 

(8) or the buttons that directly set the parameter values (kV, mA, mAs, sec) in anatomical program mode accesses free parameter setting, also known as manual mode. In manual mode the settings are only limited by the generator power and the tube specifications.

Use the MODE 

button (33) to switch between two- and three-point modes.

Three-point mode is the operating mode when the voltage (kV), current (mA) and time are set. The generator calculates the current – time product (mAs), but does not display it on the exposure parameter display. To make it visible, push the MODE button (33) once.

To make the related current (mA) and time values visible in two-point mode (or mAs mode), push the MODE button 

again.

The basic principle of exposure parameter setting is that exposure quality is generally affected by two factors: X-ray tube voltage (kV) and the current – time product (mAs). With a given mAs value the X-ray tube current (mA) and exposure time values are secondary. The only special exceptions to this are a few special cases, for example tomography or very short exposures. For this reason the generator, in case of some user selection, can change the current (mA) and time parameters while leaving the mAs value unchanged.

Following is an example of this feature.

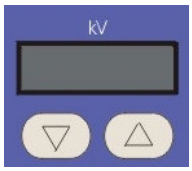
Let us assume that the X-ray tube limit is 48kW at large focal spot and 20kW at small focal spot at 0.1s exposure time. Enable maximum load (LOAD 100% field). Set 120kV voltage, 400mA current (this will be 48kW) and 0.1s exposure time. Switch to two-point mode, 40mAs is displayed. Switch to small focal spot. The small focal spot cannot handle the 48kW load, so the generator recalculates the current and time parameters, leaving the X-ray tube voltage (kV) and the mAs values, thus decreasing the load below the allowed limit. Switch back to three-point mode. The new indicated values are: 120kV, 125mA (15kW), 0.32s (40mAs). At this example we

have to mention that the X-ray tube load (kW) depends on the exposure time. The previous values are correct because with 0.32s exposure time the X-ray tube can still be loaded with 15kW.

The similar cases will be apparent in the following.

7.1 Radiation parameter setting

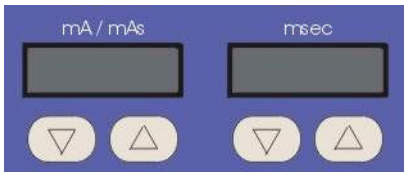
7.1.1 Setting exposure X-ray tube voltage (kV)



Use the kV up (35) and kV down (34) buttons to set this value. Pushing and holding these buttons continuously changes the value between the allowed limits in 1kV steps.

The X-ray tube voltage value appears on the kV display (B). Changing this value does not effect the mAs value, only the tube load changes. With increasing kV values, this results in decreasing maximum mA setting.

7.1.2 Three-point mode, mA / ms setting



Using the mA up (37) and mA down (36) buttons changes the mA value. Changing the mA value happens in preset steps.

Warning: When changing mAs, mA does not change according to the preset steps because in those cases the time step is determining and mA is determined by the generator by dividing mAs by time. For this reason it is normal when the mA value is for example 273mA. Using the mA up / mA down buttons the generator again selects the mA value by the mA step.

mA steps [mA]:

10, 12, 16, 20, 25, 32, 40, 50, 63, 80, 100, 125, 160, 200, 250, 320, 400, 500, 630, 800

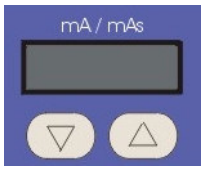
The maximum value for the TOP-X 100NR family is 800mA.

Using the SEC up (39) / SEC down (38) buttons changes the exposure time (ms/s) value. In cases of longer exposure times the generator and tube mA / kV load is less. The generator limits the adjustable exposure time accordingly.

Time steps [ms or s]:

1, 2, 3, 4, 5, 6, 8, 10, 12, 16, 20, 25, 32, 40, 50, 63, 80, 100,
120, 160, 200, 250, 320, 400, 500, 630, 800 ms,
1, 1.2, 1.6, 2, 2.5, 3.2, 4, 5, 6.3, 8, 10 s

7.1.3 mAs mode (or two-point mode)



Using the mAs up (37) / mAs down (36) buttons changes the mAs value. The kV value will not change, but the mA and time parameters will. According to exposure parameters the generator will try to keep the exposure time around the value set at installation (typically 100ms), if load and current limits make it possible. When pushed and held down, the mAs value increases according to the following steps:

mAs steps [mAs]:

0.5, 0.6, 0.8, 1, 1.2, 1.6, 2, 2.5, 3.2, 4, 5, 6.3, 8, 10, 12, 16, 20, 25, 32,
40, 50, 63, 80, 100, 125, 160, 200, 250, 320, 400, 500, 630, 800, 1000

7.1.4 PATIENT – Patient size

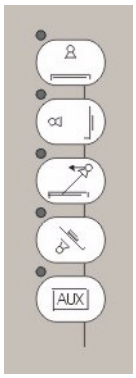
Patient size is mainly used to correct parameters set in APR mode.

If the patient is fatter or thinner than average, or the patient is a child, use one of the patient buttons (21-24). In this case you can see that the exposure voltage (kV) changes; when the child button is used, mAs also changes (increases in case of fatter patient, decreases in case of child or thinner patient). The other parameters remain unchanged. The buttons have the same functions in free parameter setting operating mode as well.

If the required change cannot be set due to load limits, the LED indicating patient size does not turn on, and the previous selection remain.

7.2 Examination device, X-ray tube and focal spot selection

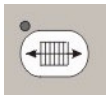
7.2.1 TECHNIQUE – examination device



You can select five examination devices in the device selection field (3-7) if they are configured during installation. In APR mode each program is assigned to a device. The LEDs above the buttons indicate which examination device is selected. Pushing any of the device selection buttons exits the generator from APR mode and turns to manual operating mode.

Symbols on the buttons in the device selection field indicate the devices. One of these is AUX, reserved for special devices (for example digital spotfilm device).

7.2.2 BUCKY – grid symbol



Use this button (31) to select whether you would like to use the device with or without grid. Exposures without a grid require lower kV and decreased mAs due to the decrease of filtering; the generator automatically changes these values in APR mode.

7.2.3 HS – high-speed

If the generator has a high-speed starter and the HS mode is configured for the selected device, the button with the HS symbol (30) is used to select one of two anode rotating speeds: normal rotation and high-speed rotation. If the LED is on, high-speed is selected.

The use of the high-speed starter results in the following:

- more power from the tube,
- higher tube current is allowed, so the exposure takes less time.

If special high power is not needed for a given examination, it is recommended to use normal rotation, saving the tube and increasing its lifetime.

High-speed rotation can be turned on with any exposure parameter settings. It can only be turned off if the current settings do not overload the tube at normal speed.

7.2.4 FOCUS – X-ray tube focal spot

Use this button (32) to select one of the usually two possible X-ray tube focal spots you would like to use:

- **S**mall focal spot
  Results in a sharper image, but cannot be loaded as much as large focal spot and takes higher thermal stress for the anode plate.
- **L**arge focal spot
  Results in a less sharp image, but can be loaded more than small focal spot.

Selection depends on the parameters required for the examination and X-ray tube load ability. Of course the generator takes into account the applied X-ray tube's load ability, so it does not allow to set any parameter combinations that exceed the limit values.

During exposure parameter setting the generator automatically sets the appropriate focal spot. Manual switching is only possible if the set parameters are allowed at both focal spot settings.

In mAs mode when using the FOCUS button if the selected parameter combination is not allowed with the selected focal spot, the generator will try to recalculate the current (mA) and time (s) values without changing the mAs value. In this case the mAs and the kV values are not changed.

In three-point mode manual focal spot selection is only possible in a very small parameter range.

A LED over the button indicates the focal spot selected for the exposure.

7.2.5 Automatic selection of large focal spot and high-speed rotation

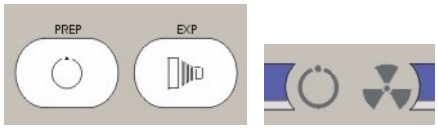
The X-ray image quality is better if the exposure is made on small focal spot. The X-ray tube can sustain larger loads at large focal spot or high-speed. During increasing the load the generator automatically switches to large focus or high speed for larger load ability.

In the configuration you can set whether the generator should first try to switch to large focal spot or high-speed. If you select keeping small focal spot, the advantage is a better resolution image. If you select keeping normal speed, the advantage is less load on the anode and less heat transmitted into the tube.

7.2.6 TUBE – X-ray tube

The X-ray tube cannot be selected directly, only indirectly through device selection. During generator or system installation the X-ray tubes for each examination device has to be set. The currently selected X-ray tube is indicated by the number 1 or 2 at the top of the LCD display.

7.3 RADIATION - Preparation, exposure



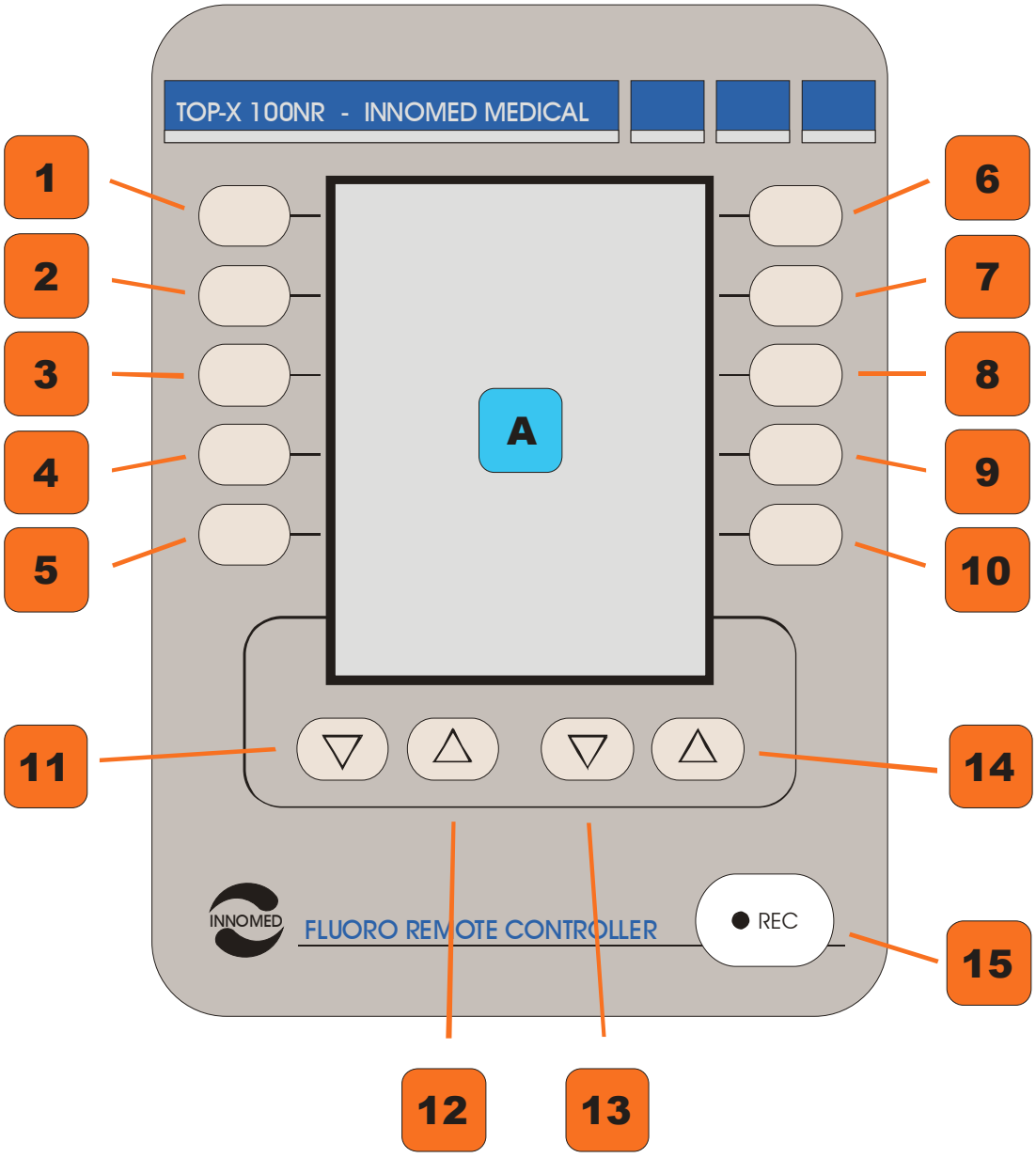
If the settings are acceptable an exposure can be made with the buttons in the RADIATION field (29, 29) or optionally with the two-state external hand-held exposure switch. Pushing the PREP button prepares the generator. When preparation is done, the PREP symbol (E) turns on and the exposure can be made with the button marked EXP in 9 seconds. The preparation period is usually between 1 and 2 seconds, set during the installation of the generator according to the applied X-ray tube and examination device.

You can also make an exposure by pushing and holding the EXP button. In this case the generator makes the exposure immediately after preparation finished.

Warning: The exposure button must be held down during the full time of the exposure process. If you let the button up before the exposure is finished, the exposure immediately aborts and the control panel displays an error message.

8. Fluoroscopic mode

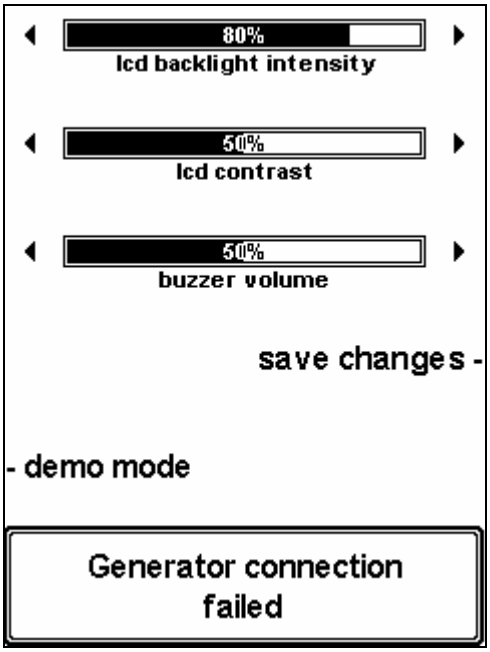
8.1 Controls on the fluoroscopic controller



8.2 Power on

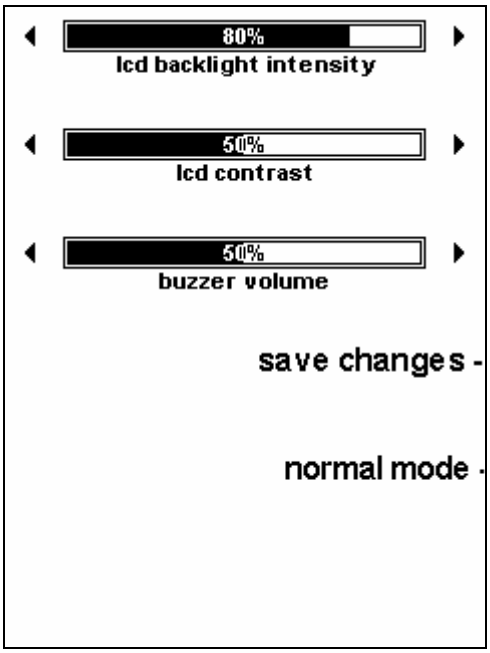
When turning the generator on (see chapter 2) the Innomed logo appears on the display (A) and the controller loads the character sets needed for display; a status line at the bottom of the screen indicates the current status. The main screen only appears after the generator has turned on completely.

If, for whatever reason, there is no connection between the generator and the controller, the following window appears on the screen. Here you can also set screen contrast (2, 7), backlight brightness (1, 6) and beeper volume (3, 8). Use the “save changes” button to save any modifications.

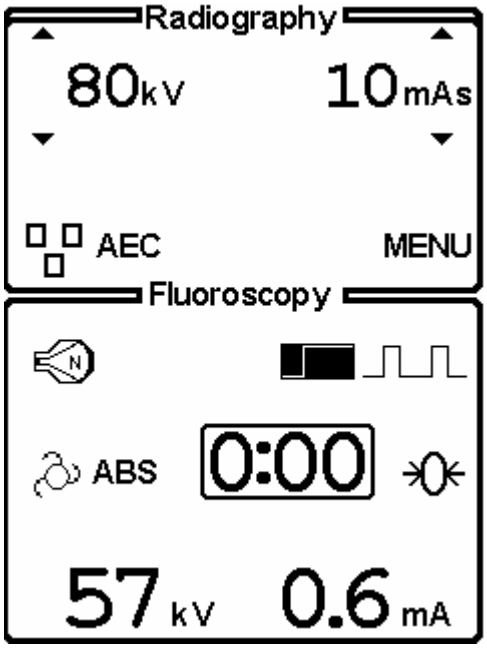


The demo operating mode is only for demonstration purposes and cannot be accessed on controllers connected to operating generators. If the controller does not operate correctly when reconnected to the generator, please contact our nearest service office.

You can also access the above window during normal operation to set the display parameters. Press and hold the time reset button (10) (see section 1.4.3) for at least 5 seconds to display this window. Press the button next to “normal mode” (10) to return to normal mode.



The following appears on the LCD screen (A) after successful power on.



Certain exposure parameters and all fluoroscopic parameters may be set on the controller.

8.3 Exposure parameters

The set of exposure parameters are similar to those described at the control panel. Further possibilities are described at chapter 7.1.

8.3.1 Exposure x-ray tube voltage (kV) setting

Use the kV up / kV down buttons (11,12) to set this value. Continuously holding one of these buttons increases / decreases the value in steps of 1kV within the allowed limits. The kV value on the control panel's kV display will be also refreshed.

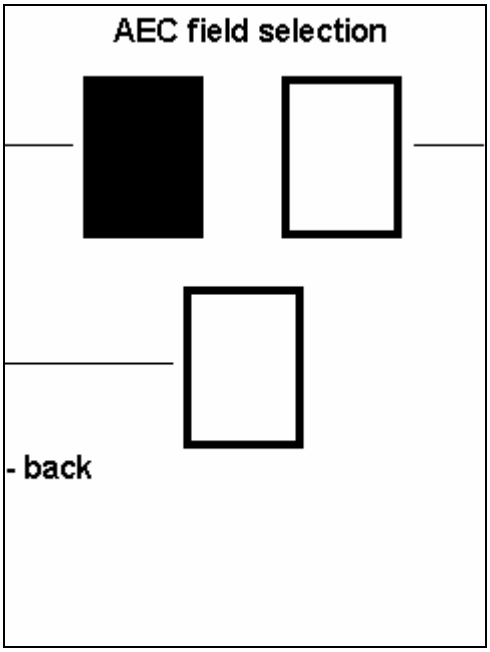
8.3.2 mAs mode (or two-point mode)

Using the mAs up / mAs down buttons (13,14) changes the mAs value. Continuously holding one of the mAs buttons changes the value according to predefined steps.

Pushing the mAs up / mAs down button the console is automatically turned into two-point mode and the new mAs value appears on the mAs display.

8.3.3 AEC dominant field selection

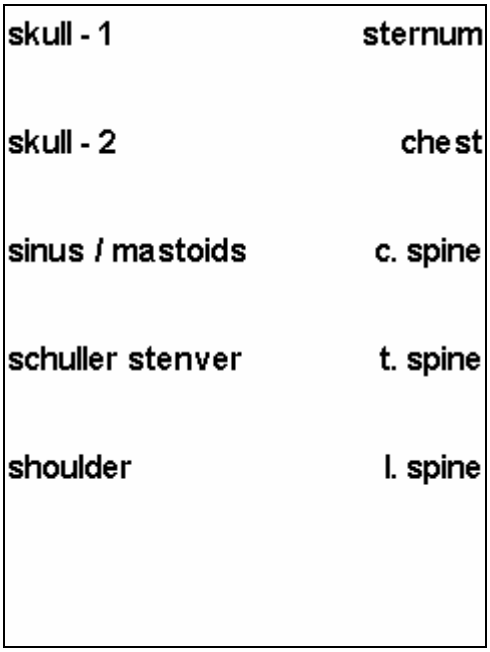
Pushing the button (3) next to the AEC symbol opens a new window on the screen.



Here you can select the desired dominant fields (2, 4, 7) and return to the main window with the back button (5).

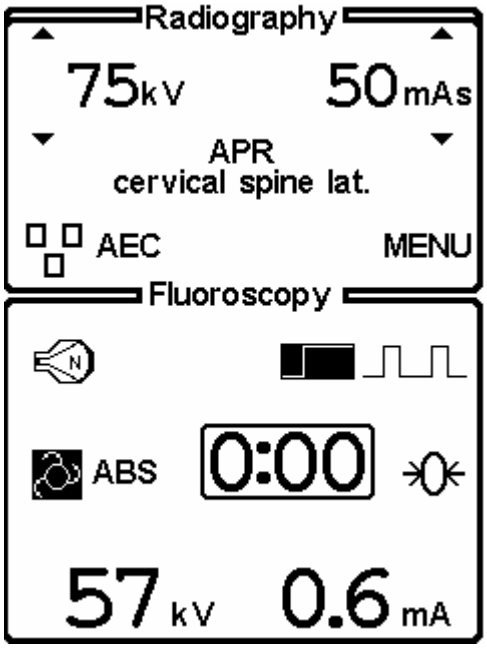
8.3.4 Selecting anatomical program

Pushing the MENU (8), then the APR (7) buttons displays the window containing the main body parts, the same as on the main operator console.



Similar to the control panel, selecting the appropriate exposure program from the main and sub body parts returns you to the main window, where you can see the

parameters according to the selected examination. As long as you do not change these parameters, the APR name is also displayed.



8.4 Fluoroscopic parameter setting

8.4.1 Fluoroscopic x-ray tube voltage (kV) setting

Use the fluoro kV up (11) / fluro kV down (12) buttons to change this value. Continuously holding one of these buttons increases / decreases the value in steps of 1kV within the allowed limits. The change of fluoroscopic kV will automatically change the fluoroscopic mA value as well. The mA value changes are proportional to the kV. The kV/mA ratio can be modified by changing the mA.

8.4.2 Fluoroscopic x-ray anode current (mA) setting

Use the fluoro mA up (13) / fluro mA down (14) buttons to change this value. Continuously holding one of these buttons increases / decreases the value in steps of 0.1mA within the allowed limits. Changing the mA value does not affect the kV value.

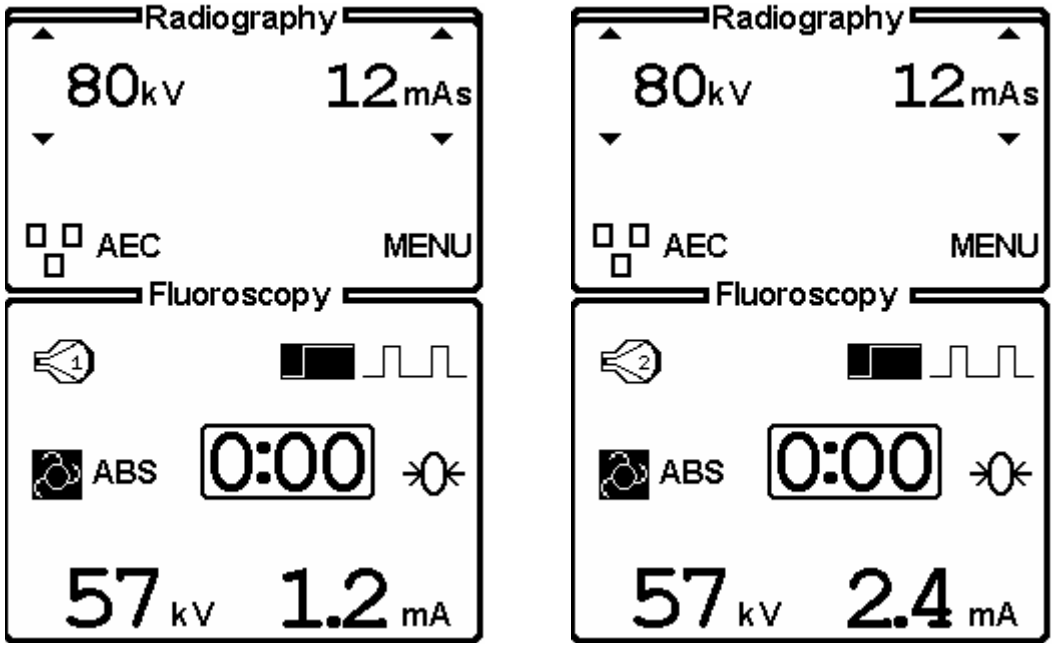
8.4.3 Fluoroscopic time

The timer on the display indicates the accumulated fluoroscopic time and only operates if radiation emits from the tube. The clock can only be cleared with the reset (10) button. When exceeding the “beep time” – set during installation – the program warns the user with a continuous sound that the fluoroscopic time is exceeding the levels safe for the patient. When reaching the maximum allowed fluoroscopic time (also set in the installation program) the generator automatically

disables radiation. The examination can continue only after resetting fluoroscopic timer.

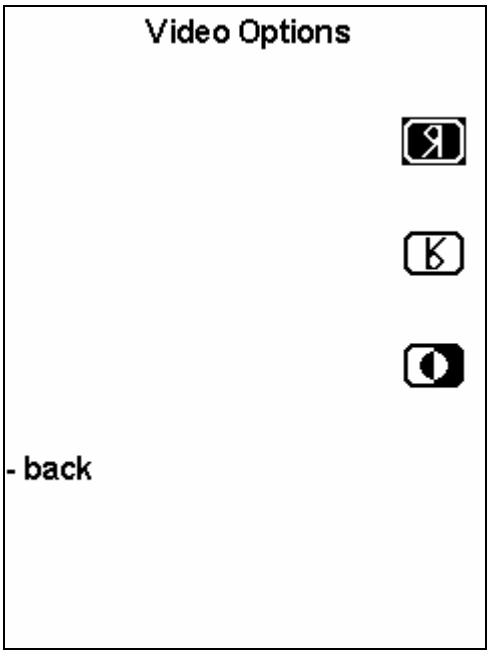
8.4.4 Zoom

This button (4) allows access to the image amplifier's zoom functions if it is not controlled from the examination table. You can select from normal up to max. four magnified image displays (depending on configuration). When magnifying, the fluoroscopic current automatically increases. The number written into the II symbol on the LCD is proportional to the selected zoom factor.



8.4.5 Video modes

Further image settings are available in the Video options (8) submenu of the MENU (8):

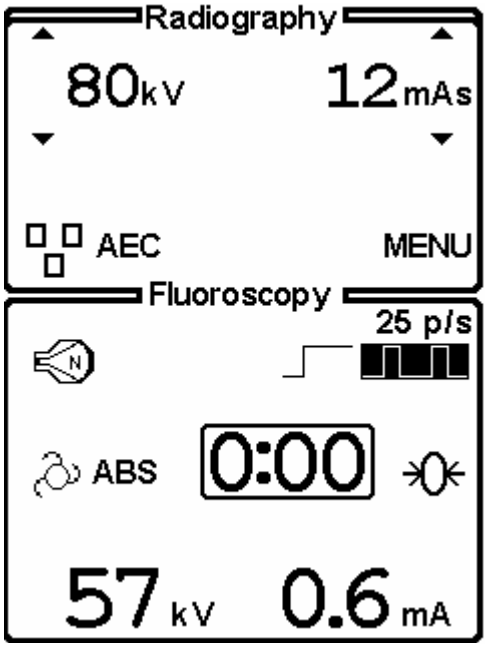


It is possible to horizontally (7) and vertically (8) mirror the image or invert the colors (9). By pressing the buttons next to the symbol, the function changes its state. If it was turned on than it turns off, and vice versa.

8.4.6 Impulse fluoroscopic operating mode

The reason of this operating mode: it is unnecessary to continuously load the patient with radiation while the camera providing the video signal on max. 25 images per second. If radiation is emitted only for a short time at the moment of image storage, and there is a longer pause until the next storage, the result is a live image similar in quality to continuous fluoroscopy, but the patient's radiation dosage is decreased to a fragment.

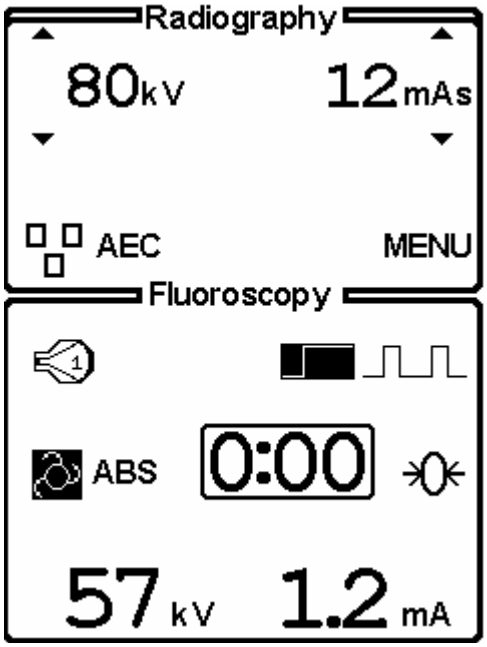
You can select impulse operating mode with the impulse button (9). In this case the current impulse per second value appears over the impulse icon.



In impulse operating mode the generator enables the radiation in synch with the square signal released by the camera. Even lower dosage is possible by emitting less than 25 radiation impulse per second, but this will decrease the continuity of motion. To modify the impulse frequency press and hold the impulse button (9) in active impulse mode. The frequency will increase or decrease, release the button when the desired frequency is reached. If you press and hold the impulse button (9) again, the frequency will change in the other direction. The adjustable impulse frequency steps are set at installation.

8.4.7 Automatic brightness setting (ABS)

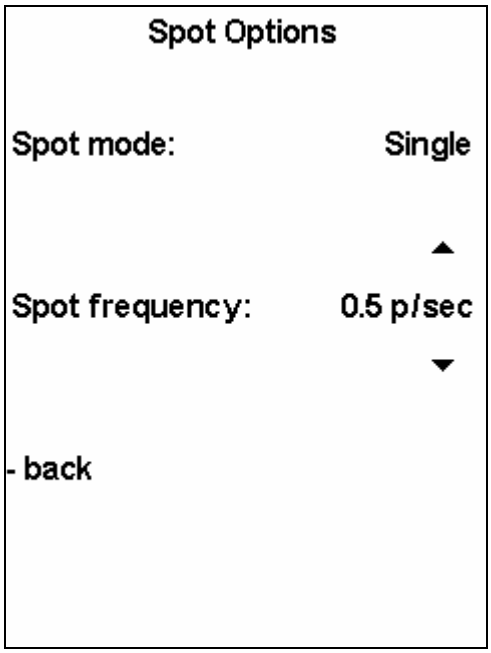
Based on the brightness signal received from the TV chain and independently from the radiation absorption of the examined organ, the system can display stable image brightness on the monitor. After you have calibrated the controller with the required brightness level, push the ABS button (5) to activate this function.

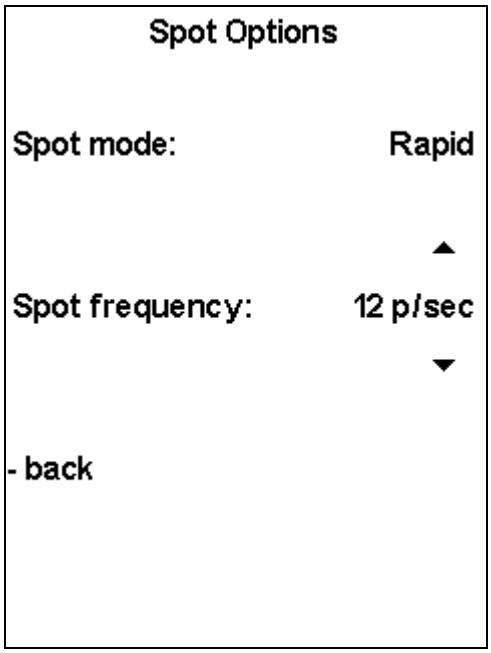


In this case the generator compensates the varying brightness with varying voltage, the result of which, as mentioned above is the change of fluoroscopic current. In case of starting with default parameters, the controller can adjust to the required brightness typically in 1 second.

8.4.8 Digital image storage from fluoroscopic operating mode

In fluoroscopic mode pushing the REC button (15) creates digital images storage. Image storage settings may be changed in the Spot Parameters submenu (9) of the MENU (8).





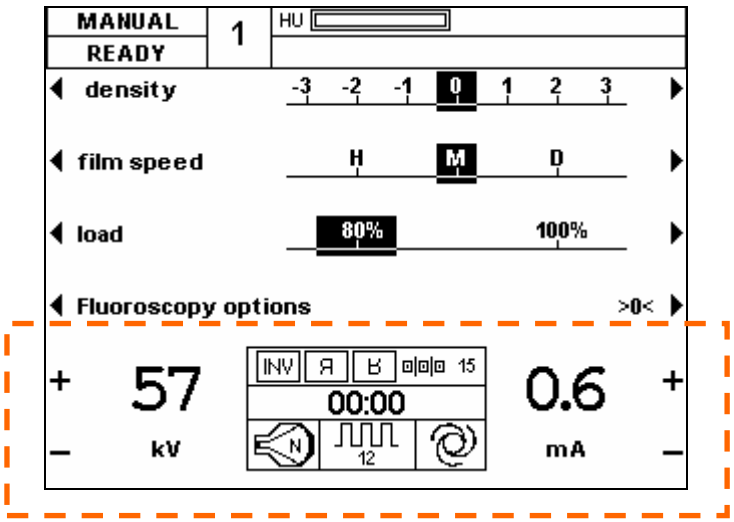
Three different image storage operating modes can be set: single, “burst” and series. In *burst operating mode* the generator makes 10 images with the set frequency, than returns to fluoroscopy mode. In *series operating mode* the images are made with the set frequency as long as the REC button is pressed. Obviously one image is made in *single operating mode*. The image creation frequency is increased and decreased with buttons 8 and 9. The adjustable image frequencies are set at the installation time.

8.5 Fluoroscopic parameter setting on the control panel

All the fluoroscopic parameter setting, which are possible on the remote controller are also available on the console. Further possibilities are described in chapter 8.4.

8.5.1 Displaying fluoroscopic parameters on the control panel

With the exception of the APR screen, the fluoroscopic parameters are always visible on the control panel.



On the left side of the display is the x-ray tube fluoro voltage; on the right, the fluoroscopic x-ray current; and in the center, the other fluoro parameters are visible. The following parameters appear in the middle box:

INV Image content inverting

A Image horizontal mirroring

B Image vertical mirroring

If these symbols appear on the display, they indicate active functions; if they do not appear, the appropriate functions are disabled.

To the right of these indications is the digital image storage fluoroscopic operating mode:

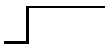
1 Single Spot – Digital storage of a single image

 Burst – Digital storage of 10 images.

 Rapid – Continuous digital image storage. In this and in the previous mode, the image creation frequency appears next to the symbol.

The following line contains the accumulated fluoroscopy time.

To the left in the bottom row is the magnification factor. To the right is the symbol indicating ABS active state. In the center are the different fluoroscopic mode states:

 Continuous fluoroscopy

 Impulse fluoroscopy. In this operating mode the impulse frequency appears under the symbol.

8.5.2 Setting fluoroscopy x-ray voltage (kV)

You can set this value on the control panel with the soft buttons next to the fluoro kV. Use + (13) button next to the symbol to increase the value, and – (14) to decrease it. Continuously holding the buttons changes the value within the allowed limits in 1kV steps.

8.5.3 Setting fluoroscopy x-ray current (mA)

You can set this value on the control panel with the soft buttons next to the fluoro mA. Use + (19) button next to the symbol to increase the value, and – (20) to decrease it. Continuously holding the buttons changes the value within the allowed limits in 0.1mA steps

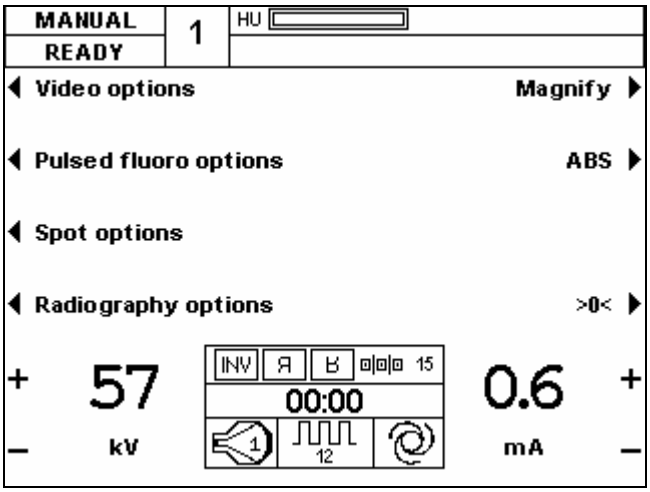
8.5.4 Fluoroscopy time

The clock on the display indicates fluoroscopy time, and only operates when x-ray emits from the tube. The timer can be reset with the soft button (8) next to the timer reset symbol. When exceeding the “beep time” value set in the install program during installation, the control panel warns with a continuous sound that fluoroscopy duration is nearing what is dangerous to patient health. When reaching the allowed maximum fluoroscopy time (also set in the install program), the generator automatically disables the x-ray. The examination can continue only when fluoroscopy timer is reset.

8.5.5 Zoom

You can access the image intensifier’s zoom functions with this parameter. You can select among normal and max. four magnified image displays. During magnification fluoroscopy current is automatically multiplied. To do this, enter fluoroscopy parameter setting with the “More options” soft button (12).

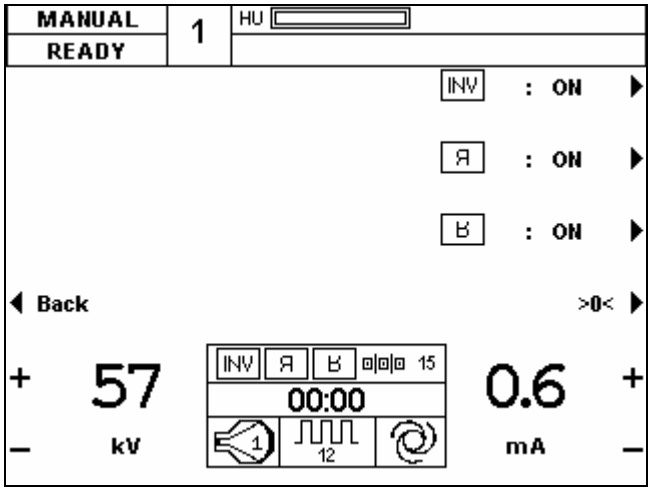
The following screen appears:



Use the Magnify soft button (15) to set magnification level.

8.5.6 Video modes

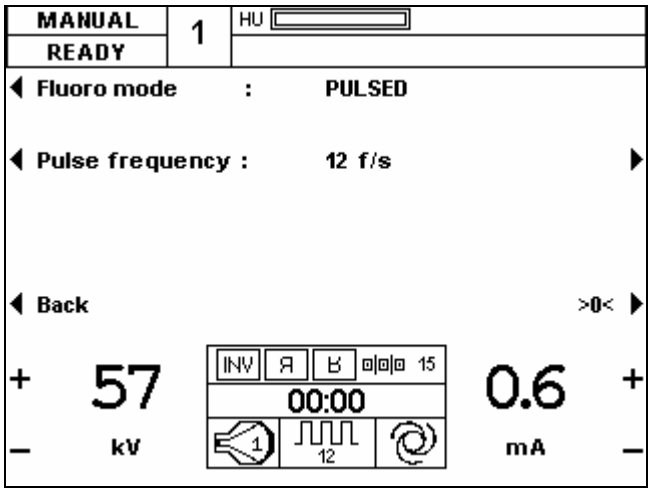
Use the Video options menu to invert image content, and to turn image horizontal and vertical mirroring on and off. Enter this menu with the soft button next to the Video options (9) label. The following screen appears:



Next to the pictograms on the right side of the screen is the state of the appropriate functions. If you push any of the soft buttons next to them (15) (16) (17), the function state changes. So if it was on, it changes to off, and vice versa.

8.5.7 Impulse fluoroscopy operating mode

To set impulse operating mode you have to enter the menu with the soft button next to the Pulse fluoro options (10). The following screen appears:

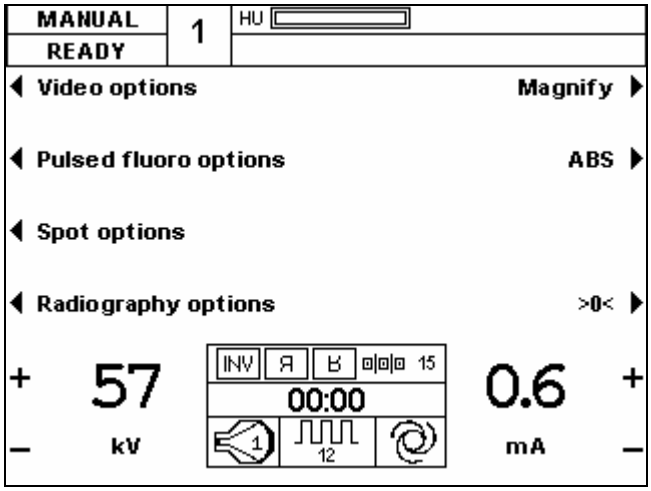


Use the soft button (9) next to the Fluoro mode label to turn impulse operating mode on and off. By selecting less than 25 x-ray impulses per second lower dosage is available, but only at the expense of image continuity. To modify impulse frequency, push the soft buttons (10), (16) next to the Pulse frequency label in active impulse operating mode. Frequency begins to increase if you push the button on the right (16), and decrease with the button on the left (10). Release the button when the desired frequency is reached. The available impulse frequencies are set at installation time.

Push the back button (12) to exit from this menu.

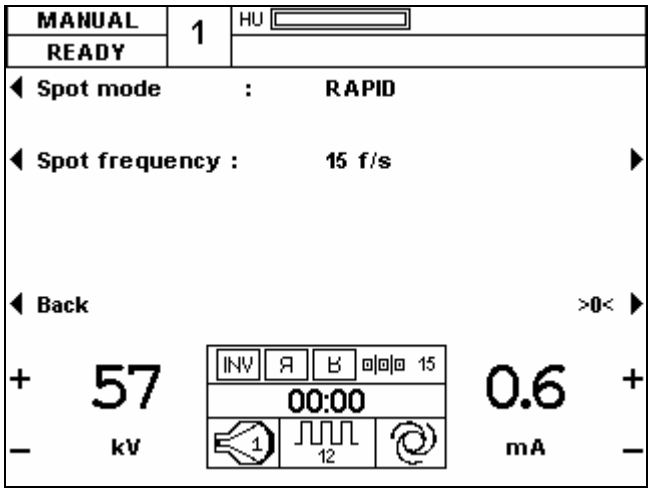
8.5.8 Automatic brightness setting (ABS)

This function can be activated by pushing the soft button next to the ABS script (16).



8.5.9 Digital image storage from fluoroscopy operating mode

Push the button next to the Spot options (11) label to enter image storage settings menu.



Three different image storage operating modes can be set: single, “burst” and rapid. In burst operating mode the generator records ten images at the set frequency, then returns to fluoroscopy. In rapid mode the recordings are also made at the set frequency, but during the full time the REC button is held down. In single mode one record is made. Recording mode is set with the soft button next to the Spot mode label (9). Image recording frequency is increased or decreased with the soft buttons (10), (16) to the right and left of the Spot frequency label. The available image frequency values are set at installation time.

9. Cleaning and maintenance

If necessary, the generator (including the control panel) cover may be cleaned according to the following.

Before cleaning completely power down the generator, including mains power and all other devices electrically connected to the generator. After power down wait at least 10 minutes.

Clean the four side and the top cover's external parts with a soft cloth slightly wet (but in no way dripping wet) with weak, diluted cleaning substance (for example dishwasher). Do not use alcohol, ether, thinner or any other solvents or chemicals.

Make sure none of the cleaning substance or water flows or splashes into the device and that none of the cleaning substance remains on the surfaces. Take care that none of the signs and labels on the surfaces are damaged and they remain visible and legible. Allow the surfaces to dry completely, but wait at least 15 minutes before turning the device back on.

The generator requires regular maintenance performed by the professional service as detailed in the installation manual.

10. Technical data

(according to standards IEC 60601-1, IEC 60601-2-7)

Modell		350HF	450HF	550HF	650HF	850HF
Maximum anode current in radiological mode	@ 80kV	300 mA	400 mA	500 mA	600 mA	800 mA
	@ 100kV	300 mA	320 mA	400 mA	500 mA	630 mA
	@ 150kV	200 mA	200 mA	250 mA	250 mA	320 mA
Maximum anode current in fluoroscopic mode (40-125kV)		10mA				
Maximum anode current in radiological mode (X-Ray tube voltage)		300 mA (100kV)	400 mA (80kV)	500 mA (80kV)	600 mA (83kV)	800 mA (81kV)
X-Ray parameters resulting the maximum output power in radiological mode		100kV, 300mA	80kV, 400mA	80kV, 500mA	100kV, 500mA	103kV, 630mA
X-Ray parameters resulting the maximum output power in fluoroscopic mode		125kV, 10mA				
Maximum output power (parameter combinations)		30 kW (100kV, 300mA, 100ms)	32 kW (80kV, 400mA, 100ms)	40 kW (80kV, 500mA, 100ms)	50 kW (100kV, 500mA, 100ms)	65 kW (103 kV, 630mA, 100ms)
Minimum current time product		0.5mAs				
Nominal shortest irradiation time in AEC mode		5ms				

Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emissions		
TOP-X generator is intended for use in electromagnetic environment specified below. The customer or the user of TOP-X generator should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	TOP-X generator uses RF energy only for its internal function. Therefore, its RF emissions are very low (apart from exposures) and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	TOP-X generator is suitable for use in all establishments other than domestic and these directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic current emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations, flicker IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
TOP-X generator is intended for use in electromagnetic environment specified below. The customer or the user of TOP-X generator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/ bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle < 5% U_T (>95% dip in U_T) for 5 sec	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle < 5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
TOP-X generator is intended for use in electromagnetic environment specified below. The customer or the user of TOP-X generator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of TOP-X generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended protective distance:**
Conducted RF IEC 61000-4-6	3 V_{RMS} 150 kHz – 80 MHz	3 V	d = $1.2 \cdot \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.5 GHz	3 V/m	d = $1.2 \cdot \sqrt{P}$ 80 MHz – 800 MHz d = $2.3 \cdot \sqrt{P}$ 800 MHz – 2.5 GHz
			Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which TOP-X generator is used exceeds the applicable RF compliance level above, TOP-X generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating TOP-X generator or its operator console. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF telecommunication equipment and TOP-X generator

TOP-X generator is intended for use in electromagnetic environment where electromagnetic disturbances are under control. Customer and user of TOP-X generator can help on preventing electromagnetic influence between portable and mobile RF telecommunication equipment (transmitters) and TOP-X generator by determining minimum separation distance between TOP-X generator and telecommunication equipment that calculated from maximum output power of transmitter, the following way:

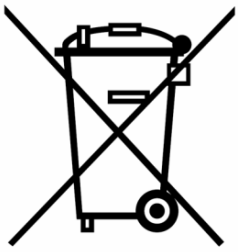
Maximum output power of transmitter W	**Separation distance as a function of transmitter frequency** m		
	150 kHz – 80 MHz $d = 1.2 \cdot \sqrt{P}$	**80 MHz – 800 MHz** $d = 1.2 \cdot \sqrt{P}$	**800 MHz – 2.5 GHz** $d = 2.3 \cdot \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

If the transmitter power is not in the table, protective distance *d* in meter (m) can be calculated by formula depending on frequency, where *P* is maximum transmit power supplied by manufacturer of the transmitter in watts (W).

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object and people.

11. Disposal of Old Electrical & Electronic Equipment (Applicable in the European Union and other European countries with separate collection systems)



This symbol on the product or on its packaging indicates that this product shall not be treated a household waste. Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment.