

# X-RAY TUBE HEAD HF1 R/8





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# **1** General description

The HF1 R/8 monobloc is a radiogenic device with rotating anode insert for radiography and fluoroscopy application, designed and manufactured with the aim of achieving a major quality in radiation field.

The 40kHz H.V. output rectified frequency guarantees a very low ripple and improves the H.V. rise time applied to radiogenic insert.

The original release of this manual is in Italian language. For further information, please refer to Italian version.

WARNING: No modification of this equipment is allowed.

# 2 Classification

CLASSIFICATION	EN 60601-1	
Type of protection against short circuits	Class I	
Operational mode	<i>Continuous operation with intermittent loading</i>	

Unit not to be used in the presence of an inflammable anaesthetic mixture with air or nitrous oxide

CLASSIFICATION	93/42/EEC DIRECTIVE
<i>In accordance with Annex IX of 93/42/EEC directive</i>	Class II b

The HF1 R/8 monobloc is classified as a Class IIb medical device, as determined by 93/42/EEC Annex IX Rule 10:

"Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb."



# **3** Technical characteristics

#### 3.1X-ray insert performance

In accordance with X-ray tube head heating curves (chap. 3.7)

Rotating anode:	3000 rpm (f = 50 Hz) 3600 rpm (f = 60 Hz)
Small focus	0,3 🔳
Large focus	0,6
Anode angle	10°
Maximum anode heat content	225 kJ
Maximum anode heat dissipation	750 W
Nominal anode input power	6 kW 🔳 25 kW 📕
For any information concerning the x-ray tube, please refer to the manufacturer of the x-ray tube technical data sheet	Ĺ

X-Ray tube manufacturer: Model: IAE RTM 780 H

#### 3.2Monobloc electric characteristics

H.V. output rectified ripple frequency	40 kHz
Nominal power	15 kW (100 kV 150mA) 0,1 sec
Maximum voltage to X-ray tube	120 kV <sub>DC</sub>
Ground to Cathode	60 kV <sub>DC</sub>
Anode to Ground	60 kV <sub>DC</sub>
Maximum current in X-ray tube (radiography) Please refer to the X-ray tube load charts	150mA
Voltage ripple at maximum power	< 2 %
Rise time at the maximum power	< 1 ms
Type of power supply	See chap. 3.3



#### 3.3H.V. transformer power supply

*Supply the H.V. transformer in compliance with the reported characteristics by using IMD Generators 15kW inverter.* 

Screw terminals	Input characteristics	Radiography / Fluoroscopy
	Type of power supply	~ Single phase
	Operating frequency	20 kHz
А, В	Max input voltage	350 Vpk
	Max input current	250 Apk

#### 3.4Filament power supply

Supply the filament in compliance with the reported characteristics:

Input characteristics			
Type of power supply	~ Single phase		
Rated voltage	160 V		
Maximum input current:			
Small focus	400 mA (rms)		
Large Focus	450 mA (rms)		
Power supply frequency	16 kHz		
Nominal power	72 VA		
Current Transformer Ratio	1:11		

#### **3.5Stator power supply**

Supply the stator in compliance with the reported characteristics:

Caratteristiche di alimentazione Input characteristics		
Type of power supply	~ Single phase	
Nominal supply voltage	230 V @ 50/60 Hz	
Steady state nominal current	1,2 A (rms)	
Peak starting current	6,5 A (rms)	
Time to full speed (230 VAC ± 10 % 50 Hz)	0,8 s	
Frequency of power supply	50/60 Hz	
Steady state nominal power	276 VA	
Maximum power	1495 VA	



### **3.6Radiological characteristics**

Minimum inherent filtration @ 75 kV	1.4 mmAl
<b>ATTENTION:</b> Final customer must guarantee 2,5 mmAl of total filtration in x- ray equipment ( according to IEC 601-1-3 applicable standard, par. 7.1).	Ĩ
Leakage radiation at 120kV 3mA (according to IEC 601-1-3 applicable standard, par. 12.4).	<0,4mGy/h

#### **3.7Thermal characteristics**

Available thermal capacity (RX)	600 kJ
Total thermal capacity	910 kJ
Thermal sensor (cfr. 3.13)	Max 60°C
Cut-off temperature	60°C ± 5 °C
Type of contact	Normally closed
Rubber bellow expansion volume	0.35 dm3
Continuous thermal dissipation	75 W

#### Heating curve 75kV 1mA

Without forced cooling (suggested)

#### Cooling curve

Without forced cooling (suggested)



## 3.8Duty cycle

Please refer to the x-ray tube max load charts included in the manufacturer datasheet.



## **3.9Mechanical characteristics**

Aluminum case structure Dimensions (see figure)



Weight (approx.) 21.5kg



## 3.10 Conditions of use

Transport and storage conditions	
Range of temperature	0° – 50° C
Relative humidity	20 – 90 %
Atmospheric pressure	700 – 1060 hPa
Working conditions	
Range of temperature	10° – 40° C
Relative humidity	30 – 75 %
Atmospheric pressure	700 – 1060 hPa

## 3.11 Electromagnetic compatibility (EMC)

This apparatus is in compliance with the standard IEC 60601-1-2 that defines the max. allowed emission levels from electronic devices and required immunity from interference caused by externally generated electromagnetic fields.

It is not, however, possible to exclude radio signals coming from transmitters such as mobile phones or similar mobile radio devices. These and other transmitting devices, including those in compliance with EMC standards, may influence the proper functioning of medical apparatus when used in proximity and with a relatively high transmitting power. Therefore, the use of radio equipment in proximity to electronically controlled system must be avoided in order to eliminate any interference risk.



Any transmissions by mobile radio equipment must be avoided. Mobile phones must be switched off in zones close to the unit. These rules must be applied when the unit is switched on (that means connected to the mains and ready to use).



## 3.12 Electric diagrams

Here below it is possible to see how to connect the HF1 R/8 monobloc through the PSM26 interface board:





## 3.13 PSM26 Interface Board



Interface board layout

Signal Pinout		Output characterist	ics
kV+	CP1: 1	Scale factor	1V = 10 kV
(HV+)		Analog signal	$0 \div 6 V_{DC}$
GND	CP1: 2	Signal GND	
kV-	CP1: 3	Scale factor	1V = 10 kV
(HV-)		Analog signal	$0 \div - 6 V_{DC}$
mA+		Current signal	Analog mA
(I+)	CP1: 4 —	Type of signal	Analog ma
TEMPERATURE SENSOR	CP1: 5, 6	Thermal NTC sensor	For Ω/°C values please see the following dedicated table
THERMAL	CP1: 7, 8	Thermal safety switch	Normally closed
SWITCH		Logic signal	switch
A / B / GND	Screws	Power input connectors	
		Common (FC) (CP2-1)	
FILAMENT	CP2: 1, 3, 5	Small focus (FP) (CP2-3)	
_		Large focus (FG) (CP2-5)	
	NODE CP3: 1, 2, 3	Common (CP3-1)	
STATOR		Main (CP3-2)	
		Shift (CP3-3)	



#### **Temperature sensor** NTC resistance / temperature cross table

Resistance (±1 Ω)	<i>Temperature</i> (±0.2°C)
1256 Ω	80°C
1480 Ω	75°C
1751 Ω	70°C
2082 Ω	65°C
2487 Ω	60°C
2985 Ω	55°C
3601 Ω	50°C
4367 Ω	45°C
5325 Ω	40°C
6530 Ω	35°C
8056 Ω	30°C
10000 Ω	25°C
<i>12493</i> Ω	20°C
15713 Ω	15°C
19901 Ω	10°C
25390 Ω	5°C
<i>32639</i> Ω	0°C



# 4 Labelling



**PICTURE 1:** Label placed on the monobloc







# 5 Symbols

The symbols that have been used are illustrated below:

Symbol	Meaning	Position
<u>285</u>	Inherent filtration	Unit label
ÍÌ	<i>Caution: see the attached documentation</i>	Unit label
	Physiological Effects	Unit label
X	<i>Equipment that requires a correct disposal (2002/96/EC)</i>	Unit label
	Manufacturer	Unit label
	Small focus	Unit label
	Large focus	Unit label
	Protective earth	Unit
$\sim$	Alternate current	Technical data sheet



# 6 Installation

To install the device in a radiological system, look over the information reported below.



ATTENTION – Everybody who uses or connects the equipment configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC 60601-1-3 and IEC 60601-2-54.

Be sure to proper connect and manage the thermal safety switch of the monobloc in order to avoid dangerous overheating and/or mechanical damages to the case structure.

## 6.1Unpacking



**ATTENTION** – UNPACK WITH CAUTION TO AVOID MECHANICAL DAMAGES OF THE CHASSIS, ELECTRONIC BOARD AND X-RAY WINDOW.

## 6.2Mechanical interface

Install the X-ray tube head through the eight M6 threaded holes available on its top surface.



**ATTENTION** – **DO** NOT EXCEED THE MAXIMUM DEPTH OF THE HOLES (8MM) IN ORDER TO AVOID DANGEROUS MECHANICAL DAMAGES OF THE TOP ALU PLATE CASING.

## 6.3Housing

$\sim$	$\sim$
	•
	1 A
<b>1</b>	u

CAUTION – It is recommended to install the X-ray tube head totally housed in a protection case, avoiding mechanical damages and preventing the direct contact by the user/patient, otherwise customer must guarantee that temperature of the parts that are likely to be touched doesn't exceed the maximum temperature allowable by the table 23 of the IEC 60601-1 third edition.



# 6.4Electrical installation

#### 6.4.1 Power connection

*For general characteristics check the related chapter in this document. The connection through a shielded cable is suggested as follows:* 

Connection terminals	A / B
Cable	$4 \times 2,5 mm^2$ shielded
Consisting of single isolated conductors with a formation of	2 x 2,5 mm <sup>2</sup> per phase
Maximum length	5,5 m
Nominal insulation	600 V <sub>DC</sub>

#### 6.4.2 Connection for filaments power supply

*For general characteristics please check the related chapter in this document. The connection through an electrical cable is suggested as the follows:* 

Connection terminals	■ / ■ / C
Consisting of single isolated conductors with a formation of	3 x 0,5 mm <sup>2</sup>
Maximum length	5,5 m
Nominal insulation	600 V <sub>DC</sub>

#### 6.4.3 Connection for stator power supply

*For general characteristics please check the related chapter in this document. The connection through an electrical cable is suggested as the follows:* 

Connection terminals	P, S, CM
Consisting of single isolated conductors with a formation of	3 x 1 mm <sup>2</sup>
Maximum length	5,5 m
Nominal insulation	600 V <sub>DC</sub>

#### 6.4.4 Protective earth connection

The connection through an electrical cable is suggested as the follows:

Connection terminal	
Nominal cross section	1 x 6 mm <sup>2</sup>
Maximum length	5.5 m



# 7 Maintenance

The X-ray tube head requires regular checks and maintenance.

Regular inspections and maintenance are aimed to maintain good operation and service safety serve and to protect the patient and operator from hazards due to any eventual breakage of mechanical parts.

The maintenance program reported below includes checks to be observed by the manufacturer of the equipment where the X-ray tube head is installed and must be carried out by expressly authorised personnel.



**C**AUTION - IN THE CASE OF REPLACEMENT OF ANY COMPONENT, USE ORIGINAL SPARE PARTS ONLY.

## 7.1Checks and inspections

*Please carry out the periodical checks listed in the following table. These checks must only be carried out by qualified personnel.* 

#### **VERIFICA / CHECK**

- Integrity of the warning and danger labels.
- Absence of cracks, clefts, oil spills, corrosions and deformations.
- Absence of unusual noise in the X-ray tube head during X-ray emission.
- Monobloc mechanical fixing and general state.
- Electronic board fixing and general state.

## 7.2Cleaning and disinfection

The X-ray tube head doesn't need particular operations of cleaning and disinfection; in case of cleaning of the X-ray tube head case surface or other parts of the equipment in which it is installed, cleaning products have not to be used if produce explosive, gaseous mixtures. If they are used make sure that gases are dispersed before switching on the X-ray tube head.



# 7.3X-ray tube seasoning

If the X-ray tube hasn't been used for a period of 3 months or more, proceed to insert seasoning by following one of the proposed options reported below. If during this procedure irregularities or faults are detected, it is necessary to stop the exposures for an appropriate period of time (30 minutes) and then restart the seasoning from the beginning:

Fluoroscopy	mode:
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Focus	kV	mA	Working time (sec)	Stand-by (sec)	N° of exposures
	80	2	30	3	1
	90	2	30	3	1
	100	2	30	3	1
	110	2	30	3	1
	120	2	30	3	2

#### Radiography mode:

Focus	kV	mA	Working time (sec.)	Stand-by (sec.)	N° of exposures	
	Warm-up					
	80	50	0,5	4	28	
	kV Step-up					
	80	50	0,01	2	3	
	90	50	0,01	2	3	
	100	50	0,01	2	3	
	110	50	0,01	2	3	
_	120	50	0,01	2	20	
			Radio	graphy 1		
	80	80	0,1	3	5	
	90	80	0,1	3	5	
	100	80	0,1	3	5	
	110	80	0,1	3	5	
	Radiography 2					
	115	80	0,1	3	10	
	120	80	0,1	3	20	





## 8 Risks

Proper use and safe operating practices with respect to X-Ray tube heads are responsibility of equipment users.

The manufacturer provides information on its products and associated hazards, but it assumes no responsibility for after-sale operating and safety practices.

Appropriate safe operating practices should be employed.

All person who work with X-ray tube head or equipment which utilizes such devices must take precautions to protect themselves against radiation exposure and possible serious bodily injury.

Do not operate this X-ray tube head except in accordance with information included in: this Technical Data Sheet, these precautions and any additional information provided by the X-ray tube and tube head manufacturer and/or competent safety authorities.

#### 8.1X-ray tube head hazards

#### HIGH VOLTAGE

All X-Ray tube heads operate at voltages high enough to kill through electrical shock. Equipment designed should prevent personnel contact with high voltages. When direct access to the X-ray tube head is required, the primary circuits should be disconnected.

#### X-RAY RADIATION



This device produces X-Ray radiation that varies in quantity and energy level, depending upon the voltage and current set up. Operating personnel must be protected by appropriate shielding. The symbol "Physiological Effects" must be permanently attached in order to prevent personnel from operating this device without X-ray protection. Shielding should be in accordance with applicable norms. If there is any doubt on the adequacy of protect in this filed should be contacted to perform an X-ray survey.

shielding, an expert in this filed should be contacted to perform an X-ray survey.

#### HOT OIL

Extreme heat occurs in the anode portion of the X-ray tube during operation. This heat is exchanged between the dielectric oil and the X-ray tube and then radiated to the air. Misuse of the X-ray tube head can result in a damage of the housing causing hot oil to escape, potentially resulting in scalds or burns. Take precautions to avoid such damages. Be sure to be in compliance with the use specifications of the manufacturer.



# **9** Disposal of the device

Once the product is at the end of its use it must be disposed following the enforced rules concerning the separate collection of waste and it cannot be treated as a simple urban waste.

The symbol means that the product has the requirements requested by new directives



introduced for the environmental protection (2002/95/EC, 2002/96/EC, 2003/108/EC) and it must be disposed properly once its life cycle is ended. When the device has reached the end of its life it must be disposed at the proper centres for the separate collection of electrical and electrical wastes, or

it must be returned to the reseller or to the manufacturer in case you want to replace the product with another equivalent new one.

The proper separate collection helps to avoid possible negative effect on the environment and on health and it facilitates the second use and the re-cycle of materials of which the device is composed of. Ask for further information to the local authorities about the areas dedicated to the wastes disposal.

Who does not dispose the product following here above mentioned, will be responsible in front of the enforced rules.



# **10** Declaration of responsibility

- **IMD Generators** is only responsible for the safety of its products when their repair and/or modification has been carried out by **IMD Generators** or by personnel expressly authorised by **IMD Generators** itself.
- IMD Generators shall not be held responsible in any way for malfunction, damage and/or danger due to incorrect use of the system or to disregard of the maintenance Regulations.
- The manufacturer of the equipment where the device is installed should take care of proper device use by trained and qualified operators.

All the technical in formations and those relevant for the compliance may be required to the manufacturer (93/42/EEC directive and following amendments):



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