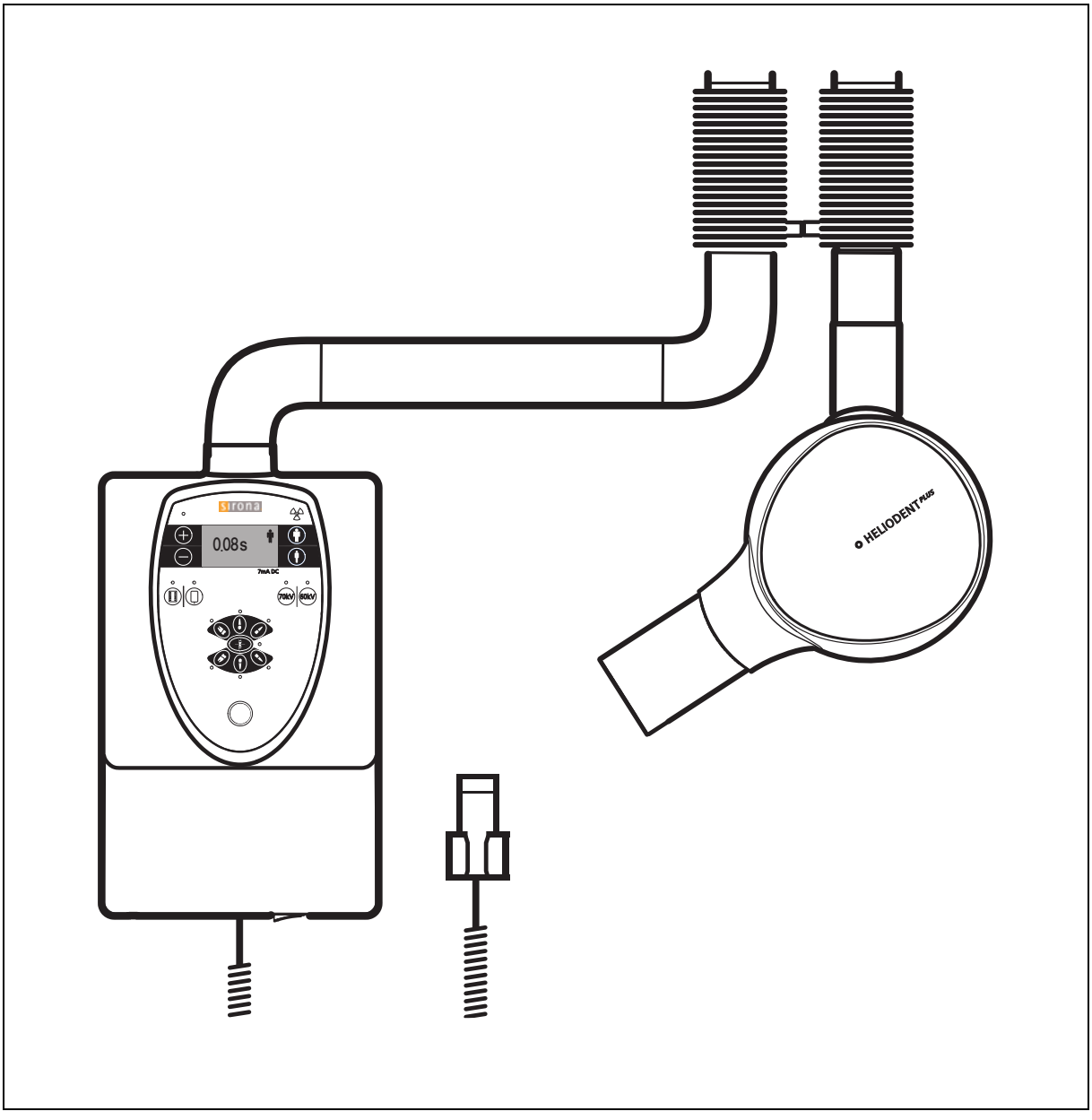
sirona
The Dental Company

HELIODENT^{PLUS}

DHHS - Statements



DHHS – Statements and Information According to 21 CFR Sub Chapter J

HELIODENT^{PLUS} dental X-Ray unit

1020.30 (h) (1) (i)

Instructions for the use of the **HELIODENT^{PLUS}** and precautionary statements are part of the Operating Instructions.

1020.30 (h) (1) (ii)

After a period of 12 months the X-Ray control must be serviced to keep it in compliance with the DHHS Performance Standard.

See: Maintenance Schedule and Instructions

NOTE:

It is the responsibility of the user to insure that the equipment is maintained in compliance with the manufacturer's recommended Maintenance Instructions.

Failure of the user to do so relieves the manufacturer or his agents from all responsibility in this matter.

1020.30 (h) (2) (i)

Peak tube potential:	70 kV
Leakage technique factors:	70 kV/0.12 mA DC
Maximum rated continuous tube current for 7 mA with a duty cycle 1 : 60:	0.12 mA DC
Minimum filtration in useful beam:	1,5 mm Al at 70 kV

1020.30 (h) (2) (ii)

Cooling curve for the tube housing:	page 4
Anode cooling characteristic:	page 5

1020.30 (h) (2) (iii)

The tube is designed for DC mode of operation with the **HELIODENT^{PLUS}** only.

Nominal tube current (fixed):	7 mA DC
Nominal peak tube potential:	70 kV
Duty cycle:	1 : 60 in seconds

1020.30 (h) (3) (i)

Rated nominal line voltage:	120 VAC or 200 – 240 VAC
permissible maximum line voltage regulation:	at 120 V: 2.5% at 200 – 240 V: 1.7%
Line voltage range:	at 120 V: ±10% at 200 – 240 V: ±10%

1020.30 (h) (3) (ii) and (iii)

Maximum line current:	at 120 V line voltage:	10 A
	at 200 – 240 V line voltage:	6 A – 5 A

at nominal values of 70kV and 7mA

1020.30 (h) (3) (v)

Generator duty cycle at the nominal values of 70kV and 7mA: 1 : 60 in sec.

Duty cycle is software-controlled (minimum time between exposures).

1020.30 (h) (3) (vi)

Maximum deviation from indicated values

a) Peak tube potential nominal 60/70kV, maximum deviation: ±6/7 kV

b) Tube current nominal 7mA, maximum deviation: ±1.4 mA

c) Exposure time: min 10ms, max. 3.2s, max. deviation: ±10%+1 ms

1020.30 (h) (3) (vi)

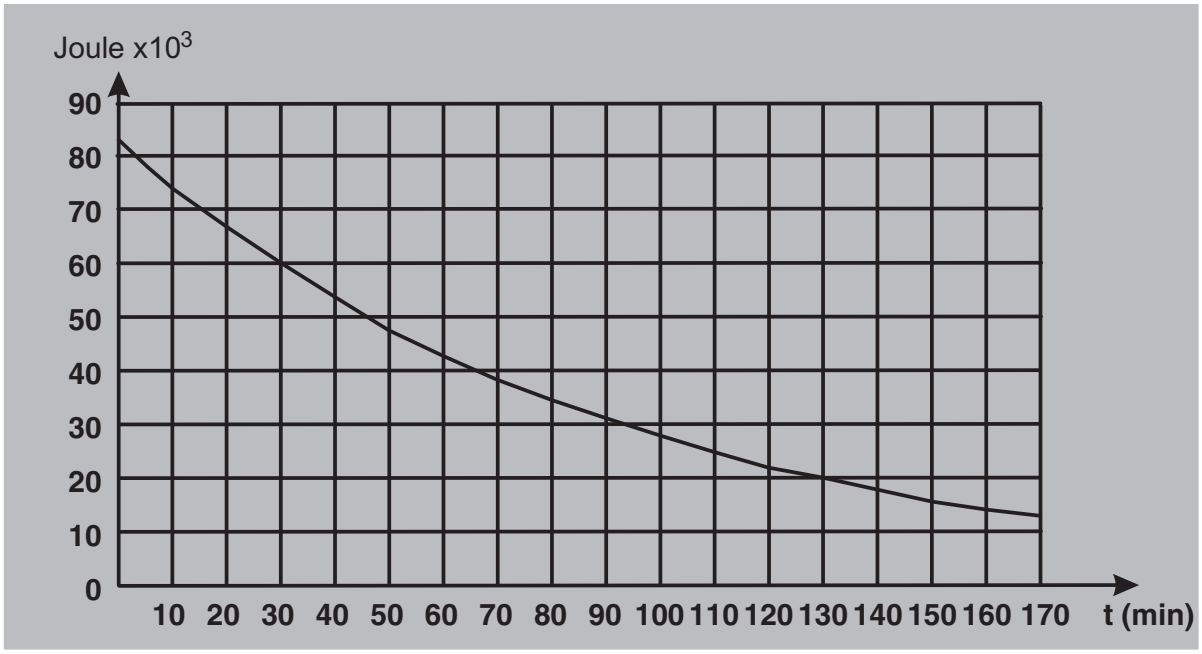
Measurement base of technique factors:

a) kV measurements have been obtained employing the following methods:
PTW-Nomex or Unfors mult-o-meter spectrometer with kV-probe

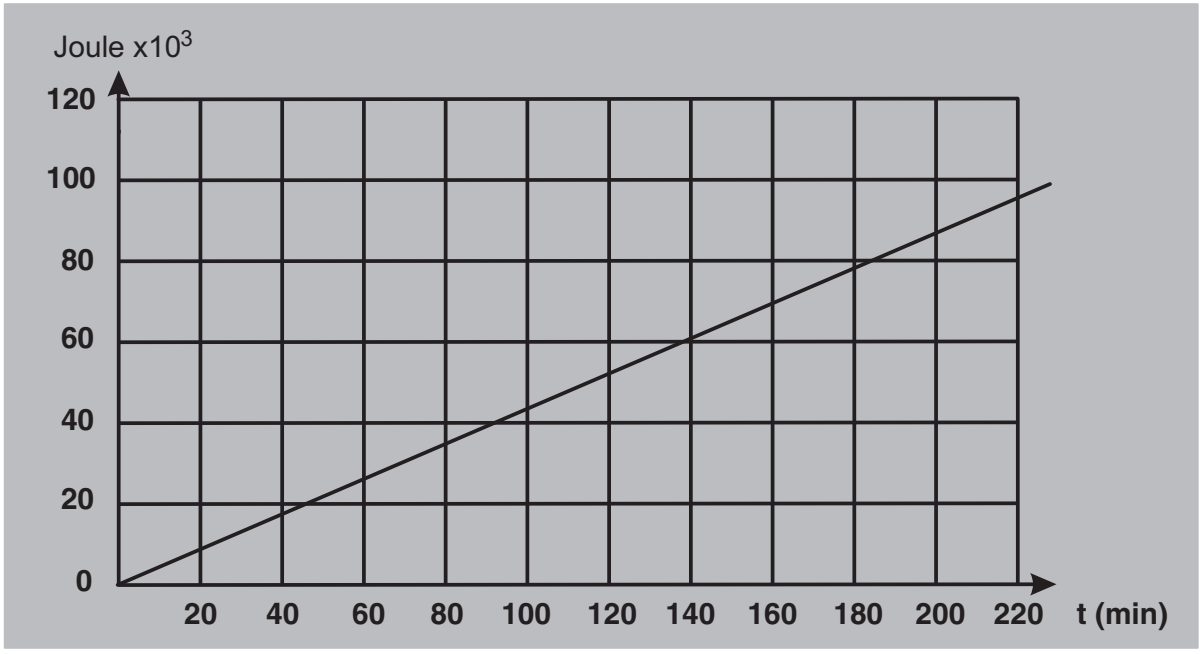
b) Tube current is measured by a common DVM .

c) The exposure time is measured with a PTW-Nomex with kV-probe or Unfors mult-o-meter.

Cooling curve for the tube housing



Heating Curve for the Tube Housing

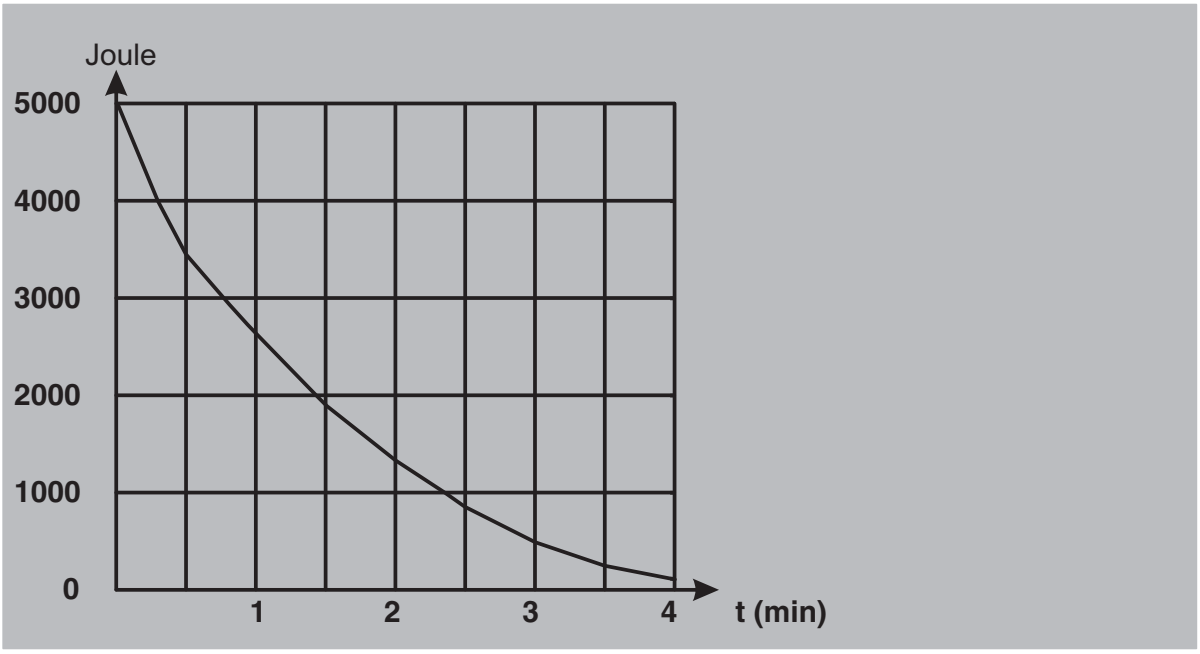


Fixed Anode Tube for X-ray Head

Technical Data

Type	P470/8.35/12G
Part number	61 51 893 D3507
Nominal voltage	60/70 kV
Nominal focal spot size	0.4mm (IEC gate controled) at 60/70 kV
Nominal continuous rating	26 W
Anode heat storage capacity	5200 Joule (7000 HU)
Maximum rating current	7 mA DC
Filament heating	1.36 ... 1.46 A/4.8 ... 5.4 V
Anode cooling	oil convection cooling
Minimum inherent filtration (Al equivalent)	1.5 mm Al
Type of operation	multipulse hight potential
Weight	approx. 2 ozs.
Application	dental radiographs

Anode Cooling Characteristic



Cone

The X-ray beam is limited for intraoral radiography by an aperture diaphragm fixed in the base of the cone, so that the radiation field has a diameter of 59mm on the skin.
The source to skin distance is 200mm with standard cone 8”.
The source to skin distance is 300mm with cone 12”.

Dose output 8.5 mGy/s ±40% at 60 kV
11 mGy/s ±40% at 70 kV

Measurement instrumentation: PWT-Nomex with ionisation chamber of 1 cm^3
or Unfors mult-o-meter

Measurement obtained at 200 mm SID and a line voltage of 230 V.

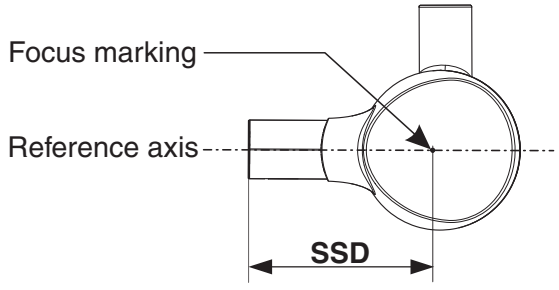
Half-value layer

The half-value layer is equal to or greater than 1.5mm Al at 70kV.

Technical Data

Nominal line voltage:	120 V, 200V – 240 V
Permitted line voltage variation:	±10% at 120 V line voltage ±10% at 240 V line voltage
Frequency:	50/60 Hz
Nominal line current:	10 A at 120 V line voltage 6 A – 5 A at 200 – 240 V line voltage
Internal resistance of power supply:	0.3 Ohm at 120 V line voltage 0.8 Ohm at 200 – 240 V line voltage
Tube voltage:	60 kV/70 kV
Tube current:	7 mA
Exposure time:	0.01 – 3.2 s
Duty cycle:	1:60
Maximal X-ray tube assembly heat content:	85 kJoule
Maximum continous heat dissipation:	70 kV 7 mA/60 = 7 W
Target material of X-ray tube:	Tungsten
Tolerance of the focal spot marking:	±1 mm
Loading factors concerning leakage radiation:	70 kV, 7 mA, duty cycle 1:60

The **HELIODENT**^{PLUS} corresponds with EN 60 601-2-28



SSD=Source to Skin Distance 8” or 12”

Original languages:

DHHS Statements and Maintenance Instruction:	english
Other documentation:	german

We reserve the right to make any alterations which may be required due to technical improvements.

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