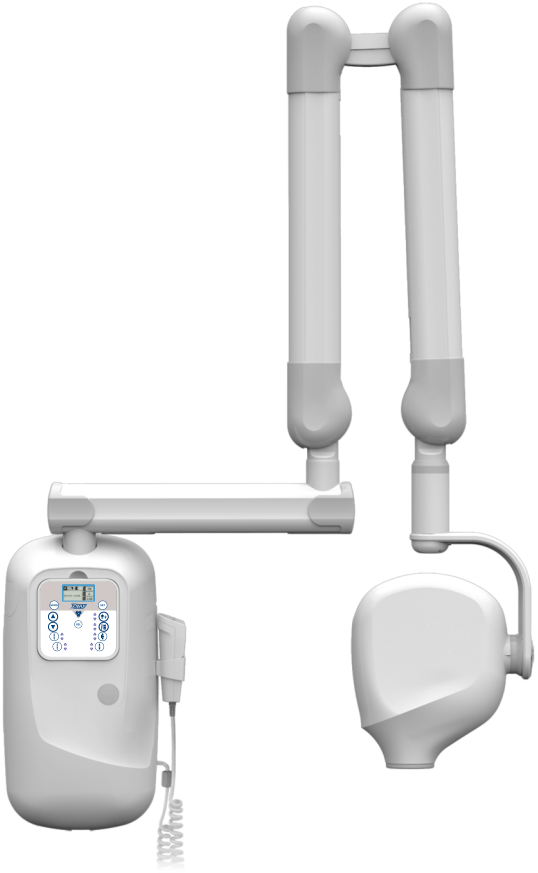
HATCH XRAY



OPERATING MANUAL

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CHAPTER 1

INTRODUCTION

1.1. Hatch X-Ray Equipment

Congratulations, your new Hatch X-Ray High Frequency Intraoral X-Ray has been engineered and manufactured to provide many years of reliable service. The system houses two microprocessors, one for control/supervisory functions and another to provide the user/machine interface. The technology incorporates feedback circuits to ensure accuracy and reproducibility of X-Ray output for dental diagnostic radiography. Hatch X-Ray will create radiographs of excellent quality, performing equally well using any image receptor.

The High Frequency Intraoral X-Ray is hereafter referred to as Hatch X-Ray in this manual. Review and follow the guidelines included in this Users' Manual to thoroughly become familiar with the operating and safety procedures. This will ensure that your Hatch X-Ray gives you the highest level of service.

1.2. Indication for Use

The Hatch X-Ray High Frequency Intraoral X-Ray is to be used as a source of X-Rays in Dental radiography. Only trained professionals should use this device. Federal law prohibits the sale of this device to individuals other than trained professionals. Use of this device, other than as described in this manual, may result in injury.

The expected service life of the product is determined based on design considerations and field performance of similar devices. The expected service life defined as minimum 10 years during which the device is expected to remain suitable for its INTENDED USE. It is also the period when all RISK CONTROL measures will remain effective to ensure that RISKS remain acceptable.

1.3. About this Manual

This manual is not to be used as a replacement for training in radiography. The document contains basic operation instructions, identification of parts, system labels and safety guidelines for the Hatch X-Ray models listed below. Additionally, troubleshooting tips are provided should the equipment not perform as intended.

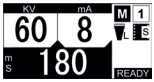
The following are guidelines for using this manual.

CAUTION

Alerts users to important instructions that require caution when operating the unit since they are related to safety

NOTE

This symbol points to an important detail / tip in the operation of the unit. Read carefully to avoid any problems.



This manual describes the user interface of the control console using images as displayed on the left. These images are indicative only and the values displayed may differ from the actual values unless specified otherwise.

1.4. Included System Components

The Wall Mounted Hatch X-Ray system is available in three model configurations using different Extension arm assembly. Unpack each component and verify that items listed below are received as appropriate. If any item is missing or damaged, notify your authorized dealer.

Table 1: Hatch X-Ray System Components

Wall Mounted		
Description		**Part No.**
Hatch X-Ray X-RAY, FS04,Wall Mount, 15” Extension arm		F303-002381-0
Hatch X-Ray X-RAY, FS04,Wall Mount, 24” Extension arm		F303-002382-0
Hatch X-Ray X-RAY, FS04,Wall Mount, 33” Extension arm		F303-002383-0
Extension arm Assembly - one only (Used with Wall Mount Units Only)	15 Inches Long (used on Model P/N-15)	
	24 Inches Long (used on Model P/N-24)	
	33 Inches Long (used on Model P/N-33)	
Note: The Tubehead is shipped attached to the Scissor Arm		
Scissor Arm Assembly (includes cables)		
70kVp 8mA Tubehead Assembly		
Base Unit Assembly		
Control Console with Cable		
Template for Single and Two Stud Wall Plate Installations		
Template for Remote Wall Plate Installations		
Remote Keypad Console (Optional)		
Remote Doorbell Switch		

CHAPTER 2

SAFETY AND PRECAUTIONS

CAUTION

- *Users must exercise every precaution to ensure personnel safety, and be familiar with the warnings and cautions presented throughout this manual and summarized below.*
- *Make sure to read and understand the safety related instructions.*
- *Make sure not to modify any component of the Hatch X-Ray system. Any modification may result in violation of compliance to the standards. Hatch X-Ray shall not be responsible for any modification causing violation of compliance, compromise on safety, performance deterioration or any other adverse effects.*
- *Warranty of this equipment will be void in the event of any modification done to the equipment, misuse of the equipment and opening or servicing by unauthorized personnel.*

2.1. Safety Symbols

The following safety related symbols are found on the equipment.

	**Caution Symbol** This symbol indicates the user to be cautious and refer to the user manual for safe operating instructions.
	**Type of Insulation** Class 1, Type B Insulation. Protection against electric shock (UL60601-1:2003). Requires protective earth connection.
	**High Voltage** Dangerous voltages present.
	**Caution: X-Ray** X-Ray source assembly/Tube Head capable of generating X-Rays. This X-Ray unit may be dangerous to patient & operators unless safe exposure factors and operating instructions are observed.
	Follow Instructions for use.
	Focal Spot.

L	Mains Line Connection.
N	Mains Neutral Connection.
	X-Ray Emission/ON.
	**Protective earth** Mains Earth is required for continued protection against shock hazards.
	**WEEE Symbol** Follow proper procedures for disposing this equipment. Cannot be disposed as general waste.

CHAPTER 3

KNOW YOUR X-RAY UNIT

3.1. Key Component Identification

As shown in “Figure 1”, Hatch X-Ray is comprised of the following components:

1. **Base Unit**
   The Base Unit provides mounting support for the Extension arm and scissor arm with attached tube-head. It provides system power connection and application via the Mains Power Line Cord and the Mains Power ON/OFF Switch. Overall operational control for Hatch X-Ray is also provided via the Keypad Console.

2. **Keypad Console**
   The Keypad Console is the user/machine interface providing all functional operating control of the Hatch X-Ray system. Consisting of an LCD display and keypad, the console keypad allows both automatic and manual selections of exposure parameters while the resultant operation status is shown via the LCD display.

3. **Extension arm**
   The Extension arm provides the horizontal space away from the wall-mounted Base Unit. Available in 15, 24 and 33 - inch lengths to meet the reach requirements of the installation site.

4. **Scissor Arm**
   The Scissor Arm consists of a vertical and horizontal arm joined via a double joint. This design enables smooth linear and upward motion transitions while allowing the attached tube-head to remain balanced in all positions.

5. **Tube-head with Beam Limiting Device**
   Provides 60 kV – 70 kV voltage range (adjustable in 1 kV steps) and 4 mA – 8 mA current range (adjustable in 1 mA steps) to reduce exposure times and the amount of radiation absorbed by the patient. The tube-head is equipped with a beam limiting device with a 23 cm (8.98 inches) source to skin distance and 6 cm (2 ⅜ inches) beam diameter at the output. The tube-head is connected to the arm by means of a rotating contact, allowing 540 degree horizontal rotation and 310 degree vertical rotation.

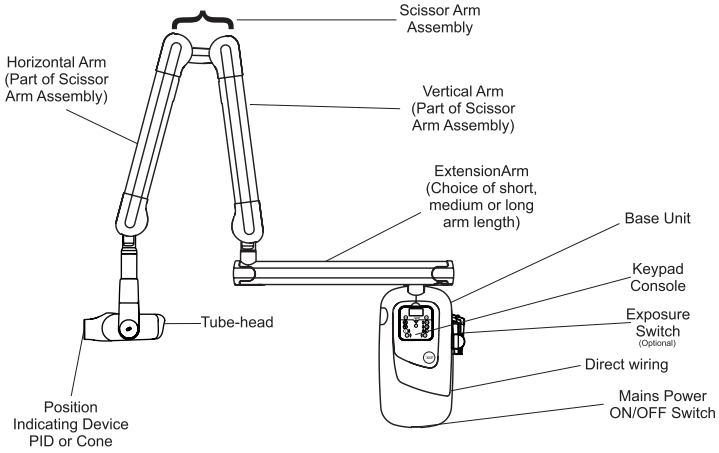


Figure 1 : Identification of Wall Mount

3.2. System Labels

This section lists the labels that are affixed on the unit. Please refer to “Figure 2” for the location where they are affixed. The mark number is given against each label below.

BASE UNIT HATCH XRAY

INPUT VOLTAGE	1 Phase 100-110V/230-240V ~
INPUT FREQUENCY	60/50Hz
INPUT RESISTANCE	0.4/0.8 ohm MAX
MOMENTARY CURRENT	11/4A MAX
STANDBY CURRENT	0.25A MAX

Label 1 : Base Unit Label

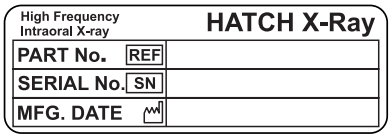
TUBE HOUSING	HATCH X-Ray
MAX TUBE kV	70 kV
MAX. CURRENT	8 mA (For 200ms)
MAX. X-RAY ON TIME	3.5 s @ Duty 1:15
TOTAL FILTRATION	≥2.5mm AL/70kV
FOCAL SPOT SIZE	■0.4 IEC 60336
X-RAY BEAM SIZE	Ø ≤ 60mm @ SSD 230mm
X-RAY TUBE	
MODEL NO.	REF OX/70-4
TUBE MFG. BY	CEI, BOLOGNA, ITALY

Label 2 : Tube Housing Label for focal spot 0.4

TUBE HOUSING

PART No. REF	
SERIAL No. SN	
MFG. DATE	
TUBE SERIAL NO. SN	

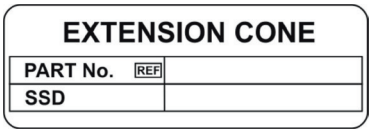
Label 3 : Tube Housing Sl. No. Label



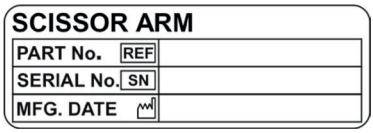
Label 4 : System Label

Label 5 : Hatch X-Ray Logo

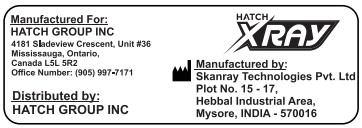
Label 6 : Angular Tape



Label 7 : Extension Cone Label

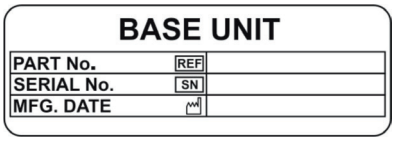


Label 8 : Scissor Arm Label

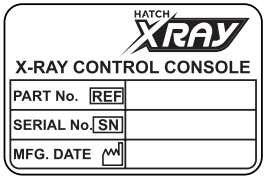


Label 9 : Manufacturer Label

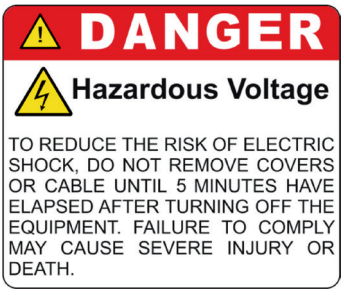
Label 10 : Extension Arm Label



Label 11 : Base Unit Sl. No. Label



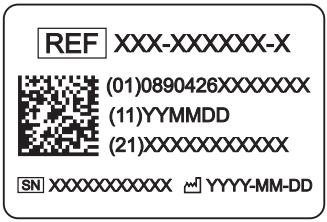
Label 12 : Console Label



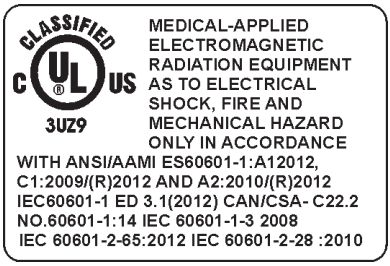
Label 13 : Danger Label

Label 14 : Warning Label

Label 15 : Radiation Caution Label



Label 16 : UDI Label



Label 17 : UL Mark Label

Label 18 : Input Configuration Label

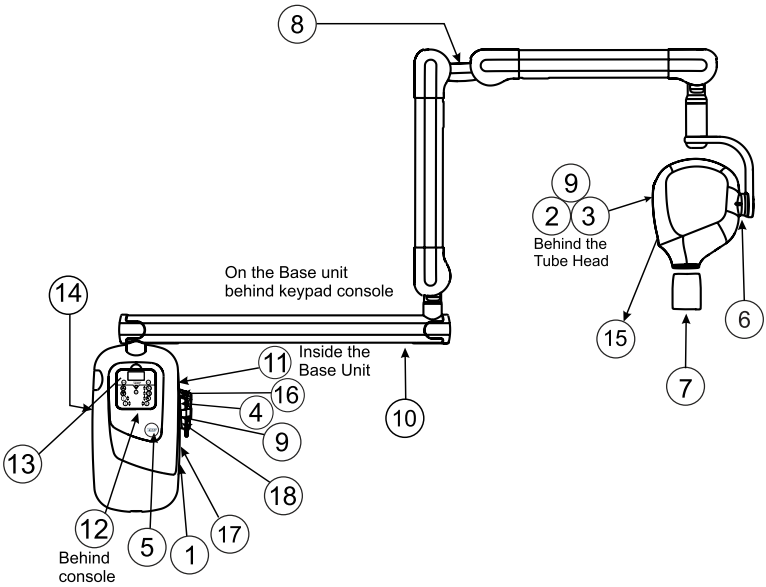


Figure 2 : Label Location

3.3. Hatch X-Ray Reach Dimensions and Movements

“Figure 3” to “Figure 5” show minimum and maximum clearances and dimensions for wall mounted.

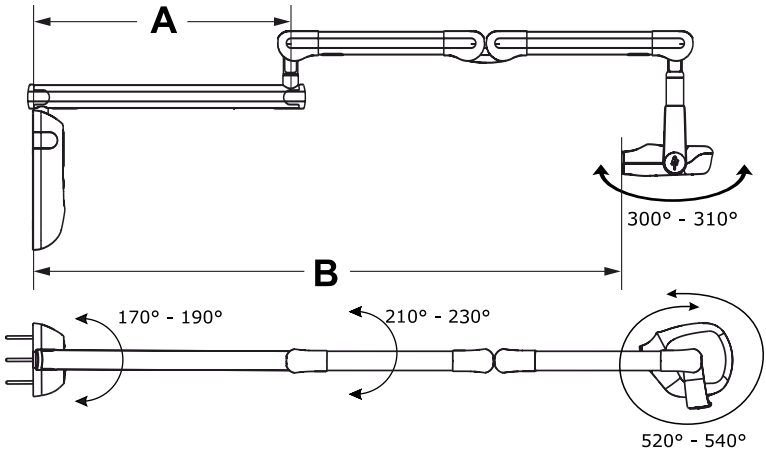


Figure 3 : Wall Mounted Hatch X-Ray Fully Extended Right Side and Top Views

Extension Arm Lenght - A	Max. Reach to Wall - B
15”(381mm)	62”(1575mm)
24”(610mm)	71”(1803mm)
33”(838mm)	80”(2032mm)

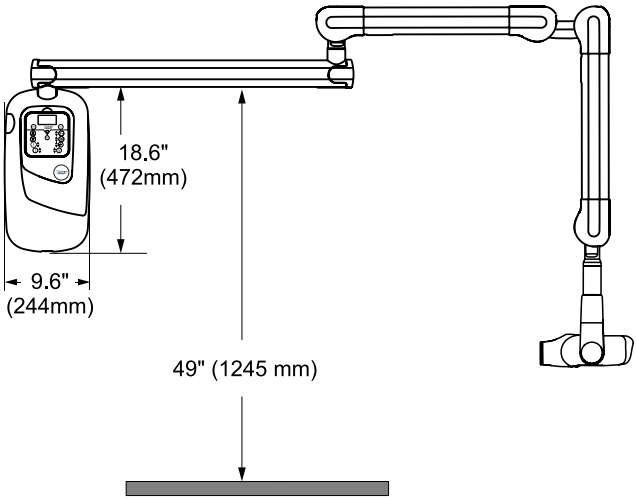


Figure 4 : Wall Mounted Hatch X-Ray Ground Clearance

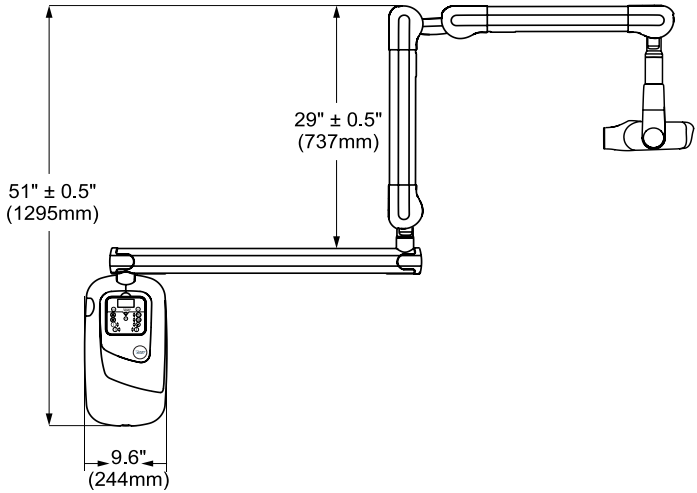
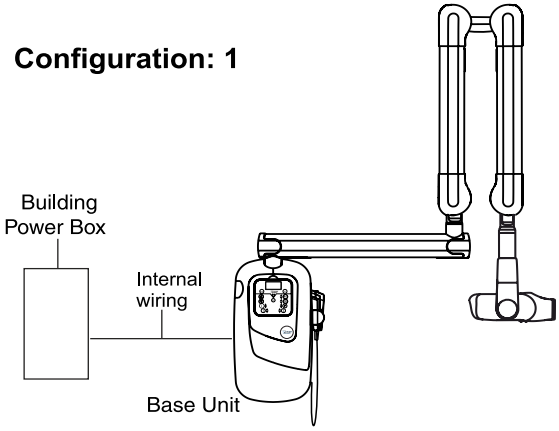


Figure 5 : Wall Mounted Hatch X-Ray Vertically Extended

**15"/24"/33" Support Tube.*

3.4. Hatch X-Ray Wall mount Configurations

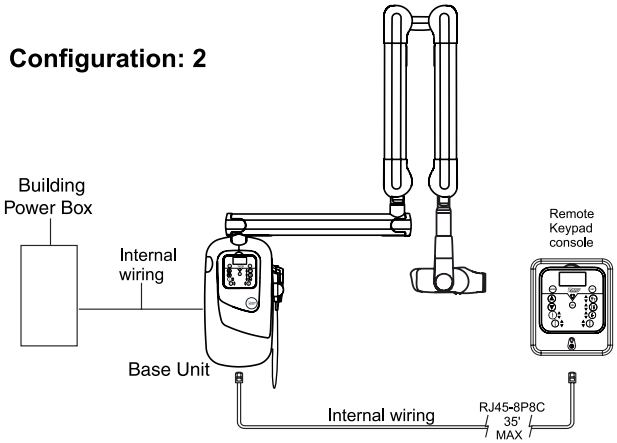


Can use Internal Keypad Console and Internal Exposure Switch (Optional)

NOTE

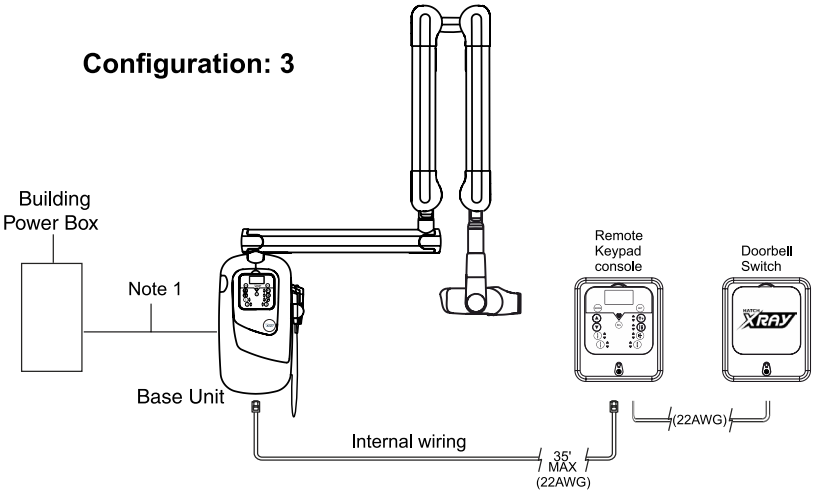
For Configurations 2 - 7

- *RJ45-8P8C 35' Cable: CAT-5 24AWG 4-Twisted Pair 1:1 Connection.*
- *RJ11-6P4C 35' Cable: Center 4 Positions Populated 1:1 Connection.*
- *3Wire, 35' Cable: Shielded or Un-shielded Cable AWG 20-28.*



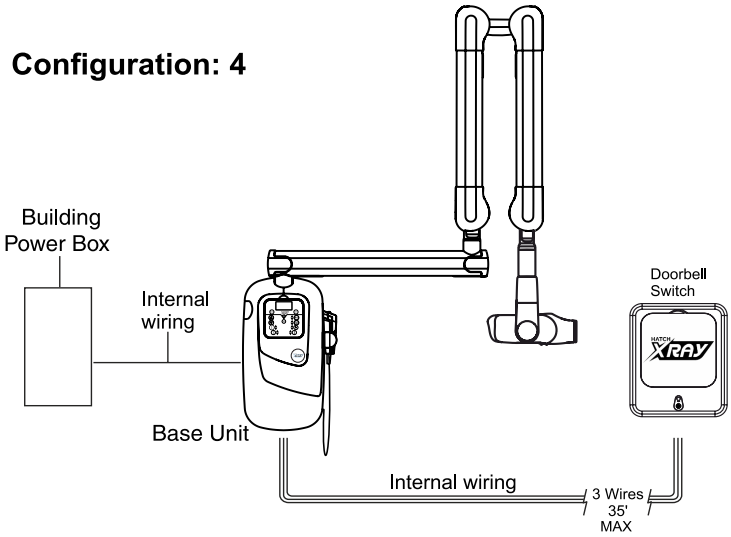
RJ45 (8P8C) with single door bell switch (optional)

Can use both Keypad Consoles (internal and remote) with Internal Exposure Switch and single door bell switch.



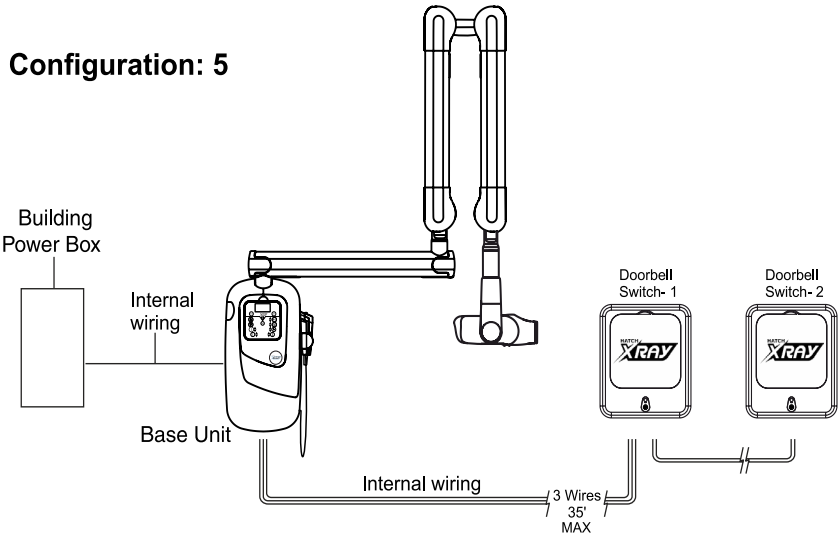
RJ45 (8P8C) with DOUBLE DOORBELL SWITCH (optional)

Can use both Keypad Consoles (internal and remote) with Internal Exposure Switch and double door bell switch:



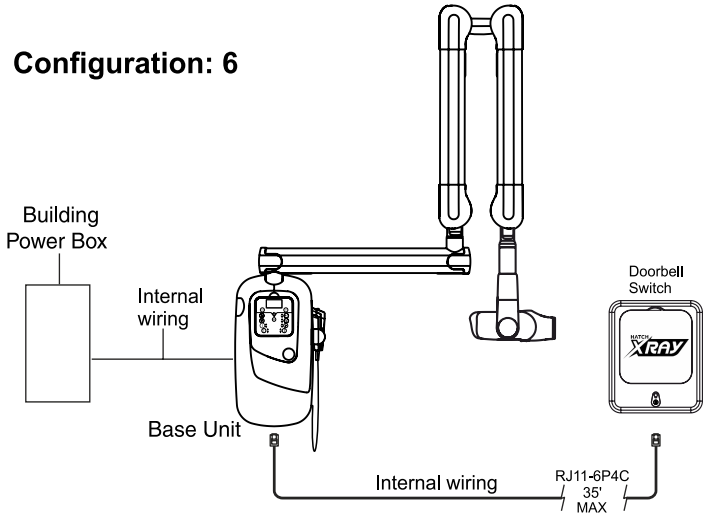
3 WIRE WITH SINGLE DOORBELL SWITCH

Can use Internal Keypad Console with Internal Exposure Switch and single door bell switch



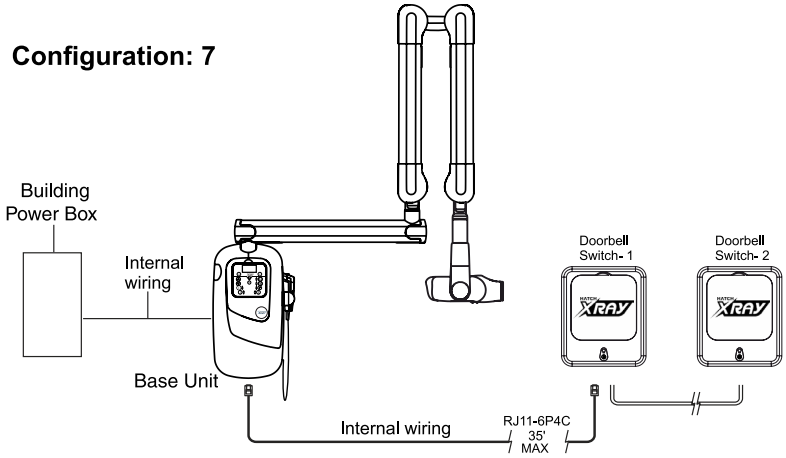
3 WIRE WITH DOUBLE DOORBELL SWITCH (optional)

Can use Internal Keypad Console with Internal Exposure Switch and double door bell switch



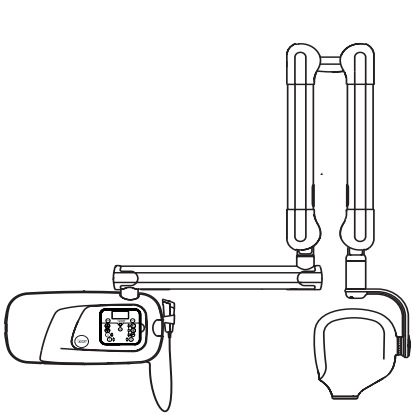
RJ11 (6P4C) WITH SINGLE DOORBELL SWITCH

Can use Internal Keypad Console with Internal Exposure Switch and single door bell switch

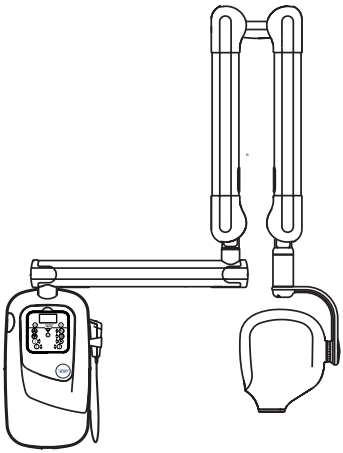


RJ11 (6P4C) WITH DOUBLE DOORBELL SWITCH (optional)

Can use Internal Keypad Console with Internal Exposure Switch and double door bell switch



2 Stud Mounting



Single Stud Mounting

3.5. Keypad Console

All functional operating control of Hatch X-Ray is provided by the keypad Console located on the base of the unit. Consisting of an LCD display and keypad, it allows both automatic and manual selections of exposure parameters. The location of the panel controls and indicators are shown by “Figure 6”, while the function of each is described on the following page.

3.5.1. Graphical LCD Display

The LCD display on the keypad Console offers a rich user interface, displaying the selected exposure parameters along with many other user-friendly features. The screen components of the home screen are shown by “Figure 6” and the associated “Detail A”.

3.5.2. Keypad

In addition to the LCD display, the keypad Console contains 11 keys and exposure LED indicator. These keys are used to select the exposure parameters. Hatch X-Ray simplifies the process of selecting exposure parameters using pre-programmed settings for every combination of image receptor, adult/child and tooth anatomy as described by “5.1. Selecting a Pre-set Mode” of this manual. Additionally, an audible signal (beep) sounds to confirm keypad button selection and when certain errors occur. This alert is also heard during any X-ray emission occurrence described on the following page.

3.5.3. Exposure Switch

Controls exposure delivery -

When pressed and held delivers exposure as set by desired procedure mode.

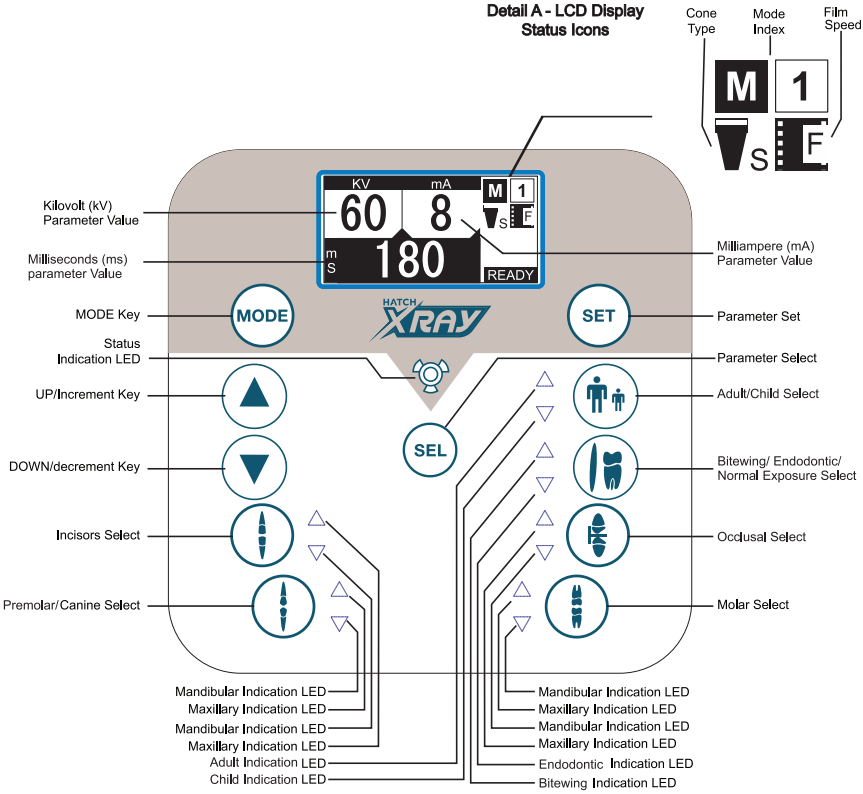
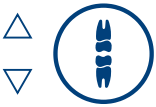


Figure 6 : Hatch X-Ray Keypad Console with LCD Display

Exposure Status LED Indicator		Extinguished: Idle / Standby Green: Ready to Deliver X-Ray Orange: Exposure in Progress Red: Operation Fault
UP / DOWN Keys		Navigate up or down a list menu. Increment or decrement parameter value.

MODE Key		Selects the exposure preset appropriate for the image receptor used.
SET Key		Accepts change in the selected parameter. Uses the highlighted item in a list menu.
SEL Key		Selects the parameter to be modified.
Adult / Child Preset Key		Toggles between Adult & Child Preset. Top LED : Adult Bottom LED: Child
Bitewing Endodontic & Normal Exposure Preset Key		Selects among Bitewing, Endodontic & Normal Exposure Preset. Top LED: Bitewing Bottom LED: Endodontic Both LEDs off: Normal Exposure
Occlusal Preset Key		Toggles between Maxillary & Mandibular Occlusal Preset Top LED: Maxillary Bottom LED: Mandibular
Molar Preset Key		Toggles between Maxillary & Mandibular Molar Preset Top LED: Maxillary Bottom LED: Mandibular
Premolar / Canine Preset Key		Toggles between Maxillary & Mandibular Premolar / Canine Preset Top LED: Maxillary Bottom LED: Mandibular
Incisor Preset Key		Toggles between Maxillary Mandibular Incisor Preset Top LED: Maxillary Bottom LED: Mandibular

CHAPTER 4

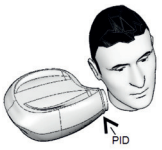
OPERATING THE UNIT

4.1. Before You Begin

⚠ CAUTION	*Ensure that the operator has read and understood this manual regarding operation of the system.* *Government regulators may require a licensed operator to use this equipment. Check with your local seller regarding this.*
Regulator Approvals	Installation and use of radiation generating equipment is regulated by the government or its authorized agencies in most countries. Check with your local seller regarding site approvals or usage.
	The operator should be well acquainted with the radiation protection methods for both the operator and patient before using this equipment.
Film Development	Majority of repeat exposures and inferior X-Ray images are attributed to the storage, handling, use and developing of X-Ray films rather than the equipment itself. Ensure that the image capture films are stored and used as per instructions.
	Let the patient know that she is going to be X-Rayed. Avoid X-Rays or take necessary precautions when X-Raying pregnant patients.

4.2. Positioning the Patient

Adults	The patient shall be seated and made comfortable so that he/she does not move during the exposure. Place protective aprons and shields where necessary.
Children	For young patients, it may be required that a guardian be available near the patient. In such cases, instruct the guardian to be on the same side of the X-Ray port; away from the X-Ray beam and behind the tube head. The guardian shall wear radiation protective clothing.



The Position Indicating Device (PID), also referred to as the Cone, should be used to approximate the area of X-Ray exposure.

NOTE

The tube-head has an built-in focus to skin distance of 9.05”(230mm) ± 0.2”(5mm). This is also referred as short cone distance,which is the safe distance at which the skin can be positioned.

Optionally, the operator can use long cone. Long cone will increase the focus to skin position distance from 9”(229mm) to 12.20”(310mm) ± 0.2”(5mm).

4.3. Achieving the Best Image Quality

Hatch X-Ray is engineered to provide the best platform for dental radiographic imaging. However the best results are obtained when the equipment is used the right way. Practicing the following points will help the user make the best out of the equipment’s output.

Patient’s Head Position

- Patient’s head should be as straight as possible.
- The patient should not move during the exposure.

Cone Position

- Cone should be positioned in such a way that the central axis of the cone is perpendicular to the teeth and should be as close to the area being imaged as possible.
- In general, the vertical angulation of the cone should be at +45° for maxilla teeth and -10° for mandible teeth.
- The horizontal angulation of the cone should also be maintained to achieve perpendicularity with respect to the teeth.

NOTE

The angle of the cone is indicated on the scale located on the vertical joint of the tube head.

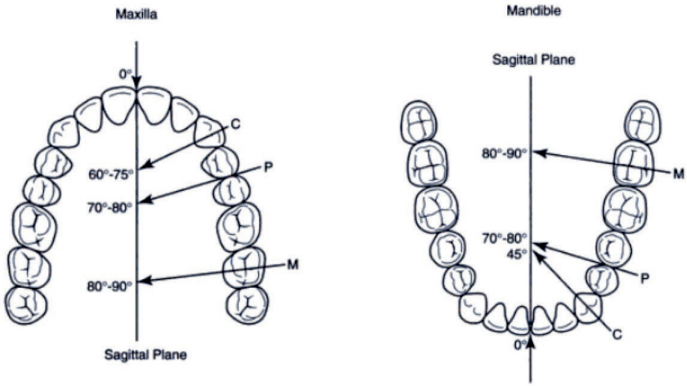


Figure 7 : Horizontal Angulation

(M – Molar; P – Pre-Molar; C – Canine)

NOTE

The Image Receptor and holder are not part of supplied accessories.

Image Receptor Holder

Using an image receptor holder and head positioning device is recommended since it gives precise control over the area to be imaged.

Placement of Image Receptor Inside the Patient's Mouth

Image receptor should be placed parallel to the long axis of the teeth.

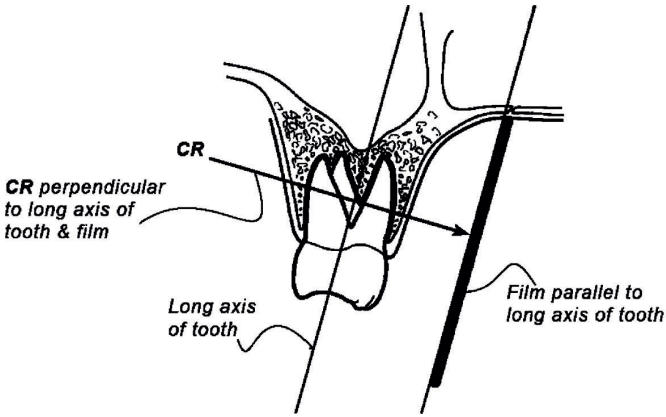


Figure 8 : Paralleling Technique

CR – Central Ray: is an imaginary beam of X-Rays in the exact centre of the position indicating device.

NOTE

Refer to Chapter "5" for details on navigating the Keypad Console for setup and operation of Hatch X-Ray

4.4. Power Turn-On Procedure

Turn on Hatch X-Ray by performing the following steps:

1. Place the Main Power Switch located on the bottom of the Base Unit to the ON (I) position. Refer "Figure 1".

NOTE

Do not press any keypad keys during self test period. Any input will be considered an error at this time.

2. On power up, observe that the system self check function initiates and the console displays Start-up Screen as shown by "Figure 13".

3. Immediately following a successful self test the console displays a home screen as shown by "Figure 14".

4.5. Hatch X-Ray Operating Procedure Summary

1. Turn on Hatch X-Ray by performing the Power Turn-On Procedure provided in section "4.4".

2. Introduce the film, plate or sensor into the patient's mouth according to the chosen technique as shown by "Figure 7" and "Figure 8" (bisecting or parallel).

3. Move the tube-head beam limiter near the patient and direct it exactly towards the tooth to be examined.

4. Arrange the tube-head with an angle suitable for the required exposure and positioning.

5. Move as far away as the Exposure switch cable allows, in a direction opposite to the X-ray beam emission while maintaining visual contact with the keypad Console and the patient.

NOTE

Refer to "Table 2" through "Table 7" for estimated exposure values of minimum patient dose that can be modified per user requirement in Custom mode.

Create an exposure by performing the Exposure Delivery Procedure provided in section "4.7". Make sure to refer to Chapter "5" for details on navigating the keypad Console for setup and operation of Hatch X-Ray as necessary.

4.6. Exposure Settings and Tables

4.6.1. Default Exposure Program Presets

By default the keypad console boots into Mode 2, Short cone, Adult, Endodontic, Maxillary Incisor Presets. The default or start-up exposure program is the exposure program set to operate Hatch X-Ray upon power turn-on of the unit. The default exposure program can be changed using the keypad Console by performing the Setting a Preset as the Start-up Mode procedure provided in section “5.4”.

4.6.2. Default Exposure Values

Estimated exposure values (kV,mA & ms) listed by “Table 2” through “Table 7” are for minimum patient dose and can be modified per user requirement in Custom mode. Refer to the tables below for Default Exposure Values for specific Hatch X-Ray application modes and options.

Table 2. Default Exposure Values for Short/Long Cone Slow Film Mode 1

Table 3. Default Exposure Values for Short/Long Cone Fast Film Mode 1

Table 4. Default Exposure Values for Short/Long Cone Mode 2

Table 5. Default Exposure Values for Short cone - PSP

Table 6. Default Exposure Values for Long cone - PSP

Table 7. Default Exposure Values - Custom Modes (All)

In order to avoid accidental exposure, the user is advised to put the console in the mode selection screen refer “Figure 15”.

4.6.3. Prep Beep Settings

Off - When the exposure switch is pressed, there will be no beep sound during preparation and gives continuous long beep during exposure.

On - When the exposure switch is pressed, there will be fluttered beep sound during preparation and continuous long beep during exposure.

Partial - When the exposure switch is pressed, a single beep is given to indicate the start of X-ray preparation.

Following this, there is silence until the start of the actual exposure. During exposure, there will be continuous long beep.

4.7. Exposure Delivery Procedure

The moment the console displays the Home screen, the unit is ready to deliver an exposure. This section describes the preparations that can be done before delivering an exposure and what happens during the procedure.

NOTE

In order to avoid accidental exposure, the user is advised to put the console in the mode selection screen. (“Figure 15”*).*

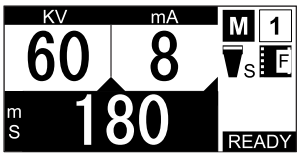


Figure 9 : Home screen

Bring the console back to home screen by pressing the MODE key. If necessary, make the following changes.

Change the Preset Mode by performing the procedure in section “5.1. Selecting a Pre-set Mode”.

Change the Preset by performing the procedure in section “5.2. Selecting a Pre-set”.

Change the film speed by performing the procedure in section “5.3. Modifying Exposure Parameters”.

Figure 10 : X-Ray - Ready

Now press **Exposure Switch** or **Remote Exposure Button** on the Doorbell switch to initiate the exposure.

Here the unit prepares itself to deliver the exposure. This stage might take a few seconds. Verify that an audible beep occurs and the X-Ray status indication LED illuminates green.

Stop or abort an exposure by simply pressing any key other than the **Exposure Switch**.

NOTE

The Exposure Switch must be kept depressed throughout the entire exposure. Releasing the Exposure Switch before the end of the exposure terminates the emission with the message displaying “X-RAY ABORTED”.

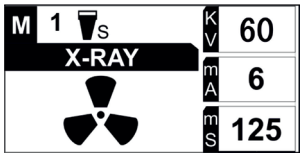


Figure 11 : X-Ray - Exposing

Verify that an audible beep occurs and the screen shows the radiation icon while the exposure is being delivered. The X-Ray status indication LED also illuminates orange.

NOTE

If you need to abort while delivering an exposure, simply release the Exposure key.

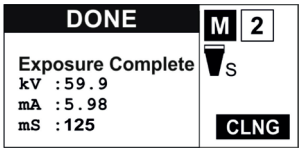


Figure 12 : X-Ray - results

Once the exposure is completed (or aborted while delivering), the X-Ray results screen displays the actual values of kV, mA and ms sensed.

The Exposure Switch may be released once the X-Ray results screen displays. If the Exposure Switch is continued to be held, the next exposure will not be initiated.

Results screen would show ABORTED rather than DONE when the exposure procedure was aborted.

The results screen is shown for 10 seconds if not interrupted by any key press (except the Exposure Switch). The screen returns to Home screen and is ready for the next exposure.

NOTE

The tube-head needs to cool down before proceeding to the next exposure. This waiting period is decided by the exposure duration selected for the last exposure. If an attempt is made to conduct an exposure during this waiting period, the console displays a message requesting the operator to wait for the remaining amount of time required by the tube-head to cool down.

Dose is directly proportional to mA and mS for a given kV" Estimated Exposure Values (kV, mA & ms) mentioned below are for minimum patient dose and can be modified as per user requirement.

The inverse square law describes the principle of dose reduction as the distance from the source increases. This assumes a point source. If radiation spreads over a spherical area, as the radius increases, the area over which the dose is distributed increases according to "A=4πr^2" where "A" is the area, "π" is "pi" and "r" is the radius of the sphere. Therefore, the dose is proportional to the inverse of the square of the radius. Thus, if you double the distance you reduce the dose by a factor of four.

The reference dose can change ± 25% depending upon accuracy of dose meter and accuracy of the kV, mA & mS delivered.

Anatomy				kV	mA	As per R20 chart Time (mS)		Reference dose for different loading factors	
								Dose Meter Reading (mR)	Dose Meter Reading (mR)
						Cone		Cone	
						Short	Long	Short	Long
Adult	Bitewing			70	6	125	360	10.56	30.3
	Endodontic	Incisors	Maxilla	70	6	160	450	13.65	38.1
			Mandible	70	6	125	360	10.56	30.3
		Canine	Maxilla	70	6	200	630	17.05	53.37
			Mandible	70	6	140	400	11.93	33.7
		Molar	Maxilla	70	6	220	710	18.76	60.25
			Mandible	70	6	160	450	13.65	38.1
	Normal Exposure	Incisors	Maxilla	70	6	160	450	13.65	38.1
			Mandible	70	6	125	360	10.56	29.38
		Canine	Maxilla	70	6	200	630	17.05	53.27
			Mandible	70	6	140	400	11.93	33.7
		Molar	Maxilla	70	6	220	710	18.76	60.25
			Mandible	70	6	160	450	13.65	38.1
		Occlusal	Maxilla	70	6	250	710	21.15	60.25
			Mandible	70	6	250	710	21.15	60.25
Child	Bitewing			70	8	71	200	5.99	16.9
	Endodontic	Incisors	Maxilla	70	6	110	320	9.35	27.34
			Mandible	70	8	71	200	5.99	16.9
		Canine	Maxilla	70	6	140	450	11.93	38.1
			Mandible	70	6	100	280	8.49	23.88
		Molar	Maxilla	70	6	160	500	13.65	42.41
			Mandible	70	6	110	320	9.35	27.34
	Normal Exposure	Incisors	Maxilla	70	6	110	320	9.35	27.34
			Mandible	70	8	71	200	5.99	16.9
		Canine	Maxilla	70	6	140	450	11.93	38.1
			Mandible	70	6	100	280	8.49	23.88
		Molar	Maxilla	70	6	160	500	13.65	42.41
			Mandible	70	6	110	320	9.35	27.34
		Occlusal	Maxilla	70	6	180	560	15.32	47.4
			Mandible	70	6	180	560	15.32	47.4

Table 2 : Default exposure values for short / long cone slow film – Mode 1

Anatomy				kV	mA	As per R20 chart Time (mS)		Reference dose for different loading factors	
								Dose Meter Reading (mR)	Dose Meter Reading (mR)
						Cone		Cone	
						Short	Long	Short	Long
Adult	Bitewing			70	6	100	320	8.49	27.34
	Endodontic	Incisors	Maxilla	70	6	125	360	10.56	30.3
			Mandible	70	6	100	320	8.49	27.34
		Canine	Maxilla	70	6	160	500	13.65	42.41
			Mandible	70	6	110	320	9.35	27.34
		Molar	Maxilla	70	6	180	560	15.32	47.4
			Mandible	70	6	125	360	10.56	30.3
	Normal Exposure	Incisors	Maxilla	70	6	125	360	10.56	30.3
			Mandible	70	6	100	320	8.49	27.34
		Canine	Maxilla	70	6	160	500	13.65	42.41
			Mandible	70	6	110	320	9.35	27.34
		Molar	Maxilla	70	6	180	560	15.32	47.4
			Mandible	70	6	125	360	10.56	30.3
		Occlusal	Maxilla	70	6	200	630	17.05	53.37
			Mandible	70	6	200	630	17.05	53.37
Child	Bitewing			70	8	50	140	4.25	11.9
	Endodontic	Incisors	Maxilla	70	6	80	220	6.8	18.76
			Mandible	70	8	50	140	4.25	11.9
		Canine	Maxilla	70	6	110	320	9.35	27.34
			Mandible	70	6	71	200	6	17.05
		Molar	Maxilla	70	6	125	320	10.56	27.34
			Mandible	70	6	100	220	8.49	18.76
	Normal Exposure	Incisors	Maxilla	70	6	80	220	6.8	18.76
			Mandible	70	8	50	140	4.25	11.9
		Canine	Maxilla	70	6	110	320	9.35	27.34
			Mandible	70	6	71	200	6	17.05
		Molar	Maxilla	70	6	125	320	10.56	27.34
			Mandible	70	6	100	220	8.49	18.76
		Occlusal	Maxilla	70	6	125	360	10.56	30.3
			Mandible	70	6	125	360	10.56	30.3

Table 3 : Default exposure values for short / long cone fast film – Mode 1

Anatomy				kV	mA	As per R20 chart Time (mS)		Reference dose for different loading factors	
								Dose Meter Reading (mR)	Dose Meter Reading (mR)
						Cone		Cone	
						Short	Long	Short	Long
Adult	Bitewing			70	6	140	140	11.93	11.93
	Endodontic	Incisors	Maxilla	70	6	125	140	10.56	11.93
			Mandible	70	6	125	125	10.56	10.56
		Canine	Maxilla	70	6	160	160	13.65	13.65
			Mandible	70	6	140	160	11.93	13.65
		Molar	Maxilla	70	6	140	140	11.93	11.93
			Mandible	70	6	140	140	11.93	11.93
	Normal Exposure	Incisors	Maxilla	70	6	125	140	10.56	11.93
			Mandible	70	6	125	125	10.56	10.56
		Canine	Maxilla	70	6	160	160	13.65	13.65
			Mandible	70	6	140	160	11.9.3	13.65
		Molar	Maxilla	70	6	140	140	11.93	11.93
			Mandible	70	6	140	140	11.93	11.93
		Occlusal	Maxilla	70	6	140	140	11.93	11.93
			Mandible	70	6	140	140	11.93	11.93
Child	Bitewing			70	8	90	90	7.65	7.65
	Endodontic	Incisors	Maxilla	70	6	110	110	9.35	9.35
			Mandible	70	8	80	80	6.80	6.80
		Canine	Maxilla	70	6	125	125	10.56	10.56
			Mandible	70	6	125	125	10.56	10.56
		Molar	Maxilla	70	6	125	125	10.56	10.56
			Mandible	70	6	125	125	10.56	10.56
	Normal Exposure	Incisors	Maxilla	70	6	110	125	7.65	7.65
			Mandible	70	8	90	90	10.15	10.15
		Canine	Maxilla	70	6	125	125	10.56	10.56
			Mandible	70	6	125	125	10.56	10.56
		Molar	Maxilla	70	6	125	125	10.56	10.56
			Mandible	70	6	125	125	10.56	10.56
		Occlusal	Maxilla	70	6	125	125	10.56	10.56
			Mandible	70	6	125	125	10.56	10.56

Table 4 : Default exposure values for short / long cone – Mode 2

Anatomy				kV	mA	Time (mS) Short Cone
Adult	Bitewing			70	8	160
	Endodontic	Incisors	Maxilla	70	8	125
			Mandible	70	8	125
		Canine	Maxilla	70	8	140
			Mandible	70	8	140
		Molar	Maxilla	70	8	160
			Mandible	70	8	160
	Normal Exposure	Incisors	Maxilla	70	8	125
			Mandible	70	8	125
		Canine	Maxilla	70	8	140
			Mandible	70	8	140
		Molar	Maxilla	70	8	160
			Mandible	70	8	160
		Occlusal	Maxilla	70	6	360
			Mandible	70	6	360
Child	Bitewing			70	8	110
	Endodontic	Incisors	Maxilla	70	8	100
			Mandible	70	8	100
		Canine	Maxilla	70	8	110
			Mandible	70	8	110
		Molar	Maxilla	70	8	125
			Mandible	70	8	125
	Normal Exposure	Incisors	Maxilla	70	8	110
			Mandible	70	8	110
		Canine	Maxilla	70	8	110
			Mandible	70	8	110
		Molar	Maxilla	70	8	125
			Mandible	70	8	125
		Occlusal	Maxilla	70	8	140
			Mandible	70	8	140

Table 5 : Default exposure values – PSP (Short Cone)

Anatomy				kV	mA	Time (mS) Long Cone
Adult	Bitewing			70	6	360
	Endodontic	Incisors	Maxilla	70	6	320
			Mandible	70	6	320
		Canine	Maxilla	70	6	360
			Mandible	70	6	320
		Molar	Maxilla	70	6	360
			Mandible	70	6	360
	Normal Exposure	Incisors	Maxilla	70	6	320
			Mandible	70	6	320
		Canine	Maxilla	70	6	360
			Mandible	70	6	320
		Molar	Maxilla	70	6	360
			Mandible	70	6	360
		Occlusal	Maxilla	70	6	450
			Mandible	70	6	450
Child	Bitewing			70	8	180
	Endodontic	Incisors	Maxilla	70	8	180
			Mandible	70	8	180
		Canine	Maxilla	70	8	180
			Mandible	70	8	180
		Molar	Maxilla	70	8	180
			Mandible	70	8	180
	Normal Exposure	Incisors	Maxilla	70	8	180
			Mandible	70	8	180
		Canine	Maxilla	70	8	180
			Mandible	70	8	180
		Molar	Maxilla	70	8	180
			Mandible	70	8	180
		Occlusal	Maxilla	70	6	360
			Mandible	70	6	360

Table 6 : Default exposure values – PSP (Long Cone)

Anatomy				kV	mA	As per R20 chart Time (mS)	Reference dose for different loading factors
							Dose Meter Reading (mR)
Adult	Bitewing			65	8	200	19.3
	Endodontic	Incisors	Maxilla	60	8	200	15.97
			Mandible	60	8	160	12.77
		Canine	Maxilla	65	8	200	19.3
			Mandible	65	8	160	15.42
		Molar	Maxilla	65	6	360	33.93
			Mandible	65	8	200	19.3
	Normal Exposure	Incisors	Maxilla	60	8	200	15.97
			Mandible	60	8	160	12.77
		Canine	Maxilla	65	8	200	19.3
			Mandible	65	8	160	15.42
		Molar	Maxilla	65	6	360	33.93
			Mandible	65	8	200	19.3
		Occlusal	Maxilla	70	8	200	22.78
			Mandible	70	8	200	22.78
Child	Bitewing			60	8	160	12.77
	Endodontic	Incisors	Maxilla	60	8	140	11.21
			Mandible	60	8	100	7.98
		Canine	Maxilla	60	8	140	11.21
			Mandible	60	8	125	9.84
		Molar	Maxilla	60	8	200	15.97
			Mandible	60	8	160	12.77
	Normal Exposure	Incisors	Maxilla	60	8	140	11.21
			Mandible	60	8	100	7.98
		Canine	Maxilla	60	8	160	12.77
			Mandible	60	8	140	11.21
		Molar	Maxilla	60	8	200	15.97
			Mandible	60	8	160	12.77
		Occlusal	Maxilla	65	8	160	12.77
			Mandible	65	8	160	12.77

Table 7 : Default exposure values – Custom modes (All)

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CHAPTER 5

USING THE CONTROL CONSOLE

The keypad Console is the user interface allowing the operator to control the X-Ray system and get feedback from it. This section describes how to use the console to complete specific tasks. As a preface, the stages through which the console passes before it becomes operable are described first.

Figure 13 : Start-up screen

Power up

On power up, the console displays the Start-up Screen as shown on the left. Following this, the console performs self test. The keypad, beeper and LCD backlight are checked. Do not press any keys (including exposure switch) during self test period.

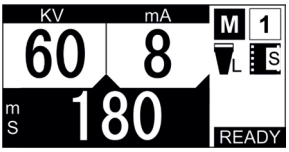

Figure 14 : Home screen

Home Screen

Immediately following a successful self test the console displays a screen similar to the one shown on the left. This screen displays current selection of exposure parameters, exposure mode details and accessories selected (cone type and film speed).

A 'READY' icon at the bottom right corner of the display indicates that the system is ready to deliver an exposure.

The S icon (when present) indicates that current combination of Preset Mode and Anatomy are different from the default startup combination. Press 'SET' key to use current combination as default, .

5.1. Selecting a Pre-set Mode

A Preset Mode is a collection of exposure parameters (kV, mA and mS) suitable for a particular type of image receptor. The keypad Console of Hatch X-Ray provides a total of seven user modes of operation, which include:

- Three factory programmed default modes, Mode1, Mode2 and PSP
- Three custom modes : Custom-1, Custom-2, and Custom-3
- One special mode: History (for recalling previously used exposure parameters)

Each mode provides 30 sets of exposure parameters based on the patient type and tooth anatomy.

The factory programmed modes varies the exposure duration to suite the accessories (cone type and film speed) selected.

Change the Preset Mode by performing the procedure provided below.

Figure 15 : Mode selection screen

Mode Selection Screen

Press the MODE button from the Home Screen to display the Mode selection list. A screen similar to the one shown on the left side appears on the display.

Use the UP/DOWN keys to navigate within the list. Press these buttons until the desired mode is highlighted.

Press the SET key to use the highlighted mode. The screen returns to home screen with the newly selected mode abbreviated on the top right side of the display.

NOTE

History mode loads the last used exposure parameters for current session. Hence the option will not be available before the first exposure. On choosing this option a list containing previous (40) exposures are displayed. Scroll through the list using the arrow keys and press SET key to use the highlighted item.

5.2. Selecting a Pre-set

A pre-set is a combination of patient type and tooth anatomy which the console uses as an index to retrieve a pre-programmed set of kV, mA and ms. For each mode (except History mode) there are 30 pre-sets available. To select one from this 30, use the patient type key and the tooth anatomy keys.

E.g. to take X-Ray image of maxillary canine of a child

- Repeatedly press the ADULT/CHILD key to select child (bottom LED).
- Repeatedly press the BITEWING/ENDONOTIC key until both its LEDs are off.
- Repeatedly press the CANINE key until the maxillary (top) LED is turned on.

NOTE

MOLAR, CANINE or INCISOR anatomies are selectable only if the BITEWING/ENDODONTIC selection is set to either endodontic or none. Similarly OCCLUSAL is selectable only if BITEWING/ENDODONTIC is set to none.

5.3. Modifying Exposure Parameters

The exposure parameters programmed in the console should be suitable for most of the applications. However, they may be modified to fine tune the exposure.

The following section explains this procedure.

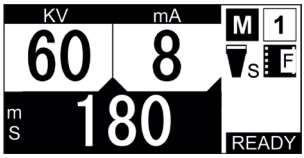

Figure 16 : Home screen with mS highlighted

Return to Home Screen (if required)

Highlight the parameter

Press SEL key to highlight the parameter that needs to be modified.

NOTE

The mS parameter is highlighted by default following power up or a change in pre-set mode or pre-set. The highlighting loops in the order, mS > kV > mA > mS.

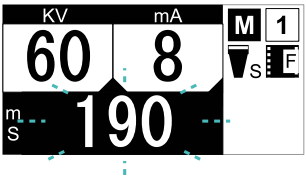

Figure 17 : mS parameter being modified (blinking)

Modify the parameter

Press UP/DOWN keys the required number of times to change the highlighted parameter. The parameter being changed blinks to indicate the operation.

NOTE

The 'READY' icon disappears to indicate that an exposure is not possible until the change is accepted/rejected.

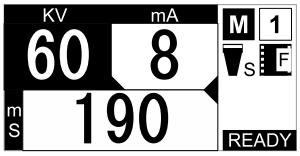

Figure 18 : mS parameter modified and accepted, kV highlighted.

Accept / Reject the change

Press SET key to accept the new value or SEL to discard the change. Either way, the console highlights the next parameter automatically.

NOTE

Screen on the left shows the result of pressing SET key. The 'READY' icon re-appears to indicate that the system is ready for an exposure. Changes made to exposure parameters of custom modes are automatically saved to console memory, while the change made to other preset modes are restored on power off.

5.4. Setting the Default Start-up Mode

By default the console selects mode 2, adult, and maxillary incisor during start-up. If you wish to select another combination as the default start-up mode, proceed as follows.

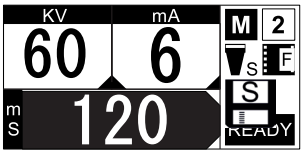

Figure 19 : Setting a Start-up Mode

Return to Home screen.

Change the preset mode and tooth anatomy as preferred.

The S icon appears at the right side of the display to indicate that current combination is not the start-up mode.

Press SET key to save current combination as the default start-up mode.

At this point the S icon disappears to indicate that current combination is saved as the default start-up mode.

5.5. Using Previously Used Exposure Parameters

The console stores the last 30 exposures in its internal memory and is not erased by a power down. You may use one of these exposure details to deliver a new exposure.

Figure 20 : History screen

Return to Home Screen.

Press MODE key to enter Mode Selection Screen. Scroll using the UP / DOWN keys to highlight History from the list and press SET key.

Scroll through the History Screen list using UP / DOWN keys to highlight the preferred exposure and press SET key to use the exposure parameters for the next exposure.

Console returns to the Home Screen after pressing SET key.

5.6. Configuring Accessories

Depending on the type of film and cone used with the system, the console varies the exposure duration to ensure proper exposure. Follow the procedure below to change the cone type and film speed used.

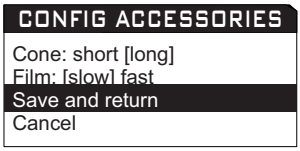

Figure 21 : Configuration Screen

Return to Home Screen.

Press MODE key to enter Mode Selection Screen. Scroll using the UP / DOWN keys to highlight 'Config Accessories' from the list and press SET key.

Current selection of Cone type and Film speed are indicated by surrounding it with a pair of braces []. To change the selection, scroll to the appropriate item and press SET key. The selection toggles though the available options.

Once the changes are made, scroll down to 'Save and Return' and press SET key. Triggering 'Cancel' returns to Mode Selection Screen without accepting the changes made.

5.7. Console Events

This section describes the special events displayed in the Keypad console. For Attention / Warning messages, refer "Table 8" and for error codes refer "Table 11".

Figure 22 : Stand-by screen

Inactive

Absence of any activity for 5 minutes continuously on the console causes the system to go to a state of inactivity. This is marked by the screen indicating a message as shown on the left side along with the display back light driven into a 'breathing' state.

Press any key to bring the console back to the Home screen.

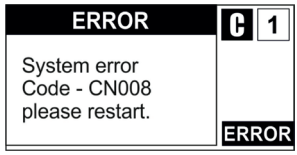

Figure 23 : Error display

Error

Any error occurring in the system is reported by the console as follows.

- Displays an error message with an error code and additional messages (example code shown is CN008).
- Display backlight turns RED
- An exposure can not be delivered until the issue is resolved.

Attention/Warning Messages	Screen	Condition
ATTENTION No modification made to settings.	Config Accessories	SET key pressed on “Save and return” option without modifying any accessories.
ATTENTION Press UP/DOWN to scroll or SET to accept.	Config Accessories	Any one of the following keys pressed. 1) Mode 2) EXPOSURE 3) Exposure Access or 4) SEL
INFO Start-up mode already saved.	Home	SET key pressed when Current combination of exposure mode and tooth anatomy is the default start-up combination.
ATTENTION Not available in History mode.	Home	“Exposure Access keys” pressed when History preset mode is selected.
ATTENTION Press UP/DOWN to scroll, SET to accept or MODE to cancel.	History/Mode Selection	Any one of the following keys pressed. 1) SEL 2) EXPOSURE or 3) Exposure Access
ATTENTION Press SET to accept change or SEL to discard.	Parameter Modification	Any one of the following keys pressed. 1) Mode 2) EXPOSURE or 3) Exposure Access
ATTENTION mA limited to 6. Use mS < 210 for full range. Press again to continue.	Parameter Modification - mA	UP / DOWN keys pressed from 6mA / 4mA respectively. 7mA-8mA options not available when mS is more than 200mS.

Attention/Warning Messages	Screen	Condition
ATTENTION mS limited to 200. Use mA < 7 for full range. Press again to continue.	Parameter Modification - mS	UP / DOWN keys pressed from 200mS / 40mS respectively. 210mS-3500mS options not available when mA is more than 6mA.
Tube cooling Please wait <n> seconds	Home	EXPOSURE key pressed after an exposure and before the cooling period expires.
System ready. Recovered from <error code> Please retry	Home	After fixing an internal error while NOT exposing.
System error. <error code> Please retry	Home	After fixing an internal error while exposing.
ERROR <error code> Please restart	Home	After an internal error that requires user / service intervention.

Table 8 : Attention / Warning Messages

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CHAPTER
6

MAINTENANCE

6.1. Cleaning and Disinfecting

NOTE

Turn OFF Hatch X-Ray Wall mount unit. Wait for 2 minutes before proceeding with service. Active internal circuits remain connected to main voltage even when main power switch is turned off.

CAUTION

- *Use a soft damp cloth to clean the outside surfaces of the equipment*
- *Do not spray or let the cleaning fluid enter the unit.*
- *Periodic disinfecting of the unit is required for hygiene. Disinfect with a compatible low or intermediate level instrument grade disinfectant after cleaning.*
- *Use a non-acetone based disinfectant liquid.*

Cleaning Methods: In order to ensure proper hygiene, especially when protective barriers are not used between each patient, clean and disinfect Hatch X-Ray by thoroughly performing the following procedures:

NOTE

Make sure that the unit is completely dry before plugging in or turning power back on.

Exterior Surfaces: Wipe the outside surfaces with a disposable towel moistened with water. Dry the external surface with disposable towels.

Parts in Contact with the Patient's Skin: To ensure proper cleaning of these parts, periodic disinfection with an approved EPA Non Corrosive Surface Disinfectant is recommended. Clean any remaining disinfectant residue from the system with a disposable towel moistened with water.

6.2. Caring for your Equipment

- Do not allow the unit to impact with any hard surfaces.
- Ensure that the control console does not fall on to hard surfaces.
- Switch off the unit when leaving for the day or when not used for a long time.
- Ensure that the unit is not subject to direct sunlight.
- Do not force the arm mechanisms or tube head into a position it is not designed for. There are movement stoppers provided.
- Avoid swinging the arms or rotating the tube head in a sudden jerky manner.

- Avoid free swinging of the arms or tube head. Meaning, always guide the movements with your hand.
- Do not hang external loads or weights on the tube head or extension arm. The arm and base units are designed for its own weight and may not hold an additional weight.
- Schedule and carry out periodic maintenance checks.

6.3. Shipping and Long Term Storage

- Use the original packing box for shipping/transporting the unit.
- When not using for a long time, cover the unit with dust proof covers and ensure the unit is not exposed to harsh environments.
- In case of non-usage for long period (>6 months) X Ray tube seasoning is recommended. Cover the cone with lead. Using the control console set the parameters as per table below. Give exposure and repeat exposure 5 times for each combination of kV, mA and ms. After all the exposures are completed, the unit is ready for use.

kV	mA	Time(ms)
60	4	40
60	6	40
60	8	40
60	4	500
60	6	500
60	8	200
65	4	40
65	6	40
65	8	40
65	4	500
65	6	500
65	8	200
70	4	40
70	6	40
70	8	40
70	4	500
70	6	500
70	8	200

Table 9 : Tube seasoning

6.4. Preventive Maintenance

- For continued service support, ensure you have entered into an annual maintenance program. This will ensure that qualified engineers periodically keep a check on the equipment.
- It is advised that the unit be subject to a maintenance schedule once every year (after 1st year of usage).
- The use beyond expected service life (10 Years) of this device is based on the preventive maintenance recommendations by the Hatch X-Ray or Hatch X-Ray authorised representative.
- All servicing should be done by qualified personnel.

CAUTION

The interior of the Main Assembly is only accessible by removing hardware with tools and should only be opened and serviced by an authorized Hatch X-Ray' Dealer Service representative. Call your authorized Hatch X-Ray' dealer for service. Since the interior of the unit contains high voltage components, failure to heed this warning may result in equipment damage, personal injury and/or death.

6.5. Disposal of the Unit

Some parts of the equipment contain material and fluids which must be disposed of at appropriate recycling centers conforming to all local, state and federal regulations. In particular the equipment contains the following materials and or components:

- **Tube head:** External packages in non-biodegradable plastic, dielectric oil, lead, copper, brass, Aluminium, Tungsten.
- **Power supply and remote control:** External packages in non biodegradable plastic, Iron, populated printed circuit boards, copper.
- **Tube head extension:** Iron, Aluminium, Copper & Silicon rubber.

NOTE

The Manufacturer and the Distributor do not accept any responsibility for the disposal of equipment or parts discarded by the user and the related costs.

6.6. Optional Accessories

“Table 10” lists the description and ordering number for accessory components currently available for use with Hatch X-Ray to meet your professional needs. Contact your Hatch X-Ray Dealer for additional information.

Description	Part No.
Hatch X-Ray Extension Cone	
Hatch X-Ray 15 - inch Extension arm	
Hatch X-Ray 24 - inch Extension arm	
Hatch X-Ray 33 - inch Extension arm	
Hatch X-Ray Aesthetic Kit (includes rubber caps, plugs)	
Hatch X-Ray Keypad Console	
Hatch X-Ray Remote Keypad console	
Hatch X-Ray Doorbell switch	
Hatch X-Ray Aesthetic Wall plate	

Table 10 : Hatch X-Ray Optional Accessories

CHAPTER 7

TROUBLESHOOTING

Hatch X-Ray has been designed with safety features to protect the patient and operator in case of failure of an electrical component. The system automatically checks for errors and will report a malfunction by means of an error code on the Keypad Console display. These error codes are listed in the"Table 11" below. The table lists the code and identifies the corresponding equipment operational fault. The corrective action for the error code is provided by "Table 12", which also lists observed problems and their potential source.

Error Code	Error
CN001	Communication error
CN002	Console and tube-head are incompatible
CN003	X-Ray preparation time-out
CN004	Anode arc fault
CN005	Cathode arc fault
CN006	Over KV fault
CN007	Over mA fault
CN008	KV regulation fault
CN009	Filament open fault
CN0010	Filament limit fault
CN0011	CAN fault
KB001	Key jam error

Table 11 : Error codes

Listed below provides troubleshooting tips to help the user recover from an equipment fault condition. It lists observed problems as well as recommends the corrective actions..

Sl. No.	Observed Problem	Recommended Action
1	Error state with display indicating CNXXXX error code	Switch off mains power. Wait for 2 minutes. Switch on mains power. If the problem persists, request service call.
2	Error state with display indicating KB0001 error code	Switch off mains power. Wait for 2 minutes. Switch on mains power and make sure that none of the console keys are pressed. If the problem persists, request service call.
3	The unit does not power on when mains is switched on.	Check if neon pilot lamp is on. If not, there may be a loose contact at the wall socket end. Or the wall outlet is not receiving power. Check local electrical circuit for trips. If neon lamp is on then check the following. Ensure that the spiral cable connection to the base is proper. Switch off mains power. Wait for 2 minutes. Switch on mains power. If the problem persists, request service call.
4	No X-Ray image even through the unit indicates normal exposure.	Verify film development and storage method. The films could be damaged or the chemicals could be contaminated Log a service call to validate exposure quality.
5	The mechanical extension arm is drifting and does not stay in set position.	This can be due to normal wear and tear or using excess force on the arms. Get the spring tension adjusted by an authorized service engineer. Log a service call.
6	Poor image quality	Please make sure that following points are observed. Correct exposure values are selected for the anatomy. When using film as image receptor its storage and processing are as recommended by the manufacturer. Positioning of tube-head and receptor is proper. Patient is positioned stably during imaging. If the problem persists, request service call.

Table 12 : Troubleshooting tips

ANNEX A

TECHNICAL SPECIFICATIONS

Tube-Head Specifications	
Generator Type	High Frequency, Microprocessor Controlled, Constant Potential (DC)
Control of High Voltage	Closed Loop
High Voltage Range	60kV – 70kV Settable (Step size 1kV)
Accuracy of High Voltage	< ± 5%
High Voltage Ripple Frequency	> 200kHz
High Voltage Ripple	Low Frequency Ripple (≤ 10kHz) shall be less than 2% p to p measured @ 70kV/8mA High Frequency Ripple (≤ 50kHz) shall be less than 10% p to p measured @ 70kV/8mA
High Voltage Rise Time	< 3ms
Control of Tube Current	Closed Loop
Tube-head current range	4mA – 8mA Settable (Step size 1mA) (7-8mA @ time ≤ 200ms)
Accuracy of current	< ± 5% (± 10% for time <40ms)
Maximum Exposure Time	3.5s upto 6mA (7 & 8 mA 200ms Max)
Minimum Exposure Time	10 ms
Exposure Timer Accuracy	± 10%
Maximum Electrical Input	560W at 70kV, 8mA
Duty Cycle	1:15 Adaptive & auto limit based on temperature.
Additional X-Ray filtration	Minimum 2.0 mm Al equivalent @ 70 kV
Total X-Ray filtration	>2.5 mm AL/70kV
Minimum source to skin distance	9”(230mm) ± 0.2”(5mm) (in-built) 12.2”(310mm) ± 0.2”(5mm) with optional cone
X-Ray field (at collimator tip)	Circular, diameter ≤ 60 mm @ SSD of 8.6” (230mm)
Leakage radiation @ 1m	< 0.88 mGy/h (100 mR/h)

Leakage radiation technique	70 kV, 6 mA, 1250ms
Tube Head Outer Covers	BAYBLEND FR 3010 PC-ABS Plastic with Glossy Finish
PID/Cone Material	Silicone Rubber/ Aluminium/ Makrolon - 2407

Table A1 : Tube-Head specifications

X-Ray Tube Insert Specifications

Parameters	Specification
Tube Insert Model	OX/70-4
Focal Spot (IEC336)	0.4
Anode angle	16°
Anode material	Tungsten
Insert Inherent filtration	0.5 mm Al equivalent @ 70 kV
Anode thermal capacity	7 kJ

Table A2 : X-Ray tube insert specifications

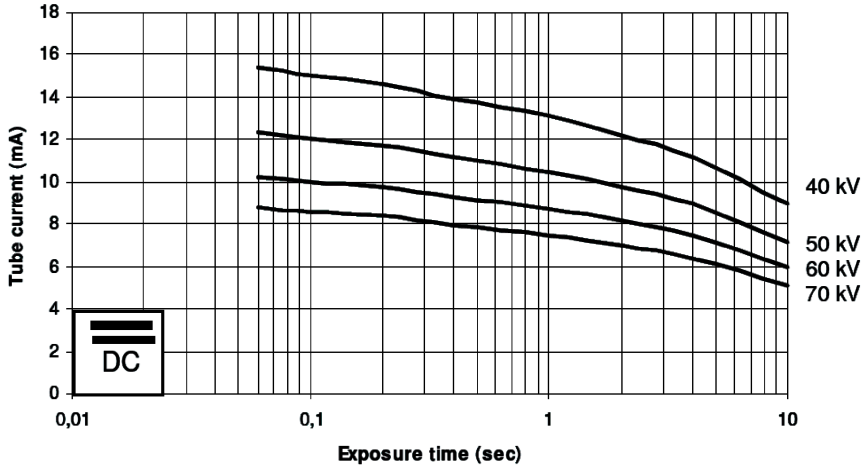

Figure A-1 : X-Ray Tube Insert Rating Chart-OX/70-4

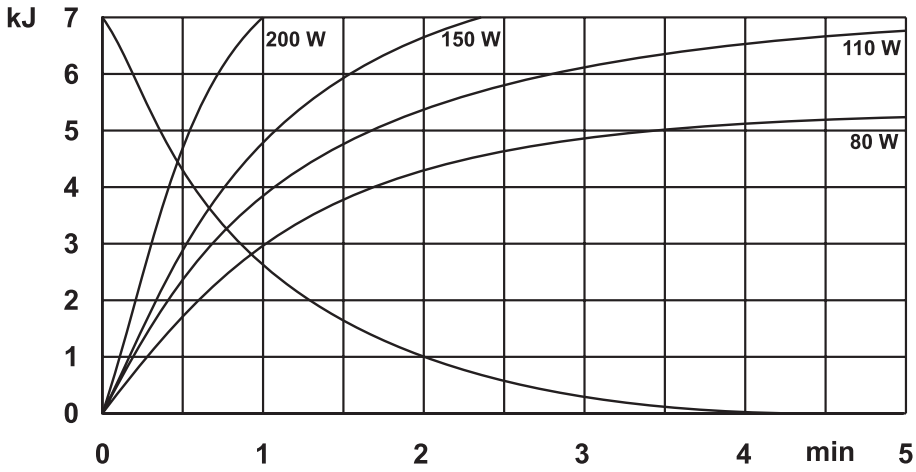

Figure A-2 : X-Ray Tube Insert Thermal data-OX/70-4

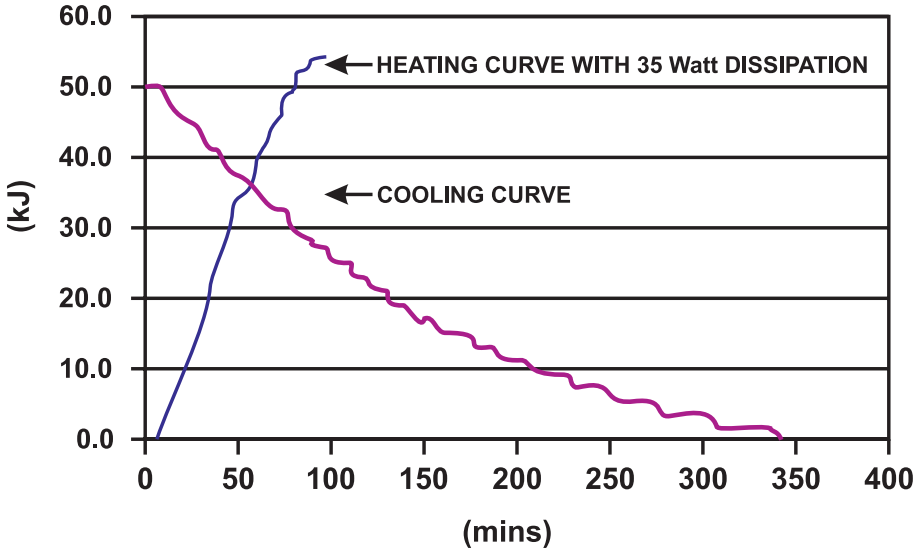

Figure A-3 : Heating and cooling curve - Product's tube inserts-OX/70-4

Mechanical Dimensions and Weight

Total Weight of System (including packing carton)	Wall Mount 15” Extension arm - 97 lbs Approx. 24” Extension arm - 102 lbs Approx. 33” Extension arm - 107 lbs Approx.
Weight of Tube Head	9.4 lbs Approx.
Support Tube Material	Aluminum
Type of painting	Glossy
Mounting type	Base Unit adapters for Wall mounted
Extended Arm Reach for Wall mount Scissor Arm.	15” Extension arm - 62” 24” Extension arm - 71” 33” Extension arm - 80”
Height of unit with Arms folded	51” ± 0.5
Support Tube Rotation about Base	180°± 10°
Scissor Arm Swing - Wall Mount	220° ± 10°
Tube Head swivel on horizontal plane	530° ± 10°
Tube Head rotation about Vertical Plane	305° ± 5°

Table A3 : Mechanical dimensions and weight

Mains Power Requirements

Line voltage range	100 - 110V / 230 - 240V AC ± 10%
Range of line-voltage regulation for operation at maximum line current	± 1% maximum at 90 VAC, 60Hz
Line frequency	Nominal: 60/50 Hz
Momentary Current (70kV, 8mA)	11A @ 100Vac and 4A @ 240Vac
Momentary power (70kV, 8mA)	1.1kVA @ 100Vac and 0.96KVA @ 240Vac
Standby Current	250mA max
Line resistance	≤ 0.4 Ohm

Inrush Current	Peak 30 A for 2ms at mains turn on
Input Power Factor	> 0.9 during any exposure
Electrical Classification	Class I, Type B
Electrical Connection	Line, Neutral and Earth (Earth is mandatory), 1-Phase

Table A4 : Mains power requirements

Environmental Conditions

Operating conditions	Temperature : +10°C to +40°C Humidity : 25% to 75% Altitude : 1500m
Conditions for transport and storage	Temperature : -30°C to +70°C Humidity : 95% non condensing Altitude : 3500m

Table A5 : Environmental conditions

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ANNEX
B

DECLARATION OF CONFORMITY

B1: Name and description of product

Medical Device Name: High Frequency Dental X-Ray System

Medical Device Model: Hatch X-Ray

Device variants:
303-00238X-0 - Hatch X-Ray X-ray with focal spot size 0.4 in wall mount configuration with Extension arm, where X= 1,2,3

B2: Following standards under which conformity is declared

ANSI/AAMI ES 60601-1: A1:2012 C1: 2009/(R) 2012 and A2:2010/(R) 2012

IEC 60601 - 1: ED 3.1 (2012)

CAN/CSA-C22 .2 No. 60601-1:14

IEC60601-1-2:2014

IEC 60601-1-3: 2008 + A1:2013

EN/IEC 60601-2-65 2012

IEC60601-2-28: 2010

CMDR SOR/98-282

B3: Marking

The products described herein are conform to the following regulatory markings

a. UL safety marking.

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ANNEX C

GUIDANCE AND MANUFACTURER'S DECLARATION

According to: IEC 60601-1-2: 2014 (4th edition)

(Group 1, class A, for use in Hospitals) (Not LIFE-SUPPORTING)

Hatch X-Ray is tested as per applicable IEC standards, to be used under electromagnetic environment specified below. The customer or the user of Hatch X-Ray should assure that it is used in such an environment.

Guidance and manufacturer's declaration – Electromagnetic emissions – For all EQUIPMENT and SYSTEMS

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions IEC 60601-1-2:2014 CISPR 11:2010/ EN55011	Group 1	Hatch X-Ray uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions IEC 60601-1-2:2014 CISPR 11:2010/ EN55011	Class A	Hatch X-Ray suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 60601-1-2:2014 IEC 61000-3-2:2009	Class A	
Voltage fluctuations / flicker emissions IEC 60601-1-2:2014 IEC 61000-3-3:2013	Complies	

Table C1 : Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Guidance and manufacturer's declaration – Electromagnetic immunity – For all EQUIPMENT and SYSTEMS

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 60601-1-2:2014 IEC 61000-4-2:2008	±8 kV contact-Direct ±8 kV contact-Indirect ± (2, 4, 8, 15) kV air	±8 kV contact-Direct ±8 kV contact-Indirect ± (2, 4, 8, 15) kV air	Floors should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 60601-1-2:2014 IEC61000-4-4:2012	±2 kV for power supply lines 100kHz repetition frequency ±1 kV for Signal lines 100kHz repetition frequency	±2 kV for power supply lines 100kHz repetition frequency ±1 kV for Signal lines ±1 kV for Signal lines 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 60601-1-2:2014 IEC 61000-4-5:2005	± 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 60601-1-2:2014 IEC 61000-4-11:2004	0% UT for 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle At 0° 70% UT for 25/30 cycle At 0° 0% UT for 250/300 cycle	0% UT for 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle At 0° 70% UT for 25/30 cycle At 0° 0% UT for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Hatch X-Ray Variants requires continued operation during power mains interruptions, it is recommended that the Hatch X-Ray be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 60601-1-2:2014 IEC 61000-4-8:2009	3 A/m 50Hz OR 60Hz	3 A/m 50Hz OR 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table C2 : Guidance and Manufacturer's Declaration – Electromagnetic Immunity – For all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – Electromagnetic immunity – For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 60601-1-2:2014 IEC 61000-4-6:2013	3V, 6V 150 kHz to 80 MHz	3V, 6V 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Hatch X-Ray, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 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).

Radiated RF IEC 60601-1-2:2014 IEC 61000-4-3:2010	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	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. Interference may occur in the vicinity of equipment marked with the following symbol: 

Table C3 : Guidance and manufacturer's declaration – Electromagnetic immunity - for all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

NOTE

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

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects 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 Hatch X-Ray is used exceeds the applicable RF compliance level above, the Hatch X-Ray should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Hatch X-Ray

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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ANNEX
D

CONTACT DETAILS

Hatch X-Ray	**Hatch GROUP INC** 4181 Sladeview Crescent, Unit #36 Mississauga, Ontario, Canada L5L 5R2 Office Number: (905) 997-7171

HATCH GROUP INC

4181 Sladeview Crescent Unit # 36, Mississauga, Ontario, Canada L5L 5R2

OPERATING MANUAL; PART NO.: 515-004627-0 REV. 01