This document is applicable to the following variants of the product those are grouped on the basis of X-Ray tube used. Variants, with in the group, are classified based on the mechanical configuration, mounting and electrical socket types.

RAYOS DC Variants with X-Ray Tube Nominal Focal Spot Size 0.4

Product	Part Number
RAYOS DC 0.4FS, Wall Mount Scissor Arm with 15” support Tube.	303-000134-80
RAYOS DC 0.4FS, Wall Mount Scissor Arm with 24” support Tube.	303-000134-81
RAYOS DC 0.4FS, Wall Mount Scissor Arm with 33” support Tube.	303-000134-82
RAYOS DC FS04, Floor Stand with Scissor Arm	303-000134-83

Table 1: Product Variants

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1 Introduction

This manual is organized to help you make the best out of your *RAYOS DC* high frequency Intra-Oral X-Ray unit.

1.1 Your X-Ray Equipment

RAYOS DC is a high frequency Intra-Oral X-Ray System with an extra-oral X-Ray source for dental diagnostic radiography. The system houses two microprocessors, one for control / supervisory functions and another for man-machine/user interface. The technology incorporates feedback circuits to ensure accuracy & reproducibility of X-Ray output.

Product Variants:

RAYOS DC has the following variants with various mechanical configuration, mounting, electrical socket types & X-Ray tube focal spot size.

a) Wall mount, Scissor Arm with horizontal support tube & Floor stand without support tube.

b) Long cone, long Arm (horizontal support tube) options.

c) Electrical socket to suit India, Europe and US with detachable Power cords.

d) X-Ray tube with nominal focal spot sizes of 0.4mm.

1.2 Indication for Use

The *RAYOS DC* Intraoral Dental X-Ray system is to be used as an extra-oral source of X-Rays in Dental radiography.

1.3 This Manual

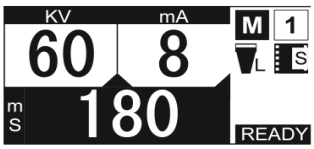
This manual contains basic operational instructions, identification of parts, system labels and troubleshooting tips. Safety tips to prevent unwanted X-Ray exposures are provided in chapter 2 Safety and Precautions.

Federal laws prohibits the sale of this device to an individuals other than trained professionals, use of this device other than as described in this manual may results in injury.

The following are guidelines for using this manual.

This symbol invites the attention of the reader to observe caution while operating the unit since they are related to safety.

This symbol points to an important detail / tip in the operation of the unit.



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.

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2 Safety and Precautions

1. Please read this section carefully. It contains important safety related instructions.
2. The owner of this Diagnostic X-Ray system shall not modify any components of the system since this may result in violation of compliance to the standards. Chicago X-Ray shall not be responsible for any such modification causing violation of compliance, compromise on safety, performance deterioration or any other adverse effects.
3. 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 an unauthorized personnel.

2.1 General Safety Tips

Radiation Safety

This X-Ray equipment may be dangerous to the patient and the operator unless safe exposure parameters and operating instructions are followed.

- Follow proper X-Ray radiation safety rules:
- Do not allow non-prescribed exposures.
- The system should be used only by dentists or trained & qualified dental technicians.
- Always point the X-Ray port at the area to be imaged.
- Patients should be provided with lead apron and thyroid collar while being exposed.
- The operator should wear proper X-Ray shielding aprons.
- The operator should be at a distance of at least 2 meter away from the tube head while carrying out the procedure.
- The operator should not be standing in the direction of the X-Ray. The operator should stand away from the X-Ray beam and behind the tube head.

Electrical Safety

Always switch off the unit and remove the mains plug when cleaning and disinfecting the unit.

The unit contains lethally high voltages. Do not attempt to open covers or repair the unit yourself or using non-certified service personnel. Contact your authorized dealer.

This is an ORDINARY MEDICAL EQUIPMENT without protection against ingress of liquids. Water or any other liquid should be prevented from leaking into the equipment, as they may cause short circuit and/or corrosion.

Mechanical Safety	Where complete safeguarding of the equipment is not possible, due care must be taken to ensure that no part of the user's or patient's body or clothing can be trapped or injured by any part of the equipment. In particular, make sure that fingers are not caught or pinched during scissor arm movement.
Electromagnetic Interference	This equipment complies with EMI regulations. Interference between the unit and other sensitive electronics can occur under extreme conditions. Do not use the X-Ray equipment in close conjunction with other sensitive devices or devices which create high electromagnetic disturbance.
Physical Injury	Exercise caution when operating the mechanical suspension arm. Since the arm mechanism allows free movement with minimal force, an inadvertently swinging arm can cause injuries. The swinging joints on the arm are potential pinch points. Exercise caution while operating the arm
Installation and Service	Ensure that your X-Ray unit is assembled and installed inside a Hospital or clinic building, which complies with all applicable laws and recommendations concerning electrical safety. Installation should be done by an authorized service engineer only. Consult the factory or your dealer for installation of the unit. Take the services of qualified personnel when relocating the unit.
Explosion Safety	1. This equipment must not be used in the presence of flammable or potentially explosive disinfecting gases or vapours, which could ignite causing personal injury and/or damage to the equipment. If such disinfectants are used, the vapour must be allowed to disperse before using the equipment. 2. This equipment is not suitable for use in presence of anesthetic gases.
Floor Stand System	Care must be taken for the movement and positing of the floor stand system. The floor stand system is meant for limited movement inside the clinic and is not suitable for mobile applications. The system must be disconnected from the main power before moving. Before moving the floor stand system around, the system must be folded to avoid unnecessary damage to the system. The wheel locks should be unlocked before moving the system. After the system is placed at the desired location, the wheel locks should be put in lock position. This equipment is meant for limited movement with in Clinic or hospital room. Adequate care should be taken while moving on ramp or on an uneven surface.
	Scissor arm can open out during movement of the unit which may cause injury to persons/patient standing close to the equipment. It is strongly recommended to lock the movement of the scissor arm in folded condition while moving.

2.2 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.

Protective Earth

Mains Earth is required for continued protection against shock hazards.

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.

Focal Spot

Mains Line Connection

Mains Neutral Connection

WEEE Symbol

Follow proper procedures for disposing this equipment. Cannot be disposed as general waste.

X-Ray Emission /ON

Follow Instructions for use.

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3 Know Your X-Ray Unit

3.1 Package Contents

RAYOS DC X-Ray system consists of the following major components. Ensure that these are identified during handover by the installation personnel.

- X-Ray Tube Head
- Base Unit
- Control console with cable
- Support Tube (for wall mount)
- Scissor Arm/Single Arm
- Long Cone (if purchased)
- Mains cord with plug compatible to your local regulations
- I Column (for floor stand)
- Casted Base (floor stand)

3.2 Identification of Main Parts

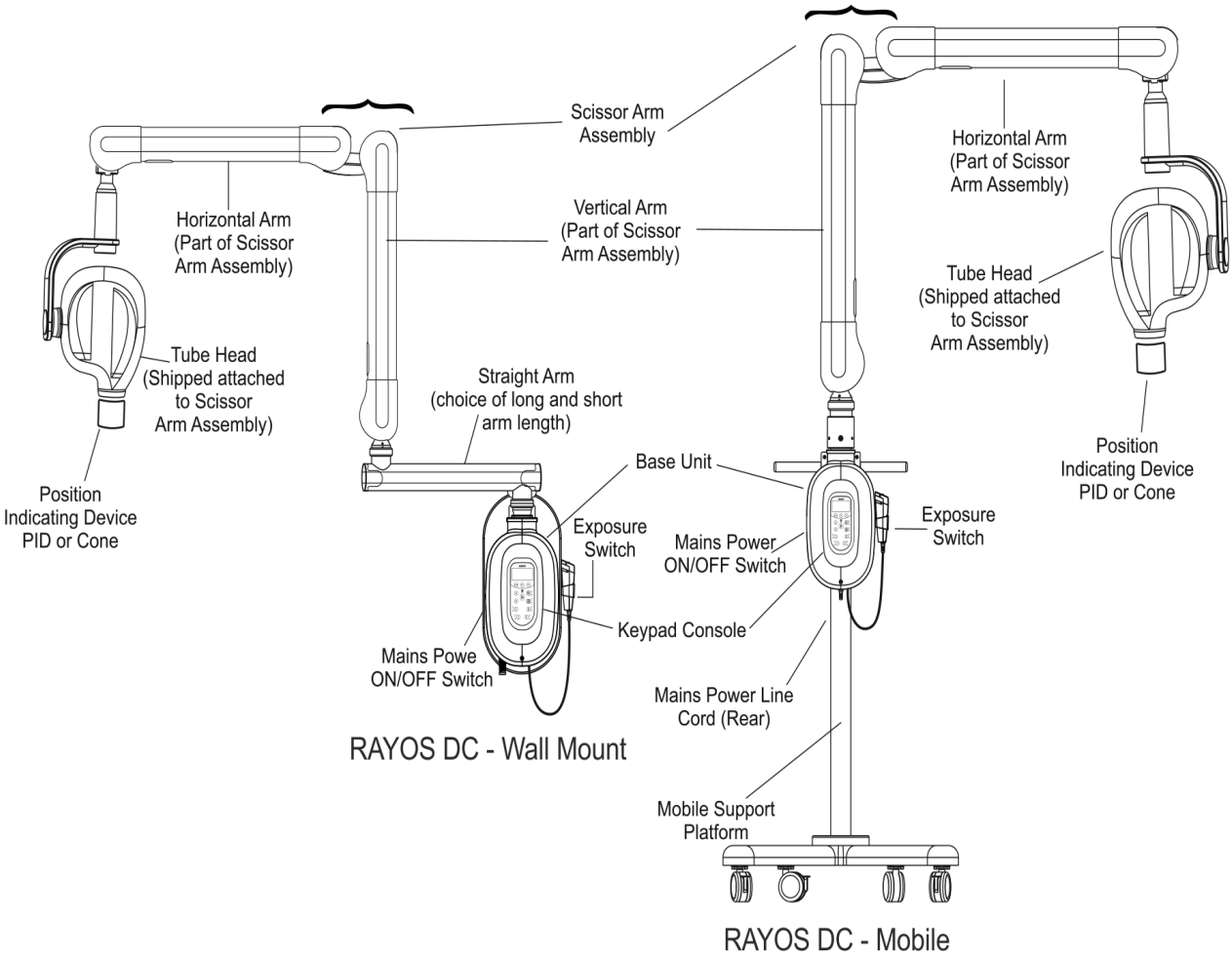


Illustration 1: Identification of Main Parts (Floor Stand (Mobile) & Wall Mount)

3.3 System Labels

This section lists the labels that are affixed on the unit. Please refer to Illustration 24: Label Location (Wall Mount)and Error: Reference source not found for the location where they are affixed. The mark number is given against each label below.

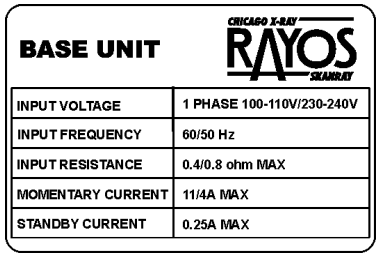


Illustration 2: Base Unit Label (# 1)

Illustration 3: Angular Tape (# 21)

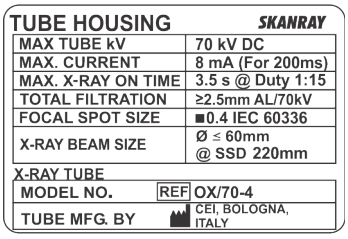


Illustration 4: Tube Housing label for focal spot 0.4 (# 3)

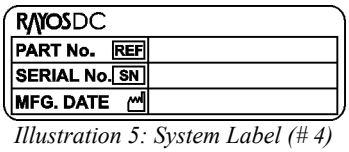


Illustration 5: System Label (# 4)

Illustration 6: Name Label on Base Unit (# 5)

Illustration 7: Skanray Logo (# 6)

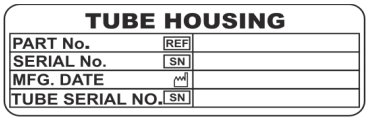


Illustration 8: Tube Housing Sl. No. Label (# 2)

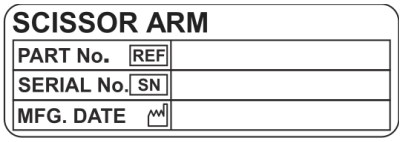


Illustration 9: Scissor Arm Label (# 8)

Illustration 10: Manufacturer Label (# 9)

Illustration 11: Support Tube Label (# 10)

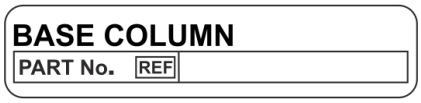


Illustration 12: Base Column Label (# 11)

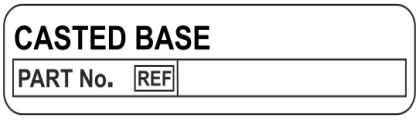


Illustration 13: Casted Base Label (# 12)

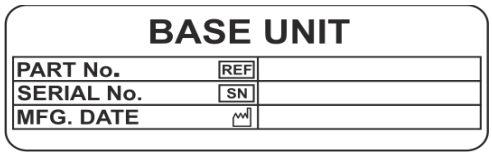


Illustration 15: Base Unit Sl. No. Label (# 15)

Illustration 17: Warning Label (# 17)

Illustration 20: 3rd Ed-UL Mark Label (# 14) (Proposed)

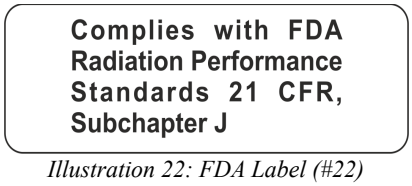


Illustration 22: FDA Label (#22)

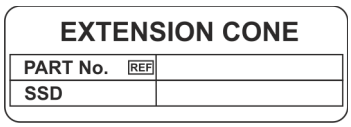


Illustration 14: Extension Cone label (Optional) (# 13)

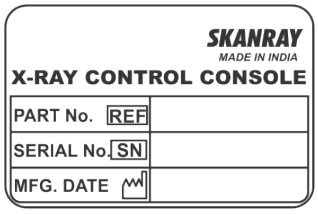


Illustration 16: Console Label (# 16)

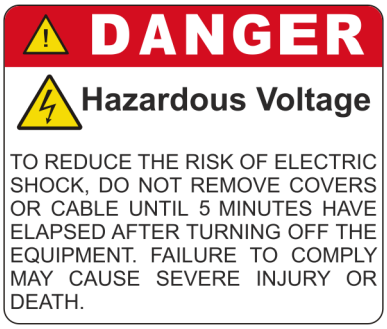


Illustration 18: Danger Label (# 18)

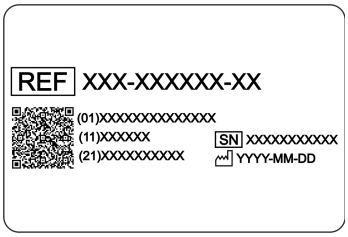


Illustration 19: Radiation Caution Label (#24)

Illustration 21: Radiation Caution Label (#23)

Illustration 23: CE Marking Label (# 7) (Proposed)

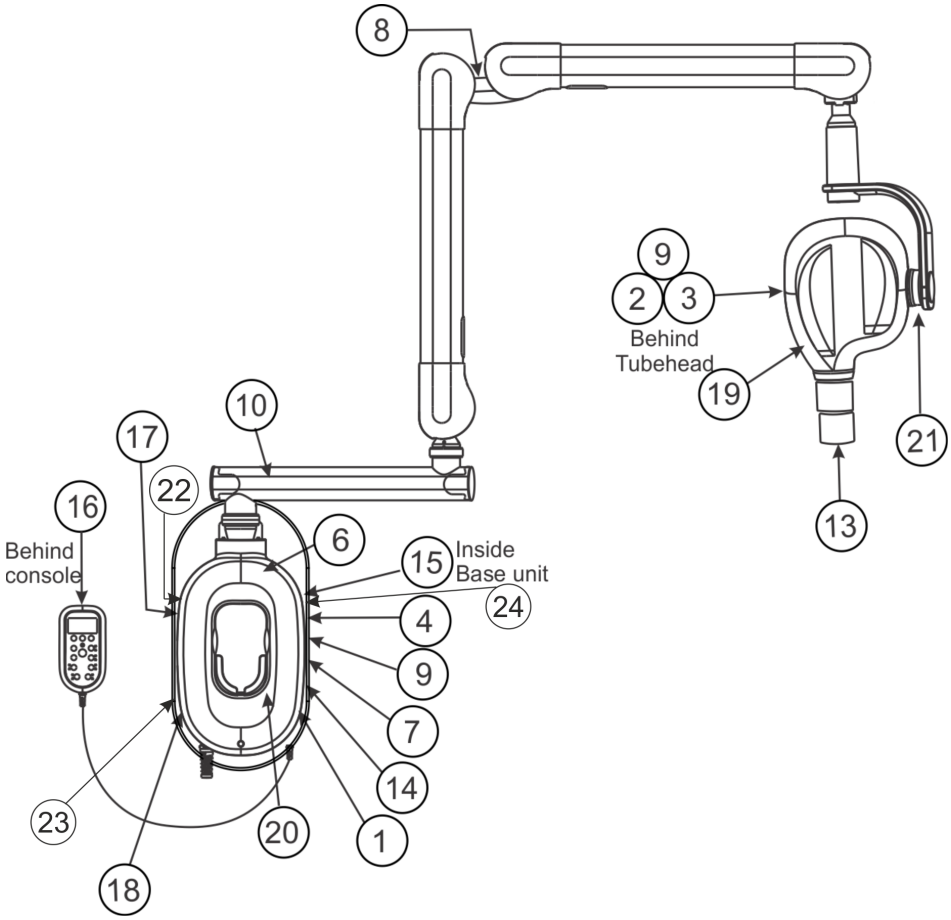


Illustration 24: Label Location (Wall Mount)

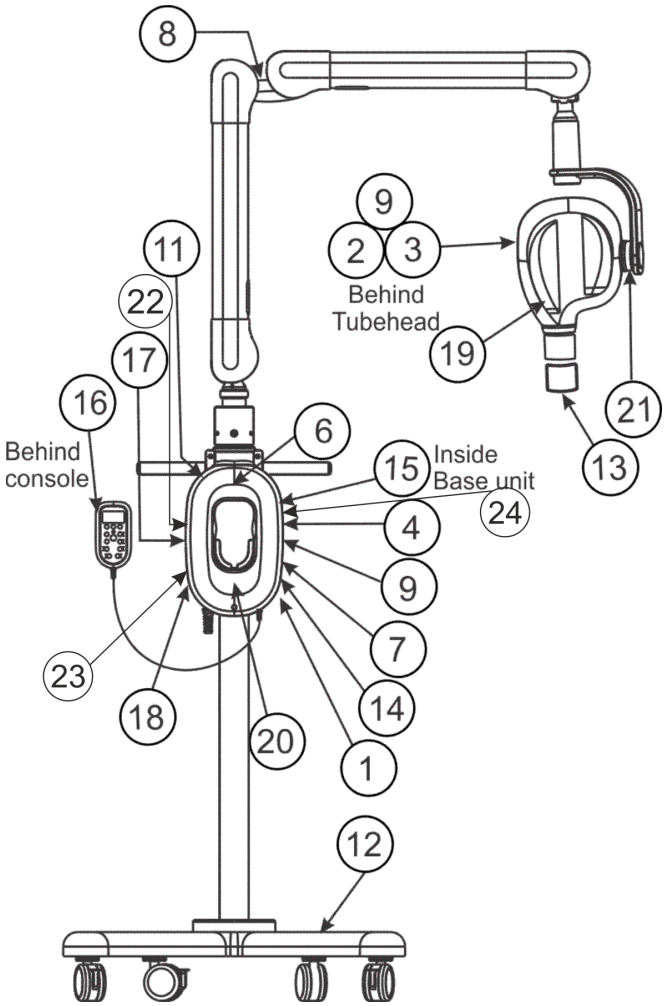
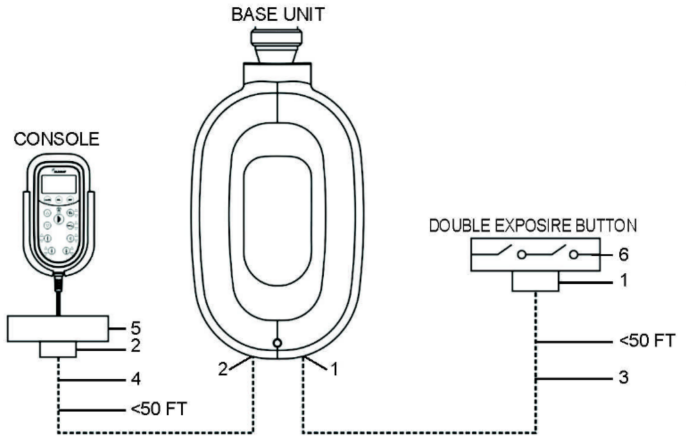


Illustration 25: Label Location (Floor Stand)

3.4 Fixed control panel

(contains a possibility to make "double exposure button" assembly)



SL NO.	MANUFACTURER	PART NO.	DESCRIPTION	CRIMPING TOOL
1	MOLEX or EQUIVALENT	90075-0027 or EQUIVALENT	4P4C MALE RJ11	69008-1120 [MOLEX or EQUIVALENT]
2	MOLEX or EQUIVALENT	90075-0031 or EQUIVALENT	6P6C MALE RJ11	69008-1122 [MOLEX or EQUIVALENT]
3	GENERIC	GENERIC	4 WIRE TELEPHONE CORD	NA
4	GENERIC	GENERIC	6 WIRE TELEPHONE CORD	NA
5	GENERIC	GENERIC	JUNCTION (EXTENSION) BOX 6P6C FEMALE TO FEMALE	NA
6	GENERIC	GENERIC	JUNCTION (EXTENSION) BOX 4P4C FEMALE TO FEMALE	NA

External Dead Man Switch (Item 3): The Cable is 1:1 4P4C connector and Dead man Switch is connected between Pin 2 and 4 (Centre Pins). For Extending the Dead Man Switch use 4P4C Extender Box (Item 5).

External Console Interface (Item 4). The cable is 1:1 6P6C connector. For Extending the Console use 6P6C Extender Box (Item 5).

3.5 Control console

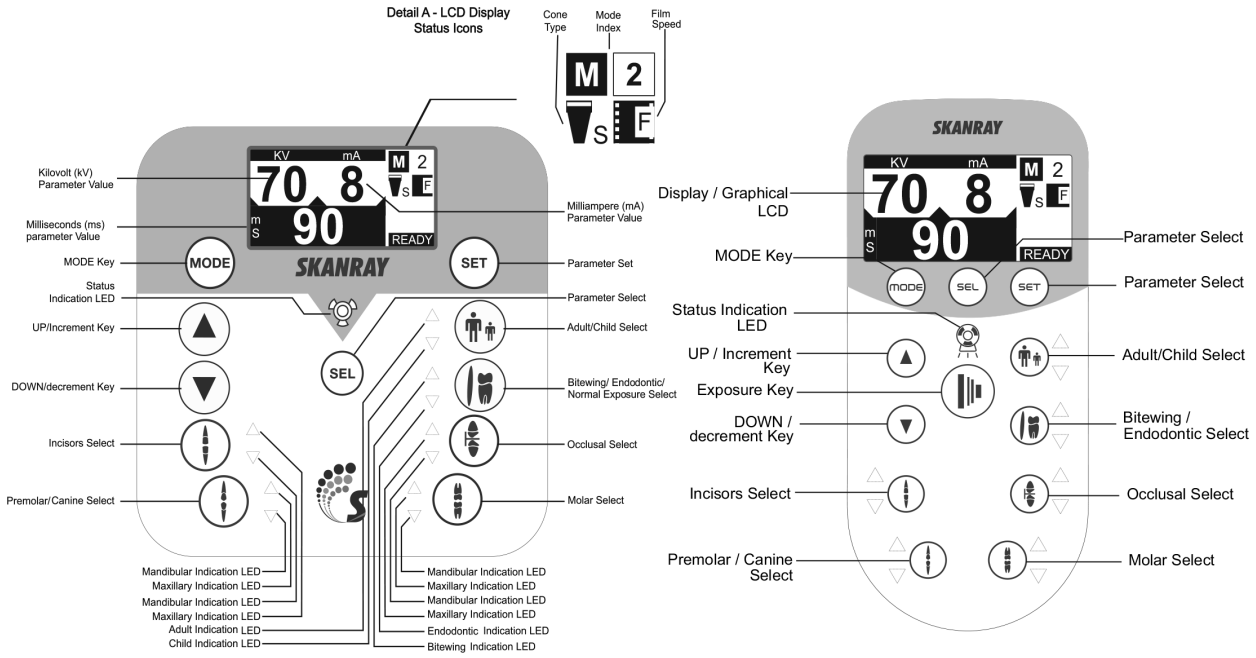
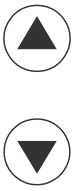
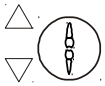


Illustration 26: Control console

3.5.1 Keypad

In addition to the LCD display, the control console contains 12 keys, exposure indication LED and an audible fixed alarm. These keys are primarily used to select the exposure parameters and to deliver an exposure. *RAYOS DC* simplifies the process of selecting exposure parameters using pre-programmed pre-sets for every combination of image receptor, patient age and tooth anatomy.

	Exposure Status LED Indicator Off : Idle / Standby Green : Ready to deliver X-Ray Orange : Exposure in progress Red : Fault Audible fixed alarm sound pressure:55-65dbA.
	Exposure / Prep Key
	UP / DOWN Keys Move up or down a list menu. Increment or decrement parameter value.
	MODE key Select the exposure pre-set appropriate for the image receptor used.
	SET key Accept change in the selected parameter. Use the highlighted item in a list menu.
	SEL key Select the parameter to be modified.
	Adult / Child Pre-set key Toggle between Adult or Child pre-set. Top LED : Adult Bottom LED : Child
	Bitewing / Endodontic Pre-set key Toggle between Bitewing / Endodontic / normal exposure pre-set. Top LED : Bitewing Bottom LED : Endodontic Both LEDs off : Normal exposure
	Occlusal Pre-set key Top LED : Maxillary Bottom LED : Mandibular
	Molar Pre-set key Top LED : Maxillary Bottom LED : Mandibular
	Premolar / Canine Pre-set key Top LED : Maxillary Bottom LED : Mandibular
	Incisor Pre-set key Top LED : Maxillary Bottom LED : Mandibular

3.5.2 Display

The LCD display on the control console offers a user interface, displaying the selected exposure parameters along with many other user-friendly features. This section describes the screen components of the home

screen.

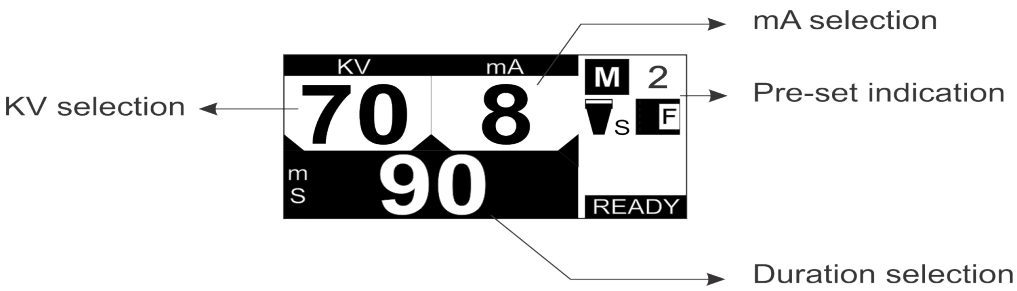


Illustration 27: Display-Overview

Illustration 28: Status Icons

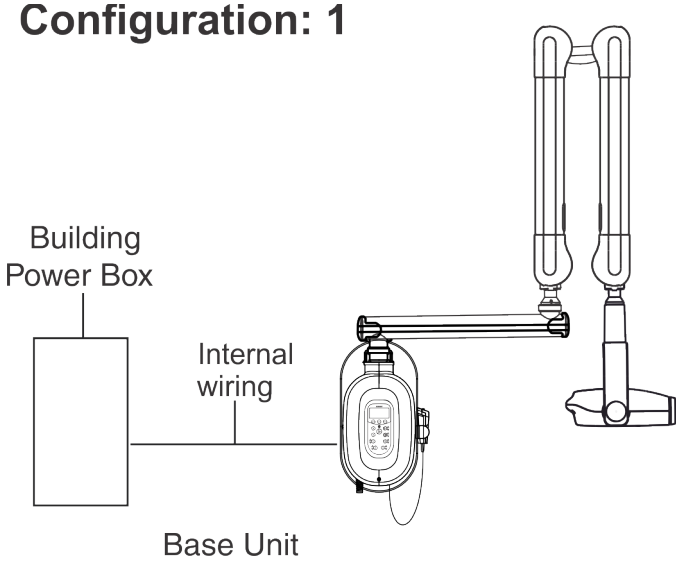
3.6 Console configurations

NOTE

(For Configurations 2 - 7)

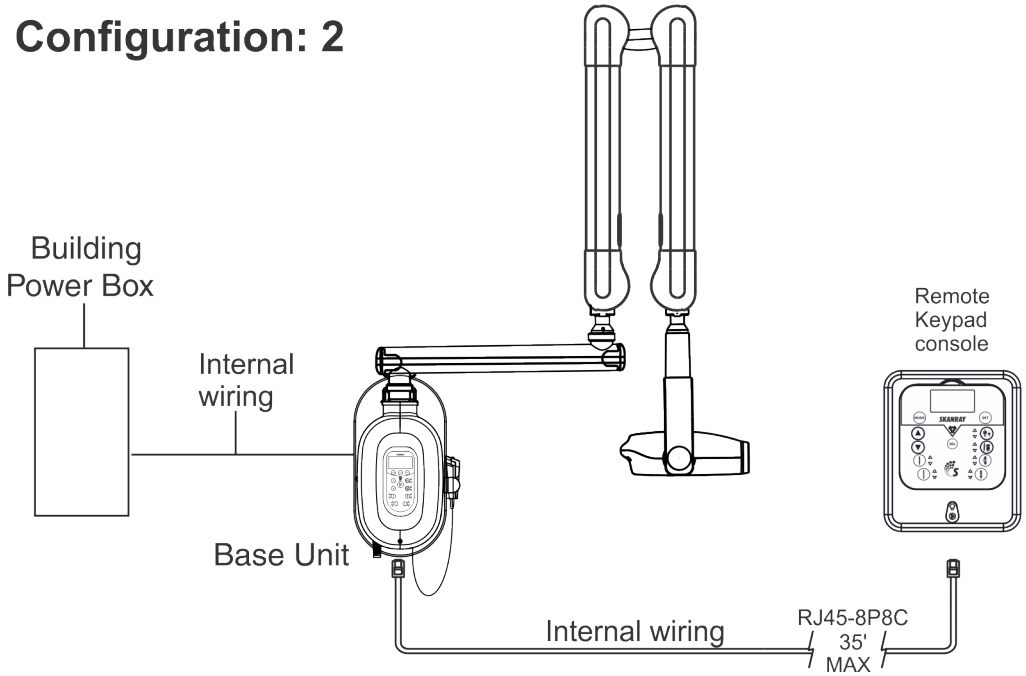
1. *RJ45-8P8C 35' Cable: CAT-5 24AWG 4-Twisted Pair 1:1 Connection.*
2. *RJ11-6P4C 35' Cable: Center 4 Positions Populated 1:1 Connection.*
3. *3Wire, 35' Cable: Shielded or Un-shielded Cable AWG 20-28.*

Configuration: 1



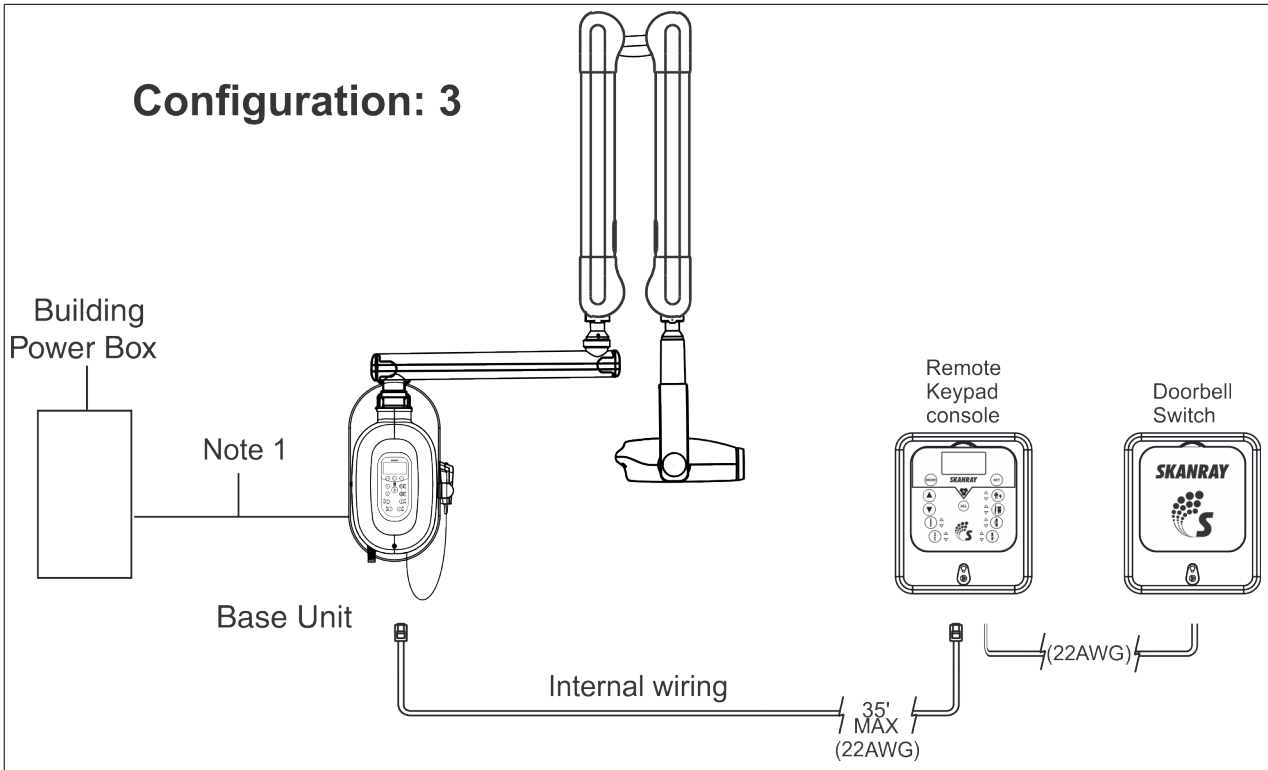
Can use Internal Keypad Console and Internal Exposure Switch

Configuration: 2

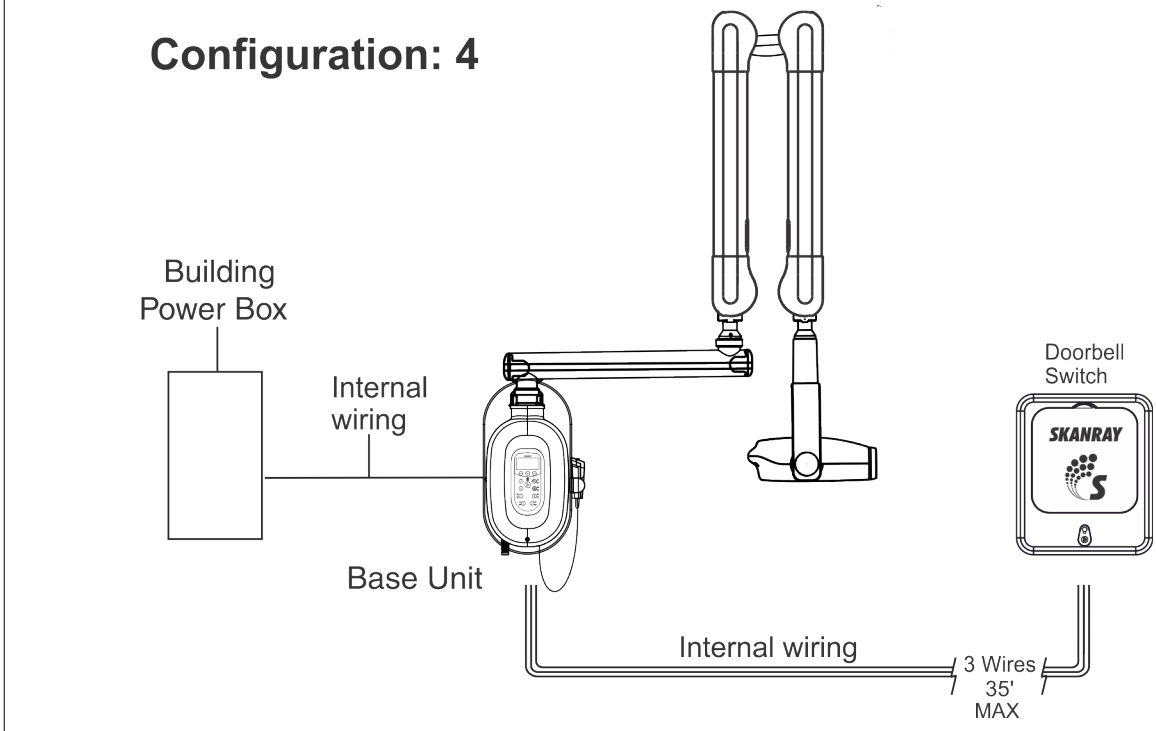


RJ45 (8P8C) with single door bell switch (Optional)

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

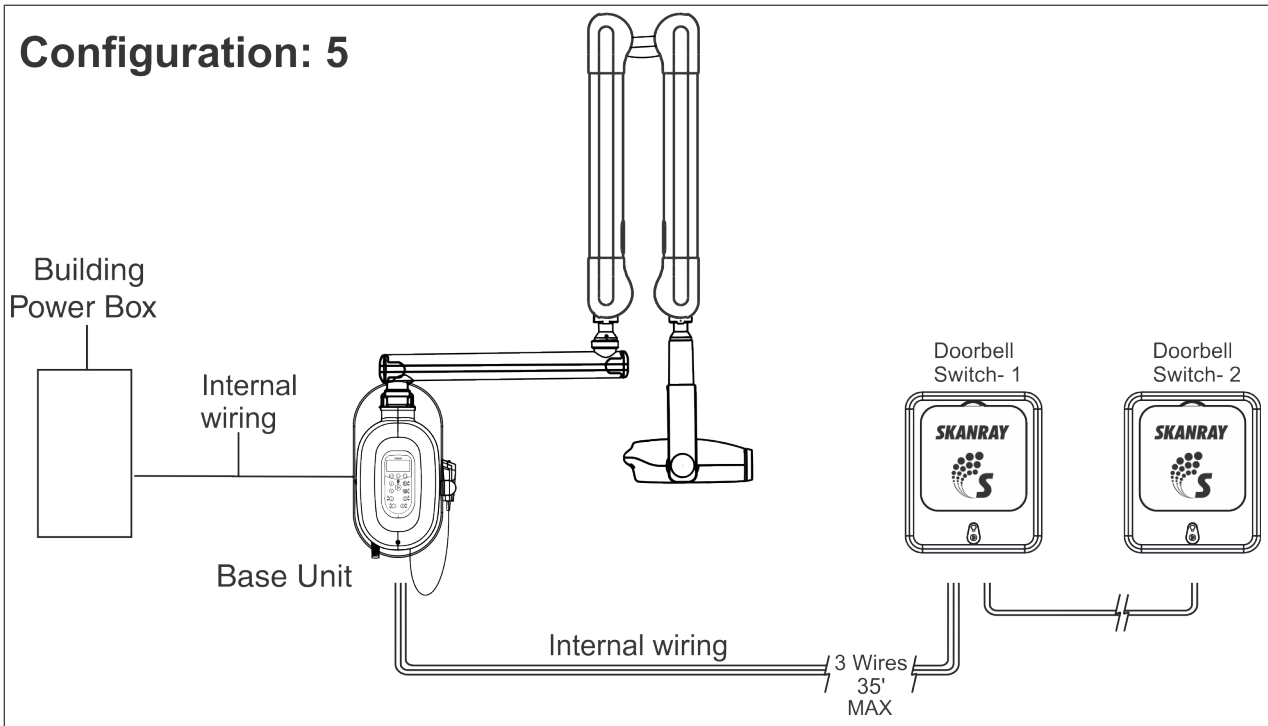


RJ45 (8P8C) with DOUBLE DOORBELL SWITCH (Optional)
Can use both Keypad Consoles (internal and remote) with Internal Exposure Switch and double door bell switch



3 WIRE WITH SINGLE DOORBELL SWITCH (Optional)
Can use Internal Keypad Console with Internal Exposure Switch and single door bell switch

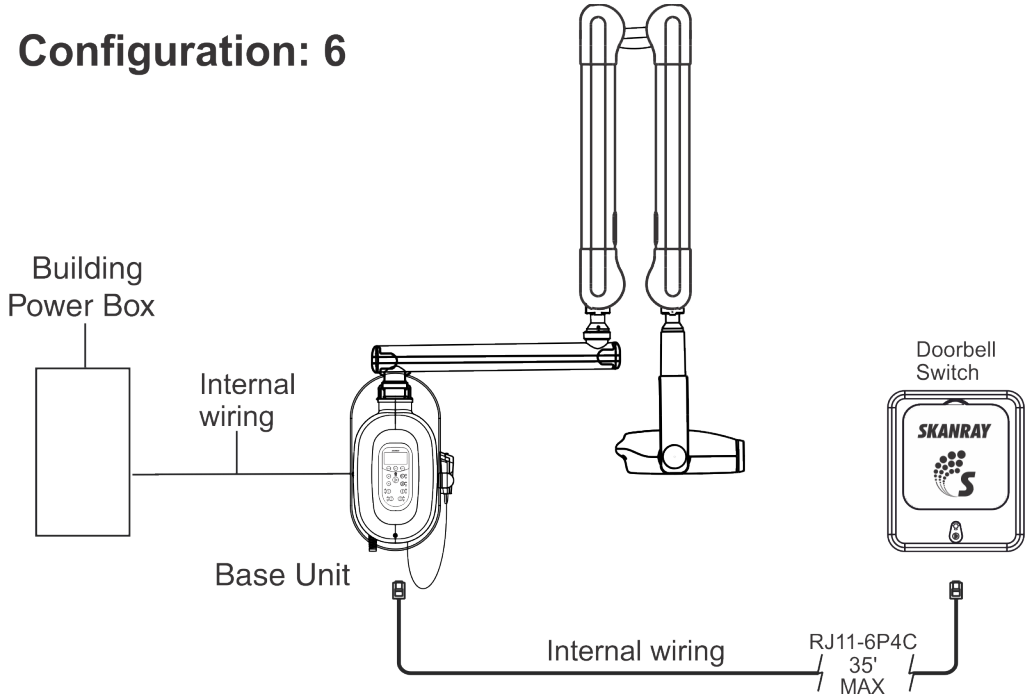
Configuration: 5



3 WIRE WITH DOUBLE DOORBELL SWITCH (Optional)

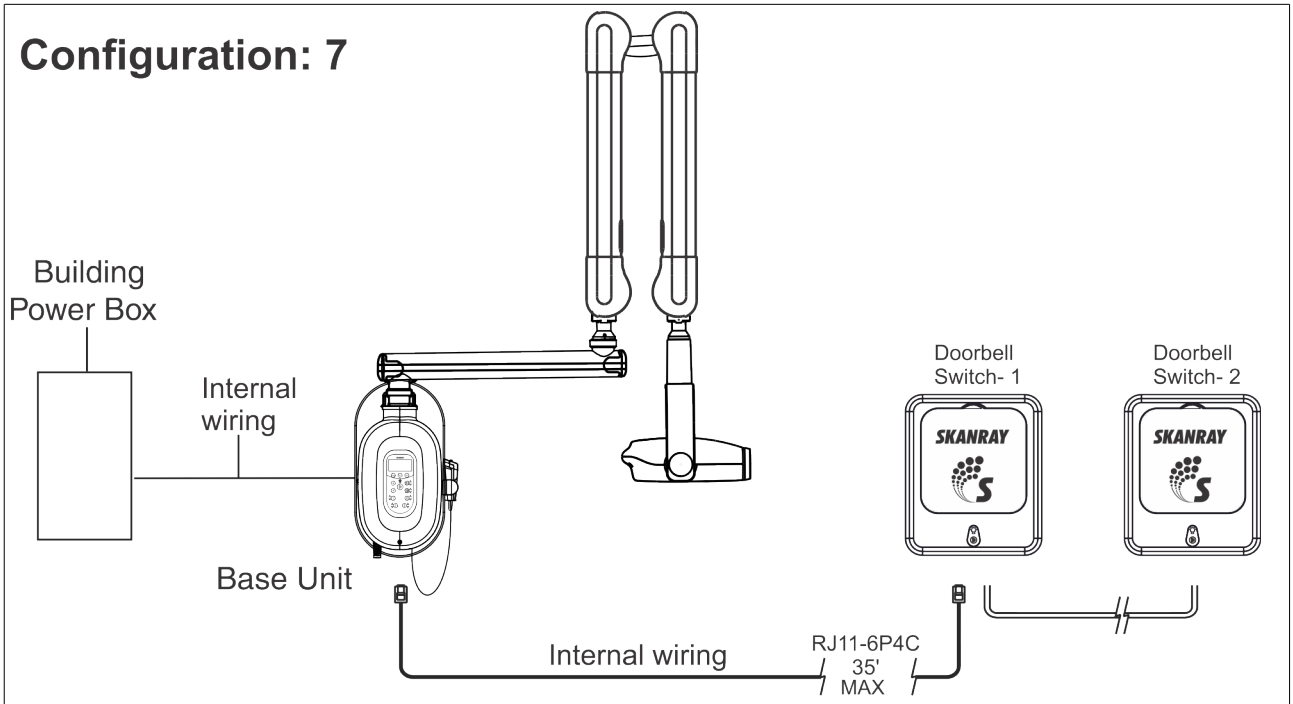
Can use Internal Keypad Console with Internal Exposure Switch and double door bell switch

Configuration: 6



RJ11 (6P4C) WITH SINGLE DOORBELL SWITCH (Optional)

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

3.7 Mechanical Dimensions and Movements

15“ Support Tube

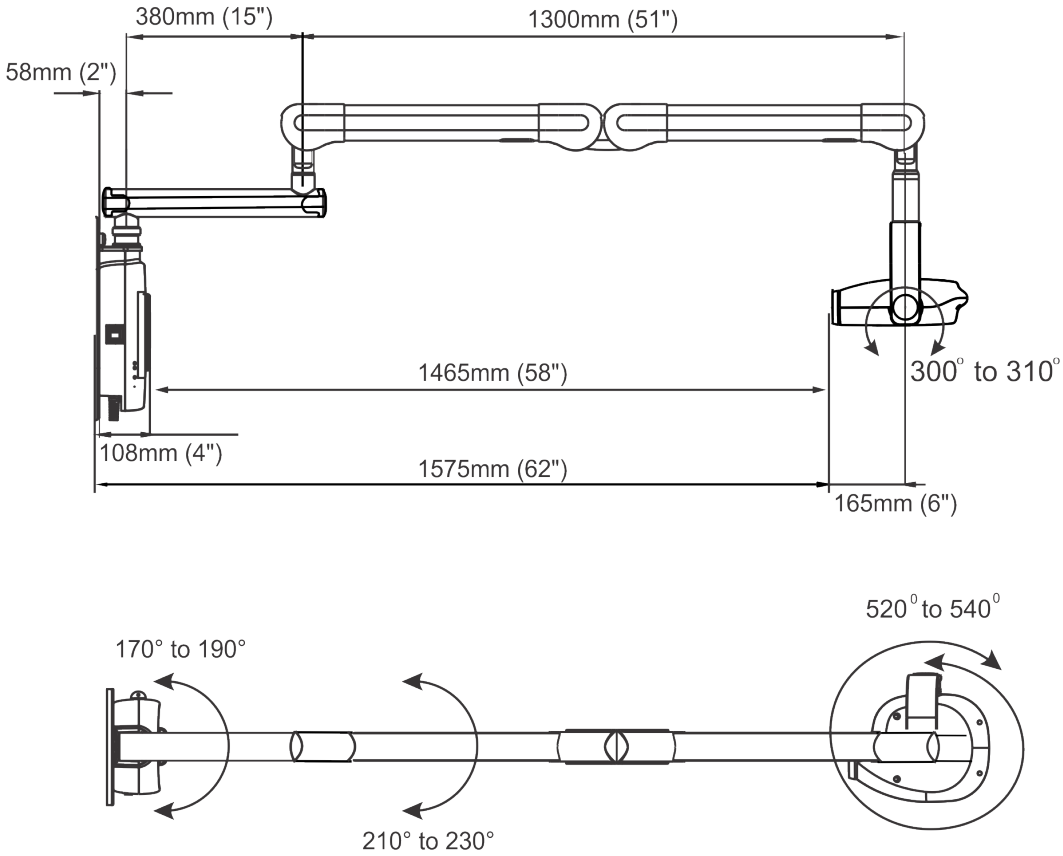
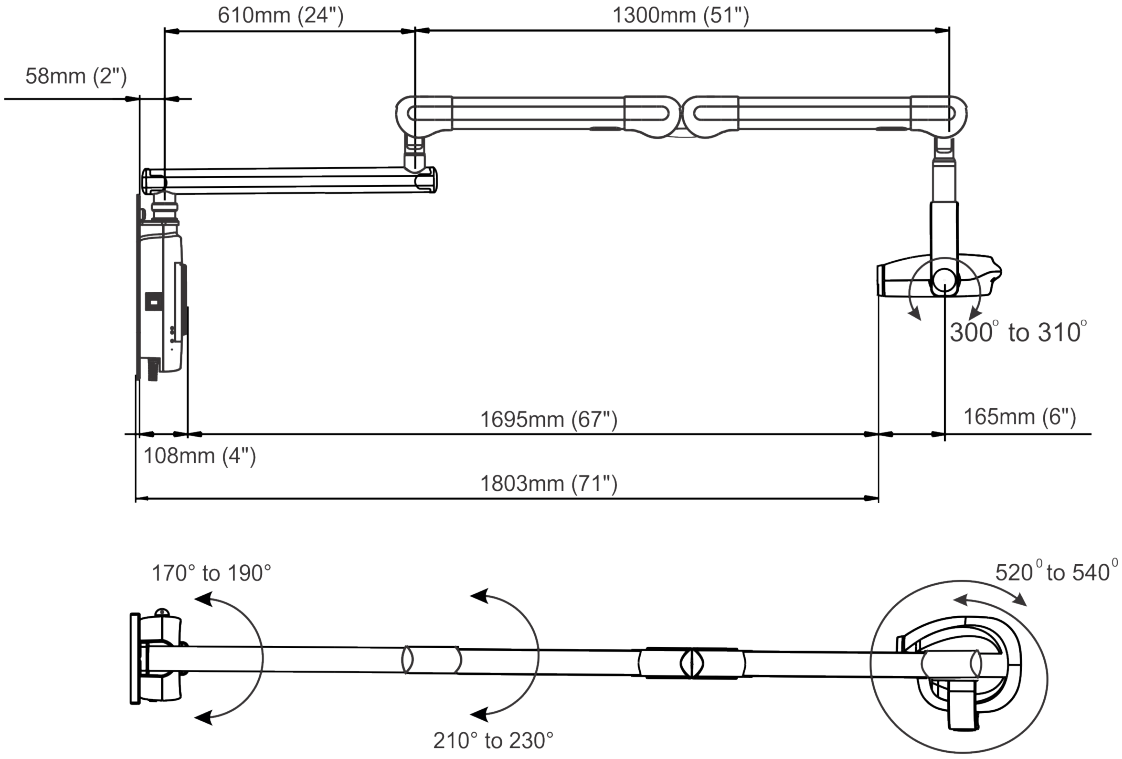


Illustration 29: Right Side and Top views (Wall mount 15” Support Tube)

24“ Support Tube



33“ Support Tube

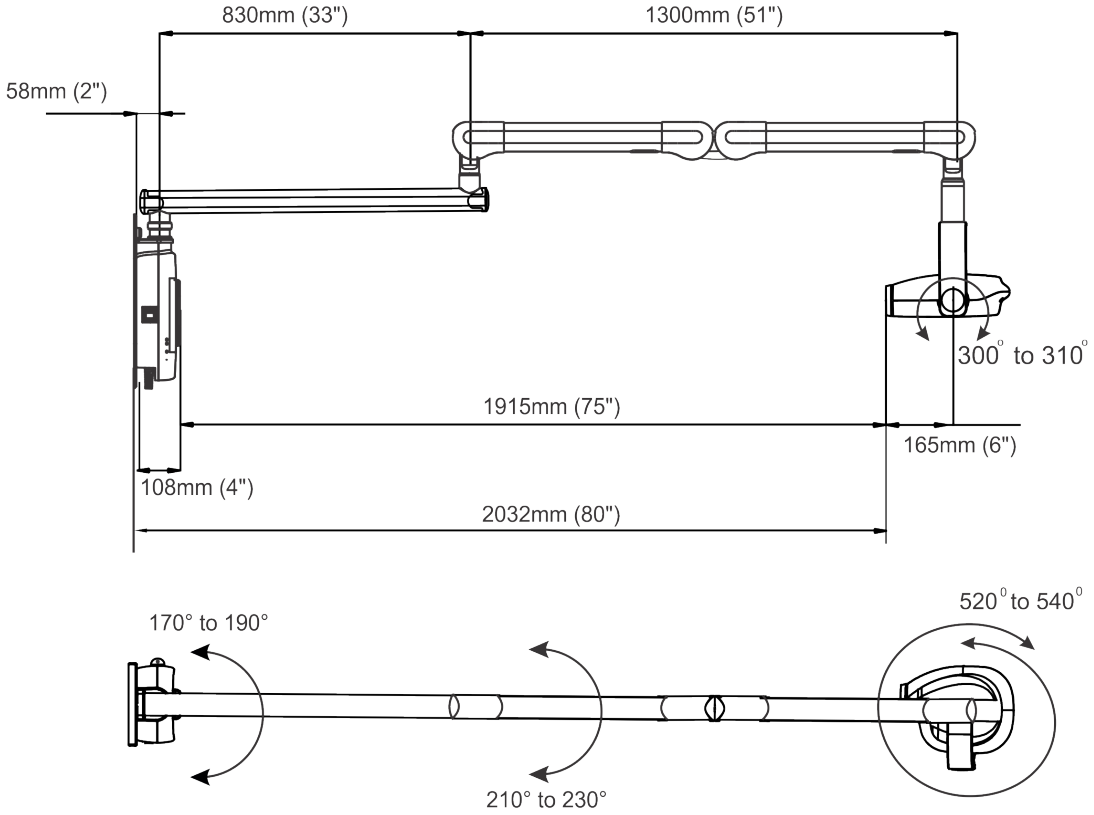


Illustration 30: Right Side and Top views (Wall mount 24”/33” Support Tube)

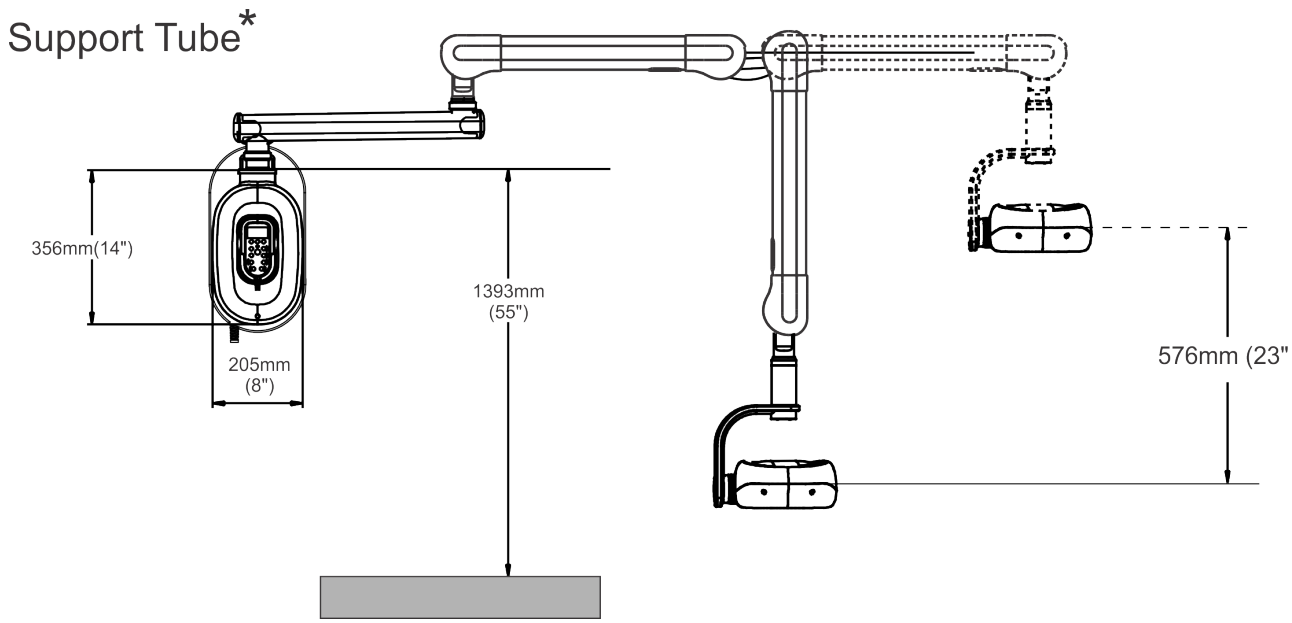


Illustration 31: Wall Mount – Ground Clearance (Wall mount)

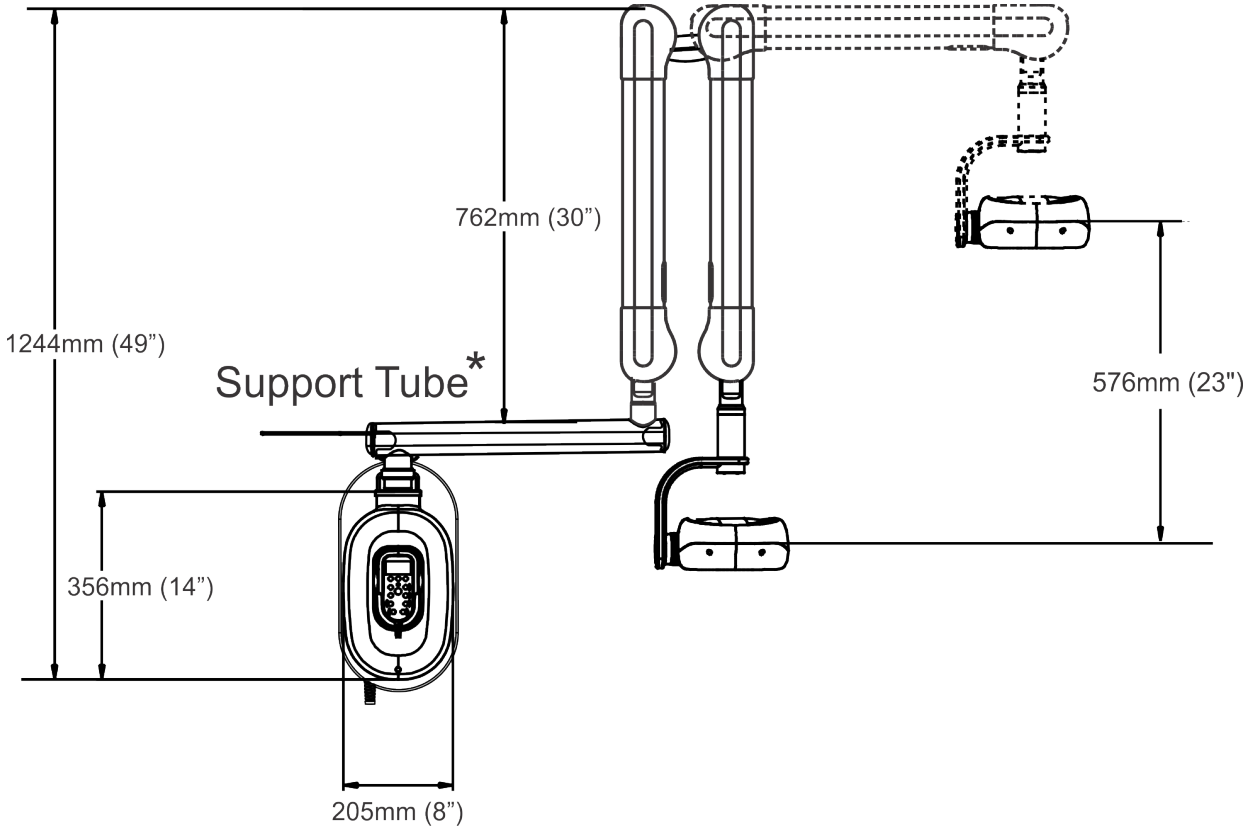


Illustration 32: Scissor Arm-Folded and Vertically Extended

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

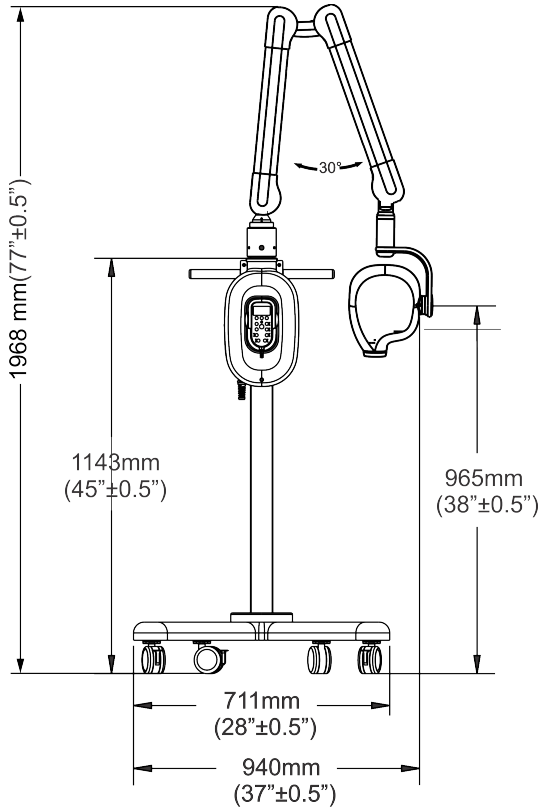


Illustration 33: Front View(Floor Stand)

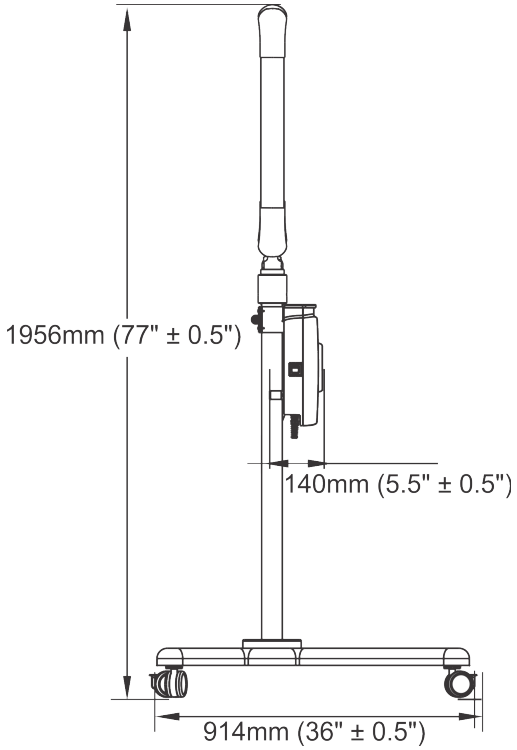
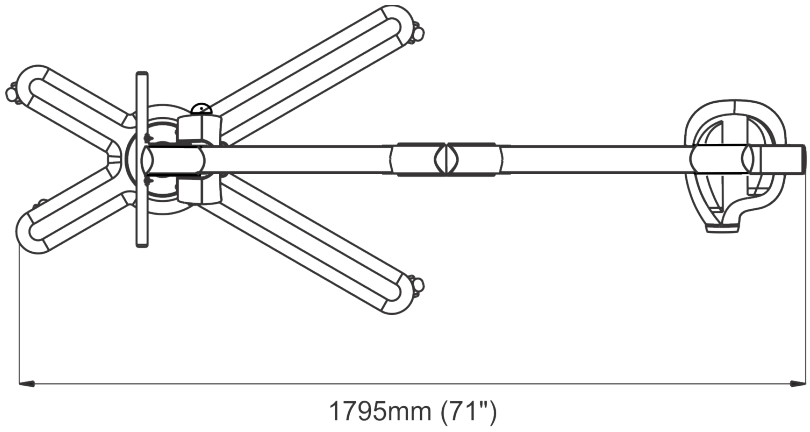


Illustration 34: Right Side View(Floor Stand)



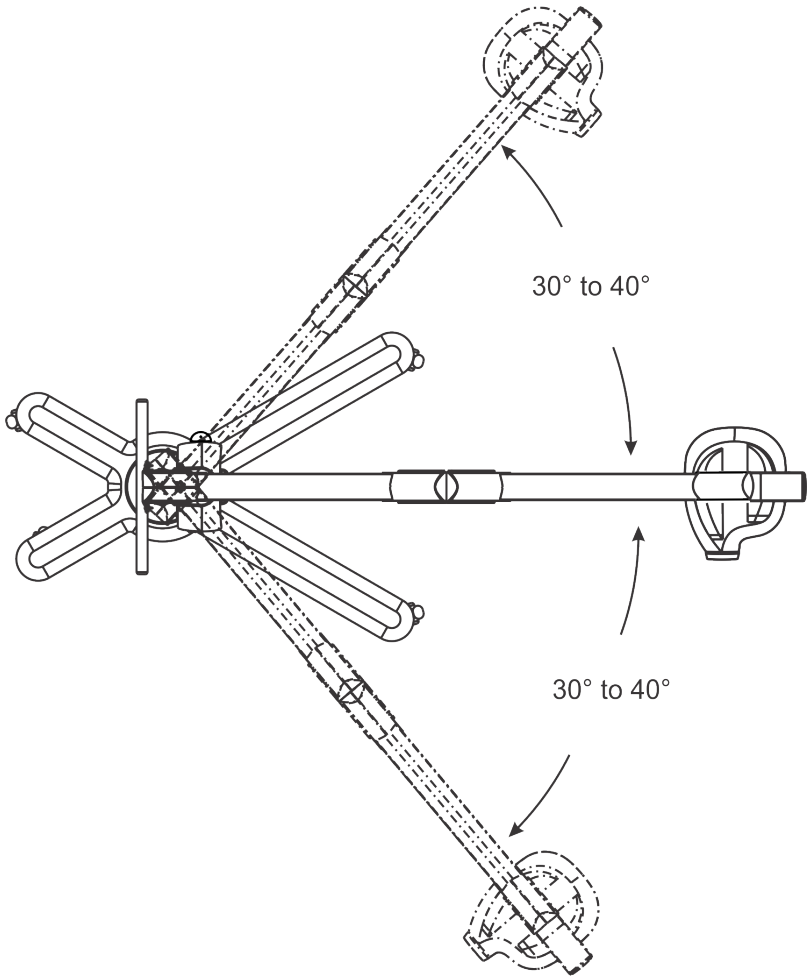


Illustration 35: Top View: Arm reach and Sweep Angle(Floor Stand)

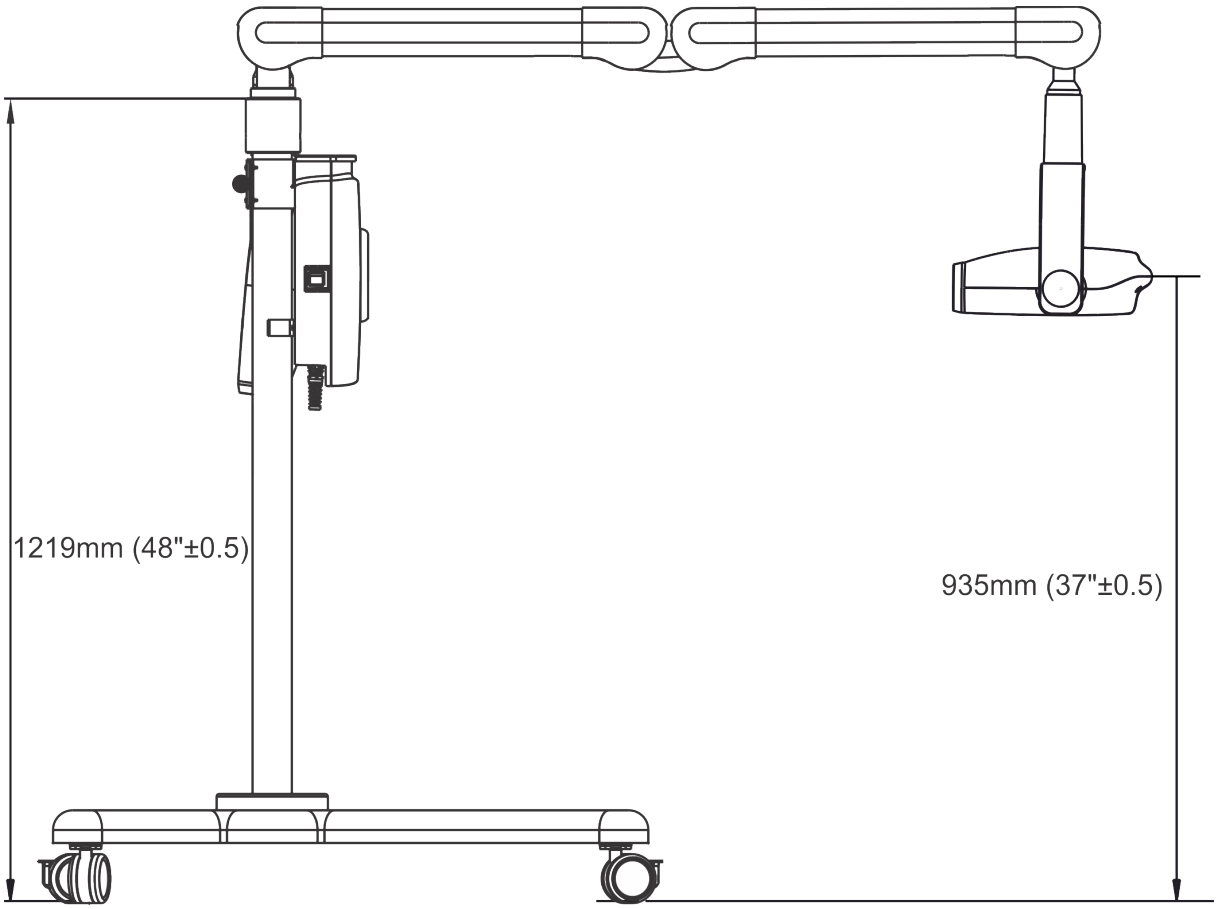


Illustration 36: Right Side View-Arm Extended(Floor Stand)

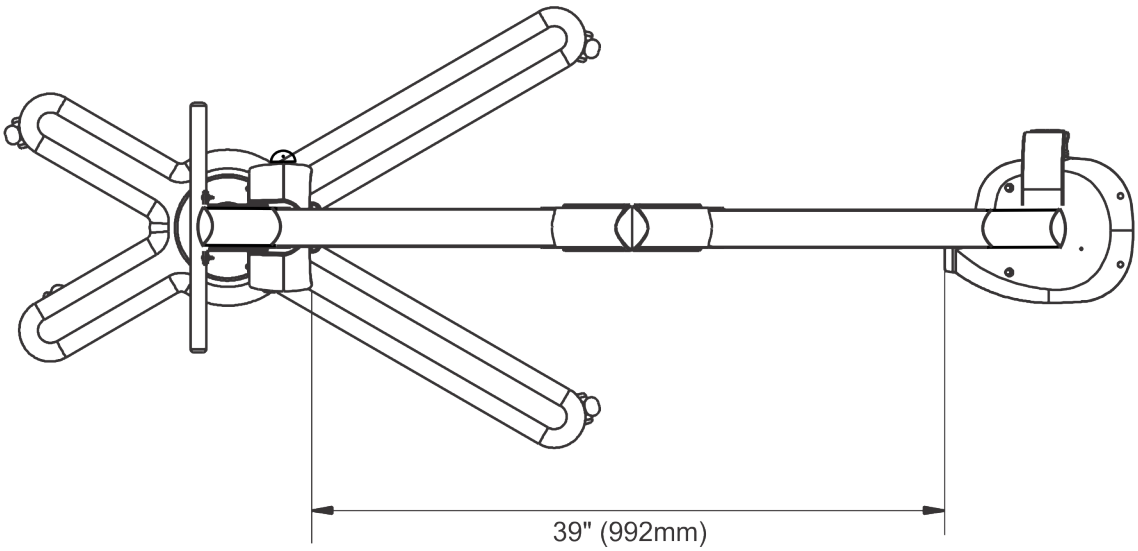


Illustration 37: Top View - Arm Extended (Floor Stand)

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4 Operating the Unit

4.1 Before You Begin

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.

You should be well acquainted with the radiation protection methods for both the operator and patient before attempting to use 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 he/she is going to be X-Rayed. Avoid X-Rays or take necessary precautions when X-Raying pregnant patients.

4.2 Positioning the Patient

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.

The tube head has an inbuilt focus to skin distance of 220 mm ± 5mm tolerance. This is also referred as short cone distance. This is the safe distance at which the skin can be placed. Optionally, the operator can use long cone. Long cone will increase the focus to skin distance from 220 mm ± 5mm tolerance to 300 mm ± 5mm tolerance.
The effect of X-Ray Radiation will reduce as the distance increases.

4.3 Achieving the Best Image Quality

RAYOS DC 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 $+45^0$ for maxilla teeth and -10^0 for Mandible teeth. The horizontal angulations of the cone should also be maintained to achieve perpendicularity with respect to the teeth.

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

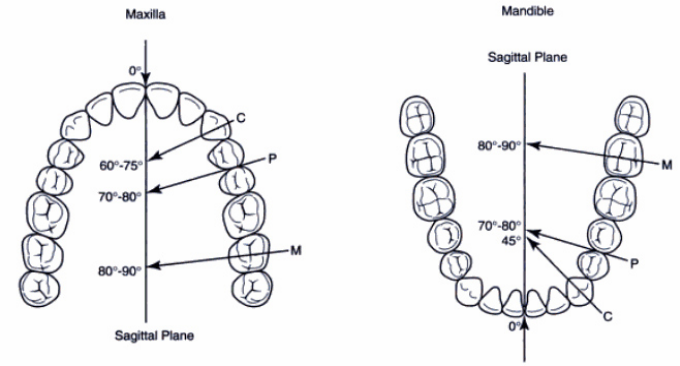

Illustration 38: Horizontal Angulation

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

Placement of Image Receptor Inside the Patient's Mouth

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

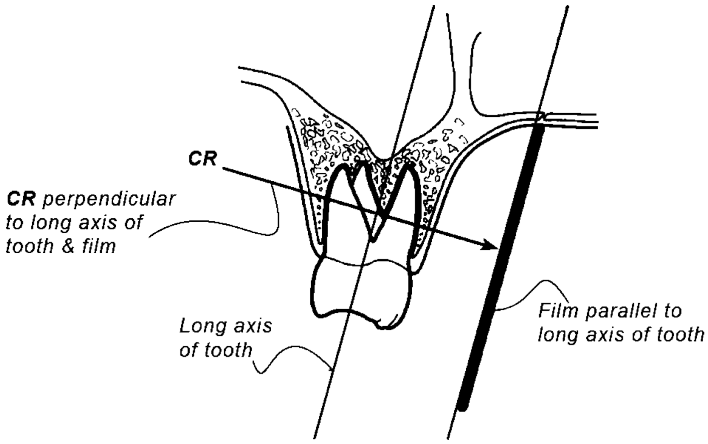

Illustration 39: Paralleling Technique

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

Image Receptor Holder

The usage of an image receptor holder and positioner is recommended since it gives precise control over the area to be imaged and the patient also is relieved of the otherwise cumbersome task of holding it by oneself.

Positioning device mentioned above is not part of supplied accessories.

Recommended Image Receptors:

Slow Speed: D Speed or E Speed, Dental Intra-Oral film, from Kodak or equivalent
Fast Speed: F Speed Dental Intra-Oral film from Kodak or equivalent

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5 Using the Control console

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

Illustration 40: Start-up Screen

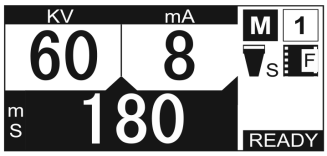

Illustration 41: Home Screen

Power up

On power up, the console shows a screen as shown on the left. While this is displayed the console goes through a state of self test for making sure that all the internal and external components of the console are working fine. Keypad, audible fixed alarm and LCD backlight are among the external components checked. During this stage please do not press any keys on the keypad for they will be treated as a keyboard error.

Home Screen

Immediately following a successful self test the console displays a screen similar to the one shown on the left. All the processes in this console starts from the home screen. Depending on whether or not the selected combination of mode, patient type, tooth anatomy, film speed (in case of Mode1) and cone type (in case of Mode1 or Mode2) are the same as that of current start-up mode the message displayed will be either

System ready

Or

System ready

Press SET key to set this as the start up mode

5.1 Selecting a Pre-set Mode

A preset mode is a set of combinations of exposure parameters (kV, mA and ms) suitable for a particular image receptor. This console provides,

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

Under each mode there are 30 sets of exposure parameters based on the patient type and tooth anatomy selected. Additionally under Mode1 or Mode2 there are options to select the type of cone used and speed of film (only in **Mode1**) which adjusts the exposure duration appropriately.

Follow the procedure listed below to change the Pre-set Mode.
In order to avoid accidental exposure, the user is advised to put the console in the mode selection screen (Illustration 42 Mode selection screen)

Illustration 42: 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 left side of the display.

History mode loads the last used exposure parameters for current session. Hence until you use the console once at least, this option will not be selectable.

Exposure parameters are different for slow films and fast film. Please use the appropriate modes based on the image receptor used. The exposure values given in the table are arrived upon for specific user conditions. This can change based on positioning of the cone, quality of film and film processing when film is used as image receptor, sensitivity of the digital image receptor etc.
Note: The recommended exposers parameter may vary depending on the sensitivity of the image receptor (Film speed, response time). The User is responsible to select appropriate Exposure parameters.

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

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

Please note that MOLAR, CANINE or INCISSOR 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 console carries exposure parameter pre-programmed for all the pre-sets in all the modes. However for any reason if you find the exposure parameters for the combination of patient type and tooth anatomy selected not suitable, this console lets you modify them on the fly.

The parameter modification screen loops through all modifiable parameters viz. kV, mA, ms, Film Speed (only for Mode 1) and Cone Type (only for Mode 1 and Mode 2) sequentially. The following section explains this procedure.

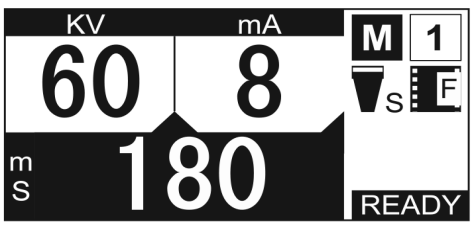

Illustration 43: Parameter Modification Screen-mS

Press the SEL key from the home screen to enter the parameter modification screen. Any time while modifying parameters if you wish to skip a parameter, press the SEL key. In case you need to come out of the parameter modification screen, press the MODE key. Parameter Modification screen starts with kV parameter.

Parameter Modification Screen: kV

Use the UP/DOWN keys to modify the kV to the desired value and press the SET key to accept the change. The kV value displayed on the parameters pane (on the right side) will be updated

with the new value and the screen jumps to the next parameter.

Parameter Modification Screen: mA

Use the UP/DOWN keys to modify mA and press SET key to accept the change. The mA value on the parameters pane is updated and the screen jumps to the next parameter.

Parameter Modification Screen: ms

Use UP/DOWN keys to modify the value and SET key to accept the change. The ms value is updated in the parameters pane and screen jumps to the next parameter.

For all the three parameters mentioned above, alongside the selected value, a scroll bar is also provided displaying current position within selectable range and the range itself.

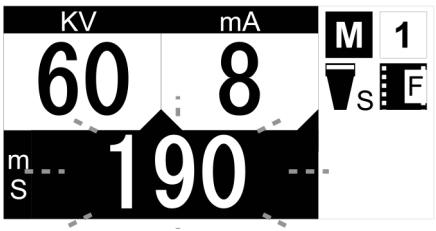

Illustration 44: Parameter Modification Screen: Film Speed

Parameter Modification Screen: Film Speed

This screen will be shown now in case Mode1 is the current pre-set mode. Here you can use the UP/DOWN keys to change the film speed between D and E. On pressing the SET key the Film Speed icon on top is updated to reflect the new selection and the screen jumps to the next parameter.

Parameter Modification Screen: Cone Type

This screen will be shown if either Mode1 or Mode2 is selected. Here you can choose between Short and Long cone types using the UP/DOWN keys and select it using the SET key. The screen automatically jumps to the next one.

Parameter Modification Screen: Save

This screen is shown if one of the custom pre-set modes are currently active. Press the SET key to save the pre-set permanently in consoles memory. This automatically brings the console back to Home Screen. See section 5.7 Customizing Exposure Pre-sets for more on this.

Pressing the SEL key repeatedly while in Parameter Modification screen will only loop within and never come out. Use the MODE key to come out to Home screen at any point. Please note that pressing MODE key will cause the console to return to Home screen discarding the last modified parameter if not accepted by pressing the SET key.

5.4 Setting a Pre-set as the Star-up Mode

By default the console selects Mode2, Adult, and Maxillary Incisor during start-up. If you wish to select another combination as the default start-up mode, proceed as follows.

Bring the console back to Home screen by pressing the MODE key (if not already in Home screen).

Change Pre-set Mode (as described under section 5.1 Selecting a Pre-set Mode) if required. This may even be one of the custom Pre-set Modes.

Change Pre-set (as described under section 5.2 Selecting a Pre-set) if required.

Additionally change the film speed or cone type parameters (if applicable to the Pre-set Mode selected) following the steps described under section 5.3 Modifying Exposure Parameters.

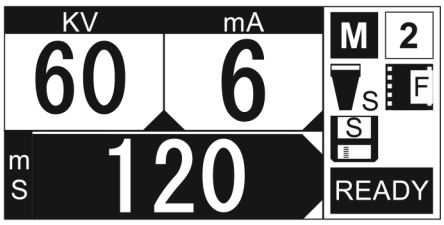

Illustration 45: Setting a the Start-up Mode

Now the Home Screen displays an additional message notifying the provision to save current selection as the start-up mode.

Press the SET key to accept current selection as the default start-up mode.

Once you press the SET key, the regular Home screen, where the messages says, System ready, is displayed suggesting that current selection has been made 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.

Illustration 46: History Screen

The Exposure History screen can be activated by clicking either the UP / DOWN key from the Home screen.

By default the most recent exposure appears at the top of the list followed by the older ones.

Now use the UP/DOWN keys to select one from the list

You may notice that the parameters pane on the right side is updated with the exposure parameters associated with the highlighted item.

Press the SET key to use the highlighted item. The console is taken back to the home screen with the selected parameters ready to be used for the next exposure.

The history mode selection lasts for only one exposure after which it returns to the start-up mode.

5.6 Delivering an Exposure

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.

Bring the console back to home screen (if it is not already in it) by pressing the MODE key.

To change the Pre-set Mode (if required), follow the procedure descried under section 5.1 Selecting a Pre-set Mode.

If required change the Pre-set by following the procedure listed under section 5.2 Selecting a Pre-set.

Optionally, customize the exposure parameters follow the direction given under section 5.3 Modifying Exposure Parameters.

Now press the Exposure key to enter the prep mode.

Here the unit prepares itself to deliver the exposure. This stage might take a few seconds.

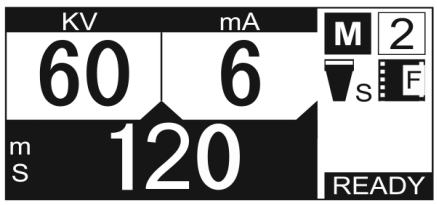

Illustration 47: X-Ray-Preparing

Illustration 48: X-Ray-Ready

Once the unit is ready to deliver the exposure it displays a screen as shown on the left side. console makes an audible alarm and the X-Ray status indication LED turns green.

At this point you are expected you press and hold the Exposure key for the entire duration of exposure selected.

Alternately if you wish to abort during the Prep or Ready state, simply press any key other than the Exposure key.

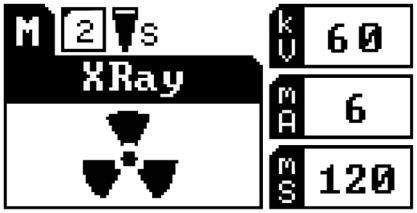

Illustration 49: X-Ray- Exposing

While the exposure is being delivered the screen shows the radiation icon and creates an audible alarm. Additionally the X-Ray status indication LED turns orange.

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

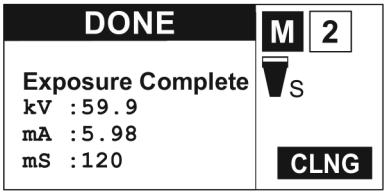

Illustration 50: X-Ray-Results

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

You may release the Exposure key on reaching the X-Ray Results screen.

In case the procedure was aborted while exposing the title of the screen would read ABORTED rather than DONE.

The results screen is shown for 10 seconds if not interrupted by any key press (other than the exposure key). Either way the screen returns to Home screen and will be ready for the next exposure.

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.

5.7 Customizing Exposure Pre-sets

The console is pre-programmed with exposure parameters for different image receptor types, patient types and tooth types. Should you ever find the need to use your own values, this is how it can be done.

Return to Home screen (if not already in) by pressing the MODE key.

Select one of the three Custom modes by following the procedure listed under section 5.1 Selecting a Pre-set Mode.

Select the pre-set which you wish to modify by going through the actions described under section 5.2 Selecting a Pre-set.

Now modify the kV, mA and ms values to the one you choose as explained under section 5.3 Modifying Exposure Parameters.

Illustration 51: Parameter Modification Screen-Save Custom Settings

In case you modify one or more parameters, you will be presented with the following screen.

Press the SET key to save the new exposure parameters permanently into console's memory.

Prep beep settings as per Intraskan DC manual / X-Zeal manual.

In case you intend on modifying more than one pre-set, it is advised not to save after modifying each pre-set, but only after the last one. In such circumstances press the MODE key when presented with the Save screen after modifying all but the last pre-sets. The modified values will still remain in memory unless you power down the whole unit. After modifying the last pre-set, press the SET key. This updates the entire Custom table at once and greatly enhances the life of the non-volatile memory of your console.

5.8 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.

5.9 Console Events

This sections describes special event related to the console.

Illustration 52: 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 backlight driven into a 'breathing' state.

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

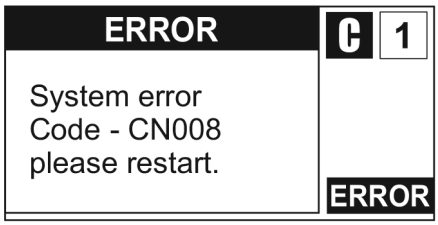

Illustration 53: Error Display

Error

Any error occurring in the system is reported by the console. You may notice the following changes in console in the event of an error.

- Console displays an error message with an error code (in the image shown it is CN001) and additional messages.
- Display backlight turns RED

You will not be able to deliver an exposure until the issue is sorted out, however rest of the console features will continue to work.

5.9.1.1 Default Exposure Values – Short/Long Cone Slow Film (E-Speed) Mode

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: FS0.4 Default Exposure Values for Short/Long Cone Slow Film – Mode 1

5.9.1.2 Default Exposure Values – Short/Long Cone Fast Film (F-Speed) Mode

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: FS0.4 Default Exposure Values for Short/Long Cone Fast Film – Mode 1

5.9.1.3 Default Exposure Values – Mode 2

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: FS0.4 Default Exposure Values for Short/Long Cone – Mode 2

5.9.1.4 Default Exposure Values – Custom Modes (All)

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 5: FS0.4 Default Exposure Values – Custom Modes (All)

5.9.1.5 Default Exposure Values – Short Cone - PSP

Anatomy kV mA				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

5.9.1.6 Default Exposure Values – Long Cone - PSP

Anatomy kV mA				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

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6 Maintenance

6.1 Cleaning and Disinfecting

Cautions:

- Use a soft cloth damped in a mild soap solution for cleaning the outside surfaces of the unit.
- 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. Very mild detergent is recommended for cleaning the equipment.

Cleaning Methods

Perform following cleaning and disinfecting steps in case of protective barriers are not used between each patient.

1. Before cleaning the equipment disconnect it from the input power supply line using the cut-out switch which must be provided when setting up or unplug the power supply cord and wait for 2 minutes.
2. Clean the external surface of the system with a disposable towel moistened with water.
3. Dry the external surface with disposable towels.
4. Part/s that come in contact with patient like Cone wipe with a germicidal broad spectrum disinfectant product following the disinfectant manufacturer's instructions.
5. Clean any remaining disinfectant residue from the system with a disposable towel moistened with water.
6. Dry the above parts with paper towels.

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 (>6months) 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.

Table 6: Tube seasoning

For 0.4 Focal spot		
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

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 or 10,000 exposures (whichever is earlier)).

All servicing should be done by qualified personnel.

6.5 Disposal of the Unit

Some parts of the equipment contain material and fluids which must be disposed off in special areas designated by the local health authorities or other local regulations at the end of the equipment's life cycle.

In particular the equipment contains the following materials and / or components:

1. Tube head: external packages in non-biodegradable plastic, dielectric oil, lead, copper, brass, aluminium, tungsten.
2. Power supply and remote control: external packages in non biodegradable plastic, iron, populated

printed circuit boards, copper.

3. Tube head extension: iron, aluminium, copper & silicon rubber.

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 Commissioning and Decommissioning of X-Ray Unit

For US & CANADA

Customers/employer/owner of the equipment/installation shall be registered with FDA/CDRH district offices (Competent Authority) under following conditions before commissioning/ decommissioning.

a) Commissioning of New X-ray equipment-Filled up Report of Assembly of Diagnostic X-ray System Form FDA2579 submitted to FDA Document mail center-W066-0609, 10903, New Hampshire Avenue, Silver Spring, MD 20993-0002 or as mentioned in the form.

b) Decommissioning of X-ray equipment from the registered location/site-Official communication to FDA/CDRH district offices.

c) Commissioning of X-ray equipment at new site after decommissioning-Filled up Report of Assembly of Diagnostic X-ray System Form FDA2579 submitted to FDA Document mail center-W066-0609, 10903, New Hampshire Avenue, Silver Spring, MD 20993-0002 or as mentioned in the form.

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7 Measurement Techniques

7.1 Direct measurement method

Instruments used in kV, mA and timer accuracies measurement

Sl No.	Description	Make	Model	Remarks
1	DSO, 200MHz	YOKOGAWA	DLM2024	Any equivalent equipment can be used (with valid calibration)

Abbreviations used:

kV= Tube potential ,

mA=Tube Current

S= Exposure time

DSO=Digital storage oscilloscope

Tube Potential testing method:

Tube potential measurement is direct method by using potential divider and DSO as shown below. Potential divider is inbuilt into the RAYOS DC and measurement point TP2 on the control board(refer Illustration 61) provided for hooking measuring probe.

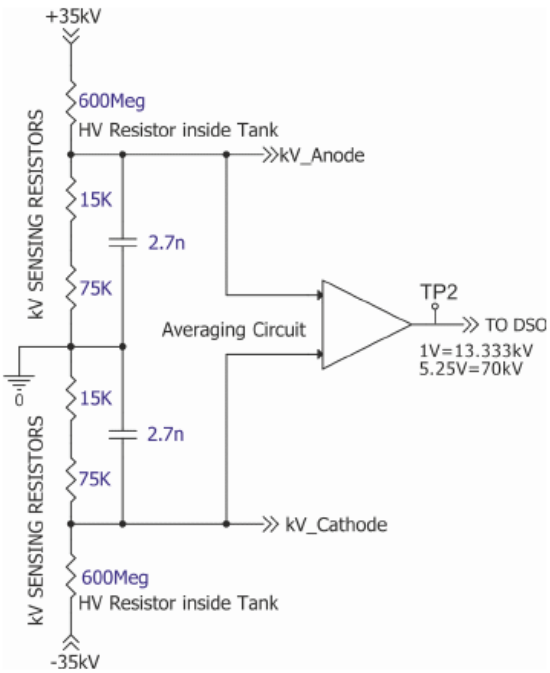

Illustration 54: kV Feedback Circuit

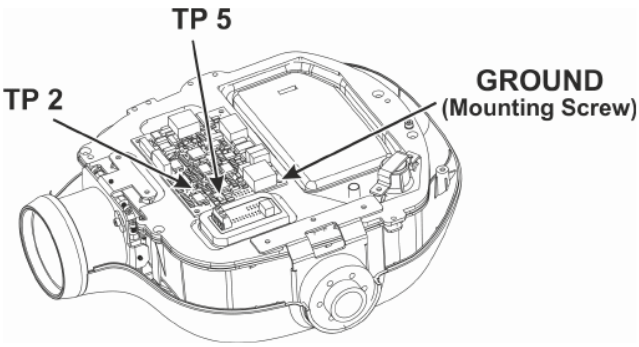

Illustration 55: Test Points

Test procedure:

(Production test will be performed with nominal input voltage 100-110VAC / 60Hz or 230-240V / 50Hz)

1. Connect the probe of the DSO to TP2 (kV feedback) with respect to ground (mounting screw) of control board as shown in the Illustration 61.

2. Switch ON the AC mains.

Indication on Control board: The fault LED D10 on test control board should not glow red. The LED D7 on test control board should glow (green color) and the LED D6 (green color) on test control board should be

blinking every 1 sec (approx).

Indication on Console board:

[Note:Do not press any key when console displays the message SELF TEST]

All LED's should glow during self test & LCD will display all 3 (Red, Green & Blue) colours in sequence. Console should boot into the home screen without displaying any error message.

3. Command exposures through operator console with kV,mA and S settings shown in table below. Press & hold exposure button till exposure done signal comes in the LCD display. Measure and Record the voltage on Oscilloscope . Tube potential signal measured from DSO are multiplied by Design factor 80/6. Each measured tube potential is verified with rejection limit.

Focal Spot	Tube kV	Tube Current, Exposure Time					
0.4	60, 65, 70	4mA, 40ms	4mA, 3500ms	6mA, 40ms	6mA, 3500ms	8mA, 40ms	8mA, 200ms

4. Rejection limit :

Design: 3%.

To be measured by a DSO having accuracy < ±2%.

Difference between kV Command to kV actual shall be <±5%

Tube Current testing method :

Tube current measurement is direct method by using shunt/Sensing resistor, 750Ohms, +/- 1% and DSO as shown below. Current sensing circuit is inbuilt into the RAYOS DC and measurement point TP5 provided for hooking measuring probe.

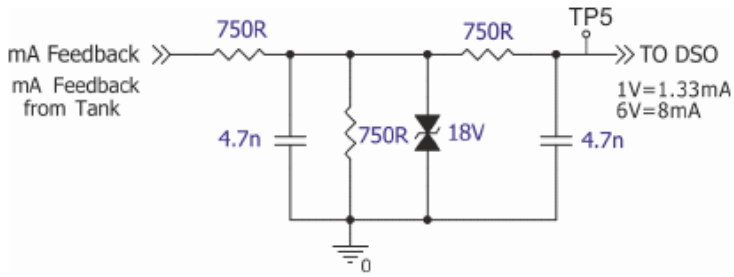

Illustration 56: mA Feedback Circuit

Test procedure:

(Production test will be performed with nominal input voltage 110Vac, 60Hz).

1.Connect the probe of the DSO to TP5 (mA feedback) with respect to ground (mounting screw) of control board as shown in the Figure 34.

2.Switch ON the AC mains.

Indication on Control board: The fault LED D10 on test control board should not glow red. The LED D7 on test control board should glow (green colour) and the LED D6 (green colour) on test control board should be blinking every 1 sec (approx).

Indication on Console board:

[Note: Do not press any key when console displays the message SELF TEST]

All LED's should glow during self test & LCD will display all 3 (Red, Green & Blue) colours in sequence. Console should boot into the home screen without displaying any error message.

3. Command exposures through operator console with kV, mA and S settings shown in table below. Press & hold exposure button till exposure done signal comes in the LCD display. Measure and Record the voltage on Oscilloscope. Tube current calculated from DSO signal multiplied by scaling factor of (8/6). Measured Tube current reading are verified with rejection unit.

Focal Spot	Tube Current Loading (mA)	KV, Time (ms)			
0.4	4, 6	60, 40	60, 3500	70, 40	70, 3500

4. Rejection limit:

Design:3%

To be measured by a DSO having accuracy < ±2%.

Difference between mA Command to mA actual shall be <±5%

Exposure time test method:

Exposure time measurement is direct method by using DSO as shown below. Exposure time is measured across test points TP2 and Ground (Chassis).

The exposure time is the time measured between start of kV waveform and start of falling edge from Final Value.

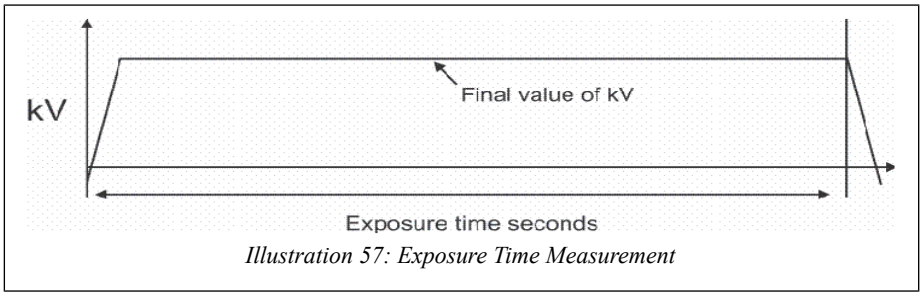

Illustration 57: Exposure Time Measurement

Test procedure:

1.Connect the probe of the DSO to TP2 (kV feedback) with respect to ground (mounting screw) of control board as shown in the Illustration 61.

2. Switch ON the AC mains.

Indication on Control board: The fault LED D10 on test control board should not glow red. The LED D7 on test control board should glow (green colour) and the LED D6 (green colour) on test control board should be blinking every 1 sec (approx).

Indication on Console board:

[Note: Do not press any key when console displays the message SELF TEST]

All LED's should glow during self test & LCD will display all 3 (Red, Green & Blue) colours in sequence. Console should boot into the home screen without displaying any error message.

3.Command exposures through operator console with kV, mA and S settings shown in table below. Press & hold exposure button till exposure done signal comes in the LCD display. Measure and Record the time on Oscilloscope. % of Error is calculated between set time (command) and measured time as

%Error=((Measured time- Set Time)/Set time) x 100%

Example: % Error with 40mS exposure time= ((39.8 - 40) / 40) x 100 = -0.005 x 100 = -0.5%

Each measured value is verified with rejection limit.

Focal Spot	kV	mA	Time (ms)
0.4	70	6	40, 400, 2000, 3500

Rejection limit set +/- 10% of set exposure time

7.2 Indirect Measurement method:

Sl No.	Description	Make	Model	Remarks
1	Accu-pro	Radcal	9096	Any equivalent equipment can be used (with valid calibration)
2	Kvp sensor	Radcal	40X12-W	

Test Procedure:

Place the kVp sensor at 25cm from the focal spot. Visually center the kVp probe in the x-ray beam path such that the beam will strike sensor in the probe as shown in the picture below Once aligned, deliver an exposure(protocol:70kV,8mA,40mS) and capture the wave form in the oscilloscope.

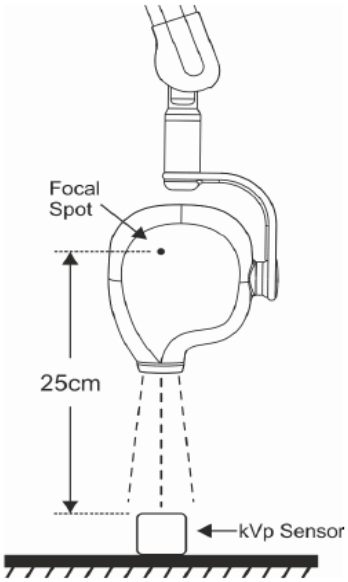

Illustration 58: kV measurement using kVp sensor

Acceptance criteria: No over shoot in the kV waveform.

8 Troubleshooting

When in a fault state, the unit would display an error message with a corresponding error code as defined here.

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 7: Error Codes

Listed below are the troubleshooting tips to help you recover from an error condition.

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	Ensure none of the console keys are active. 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

Sl No.	Observed Problem	Recommended Action
		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 8: Troubleshooting Tips

Annex A: Technical Specifications

Tube-Head Specifications

Parameters	
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	< 3%
High Voltage Rise Time	< 3ms
Control of Tube Current	Closed Loop
Tube-head current range	3.5s max (@ 4-6 mA loading), 200ms max (@ 7 & 8 mA loading) , (Step size 1mA)
Accuracy of current	< ± 5% (± 10% for current < 40 ms)
Maximum Exposure Time	3.5s(> 200ms @ 4-6 mA)
Minimum Exposure Time	10 ms
Exposure Timer Accuracy	< ± 5%
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	220 mm ± 5mm (in-built) 300 mm ± 5mm with optional cone
X-Ray field (at collimator tip)	Circular, diameter ≤ 60 mm @ SSD of 220 mm
Leakage radiation @ 1m	< 0.88 mGy/h (100 mR/h)
Leakage radiation technique	70kV, 6mA, 1250ms or 1400ms for 0.4 FS
Tube Head Outer Covers	PC ABS Plastic with Glossy Finish
PID / Cone Material	Silicone Rubber/ Aluminium/ Makrolon - 2407

Table 9: Tube-Head Specifications

X-Ray Tube Insert Specifications

Parameters	
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 10: X-Ray Tube Insert Specifications

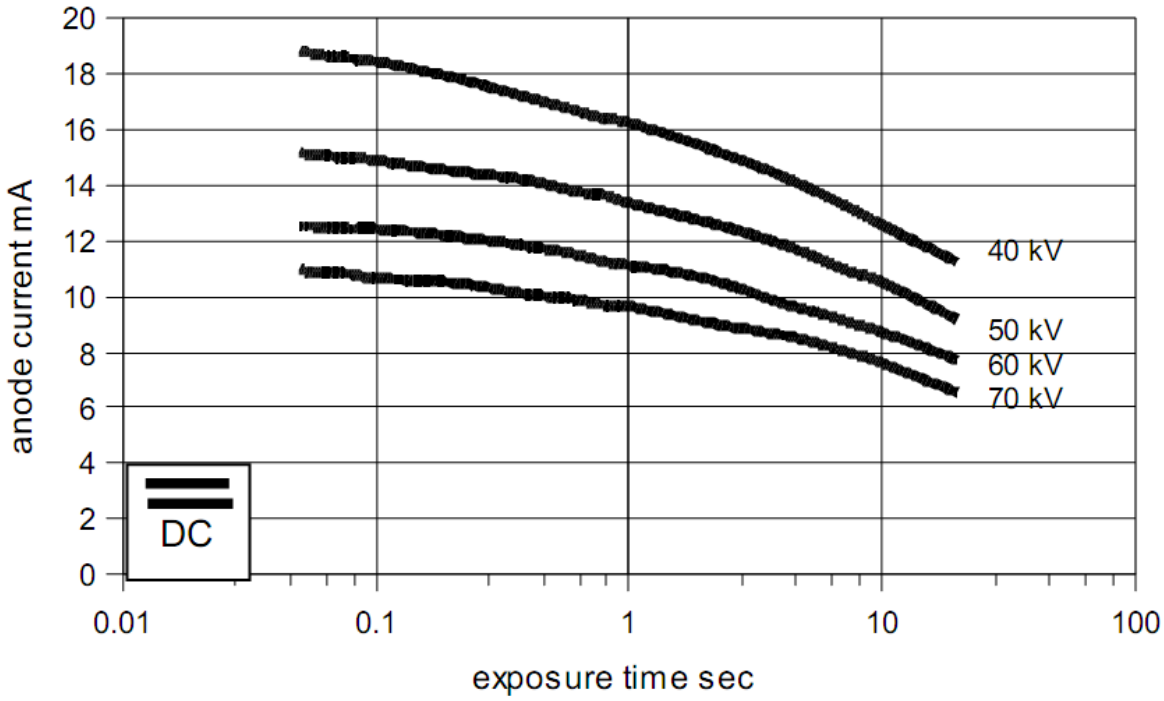

Illustration 59: Tube Insert Rating Chart-OX/70-5 & OX/70-P

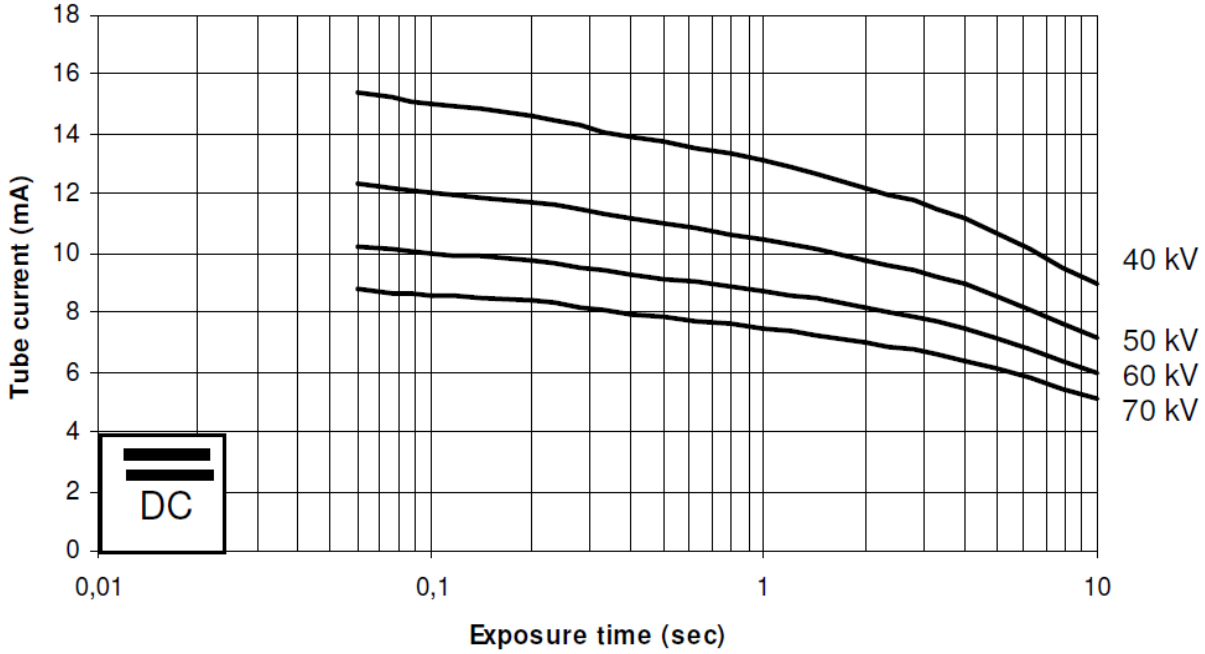

Illustration 60: X-Ray Tube Insert Rating Chart-OX/70-4

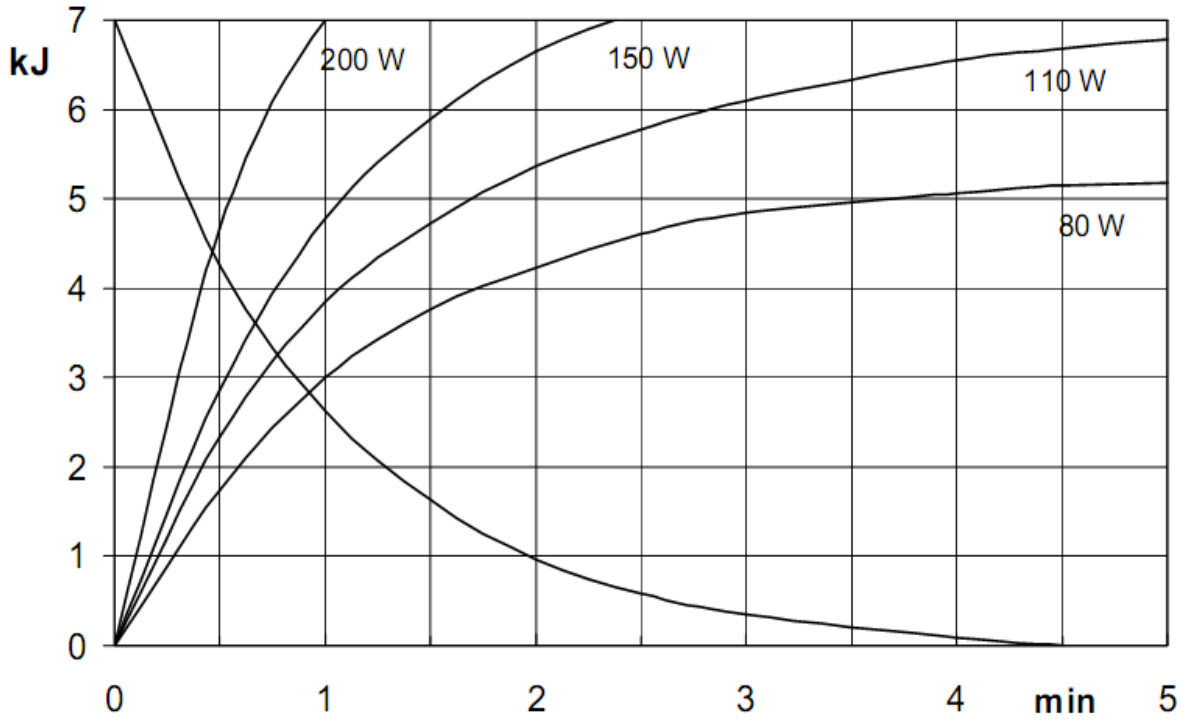

Illustration 61: X-Ray Tube Insert Thermal Data-OX/70-5,OX/70-P & OX/70-4

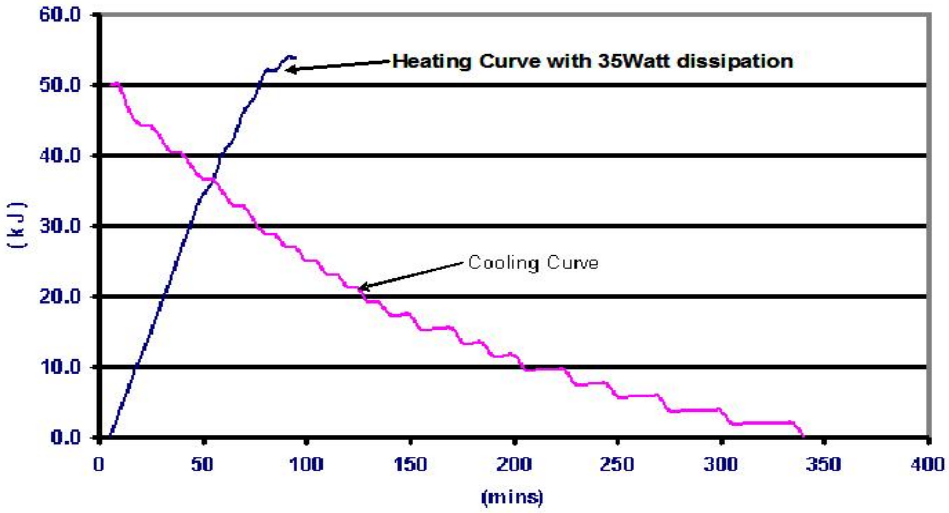

Illustration 62: Heating and Cooling Curve

Mechanical Dimensions and Weight

Total Weight of System(including Packing carton)	Wall mount (15" Support Tube) – 42 kg (92.5 lbs) max, Wall mount (24" Support Tube) – 43 kg (94.7 lbs) max, Wall mount (33" Support Tube) – 44 kg (97.0 lbs) max, Floor stand variants – 104.3 kg (230.0 lbs) max.
Weight of Tube Head	6 kg (13.3 lbs) Approx
Support Tube Material	Aluminum
Type of painting	Glossy
Mounting type	Base Unit adapters for Wall mounted or Floor Mount
Extended Arm Reach for Wall mount Scissor Arm.	1575 mm / 62", 1803 mm / 71" & 2032 mm / 80"
Extended Arm Reach for Floor stand Scissor Arm with out Support Tube	992 mm (39")
Height of unit with Arms folded	1245 mm / (49" ± 0.5) - wall mount 1956 mm / (77" ± 0.5) - floor mount
Support Tube Rotation about Base	180°± 10°
Scissor Arm Swing	220°± 10°- wall mount 75°± 5°- floor mount
Tube Head swivel on horizontal plane	530° ± 10°
Tube Head rotation about Vertical Plane	305° ± 5°

Table 11: 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% Max
Line frequency	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 @ 100Vac and <=0.8 ohm at 240Vac
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 12: 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 13: Environmental Conditions

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Annex B: Declaration of Conformity

B1: Name and Description of Product:

Medical device name: High frequency Intra oral X-ray system

Medical device model: *RAYOS DC*

Medical device Type: X-Ray System

Medical device classification:

Class Iib, Rule 10 – Medical Device Council directive 93/42/EEC,

Class II – FDA, 21CFR 872.1800

B2: Following Standards under which conformity is declared:

ANSI/AAMI ES60601-1: 2005 + C1:09 + A2:10
IEC 60601-1: 2005 + CORR. 1: 2006 + CORR. 2:2007
CAN/CSA-C22.2 No. 60601-1: 2008
IEC 60601-1-2:2006
IEC 60601-1-3: 2008
IEC 60601-2-65:2012
IEC 60601-2-28: 2010
21 CFR, Subchapter J &
CMDR SOR/98-282.

B3: Marking:

UL Safety marking (Proposed).
CE marking (Proposed).

B4: Declaration:

The Products described herein are designed, manufactured, inspected, tested and released by Skanray Technology Pvt Ltd., a contract manufacturer for Chicago X-ray in accordance with FDA's 21CFR, Part 820, ISO 9001:2008 and ISO 13485:2003.

B5: Authorised Representative:

Chicago X-Ray System, Inc.

65 East Palatine Road

Prospect Heights,

Illinois 60070 USA

Annex C: Guidance and Manufacturer's Declaration

ANSI/AAMI ES60601-1: 2005 + C1:09 + A2:10

According to: EN 60601-1-2: 2001 + A1:2006

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

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions EN 55011	Group 1	*RAYOS DC* 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 EN 55011	Class A	*RAYOS DC* is 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 EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

Table 14: Guidance and Manufacturer's Declaration – Electromagnetic Emissions – For all EQUIPMENT and SYSTEMS

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) EN 61000-4-2	± (2, 4, 6) kV contact ± (2, 4, 8) kV air	± (2, 4, 6) kV contact ± (2, 4, 8) 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 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for Signal lines	± 2 kV for power supply lines ± 1 kV for Signal lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV Differential mode ± 2 kV Common mode	± 1 kV Differential mode ± 2 kV Common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	< 5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *RAYOS DC* requires continued operation during power mains interruptions, it is recommended that the *RAYOS DC* be powered from an uninterruptible power supply or a battery.

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 15: Guidance and Manufacturer's Declaration – Electromagnetic Immunity – For all EQUIPMENT and SYSTEMS

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF EN 61000-4-6	3 Vrms 50 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the *RAYOS DC*, 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 EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 2,5 GHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
	***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 RAYOS DC is used exceeds the applicable RF compliance level above, the RAYOS DC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RAYOS DC. ***b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.***			

Table 16: Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Annex D: Contact Details

Registered Office	Chicago X-Ray System, Inc. 65 East Palatine Road Prospect Heights, Illinois 60070 USA

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