ImageScan HD

High Frequency Intraoral X- Ray System

User Manual

Table of Contents

LIST OF ILLUSTRATIONS

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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 ImageScan HD system. Any modification may result in violation of compliance to the standards. Imageworks 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.

1.1 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 observed.

- 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 staff.
- Always point the X-Ray tube-head 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 protection.
- The operator should be at a distance of at least 2 meters 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 always stand away from the X-Ray beam and behind the tube-head.

Electrical Safety

Always switch off the main power when cleaning and disinfecting the unit.

The unit contains lethal high voltages. Do not attempt to open covers or repair the unit yourself or with the help of 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 scissor arm. Since the arm mechanism allows free movement with minimal force, a swinging arm can inadvertently cause injuries.

The swinging joints on the arm are potential pinch points. Use caution while operating the arm.

CHAPTER 1: SAFETY AND PRECAUTIONS

Installation and Service	Installation and service of ImageScan HD must only be done by an authorized service engineer. Consult the factory or dealer as necessary.
	Make sure that ImageScan HD is assembled and installed in compliance with all applicable laws and recommendations concerning electrical safety.
Explosion Safety	This equipment must not be used in the presence of flammable or potentially explosive disinfecting gases or vapors, which could ignite causing personal injury and/or damage to the equipment. If such disinfectants are used, the vapor must be allowed to disperse before using the equipment.
	This equipment is not suitable for use in the presence of anaesthetic gases.
Floor Mount	Care must be taken for the movement and positioning of ImageScan HD Floor Mount.
	The Floor Mount system is meant for limited movement inside the clinic and is not suitable for Transport applications. Before moving the Floor Mount system around, the scissor arms 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 within a clinic or hospital room. Adequate care should be taken while moving on ramp or on an uneven surface.

1.2   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 Ground**
	Mains Earth Ground 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.
🗑	**WEEE Symbol** Indicates that the unit conforms with WEEE Directive 2002/96/EC and must be disposed of only at the appropriate facilities for recovery and recycling.
	X-Ray Emission Status
	X-Ray Emission /ON
■	Focal Spot
☐	Mains Neutral Connection
L	Mains Line Connection
📖	Follow Instructions for use

Chapter 2: Introduction

2.1. ImageScan HD X-Ray Equipment

The ImageScan HD 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. ImageScan HD will create radiographs of excellent quality, performing equally well using any image receptor.

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

2.2. Indication for Use

The ImageScan 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.

2.3. 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 ImageScan HD models listed below. Additionally, troubleshooting tips are provided should the equipment not perform as intended.

The following are guidelines for using this manual.

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

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 keypad Console using images as shown to the left. These images are indicative only and the values displayed may differ from the actual values unless specified otherwise.

4

2.4. Included System Components

The Wall Mounted ImageScan HD system is available in three model configurations using different Straight Arm assembly.

Top Level Variants
ImageScan HD Intraoral X-Ray Floor Mount
Wall Mounted ImageScan HD High Frequency Intraoral X-Ray with 15" Straight Arm
Wall Mounted ImageScan HD High Frequency Intraoral X-Ray with 24" Straight Arm
Wall Mounted ImageScan HD High Frequency Intraoral X-Ray with 33" Straight Arm

Unpack each component and verify that items listed below are received as appropriate. If any item is missing or damaged, notify your authorized dealer.

Description		Part No.
ImageScan HD High Frequency Intraoral X-Ray (One only)	Wall Mounted 15" Straight Arm without remote switch	303-001201-0
	Wall Mounted 24" Straight Arm without remote switch	303-001202-0
	Wall Mounted 33" Straight Arm without remote switch	303-001203-0
	Wall Mounted 15" Straight Arm with remote switch	
	Wall Mounted 24" Straight Arm with remote switch	
	Wall Mounted 33" Straight Arm with remote switch	
	Floor Mount	303-001204-0
Contents		
Note: The Tube-head is shipped attached to the Scissor Arm		
Straight Arm Assembly for Wall Mount (one only)	15" Long	309-000422-0
	24" Long	309-000423-0
	33" Long	309-000424-0
Scissor Arm Assembly Wall Mount (includes cables)		309-000425-0
Scissor Arm Assembly Floor Mount (includes cables)		309-000425-1
70kVp 8mA Tube-head Assembly(0.4FS)		309-001207-0
Base Unit Assembly Wall Mount		309-001205-0
Base Unit Assembly Floor Mount		309-001206-0
Exposure Switch with Cable		309-000428-0
Template for Wall Plate (Single Stud Mounting) Installations		207-001473-0
Lead Extension Cone Assembly		309-000208-0
16" Wall Plate with template (Optional)		205-001474-0
Remote Keypad Console with template (Optional)		309-001210-0
Doorbell Switch with template (Optional)		309-000432-0

CHAPTER 3: KNOW YOUR IMAGESCAN HD

3.1 Key Component Identification

As shown in Figure 1, ImageScan HD is comprised of the following components:

1. **Base Unit (Both Wall mount and Floor Mount Units)**
   The Base Unit provides mounting support for the straight 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 ImageScan HD is also provided via the Keypad Console.

2. **Keypad Console (Both Wall mount and Floor Mount Units)**
   The Keypad Console is the user/machine interface providing all functional operating controls of the ImageScan HD system. Consisting of a 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. **Straight Arm (Wall mount Units)**
   The Straight 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 (Both Wall mount and Floor Mount Units)**
   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. **Mobile Support Platform (Floor Mount Units)**
   The Mobile Support Platform provides a stable portable operating base for ImageScan HD Floor Mount

6. **Tube-head with Beam Limiting Device (Both Wall mount and Floor Mount Units)**
   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 220mm source to skin distance and 60mm 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.

Wall Mounted ImageScan HD   ImageScan HD Floor Mount
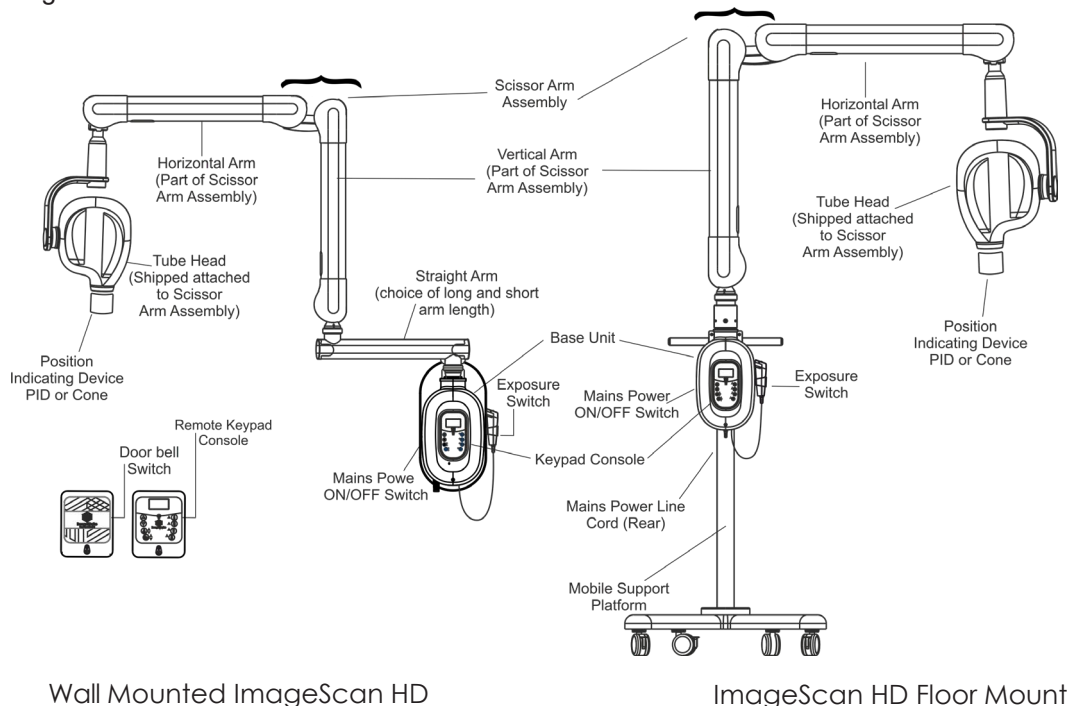
Figure 1. ImageScan HD Key Component Identification

3.2 System Labels

This section shows the required system labels that are affixed on the unit. Refer to Figure 2 for the location of each label by the corresponding item number below the label.

Illustration 1: Straight Arm Label (#1)
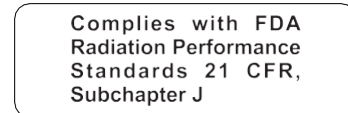
Illustration 2: FDA Label (#2)

Illustration 3: Angular Tape (#15)

Illustration 4: Warning Label (#3)
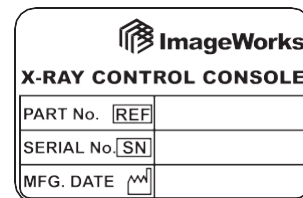
Illustration 5: X-Ray Control Console Label (#4)

Illustration 7. X-Rays Caution Label (#6)

Illustration 6: Danger Label (#5)

Illustration 8: Manufacturer Label (#7)
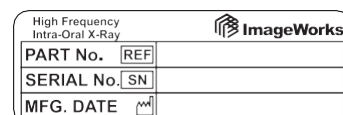
Illustration 9: System Label (#8)
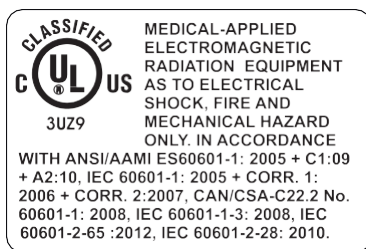
Illustration 10: 3rd Ed-UL Mark Label (#9)(Proposed)
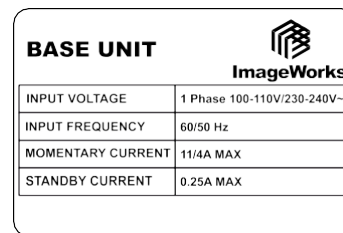
Illustration 11: Base Unit Label (#11)

BASE UNIT		ImageWorks
INPUT VOLTAGE	1 Phase 100-110V/230-240V~	
INPUT FREQUENCY	60/50 Hz	
MOMENTARY CURRENT	11/4A MAX	
STANDBY CURRENT	0.25A MAX	
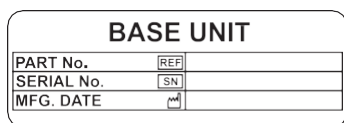
Illustration 12: Base Unit Sl. No. Label (#10)

BASE UNIT	
PART No.	REF
SERIAL No.	SN
MFG. DATE	⏲
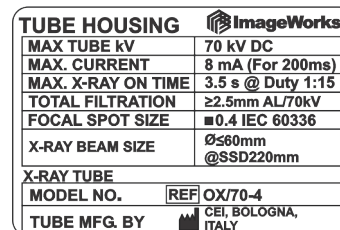
Illustration 13: Tube Housing label for focal sport 0.4 (#12)

TUBE HOUSING	ImageWorks
MAX TUBE kV	70 kV DC
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 @SSD220mm
X-RAY TUBE	
MODEL NO. REF	OX/70-4
TUBE MFG. BY	CEI, BOLOGNA, ITALY
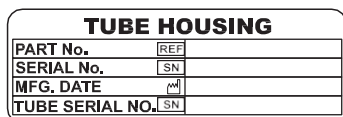
Illustration 14: Tube Housing Sl. No. Label (#13)

TUBE HOUSING	
PART No.	REF
SERIAL No.	SN
MFG. DATE	⏲
TUBE SERIAL No.	SN
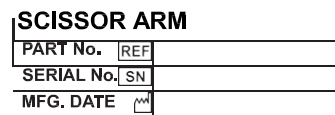
Illustration 15: Scissor Arm Label (#14)

SCISSOR ARM	
PART No.	REF
SERIAL No.	SN
MFG. DATE	⏲

Illustration 16: L-Arm Dome Label (#16)
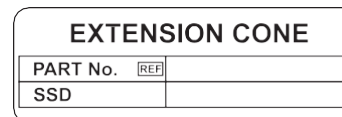
Illustration 17: Extension Cone Label (Optional) (#17)

EXTENSION CONE	
PART No.	REF
SSD	
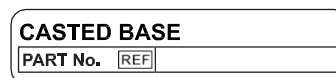
Illustration 19: Casted Base Label (#19)

CASTED BASE	
PART No.	REF

Illustration 18: Base Column Label (#18)

BASE COLUMN	
PART No.	REF
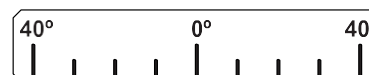
Illustration 20: Angular Tape Floor Mount (#20)

Illustration 22: CE Marking Label (#22)(Proposed)

CE 0843

EC REP
Skanray Europe s.r.l
Via Della Tecnica,
3- San Lazzaro di Savena (40068),
Bologna, Italy.
Email : skanrayeu@legalmail.it

Illustration 21: Position Indicator Arrow (#21)
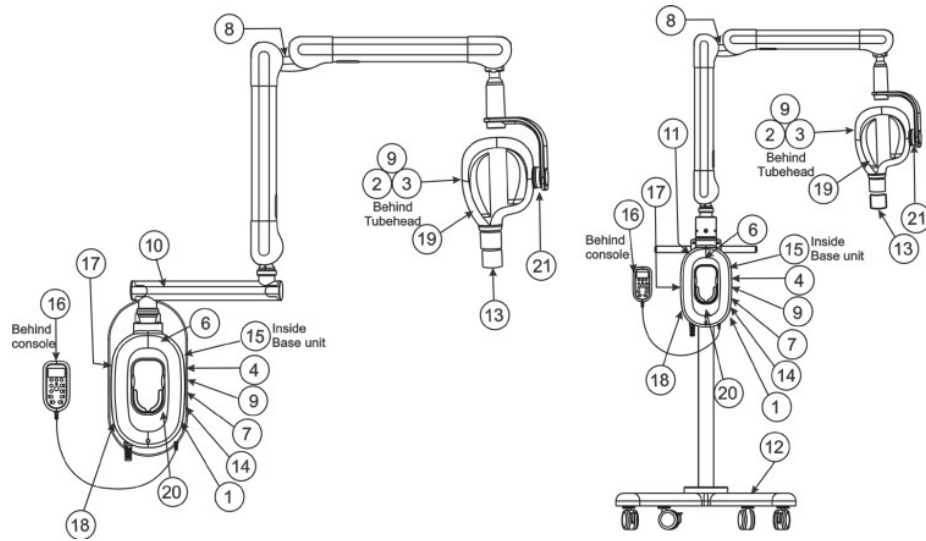
Figure 2. ImageScan HD System Label Location (Refer section 3.2, Page 12 for System Labels)

3.3 ImageScan HD Reach Dimensions and Movements

Figures 3 through 12 show minimum and maximum clearances, dimensions and sweep angles for both the wall mounted and Floor Mount units.

15" Straight Arm
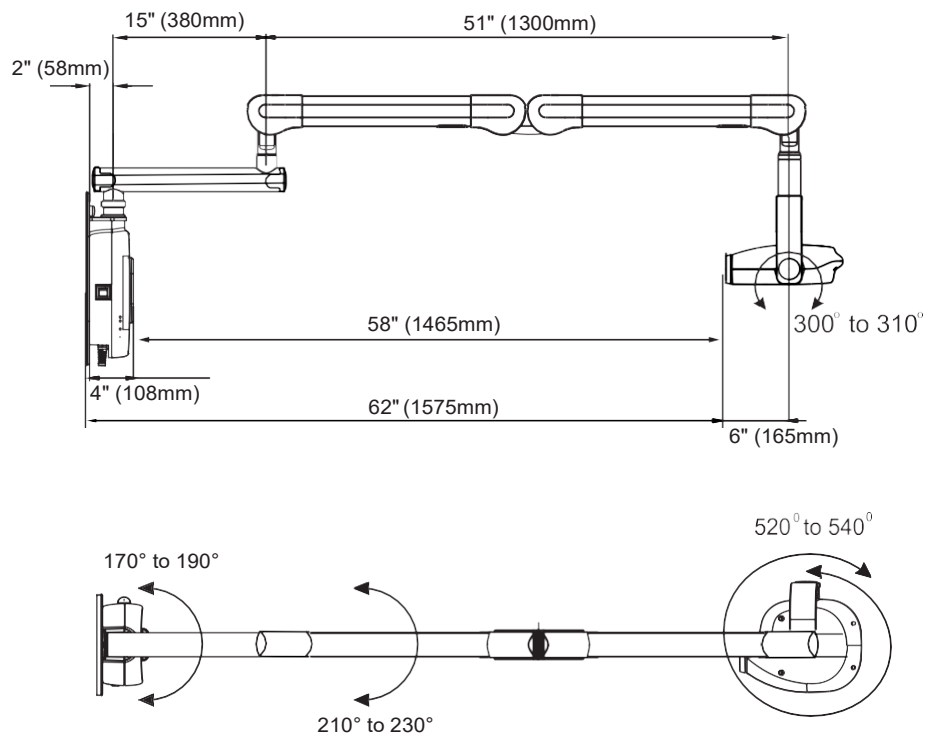
Figure 3. Wall Mounted ImageScan HD 15" Support Tube Fully Extended Right Side and Top Views

24" Straight Arm
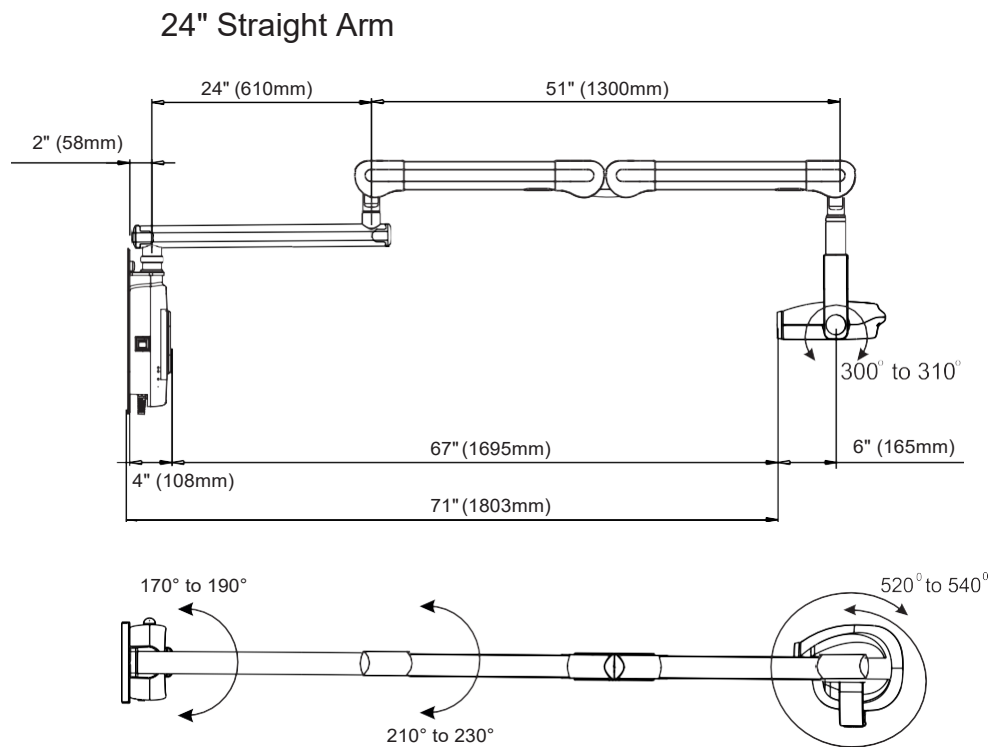
Figure 4. Wall Mounted ImageScan HD 24" Support Tube Fully Extended Right Side and Top Views

33" Straight Arm
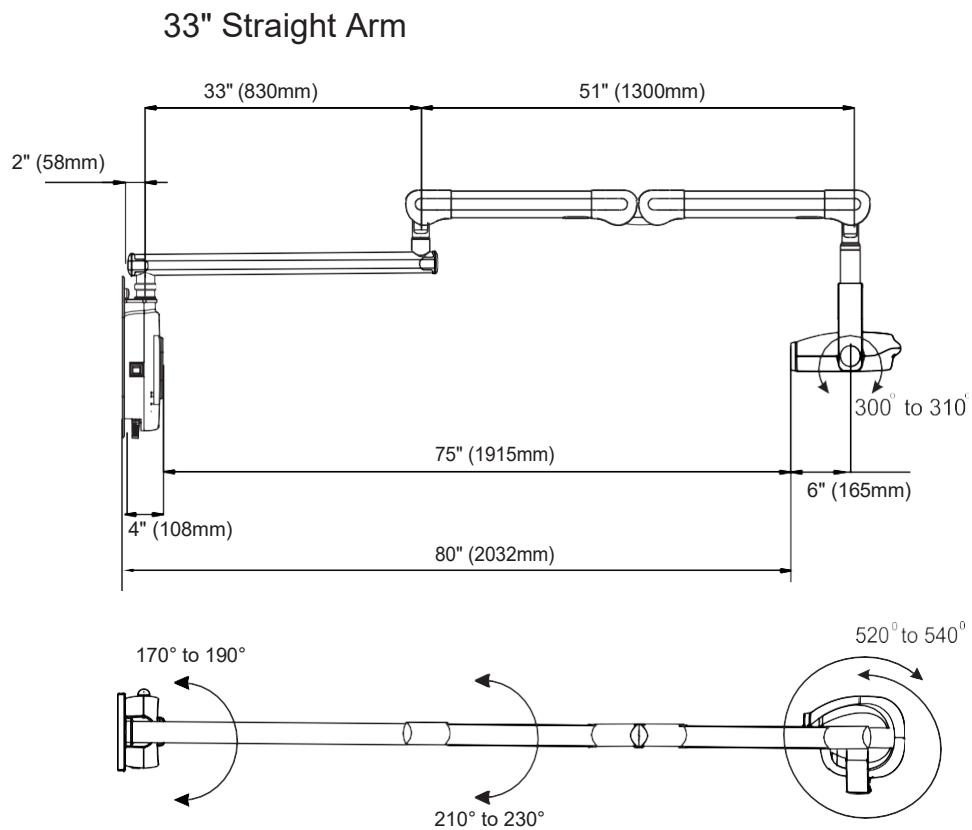
Figure 5. Wall Mounted ImageScan HD 33" Support Tube Fully Extended Right Side and Top Views

356mm (14")

205mm (8")

1393mm (55")

576mm (23")

Floor Level
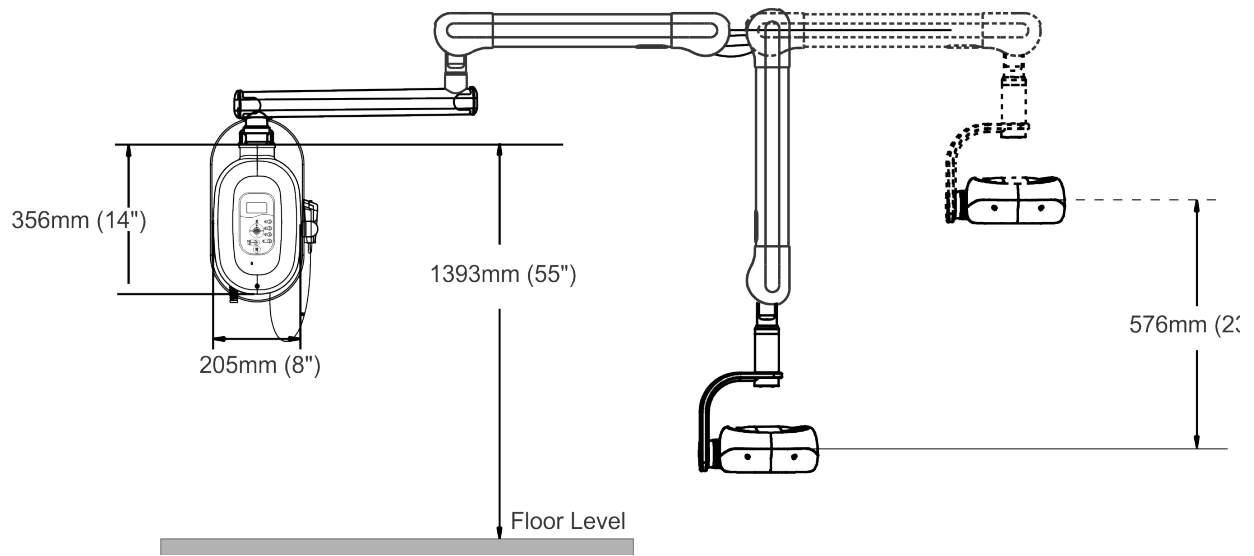
Figure 6. Wall Mounted ImageScan HD Ground Clearance & Horizontally Extended

762mm (30")

1244mm (49")

576mm (23")

356mm (14")

205mm (8")
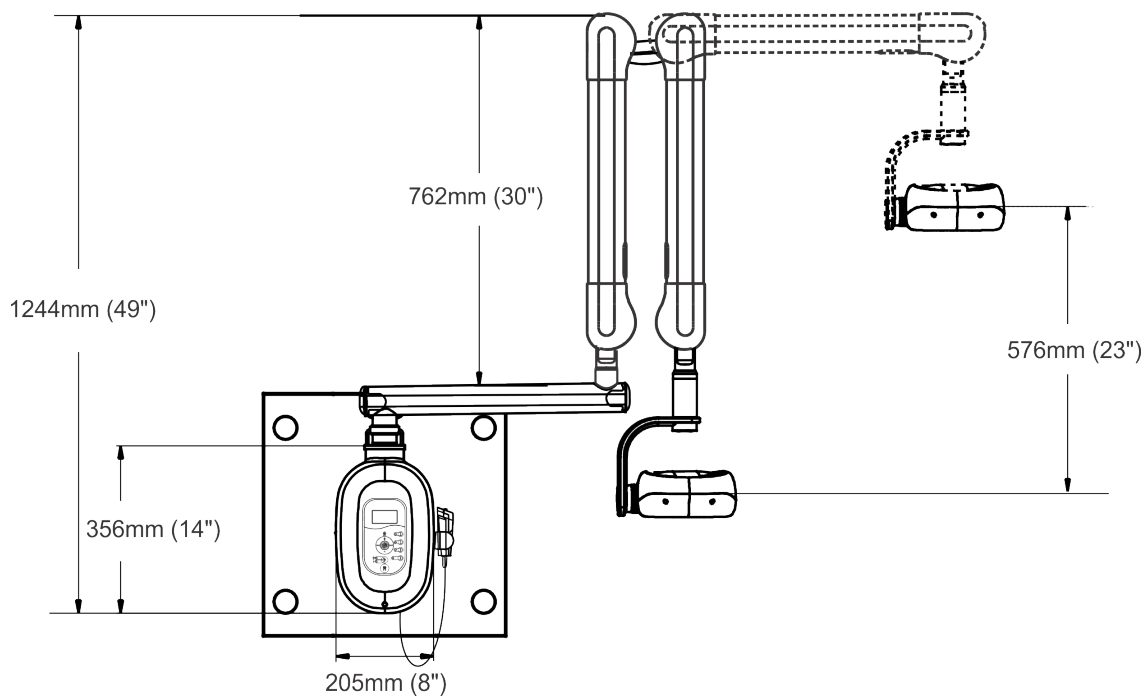
Figure 7. Wall Mounted ImageScan HD Vertically Extended

11

71" (1795mm)
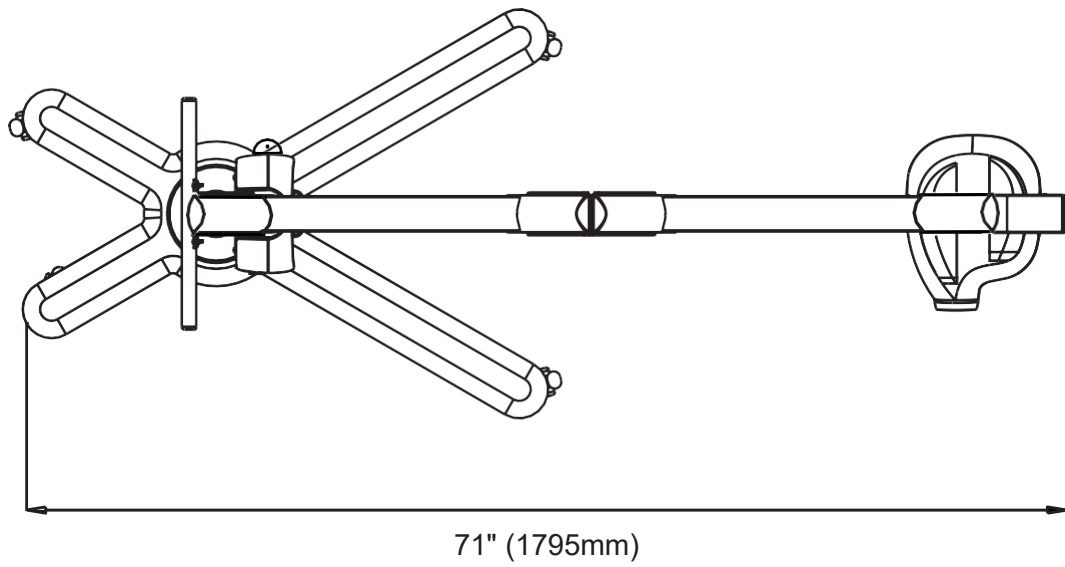
Figure 8. Floor Mount ImageScan HD Fully Extended Dimensions

30° to 40°

30° to 40°
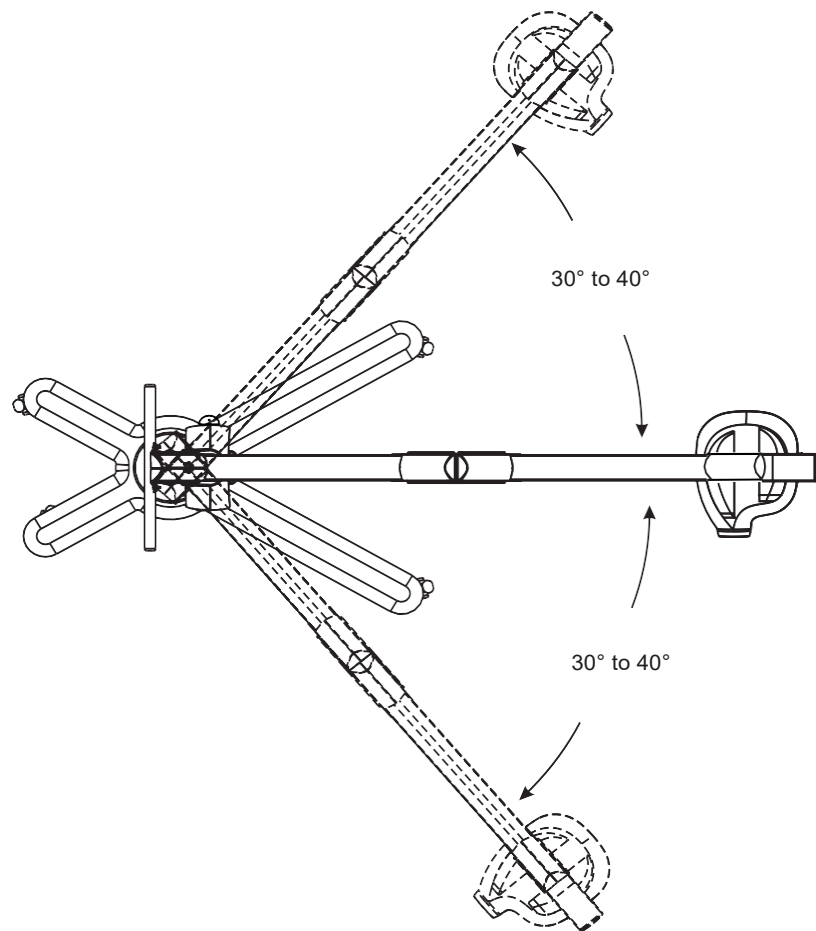
Figure 9. Floor Mount ImageScan HD Sweep Angle

48"±0.5" (1219mm)

37"±0.5" (935mm)
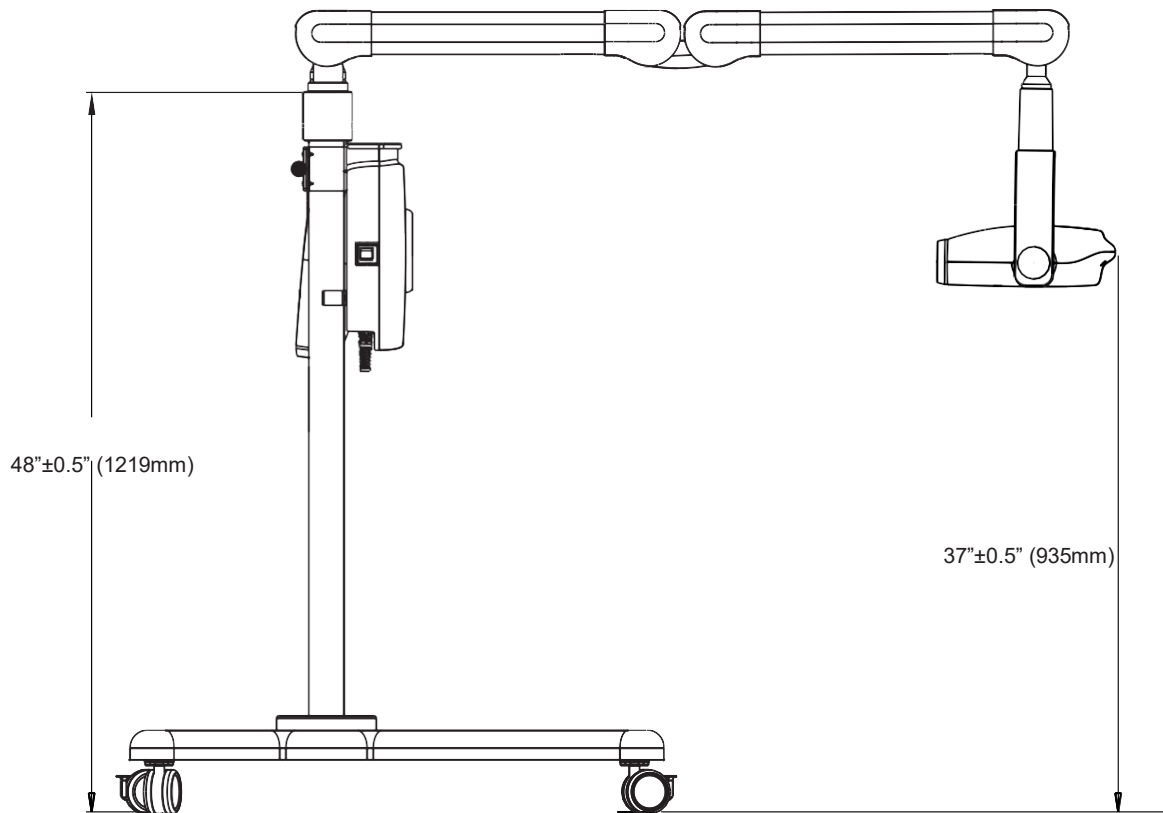
Figure 10. Floor Mount ImageScan HD Extended Dimensions

39" (992mm)
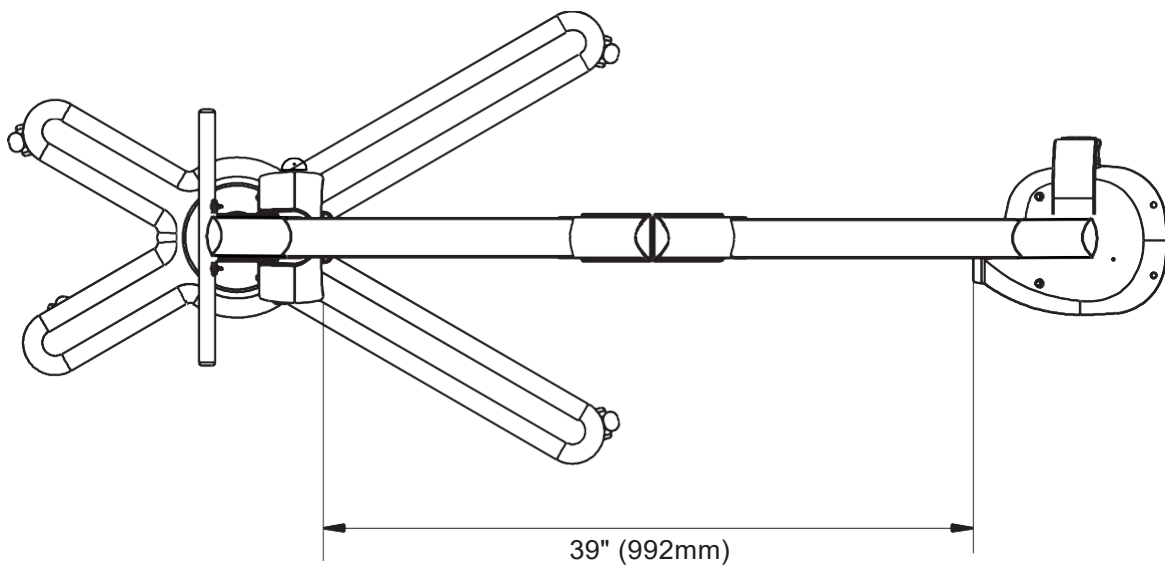
Figure 11. Floor Mount ImageScan HD - Top view

77"±0.5" (1956mm)

5.5"±0.5" (140mm)

36"±0.5" (914mm)

30°

1143mm (45" ± 0.5")

965mm (38" ± 0.5")

711mm (28" ± 0.5")

940mm (37" ± 0.5")

View A. Right Side View

View B. Front View
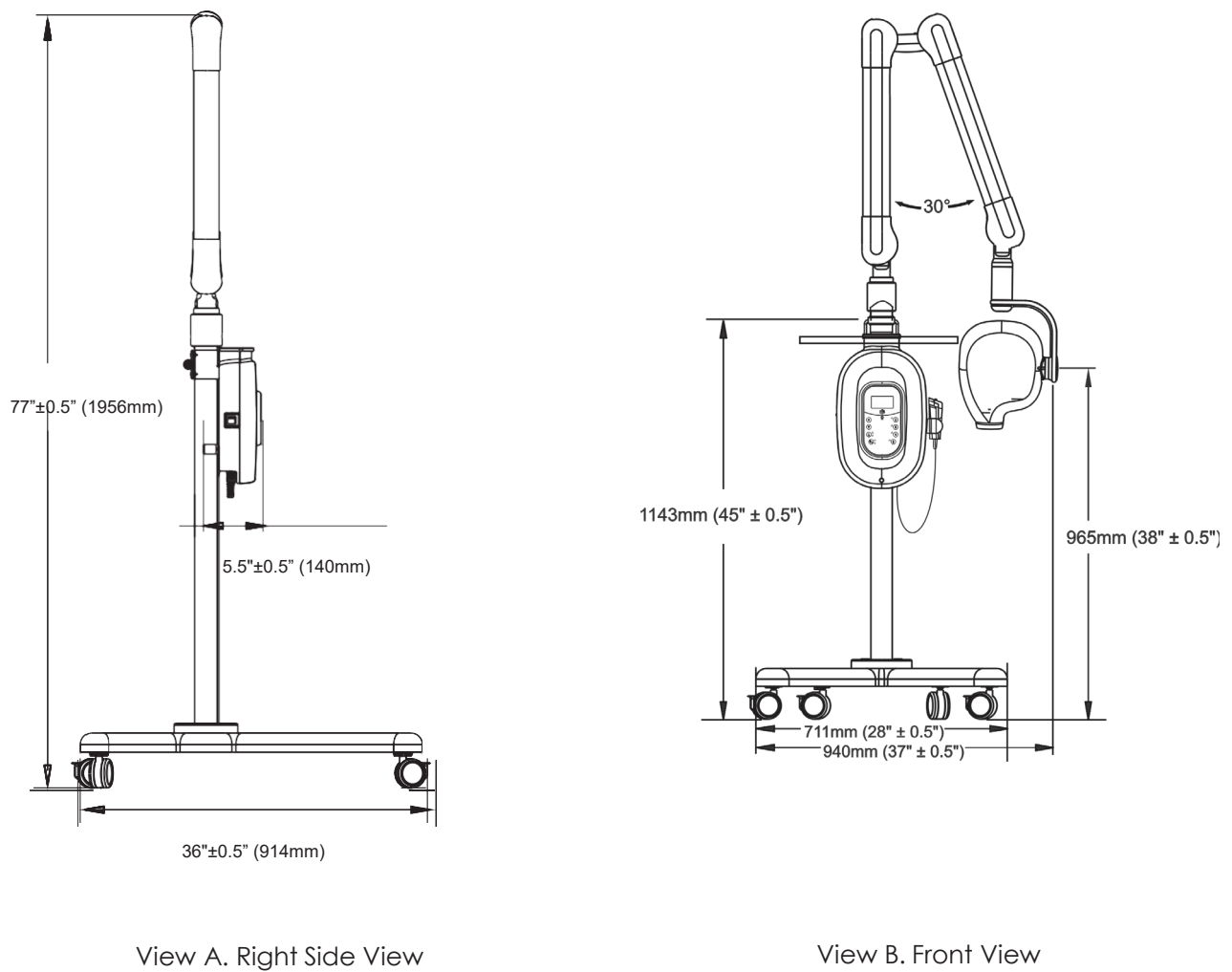
Figure 12. Floor Mount ImageScan HD - Storage Dimensions

3.4 ImageScan HD Wall mount Configurations

Figure 13: ImageScan HD Keypad Console and Wall mounting Configurations

Configuration: 1

Building
Power Box

Internal Wiring /
Mains power cord

Base Unit
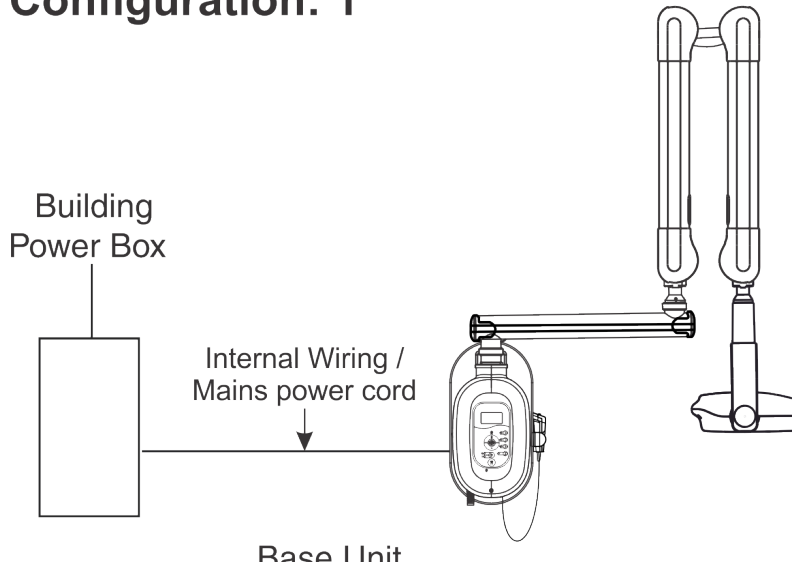
Note:
(For Configurations 2 - 7)

1. *RJ45-8P8C 35' Cable: CAT-5 24AWG 4-Twisted Pair 1:1 Connection. Similar to BELDEN P/N 1624R*
2. *RJ11-6P4C 35' Cable: Center 4 Positions Populated 1:1 Connection. Similar to P/N A2521 #B*
3. *3Wire, 35' Cable: Shielded or Un- shielded Cable AWG 20-28. P/N LAPP0028503*
4. *2 Wire shielded or unshielded cable AWG 20-28 P/N LAPP0028502*

Can use Internal Keypad Console and Internal Exposure Switch

Configuration: 2

Building
Power Box

Internal Wiring /
Mains power cord

Remote
Keypad
console

Base Unit

Internal wiring
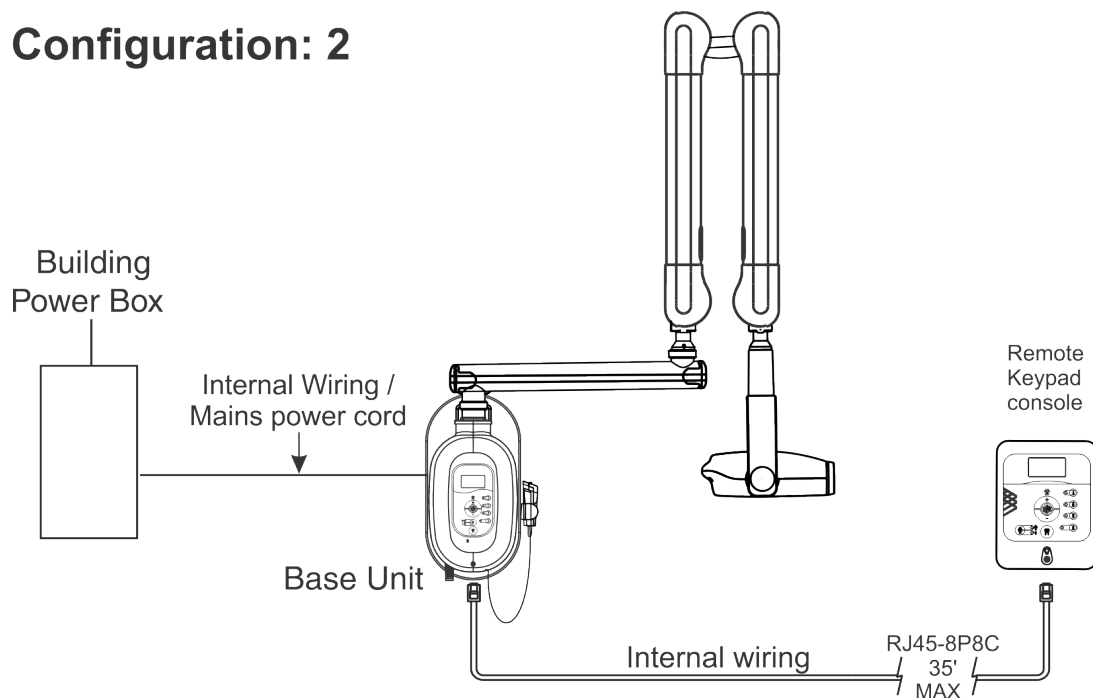
RJ45-8P8C
35'
MAX

RJ45 (8P8C) with single door bell switch
Can use both Keypad Consoles (internal and remote) with Internal Exposure Switch and single door bell

switch.

Configuration: 3

Building
Power Box

Internal Wiring /
Mains power cord

Remote
Keypad
console

Doorbell
Switch

Base Unit

Internal wiring

RJ45-8P8C
35'
MAX

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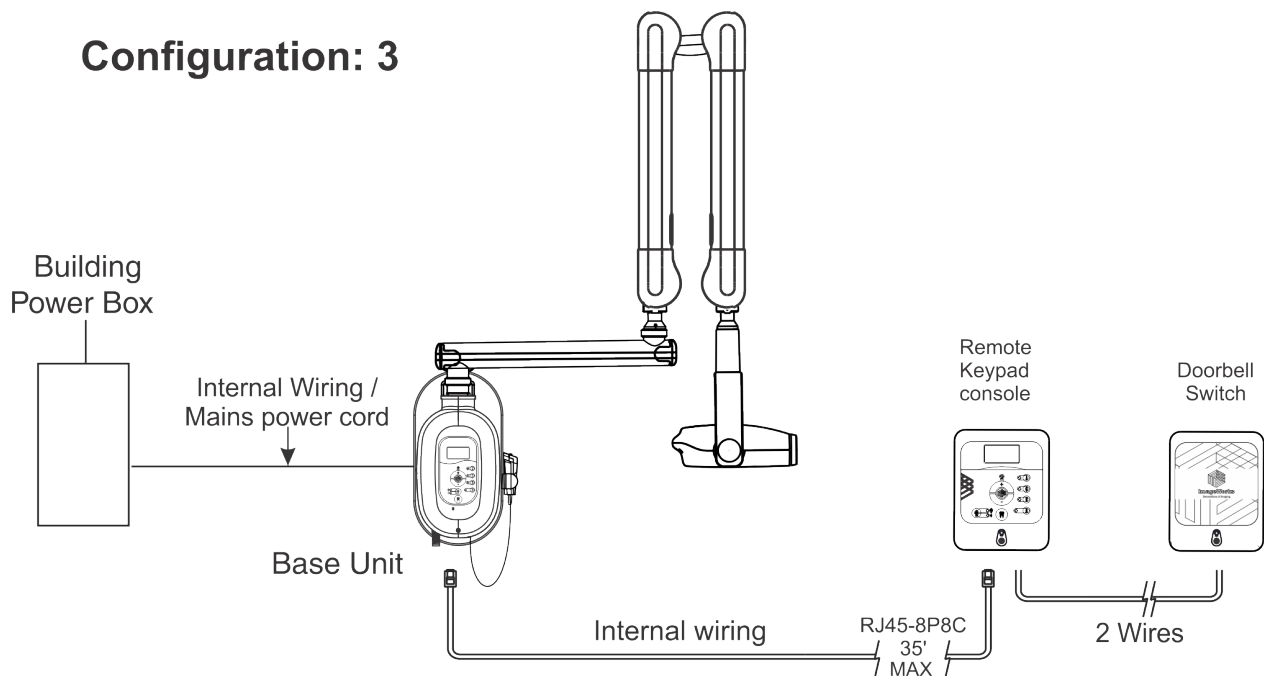
RJ45 (8P8C) with DOUBLE DOORBELL SWITCH
Can use both Keypad Consoles (internal and remote) with Internal Exposure Switch and double door bell switch

Configuration: 4

Building
Power Box

Internal Wiring /
Mains power cord

Doorbell
Switch

Base Unit

Internal wiring
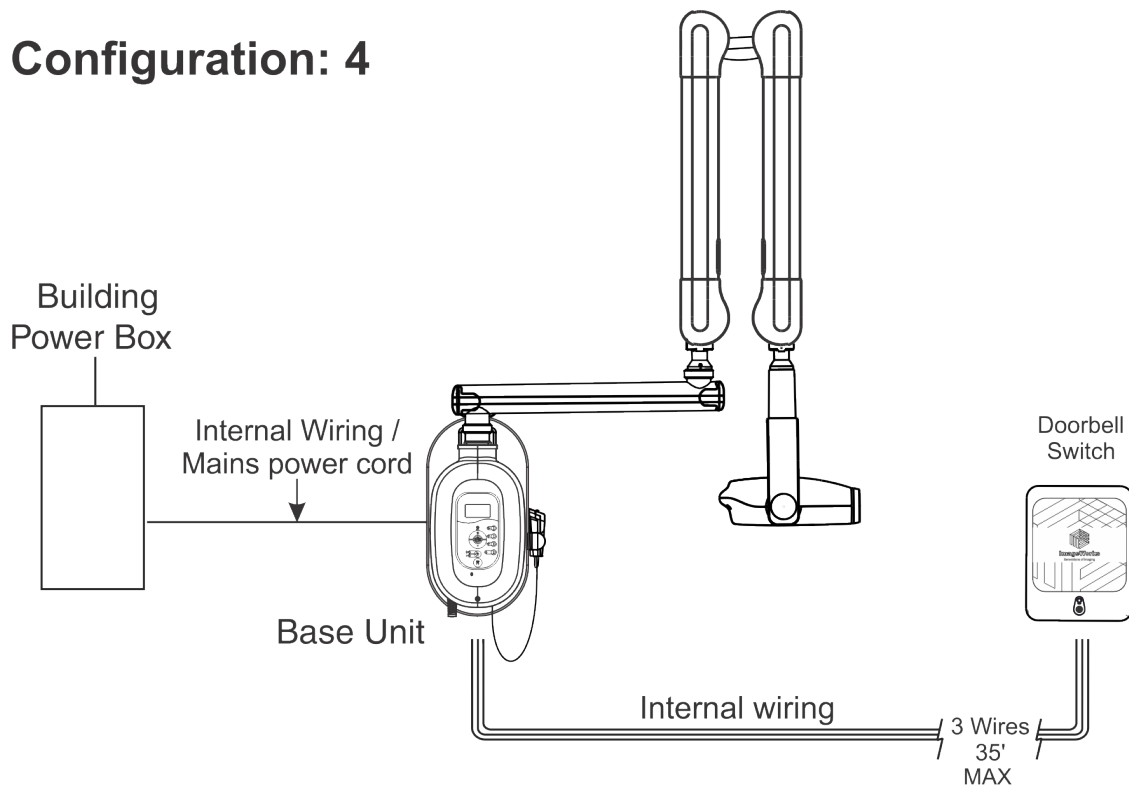
3 Wires
35'
MAX

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

Configuration: 5

Building
Power Box

Internal Wiring /
Mains power cord

Base Unit

Doorbell
Switch 1

Doorbell
Switch 2

Internal wiring

3 Wires
35'
MAX

2 Wires
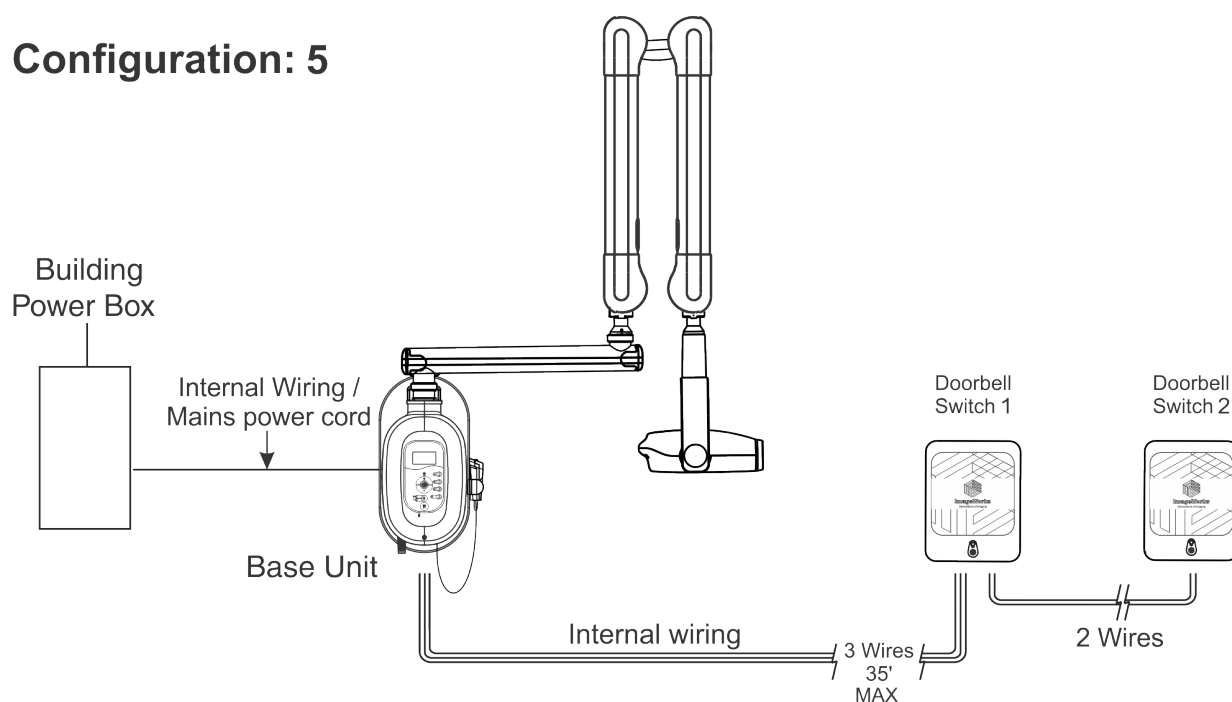
3 WIRE WITH DOUBLE DOORBELL SWITCH
Can use Internal Keypad Console with Internal Exposure Switch and double door bell switch

Configuration: 6

Building
Power Box

Internal Wiring /
Mains power cord

Base Unit

Doorbell
Switch

Internal wiring
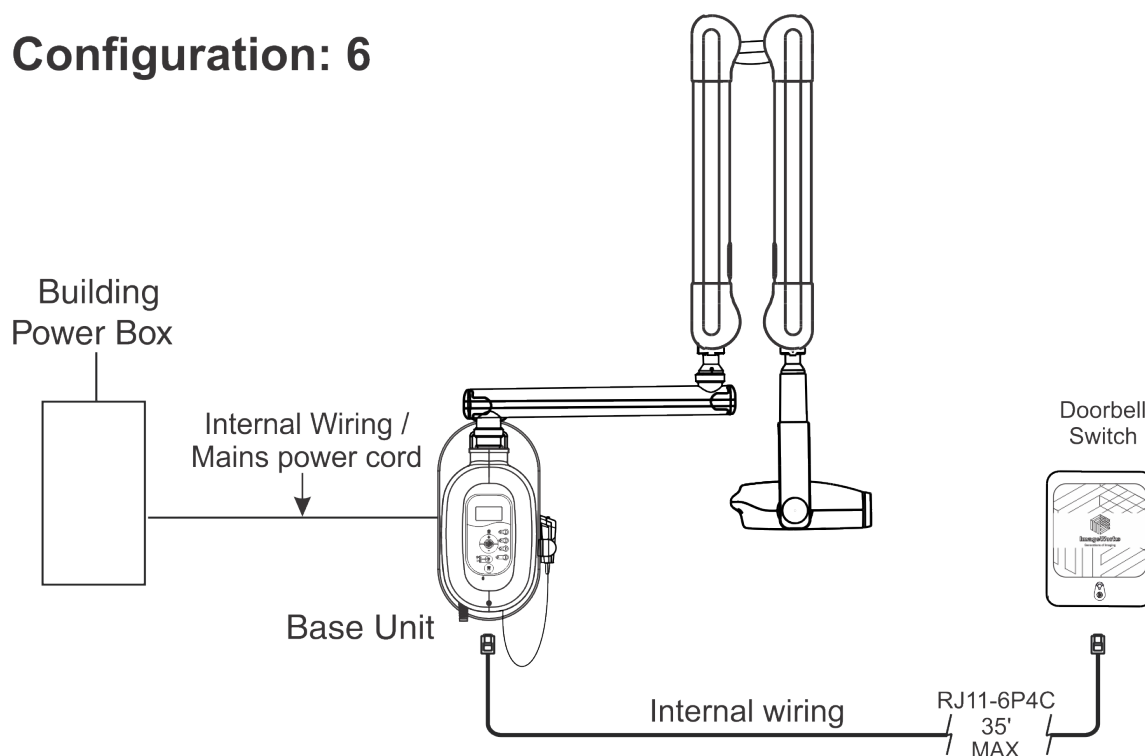
RJ11-6P4C
35'
MAX

RJ11 (6P4C) WITH SINGLE DOORBELL SWITCH
Can use Internal Keypad Console with Internal Exposure Switch and single door bell switch

Configuration: 7

Building Power Box

Internal Wiring / Mains power cord

Base Unit

Doorbell Switch- 1

Doorbell Switch- 2

Internal wiring

RJ11-6P4C 35' MAX

2 Wires
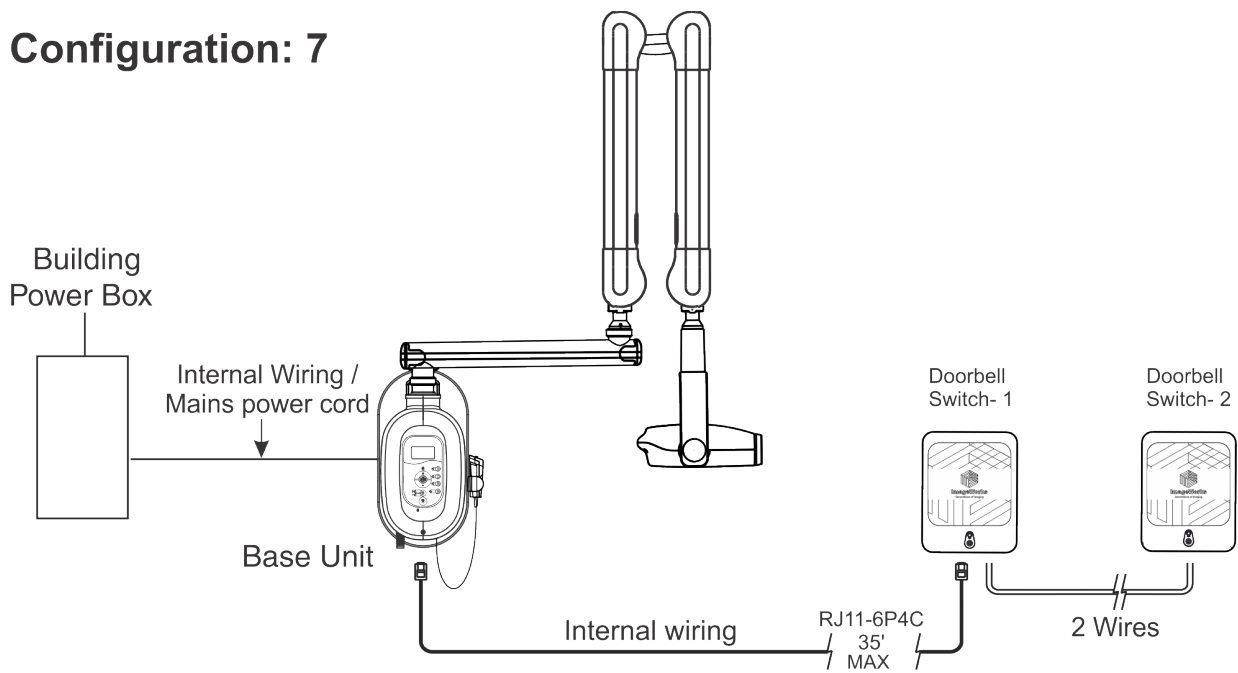
RJ11 (6P4C) WITH DOUBLE DOORBELL SWITCH
Can use Internal Keypad Console with Internal Exposure Switch and double door bell switch

☞ *ImageScan HD Floor Mount unit is powered directly through a Hospital-grade Plug. For ImageScan HD Floor Mount unit, exposure is given using Internal Exposure Switch as in Wall Mount Configuration 1.*

ImageScan HD Wall mounting Configurations
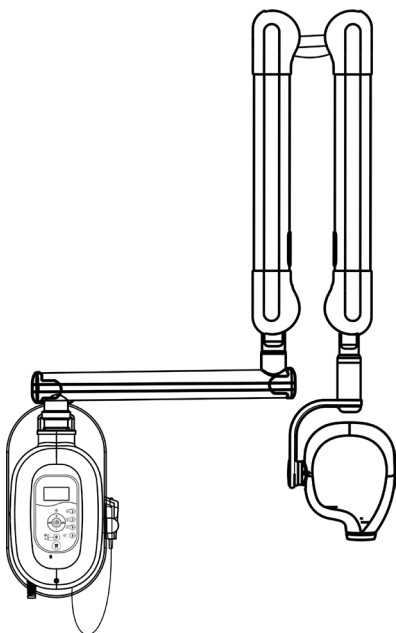
Single Stud Mounting
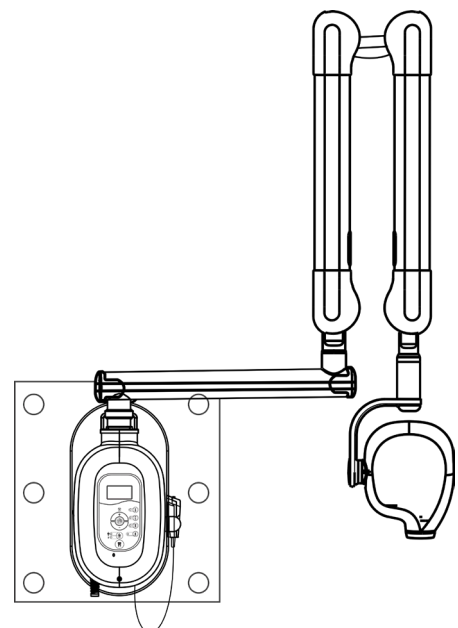
2 Stud Mounting

3.5 Keypad Console

All functional operating control of ImageScan HD is provided by the keypad Console located on the base unit, consisting of a LCD display and keypad. Apart from this, Remote Keypad Console (External Console with Doorbell Switch) and Doorbell Switch also is available as an optional accessory. This additional console will be used for different configurations of console as illustrated in Section 3.4. It allows both automatic and manual selections of exposure parameters. The location of the panel controls and indicators are shown by Figure 14, 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 14.

3.5.2 Keypad

In addition to the LCD display, the keypad Console contains 8 keys and exposure LED indicator. These keys are used to select the exposure parameters. ImageScan HD 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

section 4.7, Selecting an Exposure set 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.

Figure 14. ImageScan HD Keypad Console with LCD Display

Figure 15. **Door Bell switch**
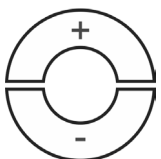
Figure 16. **Remote keypad Console**

Table A. Key description

Exposure Status LED Indicator		No Color: Idle / Standby Green: Ready to Deliver X-Ray Orange: Exposure in Progress Red: Operation Fault
+/- Keys		Navigate up or down a list menu. Increment or decrement parameter value.
Logo (Seconds / Milli Ampere)		Toggles between Seconds / mA
Adult / Child Preset Key		Toggles between Adult & Child Preset. Top LED : Adult Bottom LED: Child
Tooth selection Key		Each press selects different tooth in sequential mode.
Canine/Incisor		**Canine/Incisor** LED ON - Enable LED OFF - Disable
Bitewing		**Bitewing** LED ON - Enable LED OFF - Disable
Pre-Molar		**Pre-Molar** LED ON - Enable LED OFF - Disable
Molar		**Molar** LED ON - Enable LED OFF - Disable

4.1   Before You Begin

Regulator Approvals

Make sure that the operator has read and understood this manual regarding operation of the system. Users must exercise every precaution to ensure personal safety, and be familiar with the warnings presented throughout this manual and summarized in Chapter 1 (Page 7).

Government regulators may require that only a licensed operator may use this equipment. Check with your dealer regarding regulations.

Installation and use of radiation generating equipment is regulated by the government or its authorized agencies in most countries. Check with your local dealer regarding site approvals or usage requirements.

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. Make sure that the image capture films are stored and used per instructions.

Let the patient know that he/she is going to be exposed to X-Ray.
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. Make sure to place protective aprons and shields over the patient 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.

Position Indicating Device

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 built-in focus to skin distance of 220mm ± 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 220mm ± 5mm to 300mm ± 5mm

4.3 Achieving the Best Image Quality

ImageScan HD is engineered to provide the best platform for dental radiographic imaging. However, the best results are obtained when the equipment is used properly per the manufacturer's specifications. Practicing the following positioning techniques 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 as shown by Figure 17 below.

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

M – Molar
P – Pre-Molar
C – Canine
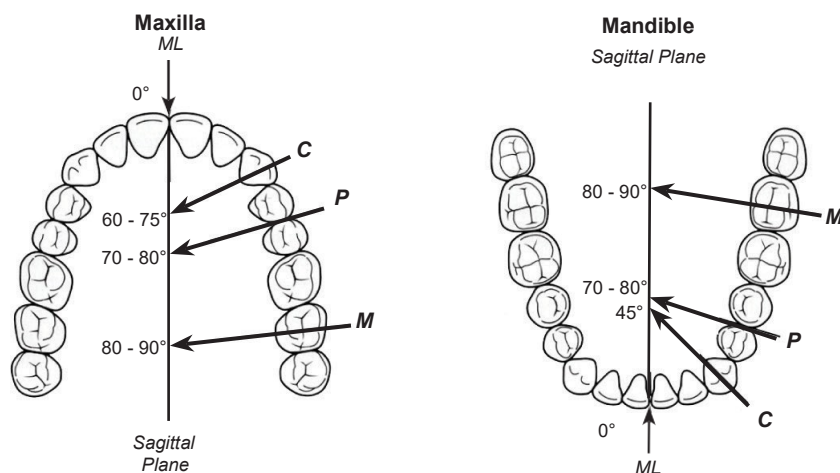
Figure 17. Horizontal Angulation

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☞ *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

The image receptor should be placed parallel to the long axis of the teeth as shown by Figure 18.

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

CR

CR *perpendicular to long axis of tooth & film*

Long axis of tooth

Film parallel to long axis of tooth
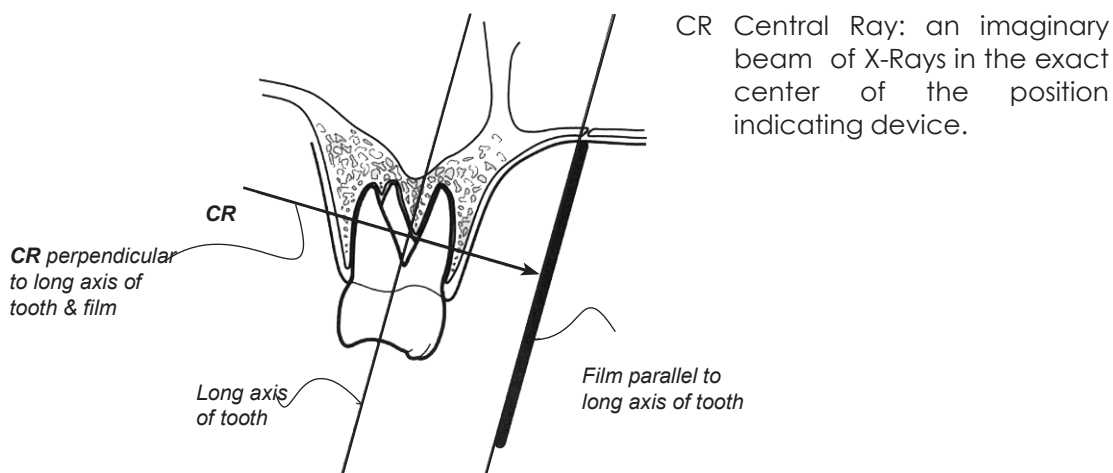
Figure 18. Paralleling Technique

☞ *Refer to Chapter 5 for details on navigating the Keypad Console for setup and operation of ImageScan HD*

4.4   Power Turn-On Procedure

Turn on ImageScan HD by performing the following steps:

1. Place the Main Power Switch located on the bottom of the Base Unit to the ON (I) position. See Figure 1.(Page 11)

☞ *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 display's Start-up Screen as shown by Figure 25 (Page 34).

3. Immediately following a successful self test, the console displays a home screen as shown by Figure 19 (page 30).

4.5   ImageScan HD Operating Procedure Summary

1.   Turn on ImageScan HD by performing the Power Turn-On Procedure provided in section 4.4.

2.   Introduce the receptor into the patient's mouth according to the chosen technique as shown by Figures 17 and 18 (bisecting or parallel - Page 27, 28).

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.

Refer to Tables 1 through 4 (Page 32 to 33) for estimated exposure values of minimum patient dose that can be modified per user requirement in Custom mode.

6.   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 ImageScan HD as necessary.

4.6   Exposure Settings and Tables

4.6.1 Default Exposure Program Presets
By default the keypad console boots into R1, Short cone, Adult, Canine/Incisor Presets. The default or start-up exposure program is the exposure program set to operate ImageScan HD 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 5.2.

4.6.2 Default Exposure Values
Estimated exposure values (kV,mA & S) listed by Tables 1 through 4 (Page 32 to 33) are for minimum patient dose and can be modified per user requirement later. Refer to the tables below for Default Exposure Values for specific ImageScan HD application modes and options.

Table 1. Default Exposure Values for Short/Long Cone R1 (Film)

Table 2. Default Exposure Values for Short/Long Cone R2 (Custom)

Table 3. Default Exposure Values for Short Cone R3 (Custom)

Table 4. Default Exposure Values for Long Cone R3 (Custom)

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 keypad 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
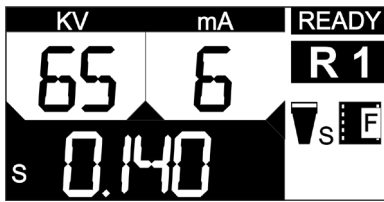
Figure 19. Home Screen

Bring the console back to home screen as shown in figure 19. Here the user can modify the mA, and S value The defaults (kV, Cone, and Preset mode) can be set during Configuration time (See Section 5.3).

Selecting an Exposure Set proceed as follows

An exposure set is a combination of patient type and tooth anatomy which the console uses as an index to retrieve the exposure parameters. For each mode, there are 8 presets available. To select one from these 8 exposure set, use the patient type key and the tooth anatomy keys.

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

1.   Press the ⬤▬🧍 key to select child (bottom LED),
2.   Press Tooth Selection Key and select Canine (LED Turns ON indicates selection of respective Teeth) (show the image of "Tooth Key")

Modifcation of mA & S values proceed as follows
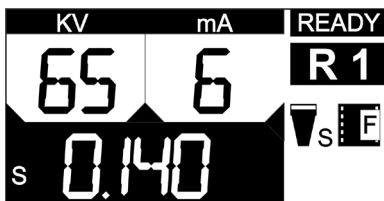
Figure 20. Home Screen
with S highlighted

Highlight the parameter

By default parameter 'S' is Highlighted 🗇)

☞   If values of mA is Highlighted and to be altered,change the values by using +/- keys.

If values of S to be altered,select by pressing 🗇) until the parameter is Highlighted and change using **+/-** keys.

Modify the parameter

Press **+/-** keys the required number of times to change the highlighted parameter. The parameter being changed to indicate the operation.
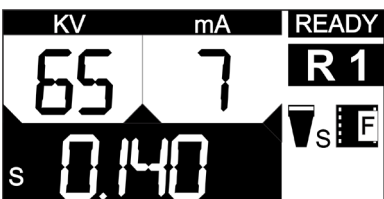
Figure 21. mA parameter
modified
and accepted

Accept the change

The set parameters are accepted automatically.

Figure 22. X-Ray - Preparing
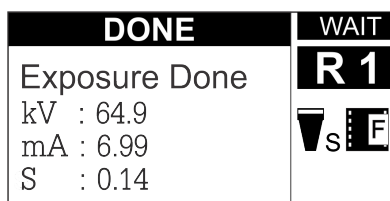
Now press **Exposure Switch** or **Remote Exposure Button** on the Doorbell switch to initiate the exposure.

Here the unit prepares itself to deliver the exposure. This stage might take a few seconds. An Audible beep sound depends on Prep beep settings (See section 4.6.3) and the X-Ray status indication LED illuminates green.

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

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 23. 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.

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

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

Figure 24. X-Ray - Results

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

The results screen is shown for 5 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.

The tube-head needs to cool down before proceeding to the next exposure. This waiting period depends on the specific 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 request- ing the operator to wait for the remaining amount of time required by the tube-head to cool down.

Table 1. Default Exposure Values for Short/Long Cone R1 (Film)

Validated Exposure Values (kV, mA & S) mentioned below are for minimum patient dose and can be modified as per user requirement.

Anatomy		kV	mA	Time (S)			
				Slow		Fast	
				Cone			
				Short	Long	Short	Long
Adult	Bitewing	70	6	0.22	0.71	0.18	0.56
	Canine	70	6	0.2	0.63	0.16	0.5
	Molar	70	6	0.22	0.71	0.18	0.56
	Pre-Molar	70	6	0.2	0.63	0.16	0.5
Child	Bitewing	70	6	0.16	0.5	0.13	0.32
	Canine	70	6	0.14	0.45	0.11	0.32
	Molar	70	6	0.16	0.5	0.13	0.32
	Pre-Molar	70	6	0.14	0.45	0.11	0.32

Table 2. Default Exposure Values for Short/Long Cone R2 (Custom)

Estimated Exposure Values (kV, mA & S) mentioned below are for minimum patient dose and can be modified as per user requirement.

Anatomy		kV	mA	Time (S)	
				Cone	
				Short	Long
Adult	Bitewing	70	6	0.18	0.56
	Canine	70	6	0.16	0.5
	Molar	70	6	0.18	0.56
	Pre-Molar	70	6	0.16	0.5
Child	Bitewing	70	6	0.13	0.32
	Canine	70	6	0.11	0.32
	Molar	70	6	0.13	0.32
	Pre-Molar	70	6	0.11	0.32

Table 3. Default Exposure Values for Short Cone R3 (Custom)

Estimated Exposure Values (kV, mA & S) mentioned below are for minimum patient dose and can be modified as per user requirement.				
Anatomy		**kV**	**mA**	**Time (S)**
				Cone
				Short
Adult	Bitewing	70	6	0.14
	Canine	70	6	0.16
	Molar	70	6	0.14
	Pre-Molar	70	6	0.16
Child	Bitewing	70	6	0.13
	Canine	70	6	0.13
	Molar	70	6	0.13
	Pre-Molar	70	6	0.13

Table 4. Default Exposure Values for Long Cone R3 (Custom)

Estimated Exposure Values (kV, mA & S) mentioned below are for minimum patient dose and can be modified as per user requirement.				
Anatomy		**kV**	**mA**	**Time (S)**
				Cone
				Long
Adult	Bitewing	70	6	0.14
	Canine	70	6	0.16
	Molar	70	6	0.14
	Pre-Molar	70	6	0.16
Child	Bitewing	70	6	0.13
	Canine	70	6	0.13
	Molar	70	6	0.13
	Pre-Molar	70	6	0.13

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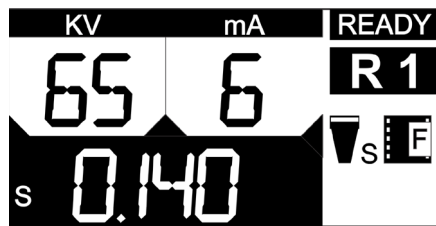
Power up - Indication
On power up, the console displays the Start-up Screen as shown on the left. Following this, the console performs self test. The keypad, beeper and LCD backlight are checked. Do not press any keys (including exposure switch) during self test period.

Figure 26: 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 top right corner of the display indicates that the system is ready to deliver an exposure.

5.1 Selecting a Preset Mode

A Preset Mode is a collection of exposure parameters (kV, mA and S) suitable for a particular type of image receptor. The keypad Console of ImageScan HD provides a total of three user modes of operation, which include:

❑ One factory programmed default modes, R1 (Film)

❑ Two custom modes : R2 & R3

Each mode provides 8 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.
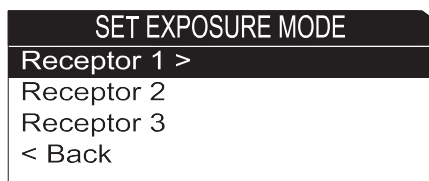
Figure 27: Mode Selection Screen

Mode Selection Screen
Go to Configuration menu as explained in Section 5.3.

Use the **+/-** keys to navigate within the list. Press these buttons until the desired mode is highlighted

Select Set Exposure Mode by pressing [icon] key.
A screen similar to the one shown on the left side appears on the display.

User can select one mode among these by pressing [icon] key.

By pressing [icon] key to returns home screen with the newly selected mode abbreviated on the top right side of the display.

5.2 Selecting kV

kV can be modified only in Manual mode.

To set Automatic mode proceed as follows.

Automatically
Manually >
< Back

Figure 28 : Automatic mode
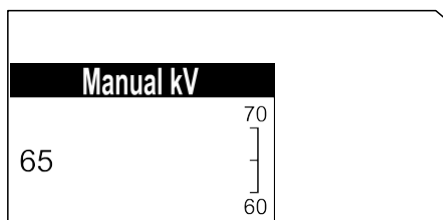
Go to Configuration menu as explained in Section 5.3.

Set **Select kV** option in Configuration menu by using ⬡ key.

In **Select kV** as shown in figure 28, set Automatic mode by pressing ⬡ key

In Automatic mode, user cannot modify the kV value.

Manual kV

65   70
                  60

Figure 29 : Manual mode

To modify kV value in manual mode proceed as follows.

Go to Configuration menu as explained in Section 5.3.

Set **Select kV** option in Configuration menu by using ⬡ key.

In **Select kV** as shown in figure 28, set manual mode by using ⬡ key.

Use Up/Down key to select the required kV and set kV value, by pressing ⬡ key as shown in figure 29.

5.3 Configuring the Defaults

To set the parameters like kV, modes and cone as required, proceed as follows.

Press **+/-** key simultaneously to access configuration menu (during start up logo)

The user can set/access the following options as shown in the Figure 30
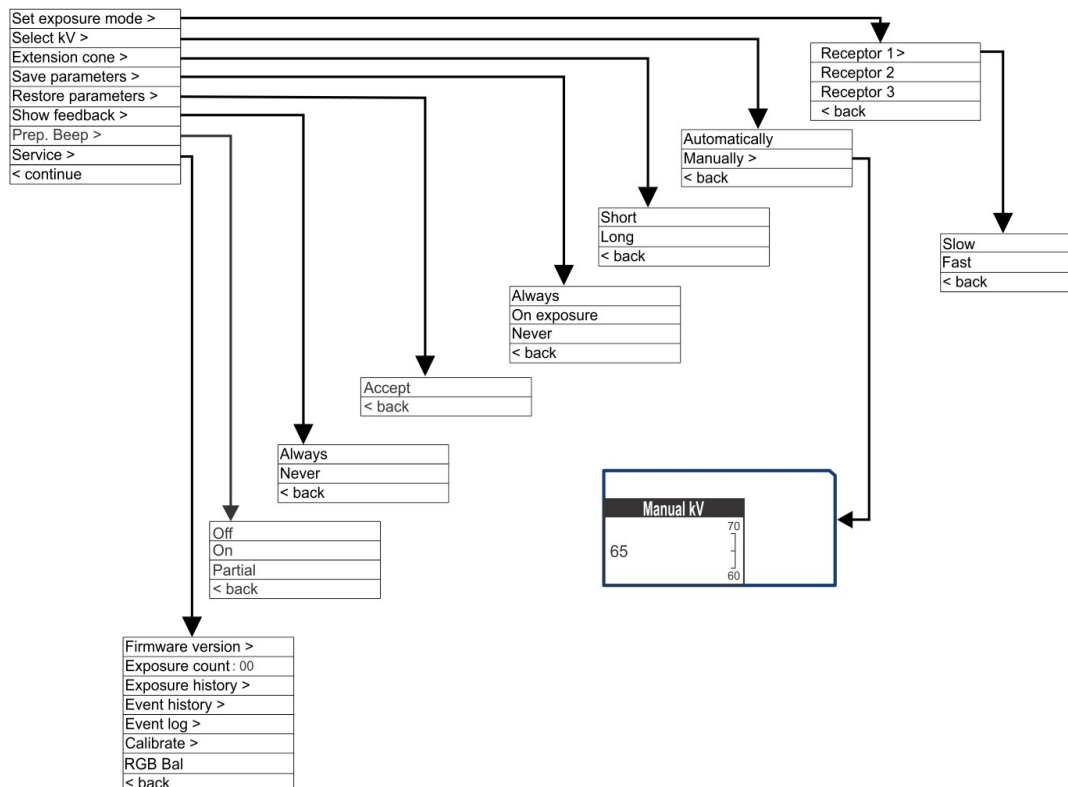
Figure 30: Configuration Screen

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❑ Use **+/-** key to navigate within Configuration menu.

❑ Press [icon] key to accept currently highlighted item.

❑ Press [icon] key to return previous menu.

5.4   Console Events

This section describes the special events displayed in the Keypad console. For Attention/ Warning messages, refer Table 5 and for error codes refer Table 7.

Figure 31. Stand-by Screen

Figure 32. Error Display

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

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 CN009).

• Display backlight turns RED

• An exposure can not be delivered until the issue is resolved.

Table 5: Attention / Warning Messages

Attention/Warning Messages	Screen	Condition

`Tube cooling`
`Please wait`
`<n> seconds`
	Home	EXPOSURE key pressed after an exposure and before the cooling period expires.

`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.

Chapter 6: Maintenance

6.1 Cleaning and Disinfecting

Important: Turn OFF ImageScan HD Wall mount or turn OFF and unplug the ImageScan HD Floor Mount Unit. Wait for 5 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 ImageScan HD by thoroughly performing the following procedures:

Important: 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.

❑ 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. Always guide the movements with your hand.

❑ Do not hang external loads or weights on the tube-head or Straight 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, Long Term Storage and Tube seasoning

❑ 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 X-Ray port with Lead .Using the Keypad Console set the parameters per Table below . Give Exposure and repeat exposure 5 times for each combination of kV, mA and S. After all the exposures are completed, the Unit is ready for use.

Table 6:

kV	mA	Time(S)
60	4	0.04
60	6	0.04
60	8	0.04
60	4	0.50
60	6	0.50
60	8	0.20
65	4	0.04
65	6	0.04
65	8	0.04
65	4	0.50
65	6	0.50
65	8	0.20
70	4	0.04
70	6	0.04
70	8	0.04
70	4	0.50
70	6	0.50
70	8	0.20

6.4 Preventive Maintenance

❑ For continued service support, ensure you have entered into an annual maintenance program with your dealer. 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) .

❑ 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 ImageWorks' Dealer Service representative. Call your authorized Imageworks' 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.

Important: 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.

Chapter 7: Troubleshooting & Error codes

ImageScan HD 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 7 below. The table lists the code and identifies the corresponding equipment operational fault. The corrective action for the error code is provided by Table 8, which also lists observed problems and their potential source.

Table 7. Error Codes

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
CN010	Filament limit fault
CN011	CAN fault
KB001	Key jam error

Chapter 7: Troubleshooting & Error codes

Table 8 provides troubleshooting tips to help the user recover from an equipment fault condition. It lists observed problems as well as recommends the corrective actions.

Table 8. Troubleshooting Tips

	Observed Problem	Recommended Action
1.	Error state with display indicating **CNXXX** error code	Switch off mains power. Wait for 2 minutes and then Switch on mains power. If the problem persists, contact authorized service personnel.
2.	Error state with display indicating **KB001** 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, contact authorized service personnel.
3.	The unit does not power on when mains is switched on.	Check for loose contact at the wall socket end. Or the wall outlet is not receiving power. Check local electrical circuit for trips. Switch off mains power. Wait for 2 minutes. Switch on mains power. If the problem persists, contact authorized service personnel.
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. Contact authorized service personnel to validate exposure quality.
5.	The mechanical Straight 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. Contact authorized service personnel.
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, contact authorized service personnel.

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CHAPTER 8: MEASUREMENT TECHNIQUES

8.1   Direct measurement method

Instruments used in kV, mA and timer accuracies measurement

S/N	Description	Make	Model	Remarks
01	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 ImageSKAN HD and measurement point TP2 on the control board(refer figure 34) provided for hooking measuring probe.

Figure 33. kV Feed
back circuit

Figure 34. Test Points

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

1. Connect the probe of the DSO to TP2 (kV 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 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.

Tube kV	Tube Current, Exposure Time					
60, 65 & 70	4mA, 0.04s	4 m A , 3.5s	6mA, 0.04s	6 m A , 3.5s	8mA, 0.04s	8mA, 0.2s

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 ImageSKAN HD and measurement point TP5 provided for hooking measuring probe.
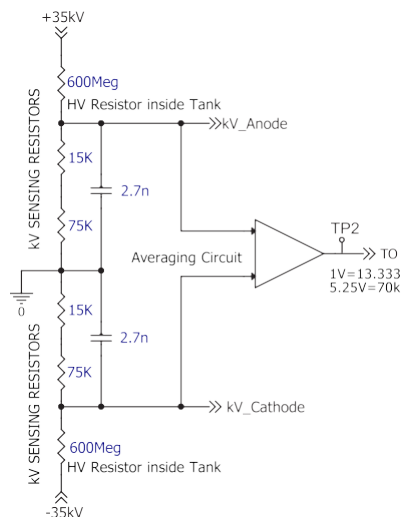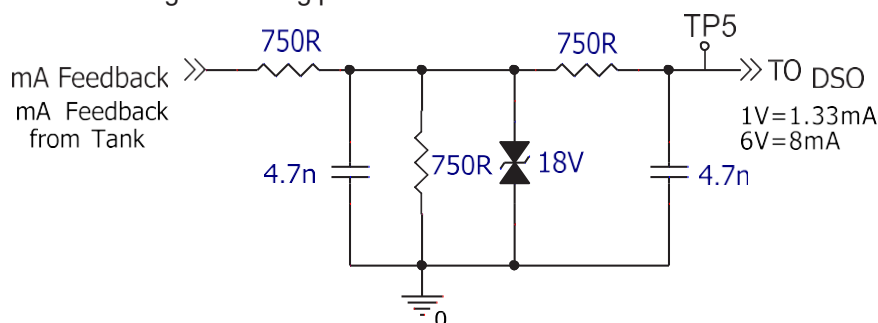

Figure 35. mA Feed back circuit
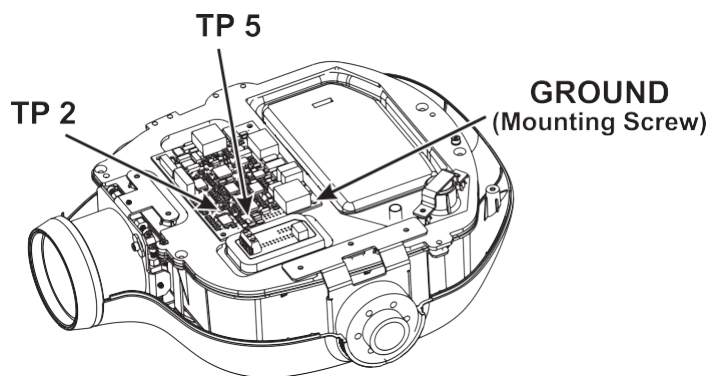
Test procedure:

(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.

Tube current loading (mA)	kV, S			
4	60, 0.04	60, 3.5	70, 0.04	70, 3.5
8	60, 0.04	60, 0.2	70, 0.04	70, 0.2

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.
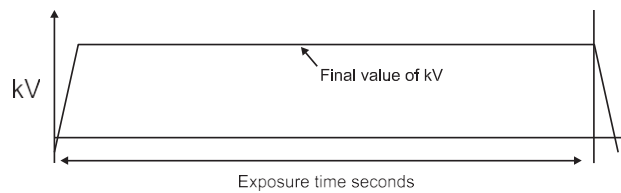
Figure 36. Exposure Time measurement

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 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 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 0.04S exposure time= ((0.0398 - 0.04) / 0.04) x 100 = -0.005 x 100 = **-0.5%***
Each measured value is verified with rejection limit.

kV	mA	S
70	6	0.04, 0.40, 2, 3.5
70	8	0.04, 0.2

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

8.2 Indirect Measurement method:

S/N	Description	Make	Model	Remarks
01	Accu-pro	Radcal	9096	Any Equivalent equipment can be used (with valid calibration)
02	Kvp sensor	Radcal	40×12-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,0.04S) and capture the wave form in the oscilloscope.
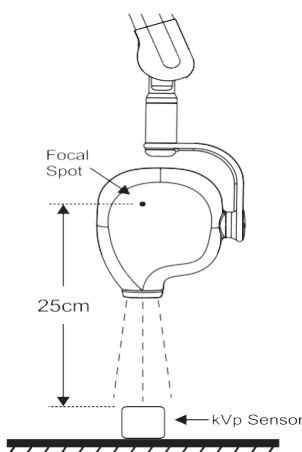
Acceptance criteria: No over shoot in the kV waveform

Figure 37. kV measurement using kVp sensor

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ANNEX A: TECHNICAL SPECIFICATIONS

Table A1. Tube-head Specifications	
Description	**Specification**
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)
Accuracy of current	< ± 5%
Maximum Exposure Time	3.5 seconds up to 6mA (7- 8mA @<= 0.2sec max)
Minimum Exposure Time	0.04 s
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/70 kV
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 and 300 mm
Leakage radiation @ 1m	< 0.88 mGy/h (100 mR/h)
Leakage radiation technique	70 kV, 8 mA, 1 s
Tube-head Outer Covers	PC ABS Plastic with Glossy Finish
PID / Cone Material/Extension Cone	Silicone Rubber/Aluminium/Markrolon - 2407

Table A2. X-Ray Tube Insert Specifications	
Parameters	**Specification**
Tube Insert Model	OX/70-4
Focal Spot (IEC60336)	0.4
Anode material	Tungsten
Anode angle	16°
Insert Inherent filtration	0.5 mm Al equivalent @ 70 kV
Anode thermal capacity	7 kJ
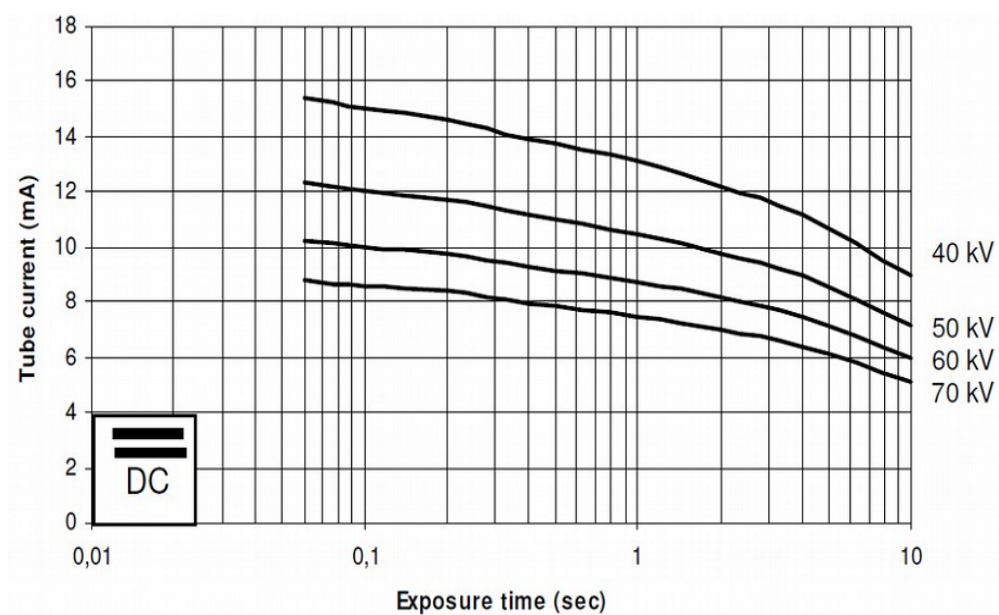
Illustration 59: X-Ray Tube Insert Rating Chart-OX/70-4

Figure A-1. X-Ray Tube Insert Rating Chart
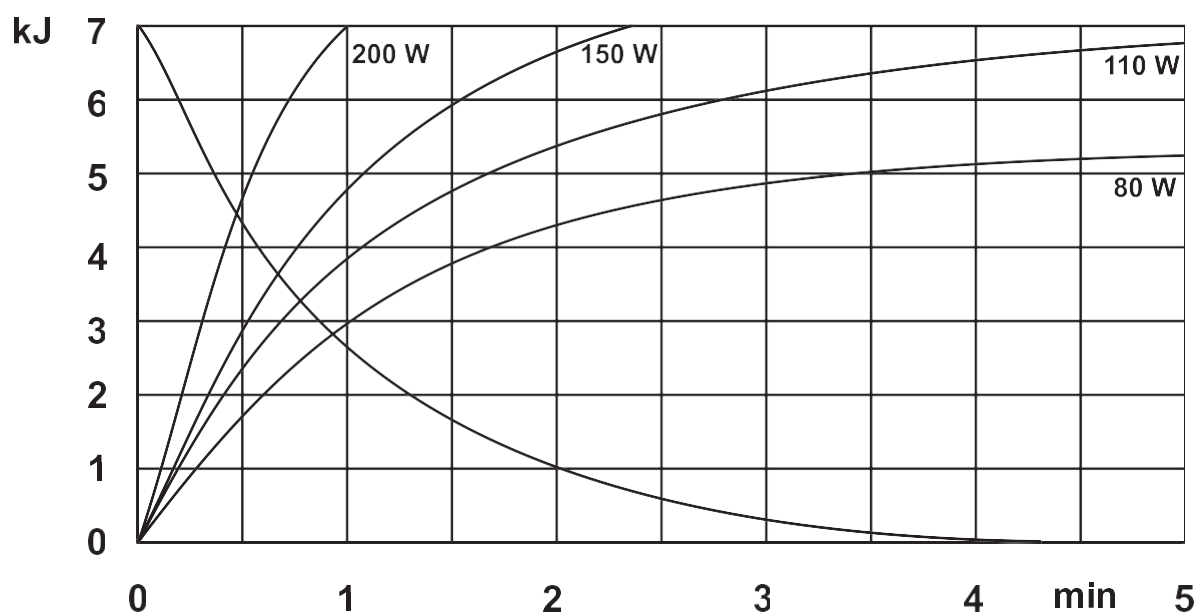
Figure A-2. X-Ray Tube Insert Thermal Data
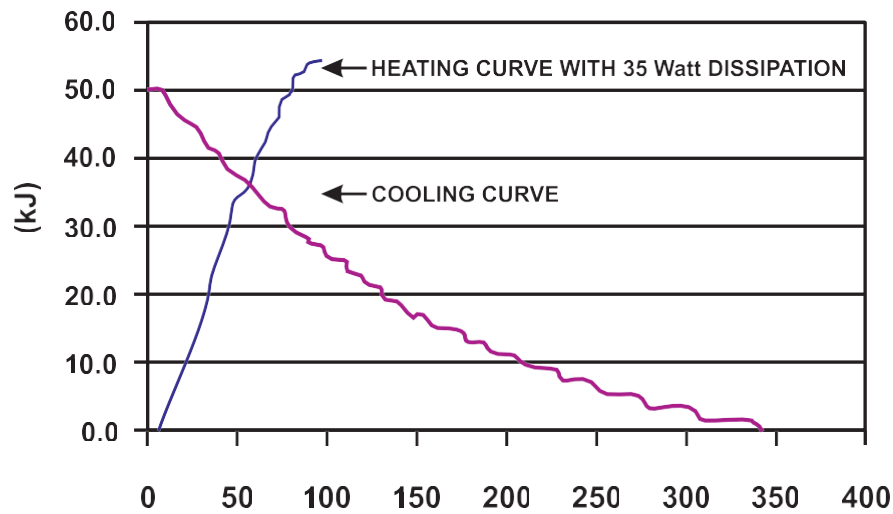
Figure A-3. Heating and Cooling Curve

Table A3. Mechanical Dimensions and Weight

Description	Comment/Value
Total Weight of System (including Packing Carton) (without Remote Switch & Optional Wall Plate(2 Stud))	Wall Mount 15" Straight Arm - 93 lbs max 24" Straight Arm - 95 lbs max 33" Straight Arm - 98 lbs max Floor Mount - 230 lbs max
Weight of Tube-head	13.2 lbs (Approx.)
Straight Arm Material	Aluminum
Type of painting	Glossy
Mounting type	Base Unit adapters for Wall mounted or Floor Mount
Extended Arm Reach	15" Straight Arm - 62" 24" Straight Arm - 71" 33" Straight Arm - 80"
Height of unit with Arms folded (Wall Mount)	49" ± 0.5
Height of unit with Arms folded (Floor Mount)	77" ± 0.5
Straight Arm Rotation about Base	180° ± 10°
Scissor Arm Swing (Wall Mount)	220° ± 10°
Scissor Arm Swing (Floor Mount)	70° ± 10°
Tube-head swivel on horizontal plane	530° ± 10°
Tube-head rotation about Vertical Plane	305° ± 5°
Pull Force of Scissor Arm about Straight Arm	< 2 kg
Pull Force of Straight Arm about base unit Assy	< 4 kg
Scissor Arm Opening Force (Wall Mount & Floor Mount)	< 1.5 kg
Pull Force of Scissor Arm about Base Column Assy	< 2.5 kg

ANNEX A: TECHNICAL SPECIFICATIONS

Table A4. Mains Power Requirements

Description	Requirement
Line voltage range	100-110 / 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 Range: 54Hz to 66Hz
Momentary Current (70kV, 8mA)	11A @ 100V AC and 4A @ 240V AC
Momentary Power (70kV, 8mA)	1.1 kVA @ 100V AC and 0.96 kVA @ 240V AC
Standby Current	250mA maximum
Line resistance	<= 0.4 Ohm at 100V AC and <= 0.8 Ohm at 240V AC
Current	Peak 30 A for 2 ms at mains turn on
Input Power Factor	>0.9 during any exposure
Electrical Classification	Class I, Type B
Electrical Connection	Line, Neutral and Ground, 1-Phase (Ground is Mandatory)

Table A5. Environmental Conditions

Description	Specification
Operating conditions	Temperature: 50°F to 104°F
	Humidity: 25% to 75%
	Altitude: 1500m
Conditions for transport and storage	Temperature: -22°F to 158°F
	Humidity: 95% non condensing
	Altitude: 3500m

B1: Name and Description of Product

Medical device name:
ImageScan High Frequency Intraoral X-Ray

Medical device model:
ImageScan High Frequency Intraoral X-Ray
303-001201-0 : ImageScan Wall mount 0.4FS High Frequency Intra oral X-ray with 15"
Straight Arm
303-001202-0 : ImageScan Wall mount 0.4FS High Frequency Intra oral X-ray with 24"
Straight Arm
303-001203-0 : ImageScan Wall mount 0.4FS High Frequency Intra oral X-ray with 33"
Straight Arm
303-001204-0 : ImageScan Floor Mount 0.4FS High Frequency Intra oral X-ray
Medical device Type: Dental X-Ray System
Medical device classification: IIb-Rule 10 -MDD, Class II FDA

B2: 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 :

The products described herein conform to the UL safety marking**(Proposed)**.

CLASSIFIED
c(UL)US
3UZ9
MEDICAL-APPLIED
ELECTROMAGNETIC
RADIATION EQUIPMENT
AS TO ELECTRICAL
SHOCK, FIRE AND
MECHANICAL HAZARD
ONLY. IN ACCORDANCE
WITH 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 60601-1-3: 2008, IEC
60601-2-65 :2012, IEC 60601-2-28: 2010.
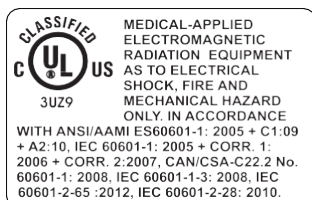
CE marking **(Proposed)**

C E 0843

B4: Declaration

The products described herein, are designed, manufactured, inspected, tested, and released by Skanray Technologies Pvt Ltd, a contract manufacturer for ImageWorks,Inc., In accordance with FDA's 21CFR, Part 820, ISO 9001:2008 and ISO 13485:2003.

B5: Authorized Representative

SMK Imaging LLC
8 Westchester Plaza, Suite 112
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1-914.592.6100 - Voice
1-800.592.6666 - Toll Free
1-914.592.6148 - Fax
Web: www.imageworkscorporation.com

ANNEX C: GUIDANCE & MANUFACTURER'S DECLARATION

According to: EN 60601-1-2: 2001 + A1:2006
(Group 1, class A, for use in Hospitals) (Not LIFE-SUPPORTING)
ImageWorks High Frequency Intraoral X-Ray is tested per applicable IEC standards, to be used under electromagnetic environment specified below. The customer or the user of ImageWorks High Frequency Intraoral X-Ray should assure that it is used in such an environment.

Table C1. Guidance and Manufacturer's Declaration –
Electromagnetic Emissions For all EQUIPMENT and SYSTEMS

Emissions Test	Compliance	Electromagnetic Environment - Guide
RF emissions EN 55011	Group 1	ImageScan HDHigh Frequency Intraoral 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 EN 55011	Class A	ImageScan HD High Frequency Intraoral X-Ray is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network supplying buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/flicker EN 61000-3-3	Complies	

ANNEX C: GUIDANCE & MANUFACTURER'S DECLARATION

Table C2. 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) 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 & voltage variations on power supply input lines EN 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0,5 cycle	< 5 % UT (> 95 % dip in UT) for 0,5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ImageScan High Frequency Intraoral X-Ray requires continued operation during power mains interruptions, it is recommended that this High Frequency Intraoral X-Ray be powered from an uninterruptible power supply or a battery.
	40 % UT (60 % dip in UT) for 5 cycles	40 % UT (60 % dip in UT) for 5 cycles	
	70 % UT (30 % dip in UT) for 25 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 5 sec	
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.

ANNEX C: GUIDANCE & MANUFACTURER'S DECLARATION

Table C3. 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 EN 61000-4-6	3 Vrms 50 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable/mobile RF communications equipment should be used no closer to any part of the Imageworks High Frequency Intraoral 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 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,a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following

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 ImageScan HD is used exceeds the applicable RF compliance level above, the ImageScan HD High Frequency Intraoral 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 ImageScan HD High Frequency Intraoral X-Ray.

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

ANNEX D: CONTACT DETAILS

Corporate Head Quarters/ Factory and Technical Support

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