SDX User Guide

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Safety Issues

Equipment to be Operated by Qualified Personnel Only

SDX is an X-ray emitting, electro-medical device and can be used only under the supervision of qualified medical staff. The equipment must be used according to the procedures in this manual and never for purposes different than those for which it has been designed, nor should any items be connected to it that were not supplied as part of the system. Ensuring that the SDX equipment and the facility in which it is used are properly registered with local, state, or national agencies remains the responsibility of the customer, as are any legal requirements connected with the possession, installation, and use of the equipment.

Protecting SDX Equipment from RF Interference

Although the equipment is designed to provide a reasonable degree of protection from electromagnetic interference according to International Electrotechnical Commission (IEC) regulations, it must be installed at an adequate distance from electricity transformer rooms, static continuity units, two-way amateur radios and cellular phones. To ensure proper operation of the SDX, the latter can be used only at a minimum distance of 5 feet (1.5m) from any part of the SDX equipment.

Any instrumentation or equipment for professional use located near SDX must conform to Electromagnetic Compatibility regulations appropriate to this type of equipment. Non-conforming equipment, with known poor immunity to electromagnetic fields, may not operate properly unless they are installed at a distance of at least 10 feet (3m) from SDX and supplied by a dedicated electric line.

Take Appropriate Precautions during SDX Operation

Appropriate accessories, such as lead aprons, must be used, where necessary, to protect the patient and the operator from radiation.

The SDX system has been determined to be in accordance with international safety standards and is deemed suitable for use within the patient area, which extends from the patient for a distance of 5 feet (1.5m). Outside the patient area, the presence of approved non-medical grade equipment and Listed / Approved / Certified Information Technology Equipment (ITE) computer equipment is acceptable.

Label Locations

NOTE: These items refer to labels pictured on the following page. With the exception of labels 2b and 5c, all labels are located externally on the equipment as shown. Labels 2b and 5c are only accessible when the appropriate enclosure covers are removed.

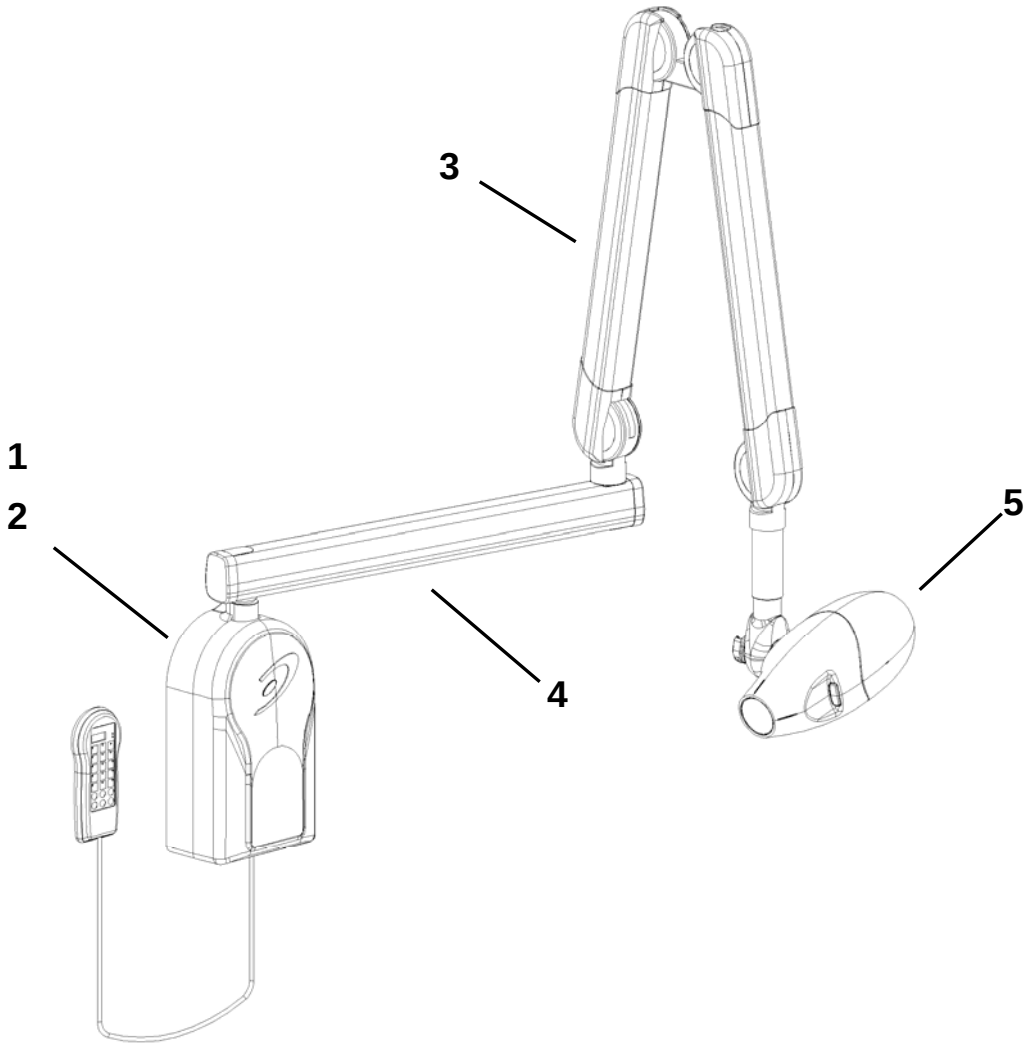
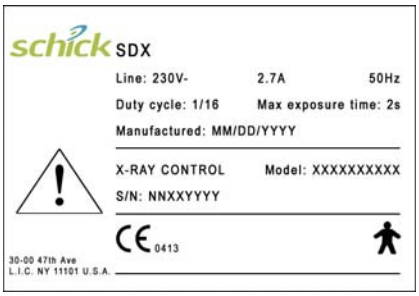
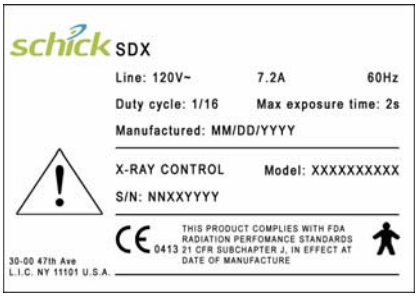


Figure 1. SDX System Label Locations

1a
SDX label (230V)

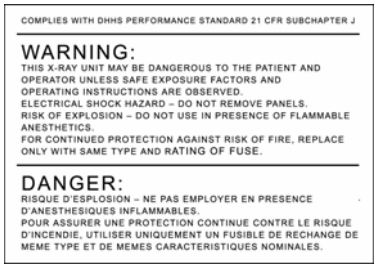


1b
SDX label (120V)



1c
ETL label
(120V only)

2a
"WARNING" label
(120V only)

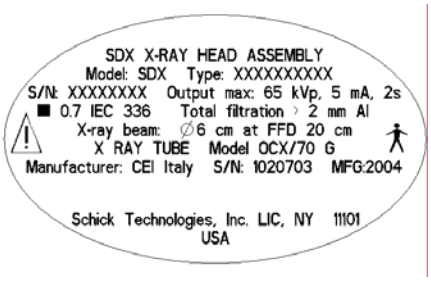


2b
High Voltage
label

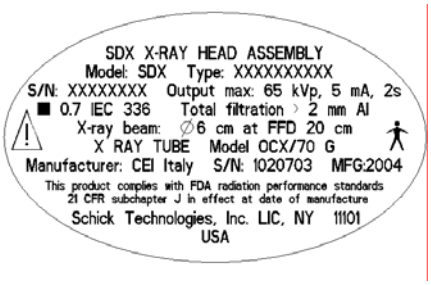
3
Scissors arm
label

4
Extension arm
label

5a
X-ray Tube label (230V)



5b
X-ray Tube label (120V)



5c
High Voltage
label

Symbols

The following symbols are used in this manual and on SDX. Symbols and icons located on the Remote Keypad can be found on Figure 3 and are described in Table 1.

Symbol	Description
	Type B Equipment
	Indicates an attention to users to consult accompanying documents for more information.
~	Alternating current
N	Connecting point to the neutral conductor
L	Connecting point to the live conductor
	Protective ground
	Functional ground
	OFF
	ON
	Focal point according to IEC 336
	X-ray emission

1. Overview

1.1. Purpose

The Schick Intra-oral X-ray System (SDX) produces X-rays that are used during dental examinations. SDX can be used with existing film-based technology as well as with Schick Technologies CDR2000 and CDR Wireless Sensors.

Engineered especially with Schick Technologies customers in mind, SDX provides a convenient, versatile interface for both CDR2000 and CDR Wireless Sensor types. For easy connection, CDR2000 Sensors can be plugged directly into a compatible connector on the SDX tube enclosure. CDR Wireless Sensors benefit from an Antenna and Receiver that have been integrated directly into SDX, eliminating the installation of a separate Antenna / Receiver unit. Information about using CDR Sensors with the SDX system can be found in the CDR Wireless / SDX Software User and Installation / Service Guides.

If you do not use CDR Sensors, we recommended that you use high-speed films or EKTASPEED films in order to limit the dosage absorbed by the patient.

1.2. Indications for Use

SDX is indicated for individuals who require dental radiographic examinations for the assessment of their oral health.

1.3. System Description

SDX is composed of a Timer Module (that controls the equipment functions), an X-ray Head (including the collimator), and a Remote Keypad (used to select exposure parameters and to operate the system).

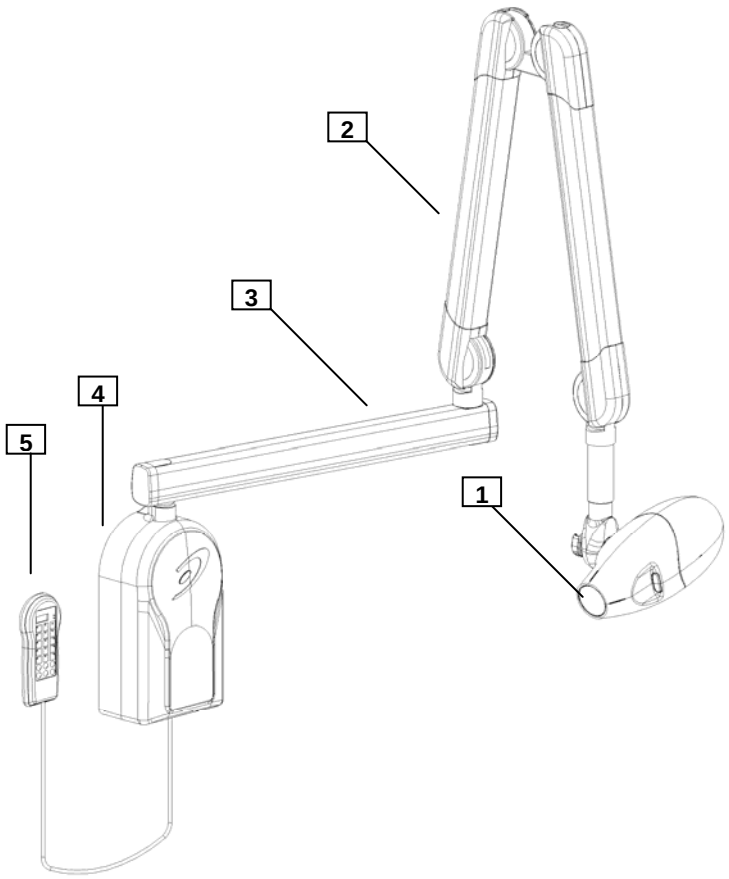
The Timer Module uses microcontroller technology to provide high quality X-ray images. Most conventional X-ray sources use the inherent capability of the X-ray Tube to conduct electric current in only one way. In comparison, SDX uses constant voltage technology to generate continuous and steady exposures. Microprocessor-controlled circuitry ensures that exposure times and emission parameters, kVp and mA, remain constant during the exposure. Selecting a different tooth anatomy is done at the press of a button on the Remote Keypad; this also selects an exposure time appropriate to the selected tooth and patient size.

The X-ray Head is compact, measuring only 10.6 in (27 cm), while the focal spot-to-skin distance remains the standard 7.8 in (20 cm). Because the X-ray Head is only 9.9 lbs (4.5 Kg), the arm is easy to handle and position.

To maintain its operational efficiency and prolong its functional life, SDX includes a low, tube-cooling time in order to limit the waiting interval between one exposure and the next, even when the equipment is being used intensively. Cooling time varies according to usage conditions and can assume 1 : 30 values (30-second wait period for every 1 second exposure) or 1 : 45 (45-second wait period for every 1 second exposure). SDX calculates usage conditions and applies the correct waiting time between consecutive exposures.

1.4. Parts Location

The SDX system (shown in Figure 2) consists of the following hardware: X-ray Head assembly, Scissors Arm, Extension Arms (of either 31.5, 23.6, or 11.8 inches (80, 60, or 30 cm)), Timer Module, Remote Keypad, and optional Mobile Stand.



1 X-ray Head

2 Scissors Arm

3 Extension Arm (various lengths)

4 Timer Module

5 Remote Keypad

6 Mobile Stand (not shown) (optional)

Figure 2. SDX System (Wall-Mounted Option)

2. General Use Instructions

2.1. Equipment Startup

NOTE:To avoid receiving an error during the system self-test, do not press any of the buttons on the Remote Keypad until the indicators and the exposure time have returned to their default settings.

1. To turn on the SDX, press the main switch located on the bottom part of the Timer Module cover. This will initiate a system self-test, during which the Keypad LEDs illuminate.
2. At the end of the self test, the SDX returns to the configuration the last time it was operated. At this point the SDX is in Standby condition.

2.2. Preset / Manual Exposures

Exposure durations may be set automatically by selecting tooth anatomy and patient size in conjunction with imaging media type, or by manually incrementing or decrementing the value shown in the Keypad display. Factory presets are available for film and CDR Sensors (refer to Table 2, Table 3, and

Table 4). User-defined presets are available by choosing the AUX selection (see **Section 2.3**).

2.2.1. Selecting Receptor Type for Anatomic Exposures

NOTE:Bold numbers in the following procedure refer to Figure 3.

The SDX enables users to select an exposure setting optimized for the type of receptor (digital Sensor or film) being used. Four selections are possible using button (**13**): Indicators (**14**) and (**15**) select film types D and E, respectively. Indicator (**16**) is for CDR Sensors. Indicator (**17**) accesses customized, preset exposure times configured by the operator (see **Section 2.3**).

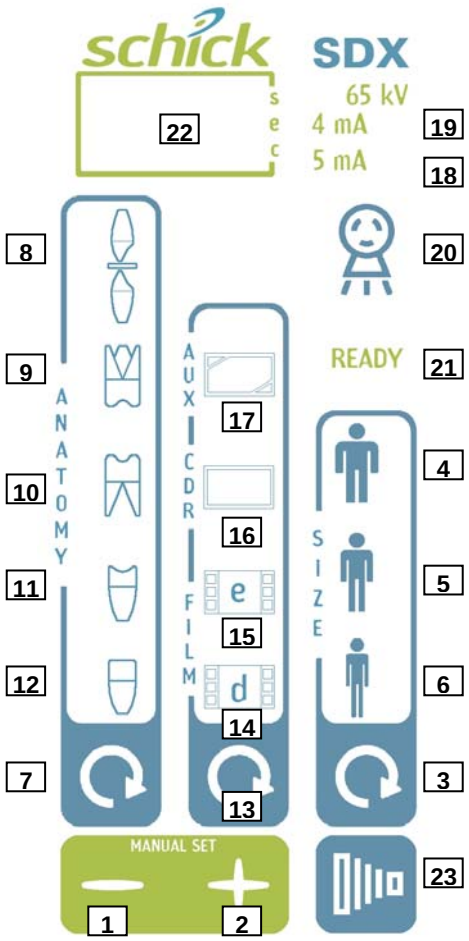


Figure 3. SDX Remote Keypad

Table 1. SDX Remote Keypad Description

No.	Group	Item	Description
1	Manual Set		Manually decrease exposure time
2	Manual Set		Manually increase exposure time
3	Size		Select patient size
4	Size		Large patient selection (preset exposure)
5	Size		Normal patient selection (preset exposure)

No.	Group	Item	Description
6	Size		Small patient selection (preset exposure)
7	Anatomy		Select tooth anatomy to be imaged
8	Anatomy		Posterior Bitewing selection (preset exposure)
9	Anatomy		Upper molars selection (preset exposure)
10	Anatomy		Lower molars selection (preset exposure)
11	Anatomy		Pre-molars selection (preset exposure)
12	Anatomy		Incisor-canine selection (preset exposure)
13	Aux / CDR / Film		Select imaging media
14	Film		D-speed film selection (preset exposure)
15	Film		E-speed film selection (preset exposure)
16	CDR		CDR Sensor selection (preset exposure)
17	Aux		Customizable exposure setting
18	65 kV	5 mA	5 mA anodic current selection
19	65 kV	4 mA	4 mA anodic current selection
20	Active		X-ray emission occurring
21	Ready	READY	Ready to take X-ray exposure
22	—		3-digit exposure time display (in seconds)
23	—		Take X-ray exposure

2.2.2. Selecting Preset Anatomical Exposures

NOTE:Bold numbers in the following procedure refer to Figure 3.

In preset mode, the patient size (**3**) and the type of tooth (**7**) can be varied. Pressing the Patient size selection button (**3**) emits an audible signal and toggles through the body types: LEDs (**4** to **6**). Pressing the Anatomy selection button (**7**) toggles through the tooth types: LEDs (**8** to **12**).

Table 2. Exposure Times for Type D and Type E Films (in Seconds)

Anatomy / Indication		**Type D Film** d			**Type E Film** e		
Size	**LED**	**Large**	**Normal**	**Small**	**Large**	**Normal**	**Small**
Posterior Bitewing		0.60	0.45	0.30	0.38	0.30	0.20
Upper molars		0.62	0.47	0.31	0.39	0.29	0.20
Lower molars		0.49	0.36	0.25	0.31	0.23	0.16
Premolars		0.39	0.29	0.20	0.26	0.20	0.13
Incisors / canines		0.31	0.23	0.16	0.20	0.16	0.10

*NOTE:For Type D and E films, SDX automatically selects a 5mA anode current (shown by LED (**18**), to provide good quality images with reduced exposure times. SDX can also be configured for ultra-sensitive films (Type F), with the assistance of a Service Engineer.*

Table 3. Exposure Times for Type F Film (in Seconds)

Anatomy / Indication		**Type F Film**		
Size	**LED**	**Large**	**Normal**	**Small**
Posterior Bitewing		0.25	0.20	0.13
Upper molars		0.25	0.20	0.13
Lower molars		0.20	0.16	0.10

Anatomy / Indication		Type F Film		
Size	**LED**	**Large**	**Normal**	**Small**
Premolars		0.16	0.12	0.08
Incisors / canines		0.13	0.10	0.07

Table 4. Exposure Times for CDR Sensors (in Seconds)

Anatomy / Indication		CDR Sensor 		
Size	**LED**	**Large**	**Normal**	**Small**
Posterior Bitewing		0.18	0.14	0.07
Upper molars		0.22	0.18	0.12
Lower molars		0.18	0.14	0.09
Premolars		0.16	0.12	0.07
Incisors/canines		0.14	0.12	0.07

*NOTE: For CDR Sensors, SDX automatically selects a 4mA anode current (shown by LED (**19**), to provide good quality images with reduced radiation exposure.*

2.2.3. Selecting Manual Exposures

NOTE:Bold numbers in the following procedure refer to Figure 3.

To access the manual mode, press either the Increase (**2**) or Decrease (**1**) button. The system exits the preset exposure mode and switches off the LEDs corresponding to the tooth type and patient size (the selected imaging media LED remains on).

The alphanumeric display (**22**) shows the last preset time exposure; to change it, press the Decrease or Increase buttons until the desired value is displayed. An alarm sounds as the setting is changed. To change the exposure times more quickly (4 units a second), press and hold button (**1**) or (**2**) for more than 2 seconds.

NOTE:Exposure times can vary from a minimum of 0.01 seconds to a maximum of 2 seconds according to the following list:0.01– 0.02 – 0.03 –0.04 – 0.05 – 0.06 –0.07 – 0.08 - 0.09 – 0.10 – 0.12 – 0.14 – 0.16 – 0.18 – 0.20 – 0.22 – 0.25 – 0.28 – 0.32 – 0.36 – 0.40 – 0.45 – 0.50 – 0.56 – 0.63 – 0.71 – 0.80 – 0.90 – 1.00 – 1.10 – 1.25 – 1.40 – 1.60 –1.80 – 2.00.

NOTE:For exposure times lower than 0.04 seconds, the <25% limit between the value of different selections is not observed (EN60601-2-7 regulation).

2.3. Modifying the Custom Exposure Table

SDX can be customized for exposure times different than those preset by the manufacturer by patient anatomy. This is possible through the use of a customizable table, corresponding to the Aux symbol and LED (**17**) on the Remote Keypad. To access the table and modify it, perform the following procedure.

NOTE:Bold numbers in the following procedure refer to Figure 3.

1. Press the imaging media button (**13**) to select Aux (**17**) (if not already selected). To enter editing mode for custom exposure times, press (**13**) and (**7**) at the same time. Editing mode is confirmed when the Aux LED (**17**), the time for the selected tooth / size combination (**22**), and the anode current LEDs (**18**) and (**19**) are flashing.
2. Press the patient size (**3**) and anatomy (**7**) buttons to display the exposure times for those settings, then use the increase (**2**) or decrease (**1**) buttons to change the custom exposure time for that size / tooth anatomy combination.
3. Press the imaging media button (**13**) and either the increase (**2**) or decrease (**1**) button at the same time to change the anodic current used for that size / tooth combination.
4. Repeat steps 2 and 3 to change other exposure times in the table.
5. Confirm the changes by pressing the Exposure button (**23**). When the display / LED stops flashing, the new exposure time has been saved.
6. To exit the customized table without storing data it is necessary to turn off the SDX. Wait until all of the Keypad indicators are off before turning the system on again.

2.4. Positioning the X-ray Head

1. Set the X-ray Head at an angle appropriate for exposure, given the considerations for anatomy and X-ray Head placement (**see Figure 4**, **Figure 5**, **Figure 6**, **Figure 7**).
2. Position the imaging media (CDR Sensor or film) in the patient's mouth, following either a bisecting or parallel technique. For more information, see **Section 2.5**.
3. Verify imaging media and X-ray Head placement, making any positioning adjustments as necessary.

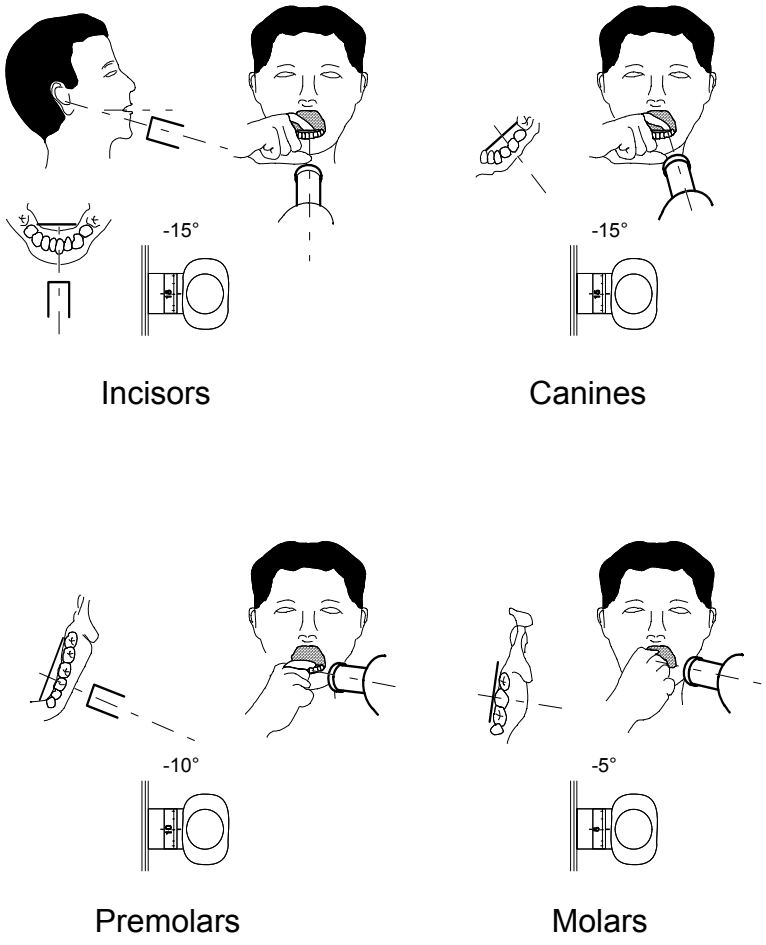


Figure 4. X-ray Head Positioning for Lower Jaw (Mandibular) Exposures

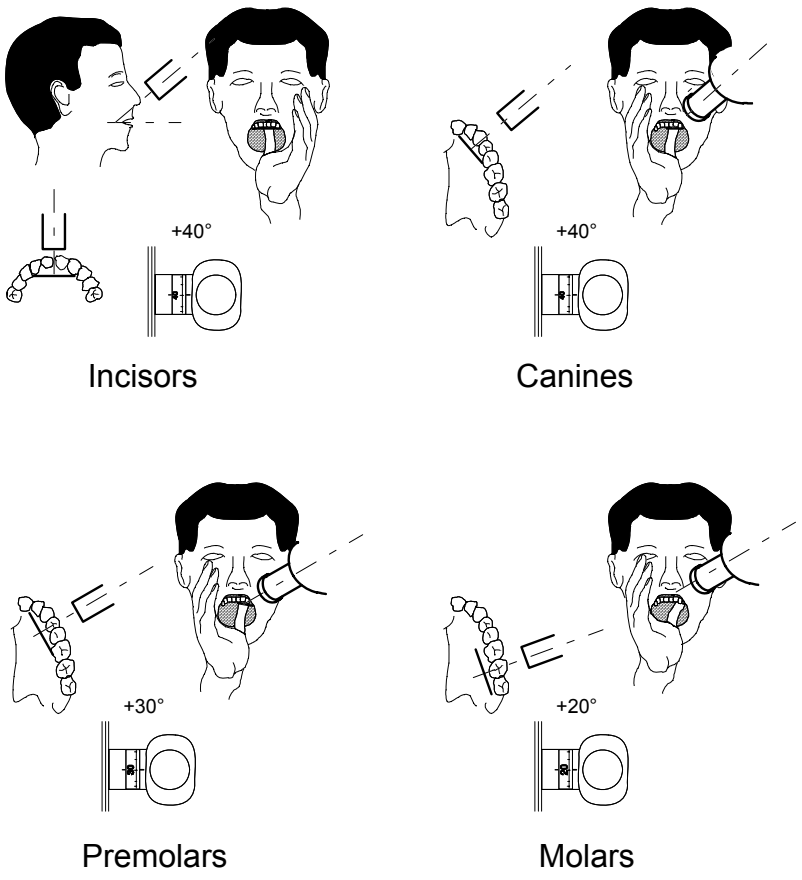


Figure 5. X-ray Head Positioning for Upper Jaw (Maxillary) Exposures

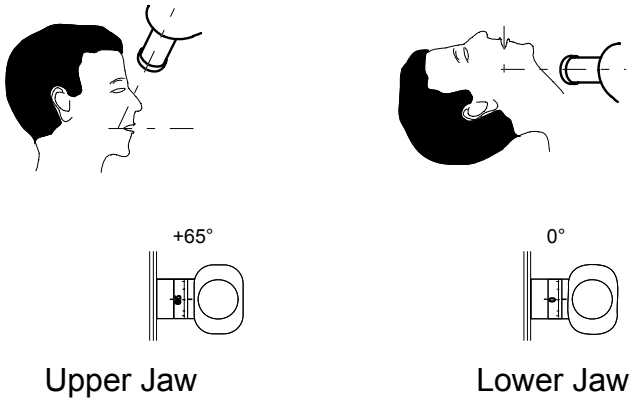


Figure 6. X-ray Head Positioning for Occlusal Exposures

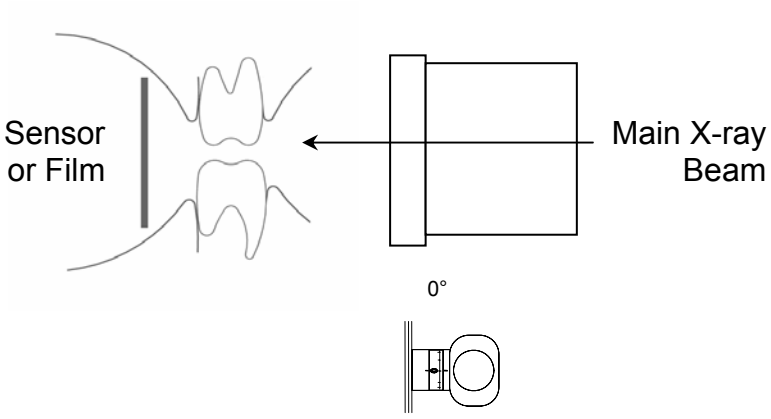


Figure 7. X-ray Head Positioning for Bitewing Exposures

2.5. Exposure Techniques

This section describes the different techniques generally used for intraoral exposures. For CDR2000 and CDR Wireless Sensors, we recommend the parallel technique as shown and described in **Section 2.5.2**.

2.5.1. Bisecting Technique

2.5.1.1. X-ray Beam Incidence – Vertical angle

For an accurate image capture of the tooth with minimal distortion, the X-ray beam must be perpendicular to the bisecting line of the angle formed by the longitudinal axis of the tooth and by the film (for CDR Sensors we recommend the parallel technique described in **Section 2.5.2**).

After positioning the X-ray Head and the patient's head, it is possible to apply an average vertical incidence for each area. The X-ray beam incidence angle can be correctly set using the graduated dial around the X-ray Head.

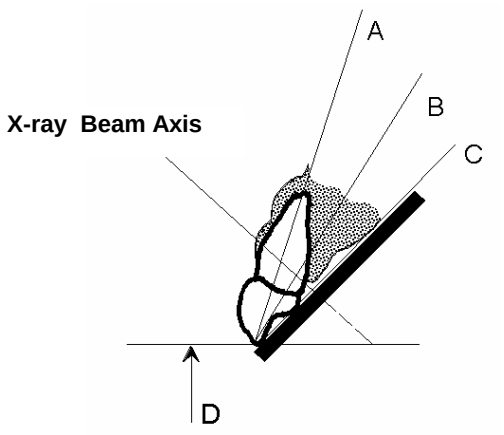


Figure 8. Bisecting Technique (Vertical)

Legend Figure 8:

A - *Tooth longitudinal axis*

B - *Bisecting line*

C - *Film level*

D - *Occlusal level*

2.5.1.2. X-ray Beam Incidence – Horizontal direction

The X-ray source must be positioned so that the X-ray beam contacts the inter-proximal spaces horizontally (see Figure 9), in an ortho-radial direction, in order to avoid superimposing adjacent tooth structures (see Figure 10).

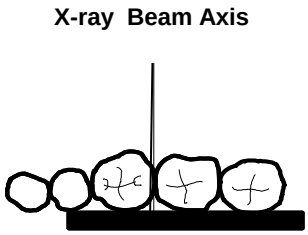


Figure 9. Correct Bisecting Technique (Horizontal)

(Correct position)

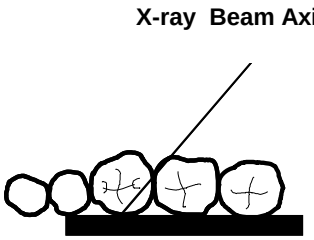


Figure 10. Incorrect Biesecting Technique (Horizontal)

(Wrong position)

2.5.2. Parallel Technique

Using this technique, the CDR Sensor or film media is placed parallel to the tooth axis. Due to anatomic factors, the Sensor is generally positioned away from the lingual surface of the tooth, except for molars.

When placed intraorally, various positioning accessories, including aiming rings, tabs, and holders, are available to stabilize the digital Sensor or film to prevent image distortion. The parallel technique provides more consistent results when compared with the bisecting technique and lends itself to more easily repeatable X-rays (see Figure 11 and Figure 12).

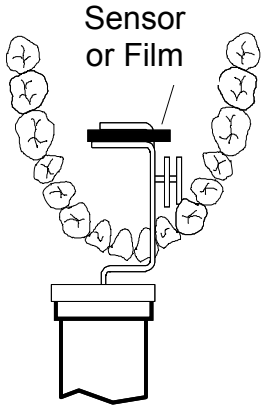


Figure 11. Parallel Technique (Horizontal)

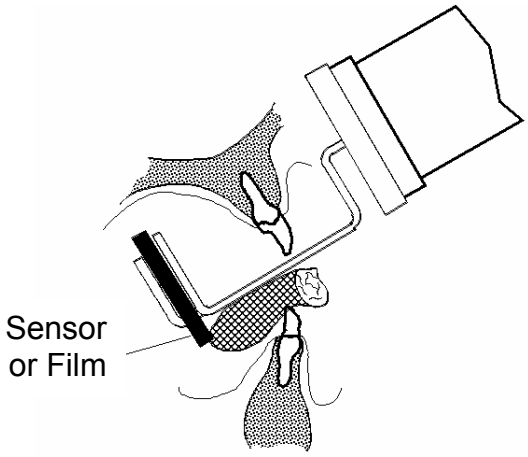


Figure 12. Parallel Technique (Vertical)

2.6. Exposures

NOTE:Bold numbers in the following procedure refer to Figure 3.

1. Set the exposure time as described in **Section 2.2**.
2. Follow the appropriate exposure technique described in **Section 2.5**.
3. Move as far from the X-ray source as the Remote Keypad cable will permit, avoiding excessive stress on the cable.
4. Press and hold down the X-ray Exposure button (**23**) during the exposure. The start of the exposure is shown both visually, by the X-ray signal LED (**20**), and audibly, by an uninterrupted alarm.
5. At the end of the exposure three horizontal segments appear on the Keypad display representing the automatic cooling phase of the X-ray Tube. This cooldown duration is equal, by default, to 15 times the exposure time; during this period it is not possible to perform a new exposure.

WARNING: The Exposure button must be pressed and held down during the whole exposure. If the patient moves during the exposure, release the button immediately to interrupt the emission of X-rays.

The SDX system is designed to display the delivered dose of the last exposure. This function can be switched on by configuring the system and can be modified by the service technician. The value of the delivered dose is displayed at the end of the exposure and remains on the Keypad for a period of 5 seconds; after this time, the system returns to the Waiting condition or the tube cooldown condition without any display.

WARNING: The displayed dose, expressed in mGy, was calculated empirically in tests performed on equipment representative of production and is an approximate value that may vary by ± 25% when compared with the dose actually delivered. Delivered dose is calculated at 20 cm from the focal point.

3. Error Messages

The SDX system displays equipment status and error codes on the Keypad. Error messages belong to three groups, according to the seriousness of the errors and their potential effects on operator safety or SDX system function. The following tables describe the various messages that may appear on the Keypad.

For troubleshooting procedures related to specific error codes described in this section, refer to the SDX Installation / Service Guide.

3.1. Startup Alarms (CH0-CH2, E01-E03)

These alarms do not allow any exposure to be performed. It is possible to clear the error condition by switching the SDX equipment off and then on (after waiting until all of the Keypad indicators are off before turning the system on again), but if the problem persists, please contact an authorized support center for Schick Technologies products in your region or country for additional assistance.

Table 5. Error Codes and Alarms during Setup

Display	Error	Audible alarm
CH0	Checksum error (EEPROM + EPROM)	Absent
CH1	Configuration write error (EEPROM + EPROM)	Absent
CH2	Checksum error in program memory	Absent
E01	Exposure button pressed at startup	Absent
E02	Other button (not Exposure) pressed at startup	Absent
E03	Multiple buttons pressed at startup	Absent

3.2. Exposure Alarms (E11-E24)

Errors that occur during exposure always interrupt the exposure itself. An audible signal (present or absent) depends on the time the error occurred and the success of the exposure interruption. These error conditions cannot be cleared without turning off the equipment and indicate, in most cases, that technical assistance may be needed.

Table 6. Error Codes and Alarms during X-ray Exposure

Display	Error	Audible alarm
E11	Filament circuit malfunction	Absent
E12	X-RAY ON signal risetime too slow	Absent
E13	Emission continues after end of exposure	Present while X-RAY ON signal is active
E14	Backup timer error	Present while X-RAY ON signal is active
E15	PFC overvoltage	Present while X-RAY ON signal is active
E16	PFC undervoltage	Present while X-RAY ON signal is active
E17	kV feedback exceeds upper threshold	Present while X-RAY ON signal is active
E18	mA feedback exceeds lower threshold	Present while X-RAY ON signal is active
E19	mA feedback exceeds upper threshold	Present while X-RAY ON signal is active
E20	Filament current overload	Present while X-RAY ON signal is active
E21	Anode overload	Present while X-RAY ON signal is active
E22	kV overvoltage	Present while X-RAY ON signal is active
E23	Unintended X-ray emission detected (X-RAY ON signal present)	Present while X-RAY ON signal is active
E24	X-RAY ON signal falls before end of exposure	Present while X-RAY ON signal is active
NOTE: X-RAY ON is an electrical signal generated on the Power Board inside the Timer Module.		

WARNING: Always switch the equipment off when an exposure error is displayed and the audible alarm is active.

3.3. Resettable Error Alarms (A01-A03)

Errors that do not directly affect the safety of the operator, patient, or equipment are considered resettable errors. The error causing the alert condition is always displayed by a flashing green LED on the Remote Keypad and the corresponding error message that has an "Axx" syntax. The error condition prevents further exposures until it is reset by pressing any key.

Table 7. Resettable Error Codes and Alarms

Display	**Error**	**Audible alarm**
A01	X-ray button already pressed when pressing one of the selection buttons with the SDX system in idle mode	Absent
A02	Exposure button released during exposure	Present while X-RAY ON signal is active
A03	Exposure button released during pre-heating phase	Absent
NOTE 1: If error A01 occurs, release the Exposure button and press any key to clear the error. If the error persists, contact your authorized support center for Schick technologies products in your country or region for additional assistance. NOTE 2: If error A02 occurs, and film media is being used, the film must be replaced before proceeding with a new exposure, after waiting until the automatic pause has finished. If another exposure is taken without replacing the film, non-diagnostic results would be obtained due to double exposure. NOTE 3: If error A03 occurs, there was an interruption in the exposure during preheating; however, no radiation dose was delivered.		

4. Troubleshooting Problems in X-Ray Images

NOTE: For troubleshooting information related to images acquired with CDR Sensors, please refer to CDR Wireless / SDX Software documentation.

4.1. Film Media Exposure Issues

4.1.1. Light Images

Possible causes:

- Inadequate exposure to X-rays
- Inadequate development time
- Damaged developer
- Developer temperature lower than the required value
- Incorrect dilution of developing fluids

4.1.2. Dark Images

Possible causes:

- Excessive exposure to X-rays
- Excessive development time
- Developer temperature higher than the required value
- Incorrect dilution of developing fluids

4.1.3. Out-of-Focus Images

Possible causes:

- Patient moved during exposure
- X-ray Head moved during exposure

4.1.4. Fishbone-Marked Images on Film

Some intraoral films have a thin lead layer in the box with fishbone marks engraved in the lower part. These films can be exposed to radiation only on one side. If the film is exposed to the wrong side, the lead layer will absorb a large amount of radiation during exposure. The result will be a lighter X-ray and the film will show fishbone marks.

4.1.5. Partially Exposed Images

Possible causes:

- X-rays directed far from the medial section of the film
- Low fluid level, with subsequent partial development of the film
- Two or more films one close to the other in the developer

4.1.6. Darkened Images (Since Initial Exposure)

Possible causes:

- The film has been in storage too long (check expiration date)
- Accidental exposure of the film to X-ray
- Accidental exposure of the film to other sources of natural or artificial light

4.1.7. Dark Lines

Dark lines may appear if the film is folded excessively.

4.1.8. Electrostatic Marks

If the film is compressed excessively during storage in environments where the air is dry, electrostatic electricity can be released along the compression points, forming black marks on the film.

4.1.9. Chemical Spots

The scattering of developing or fixing fluid on the film before development and poor fixing procedures may cause spots on the film. These defects appear as dark spots when they are caused by the developing fluid, or as light spots when they are caused by the fixing bath.

4.1.10. Lost Emulsion

If the film is kept in a warm water bath too long (for instance, all night), the emulsion can soften and partially come off the base of the film. After development, the film will be scratched.

5. Cleaning and Disinfection

Observe the following precautions and follow proper cleaning and disinfecting procedures to ensure these procedures are performed safely and provide proper hygiene within the patient area:

- Before cleaning the SDX equipment disconnect it from the input power line using the circuit breaker dedicated to the system and installed prior to SDX installation (refer to the SDX Installation / Service Guide for details on electrical connections.) This step is necessary as some internal SDX parts continue to carry and conduct electrical current even after the On / Off switch (located on the Timer Module) has been turned off.
- Make sure that water or other fluids do not seep into the SDX equipment, causing potential damage to internal, electrical, and mechanical components.
- Never use solvents (such as alcohol and Trichloroethylene) or corrosive or abrasive substances when cleaning.

5.1. External Surfaces

Use a soft, lint-free cloth when wiping exterior surfaces of the SDX equipment. For stronger action, use a neutral soap to clean coated surfaces.

5.2. Parts that May Contact Patient's Skin

These parts should be cleaned at regular intervals using a 2% Glutaraldehyde solution and lint-free cloth to wipe down all exposed equipment surfaces and to make sure these areas are completely dry before turning the system on.

6. Maintenance

6.1. Preventive Maintenance

There are no user-serviceable components in the SDX system. However, before operating the system, users shall check it for any signs of physical damage or defect. Contact your authorized support center for Schick Technologies products in your region or country for additional assistance.

6.2. Periodic Maintenance

Periodic maintenance should be performed as needed, but at least once a month. It consists of various checks performed by the operator or by a qualified service technician. For procedures related to the checks specified below, refer to the SDX Installation / Service Guide. The following checks will be performed by the operator:

- Check that the labels are intact, readable, and adhere well to the surfaces on which they were positioned
- Check that there are no oil marks on the X-ray Head
- Check that there is no external damage to the SDX equipment, including the Remote Keypad and its cable, which could compromise its ability to operate safely and to provide the proper emission of X-rays
- Check the balance of the Scissors Arm
- Check that the X-ray beam is centered by verifying an exposure, using either film or Sensor positioned at the end of the cone, that the X-ray beam is well-directed.
- Check the operation of the X-ray Exposure LED and the audible alarm.

6.3. Material Disposal

At the end of its life cycle, some SDX materials and fluids must be disposed of in special areas designated by the local health authorities. The equipment contains the following materials and / or components:

- X-ray Head: external packages in non-biodegradable plastic, dielectric oil, lead, copper, brass, aluminum, resin, tungsten, beryllium
- Power supply and Remote Keypad: external packages in non-biodegradable plastic, iron, copper, plastic reinforced by fiberglass
- X-ray Head extension: iron, aluminum, copper.

NOTE: The Manufacturer and the distributor do not accept any responsibility for the disposal of equipment or parts discarded by the user or the costs related to that disposal.

7. Reference

General		
Equipment	SDX	
Manufacturer	Schick Technologies	
Class	Class I, Type B (EN 60601-1 classification)	
Mode of operation	Equipment is intended for continuous use	
Protection level	Standard apparatus IP20	
Additional note	Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	
Line voltage	230 V~	115 V~
Line frequency	50 – 60 Hz	
Rated current	0.2 A continuous 2.7 A (rms) during exposure	0.4 A continuous 7.2 A (rms) during exposure
Power consumption	50 VA continuous 0.65 kVA @ 230 V~ during exposure	50 VA continuous 0.7 kVA @ 120 V~ during exposure
Max. apparent line resistance	0.8 Ω	0.4 Ω max
Line voltage regulation	–	< 3 % at 99 V
Main fuse	3 AT	6.25 AT
Preset exposure times	from 0.01 to 2s in 35 steps	
Automatic selection	60 preset times	
Time accuracy	±5 % or ± 2 ms, whichever is greater	
Circuit type	constant potential	
High voltage value	65 kV_p	
X-ray Tube current	4 and 5 mA selectable	
kV accuracy	± 5 %	
X-ray Tube (anode) current accuracy	± 5 %	
Max. exposure time	2 s	
Electronics box dimension	13.5 x 7.6 x 3.9 inches (345 x 195 x 100mm)	

X-ray Tube Head	
Rated voltage	65 kV_p
X-ray Tube power	325 W max.
Total filtration	≥ 2 mm Al @ 65 kV_p
HVL (Half Value Layer)	> 1.5 mm Al eq.
Transformer insulation	Oil bath
Interval between exposures / duty cycle	15 times X-ray time / 1 : 15 (adaptive)
Focal spot	0.7 (IEC 336) @ 5 mA
Minimum focal spot-to-skin distance	8 inches (20.3 cm)
X-ray diameter (@ 20cm focus)	2. 4 inches (6.1 cm)
Cooling	Convection
Radiation leakage at 1 m	< 0.25 mGy / h
Technical factors for radiation leakage	65 kV - 5mA - 1s / Duty cycle 1 : 15
Inherent filtration	0.5 mm Al eq. @ 70 kV_p
Anode tilt	19°
Anode material	Tungsten
Maximum filament current	2.8 A
Maximum filament voltage	4.1 V
Anode thermal capacity	6 kJ
Anode cooling capacity (max)	90 W

Environmental conditions	
Operating temperature range	50°F – 104°F (+10°C – +40°C)
Operating relative humidity range	30% – 75%
Temperature range for transport and storage	-4°F – 158°F (-20°C – +70°C)
Max. relative humidity for transport and storage	<95 % non condensing
Min. atmospheric pressure for storage and transport	630hPa
Weight of equipment and detachable parts	
Gross weight including packing	77 pounds (35 kg)
Net weight of equipment in standard configuration	49 pounds (22 kg)
60 cm extension arm (standard)	6 pounds (2.9 kg)
80 cm extension arm	8 pounds (3.5 kg)
30 cm extension arm	4 pounds (1.9 kg)
Scissors arm	20 pounds (9 kg)
Wall plate with generator	11 pounds (5 kg)
X-ray Head	10 pounds (4.5 kg)

Table 8. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

PLEASE NOTE: The SDX system is intended for use in the electromagnetic environment specified below. The operator of the SDX system must ensure it is used in such an environment.

Emissions Test	Compliance	Guidance
RF emissions CISPR 11	Group 1	The SDX system 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 CISPR 11	Class B	The SDX system is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 9. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

PLEASE NOTE: The SDX system is intended for use in the electromagnetic environment specified below. The operator of the SDX system must ensure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 610004-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2kV common mode	± 1 kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle < 40% U_T (>60% dip in U_T) for 5 cycles < 70% U_T (>30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	< 5% U_T (>95% dip in U_T) for 0.5 cycle < 40% U_T (>60% dip in U_T) for 5 cycles < 70% U_T (>30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SDX system requires continued operation during mains interruptions, it is recommended that the SDX system be powered from an uninterruptible power supply or battery. NOTE: U_T is the AC mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the SDX system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d= 1.2 √ P for 80 MHz to 800MHz d= 2.3 √ P for 800 MHz to 2.5GHz Where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each range. [b] Interference may occur in the vicinity of equipment marked with the following symbol. 

NOTE 1: At 80 MHz, the higher frequency range applies.

NOTE 2: 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 the SDX system is used exceeds the applicable RF compliance above, the SDX system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SDX system.

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

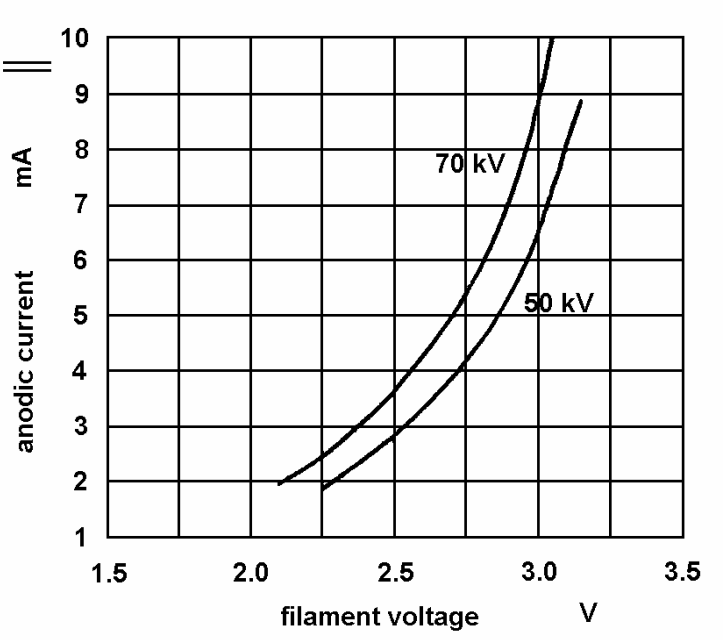
Table 10. Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the SDX System

PLEASE NOTE: The SDX system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of SDX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications.

Rated maximum output power of the transmitter (W)	**Separation distance according to the frequency of the transmitter (m)**	
	150 kHz to 800 MHz $d=1.17x\sqrt{P}$	800 MHz to 2.5 GHz $d= 2.3 x \sqrt{P}$
0.01	0.17	0.23
0.1	0.37	0.73
1	1.17	2.30
10	3.69	7.27
100	11.7	23.00
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.		

7.1. X-ray Tube Emission, Exposure, and Cooling Curves

Emission feature



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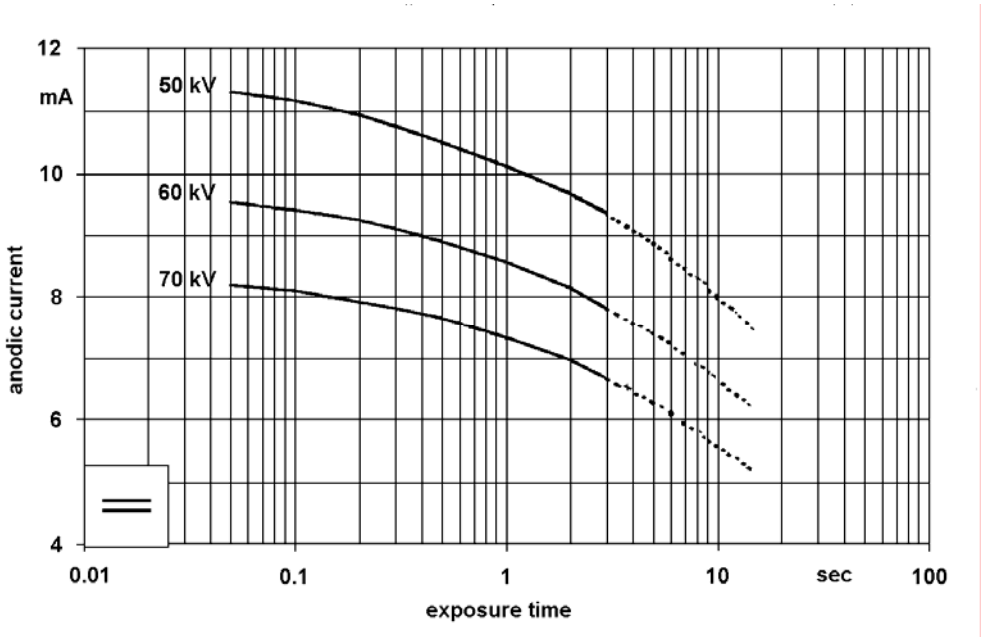
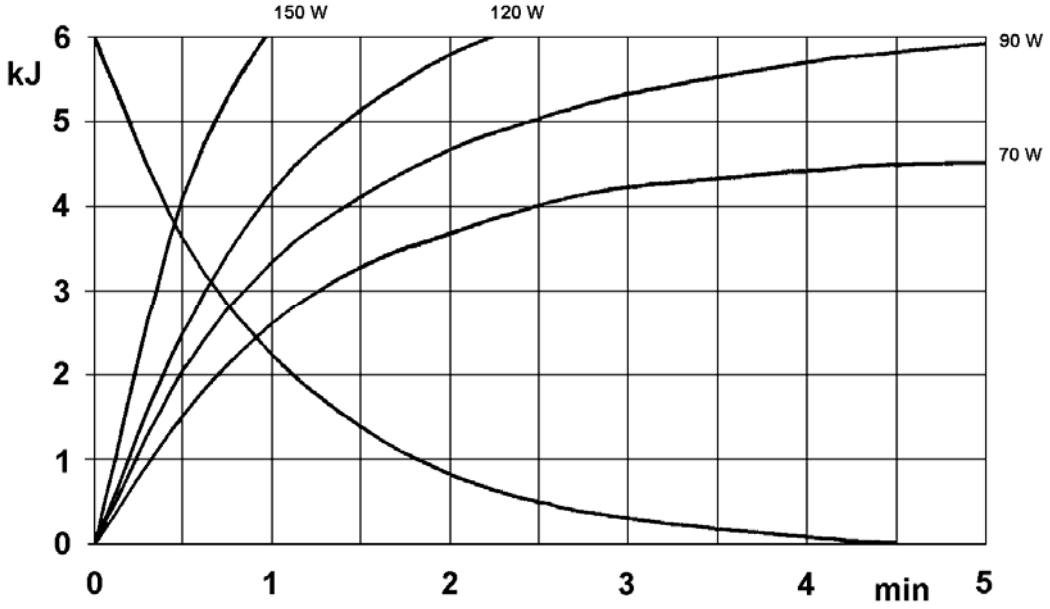
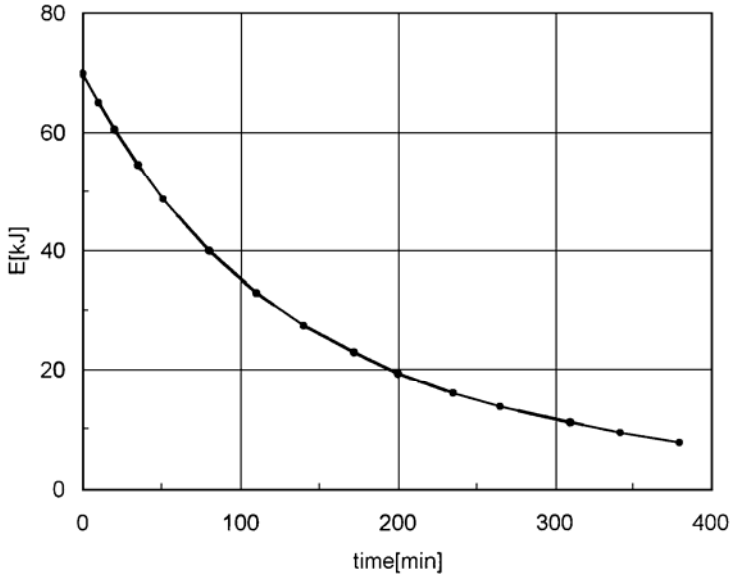


Curve anode cooling



Curve X-ray Tube cooling



7.2. Standards and Regulations

SDX equipment complies with the following regulations.

Table 11. SDX System Compliance Standards

Specification	Description
CFR 21 Subchaper J	For version operating at rated line voltage 99-132V
EN60601-1	Medical Electrical Equipment Part 1: General Requirements for Safety
EN60601-1-1	Medical Electrical Equipment Part 1: General Requirements for Safety 1.Collateral Standard: Safety Requirements for Medical Electrical Systems
EN60601-1-2	Medical Electrical Equipment Part 1: General Requirements for Safety 2.Collateral Standard: Electromagnetic Compatibility Requirements Tests
EN 60601-1-3	Medical Electrical Equipment Part 1: General Requirements for Safety 2.Collateral Standard: General Requirements for Radiation protection in Diagnostic X-ray Equipment
EN 60601-2-28	Testing and Measuring Equipment: Allowed Subcontracting
EN61000-4-2	Electrostatic Discharge Susceptibility
EN61000-4-3	Radiated Susceptibility - Electric Field
EN61000-4-4	Electrical fast Transient Burst
EN61000-4-5	Power Line Conducted Surge Susceptibility
EN61000-4-6	Conducted Transients Susceptibility
EN61000-4-11	Voltage Dips and Interrupts
FCC Rules Part 15	Subpart C, Section 15.249: Field Strength of Fundamentals and Harmonics (a) and Spurious Radiation (c)
CE	Indicates compliance of SDX to European Union Medical Devices Directive 93/42/EEC.

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