

Flight Dental Systems

**A Division of HR Dental
Products Inc.**



**X-VISION PORTABLE X-RAY
USER'S MANUAL
Model: XR-3800**

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I. CERTIFICATE OF WARRANTY

1.1 Range and Terms of Warranty

Flight Dental System's warranties this product to be free of defects in materials and workmanship for a period of one (1) year from the date of purchase unless an extended warranty has been given for the unit. In that case, the warranty will be given for 5 years from the date of purchase.

1.2 Procedure for After Sales Service

- When a malfunction of this equipment occurs, stop operating it and check the related articles of this "User's Manual".
- Before contacting us, please turn off the equipment and locate the model name, serial No. and purchase date.
- Flight Dental System's is not responsible for ANY indirect harm caused by the mishandling of this equipment.
- Flight Dental System's cannot certify this product from defects beyond the warranty period.
- Contact Flight Dental System's at 905 799 0517 if service or technical support is required.

II. GETTING STARTED

2.1 Intended Use

Flight Dental System's X-Vision Portable X-Ray System is intended to be used by appropriately trained personnel as an extraoral x-ray source for producing diagnostic x-ray images using intraoral imaging sensors. Its use is intended for both adult and children.

⚠ WARNING!

WARNING: U.S. Federal law restricts this device to be sold by or on the order of a physician or any other licensed practitioner.

⚠ WARNING!

WARNING: Resellers and Assemblers please register with your local state authorities and abide by local regulations. Complete FDA 2579 or similar registration for the device in your state.

2.2 Principles of Operation

Flight Dental System's X-Vision Portable X-Ray system is designed for use in radiography to illuminate dental structures, reveal malignant or benign masses, bone loss, cavities and other areas that aid in a dental diagnosis. The controlled x-ray beam penetrates oral structures at different levels, which depends on varying anatomical densities, and then exposes this onto image receivers such as a film or digital sensor to form a radiographic image.

2.3 Compliance

The owner/operator is responsible for verifying a continued compliance to exposure rates, leakage radiation, alignment of the useful beam, and the calibration of kVp and mAs. Annual verification by a qualified service technician may be required by your local authorities. Compliance with applicable statutory and regulatory requirements is the responsibility of the owner/operator. Consult local, state, and/or federal agencies in your area regarding the specific requirements and regulations applicable to the use of this type of electronic medical equipment.

2.4 Cleaning









Ensure the adapter is unplugged and the power switch is off before attempting to clean. Use only non-alcohol based disinfectants wipes or a cloth dampened with the medical disinfectant of your choice to clean the unit. The system is not designed to be subjected to any kind of sterilization procedure and not designed to be used to sterilize anything as well.

 **WARNING!**

Do not modify this equipment without authorization from Flight Dental Systems.

2.5 Symbols

Symbols used in this publication and on the equipment have the following meanings.

| Symbols | Description | Symbols | Description |
|---|------------------------------------|---|---|
|  | Emitting X-Ray Source |  | Electrical Shock Hazard |
|  | Warning for Ionizing Radiation |  | High Voltage |
|  | Consult Manual before Use |  | Warning |
|  | Type B Applied Part Medical Device |  | Product should not be discarded as unsorted waste |

WARNING

This is a warning that improper use of this equipment can lead to serious hazard for the patient or user.

CAUTION

Be cautious as in certain situations or circumstances the equipment can be damaged and possibly lead to personal injury.

NOTE

Please note that special attention is needed during operation of this equipment.

III. SAFETY

3.1 Electrical Safety

 **WARNING!**

Electrical circuits inside this equipment uses voltages which are capable of causing serious injury or death from electric shock.

To avoid this hazard, operators should never remove any of the cabinet covers.

Observe the following safety procedures to avoid electrical shock, system malfunction, or serious injury to operators and patients.

- Under no circumstance should the safety interlocks in the system be bypassed, jumped, or otherwise disabled.
- Under no circumstance should the system or assembly covers be removed by anyone other than a Flight Dental System's trained or authorized service technician.
- Do not place food or beverage containers on any part of the equipment. Introduction of conductive substances into the electrical circuitry may lead to personal injury.

 **WARNING!**

Flight Dental System's X-Vision Portable X-Ray is not waterproof. Water, soap, or other liquids, if allowed to drip into the equipment, can cause electrical short circuits leading to electric shock and ultimately become a fire hazard. If liquids should accidentally spill into the electronic systems, **do not** connect the power cord to a supply connection or turn the system on until the liquids have completely dried or evaporated.

3.2 Emergency Procedure in the case of Electrical Fires

The user should develop an emergency procedure for the area in which the system is used that includes the following safety measures:

- Turn the system off and unplug the main power cable from the outlet.
- Evacuate everyone from the area.
- Call for help.
- Use only types of fire extinguishers approved for electrical fires.

⚠ CAUTION!

The use of a wrong type of fire extinguisher presents electrical shock and burn hazards. To avoid these hazards, a fire extinguisher which has been approved by the appropriate local, state, and federal codes must be available in the room where the equipment is being used.

3.3 Electromagnetic Compatibility Statement

This equipment generates energy on the electromagnetic spectrum that is slightly higher in frequency (lower wavelength) than radio frequency energy. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures.

- Reorient or relocate the receiving device.
- Increase the separation distance between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult Flight Dental System's Technical Support Department or an Authorized Field Service Technician for help.

3.4 Radiation Safety

3.4.01 General



WARNING!

This X-Ray unit may be dangerous to the patient and operator unless safe exposure values are used and correct operating procedures are observed. Adhere to local and state guidelines for proper use of X-Rays and if necessary wear the appropriate lead apron as required.

The X-Ray tube assembly produces ionizing radiation when energized. Hence, when in use, it is recommended that only trained operators handle the equipment.

It is imperative that the owner of the equipment designates areas suitable for a safe operation and service of the system and that the operator ensures that it is used only in these designated areas.

It is the responsibility of owner to check with local and state government for requirements.

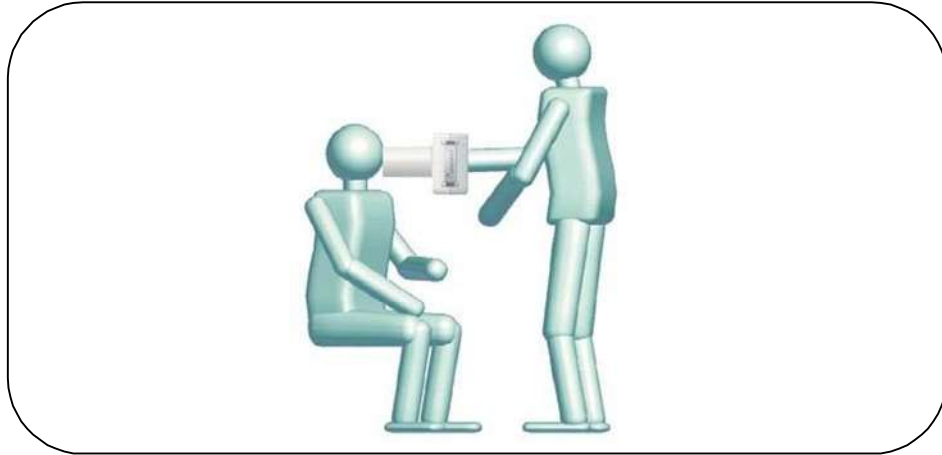


NOTE!

The beam limiting device (Collimator cone) is lined with 0.5mm Pb to prevent leakage of radiation.

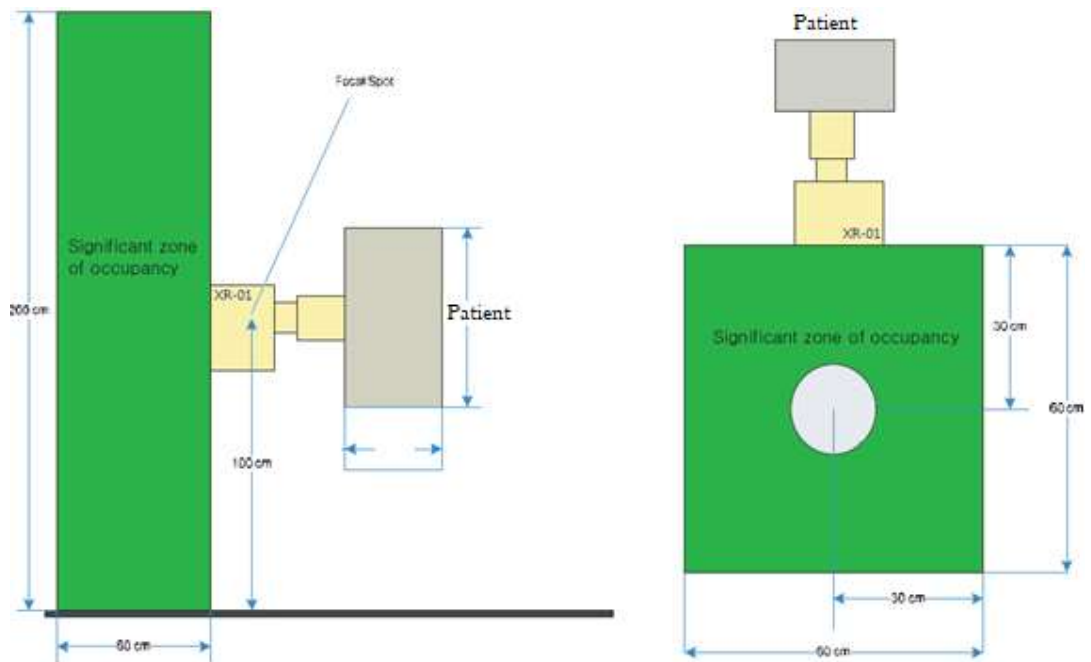
3.4.02 Handheld Function

Flight Dental System's X-Vision Portable X-Ray is designed to be used as a handheld equipment; it is convenient for use anytime and anywhere.



3.4.03 Significant Zones of Occupancy

Please establish a significant zone of occupancy for the operator as shown below in green. This significant zone of occupancy is a safe zone that allows the operator to efficiently handle the X-ray unit while minimizing the risk of radiation at the same time. Further reduction in radiation exposure can be obtained by wearing protective radiation garments on the operator.



3.4.04 Leakage and Scatter Measurement

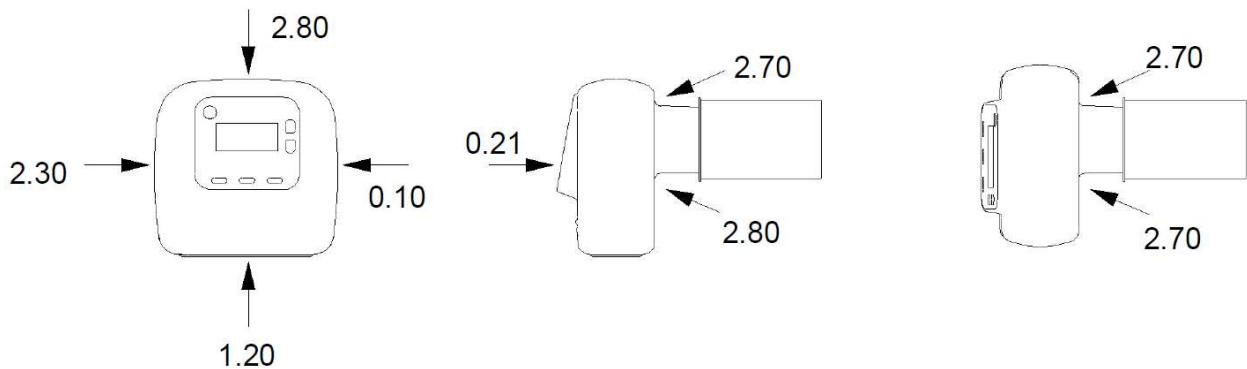
Occupational Dose Limits (Per Annum)

| Type | Occupational Dose Limit |
|---------------------------------|-------------------------|
| Total effective dose equivalent | 5000 mrem/yr |
| Lens of the eye | 15000 mrem/yr |
| Skin | 50000 mrem/yr |
| Hands and feet | 50000 mrem/yr |

Specified in 10 CFR 20.1201 and 10 CFR20.1208

Leakage

The inherent shielding of Flight Dental System's X-Vision Portable X-Ray was sufficient to eliminate leakage of radiation. The measurement was performed at 10 mm from the device surface at 9 points as follows: (Units: mGy/hr to mR/hr is 1 mGy is equal to 100 mR). 0.01 mrem is the dose produced by exposure to 1 milligray (mG) of radiation. The diagram below uses mRem as the unit of measure.



According to FDA guidance "Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use" and IEC 60601-1-3 standard, leakage of radiation shall not exceed 0.88 mGy/hour or 100.32 mR/hr and 0.25 mGy/hour or 28.5 mR/hr respectively. All X-Ray units leaving our warehouse have been inspected strictly with leakage limits of 0.04 mGy/hour or 4.56 mR/hr, which is 6.25 times more stringent than FDA/IEC's minimum requirements.

Scatter

The vertical and horizontal significant zone's of occupancy have been established and verified by our internal design team. The estimated annual dose to operators who stay in the safety zone is approximately 1 mSv if maximum exposure time is assigned for each exposure.

3.5 Storage and Transportation Environment

Avoid the following environments during storage or transportation;

- Where the equipment is exposed to water vapor.
- Where the equipment is exposed to direct sunlight.
- Where the equipment is exposed to dust.
- Where the equipment is exposed to high humidity.
- Where there is a ventilation problem.
- Where the equipment is exposed to a salty/saline atmosphere.
- Where the equipment is exposed to chemicals or gas.
- Equipment must be properly secured in a safe location to prevent unauthorized use.

For normal operation, you must keep the equipment away from places with strong vibrations and maintain the following ranges in temperature and humidity.

Usable Range of Temperature and Relative Humidity

- Temperature : $-5^{\circ}\text{C} \sim 40^{\circ}\text{C}$ or $23^{\circ}\text{F} \sim 104^{\circ}\text{F}$
- Humidity : 30% ~ 75%RH
- Atmosphere : 700 ~1060hPa

For storage and transportation conditions, the product must maintain the following range of temperature, humidity, and atmospheric pressure.

- Temperature : $-10^{\circ}\text{C} \sim 70^{\circ}\text{C}$ or $14^{\circ}\text{F} \sim 158^{\circ}\text{F}$
- Humidity : 10% ~ 90%RH
- Atmosphere : 500 ~1060hPa

IV. PRECAUTIONS

⚠ NOTE !

The system should only be used by personnel possessing relevant qualifications, including adequate training in radiation protection.

⚠ NOTE !

Radiation safety training requirements vary from country to country. Please consult with your local Radiation/Health authority for more details.

4.1 Radiation Safety Precaution

Before operating this equipment, make sure the User's Manual, Training Manual, and maintenance schedules have been thoroughly reviewed. X-ray equipment must only be operated by trained personnel in a controlled setting otherwise radiation exposure may be dangerous to the patient, operator or ancillary people.

Pregnant women are advised to avoid X-rays to minimize the chances of causing any harm to the fetus unless the prescribing physician has deemed that the benefits of such a procedure outweigh its risk.

Personal radiation exposure monitoring devices and radiation protection equipment (optional in certain States) should be provided to the operators during use of this equipment. In this way, the maximum permissible whole-body or partial-body radiation dose of operator in accordance with local/state regulations shall be established.

The Backscatter Shield (0.35 pb equivalent – 6" diameter) is designed to protect operators from scatter radiation. Make sure to follow these step before operating:

- a) Check the Backscatter Shield and Collimator for damage before each use. Do not operate if either of them is broken.
- b) Operator should stay within the significant zone of occupancy. (see 3.4.3 for more details)

As an operator, never stand in the direct line of the primary X-ray beam. If a patient needs assistance during operation of this equipment, wear personal protective equipment such as a lead apron *(optional in certain States).

4.2 Precautions Before Operating

1. Before operating, carefully read the User's Manual and follow the directions in adjusting the settings.
2. Check that the power adapter is not plugged in.
3. Ensure that the battery is fully charged before first using the product.



Remove the power cord before using as the unit is **not functional** while charging.

4.3 Checking Before Operating

1. Carefully ensure that the whole system is functional
2. When there is a problem with the system or the patient, do not use system and troubleshoot with manual.

4.4 System Malfunction

In case of malfunction, do not attempt to operate the system until it has been checked out by a qualified Flight Dental System's service technician.

4.5 Inspection

1. Periodically inspect the system and ensure that all the parts are functioning properly.
2. In case of long periods of inactivity, confirm the functional status of this equipment by an authorized Flight Dental System's authorized distributor or other expert in the field.
3. Only clean this product with neutral detergents.
4. Do not apply any erosive detergent or fluids.

V. COMPOSITION

5.1 Composition

The Portable X-Ray System comes with a Main Body along with Accessories

Main Body

- X-Vision Portable X-Ray
- Beam limiting Device (Collimator)

Accessories

-
- AC/DC Adaptor
 - Power Cord
 - Hand Switch
 - Carrying Box
 - Back Scatter Shield

5.2 AC/DC Adapter

- Model Name :GST60A24-P1J
- Manufacturer : Mean Well Enterprises Co.,Ltd.
- Rated Input : 100-240Vac, 50-60Hz, 1.4-0.7A
- Rated output : 24Vdc/2.5A, 60WMAX

 **WARNING!**

Only recharge the unit with the power cord supplied by Flight Dental Systems

5.3 Battery

⚠ WARNING !

Only use the battery supplied by Flight Dental Systems.

The user is responsible for any malfunction from usage with another battery.

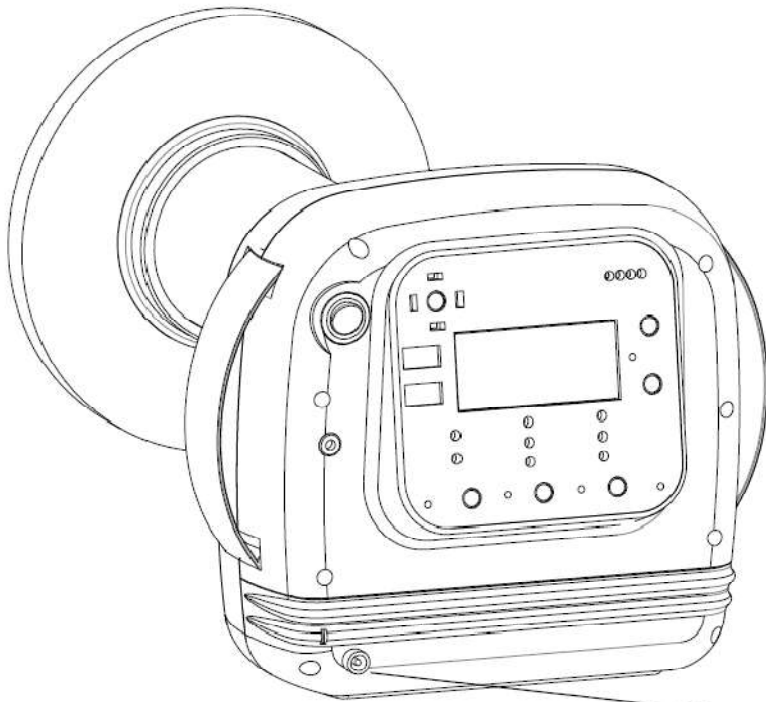
5.3.01 Model Name : 7S1PXR001(Li-Polymer Type)

5.3.02 Manufacturer: HR Dental Products Inc.

5.3.03 Voltage :25.2Vdc

5.3.04 Capacity :2900mAh

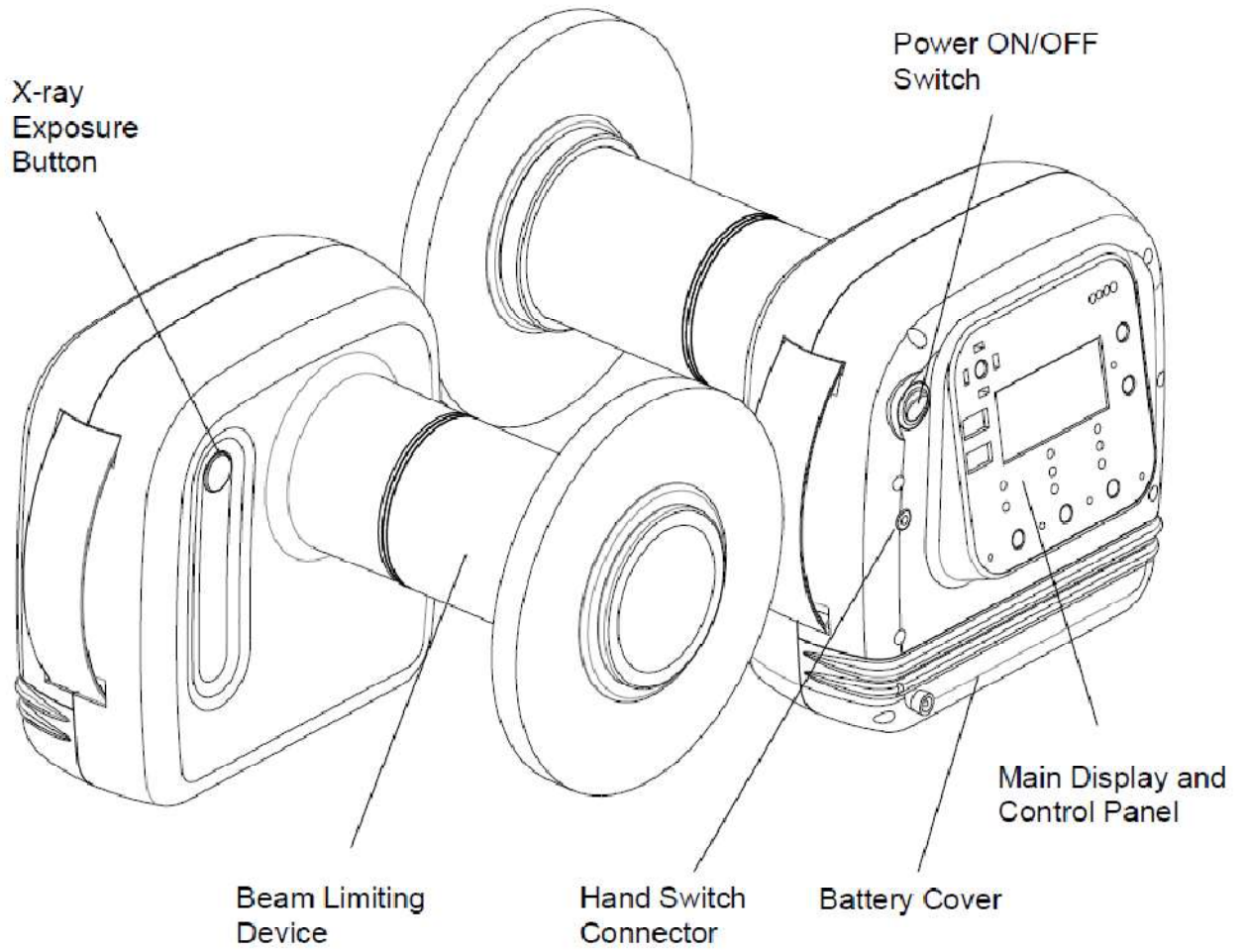
5.3.1 Recharging the Battery



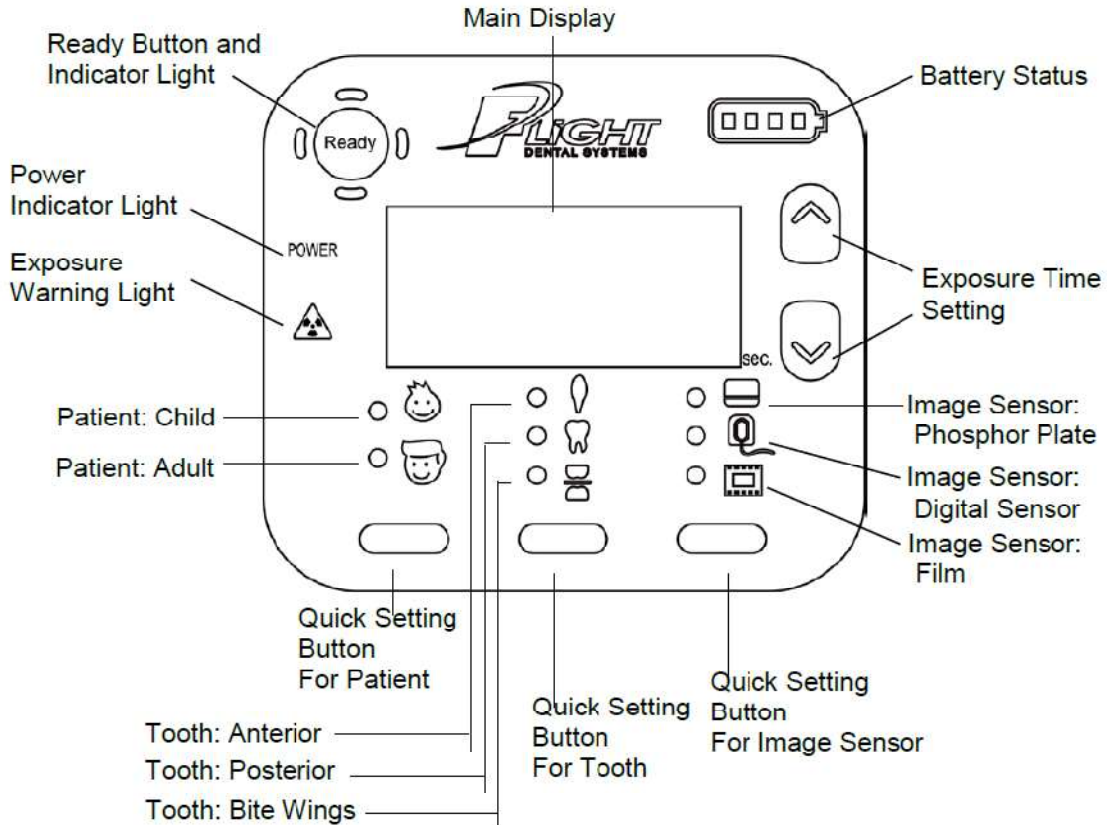
Assemble Power Cord and
adapter then charge directly

1. Assemble Power Cord and Adapter together then plug directly into unit as indicated above.
2. If the unit is Powered ON, the LED indicator light will appear green.
3. The LED indicator appears orange if the unit is recharging.
4. The LED indicator appears green if the recharging process is complete. A Full Charge takes about 4 hours.

VI. EXPLANATION OF EACH PART



6.1 Main Display and Control Panel



1. Power Indicator Light: Light will appear green when powered on.
2. Main Display: Displays current exposure time or error code if an error happens.
3. Battery Status: Displays the remaining battery power. Indicates low battery when all 4 blocks disappear.
4. Exposure Time Setting: Manually adjust the exposure time, press "up" button to increase, "down" button to decrease. (0.01sec /step)
5. Quick Setting Button For Patient:
Use the default time setting for each kind of patient.
6. Quick Setting Button For Tooth:
Use the default time setting for each kind of tooth.
7. Quick Setting Button For Image Sensor:
Use the default time setting for each type of image sensors.

8. Ready Button and Indicator Light:

Press the "Ready Button" to disable the safety lock in order to start an exposure. The indicator light will appear green when the safety lock is disabled. The indicator light will be orange when initiating or cooling, and the user will be unable to adjust any parameters on the equipment other than turning the unit off during this period as the equipment warms up or cools down.

9. Exposure Warning Light:

A yellow light will appear while generating X-Rays beams and a beeping sound will be heard. Stabilize the equipment at this point to generate a clear image.

VII. OPERATION

⚠ NOTE!

Before using this X-Ray system, please clean the surfaces that will be in contact with the patient (see section 2.3)

⚠ CAUTION!

Before operating, please make sure the radiation safety precautions measures indicated in section 4.1 are satisfied.

⚠ CAUTION!

DO NOT OPERATE THIS DEVICE UNTIL YOU HAVE READ THIS USER'S MANUAL AND ITS ACCOMPANYING TRAINING MANUAL!

7.1 Power ON

When the power is switched on, the X-Vision X-Ray System needs 5 seconds to initiate and warm up.

In the initiation process, the main display will show 0.00 and the ready indicator lights will be orange. The user will be unable to generate an exposure or use the unit until the ready indicator turns off and the initiation process is complete.

After the initiation process or after the cooling down process is complete, the user has 12 minutes to use the equipment. Otherwise the system automatically turns off and a buzzer sound will beep. If the operator is done using the equipment he/she should turn off the power switch to save battery life.

When the battery power is less than the minimum dose required for capturing an image, the main display will show E00 and the operator will be unable to make an exposure on the unit.

Operators should recharge the battery with the charging unit and adapter supplied by Flight Dental Systems only.

7.2 Adjustment of Exposure time

Flight Dental System's X-Vision X-Ray system has a fixed tube voltage and tube current of 60 kV, 2.0 mA. Only the exposure time is adjustable from 0.01-2seconds.

Adjust exposure time by pressing the Exposure Time Setting "UP" button to increase and the "down" button to decrease duration. (see section6.1)

Pre-set exposure factors are provided in Table 7.2.1. Exposure time may vary from different imaging sensors, film speeds, brands, types, patient size, and distance to patient.

Pediatric considerations

This X-Ray system is designed for both adult and children. However, the pre- set exposure factors are not applicable for every patient, especially for children. The pediatric population or smaller patients may be more sensitive to X-ray exposure. We recommend that the dentist considers the patient's age, size and health history before any form of X-ray examination. Also, protective thyroid collars and aprons should be used whenever possible. In regards to the safe imaging of the pediatric population, you can find more details from following websites:

Image Gently

<http://www.imagegently.org/>

FDA Guidance

<https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm>

7.2.1 Pre-set exposure times

| Item | Part | | Exposure Time |
|----------------|--------|------------|---------------|
| Phosphor Plate | Adult | Anterior | 0.27 sec |
| | | Posterior | 0.32 sec |
| | | Bite Wings | 0.34 sec |
| | Child* | Anterior | 0.15 sec |
| | | Posterior | 0.26 sec |
| | | Bite Wings | 0.27 sec |
| Digital Sensor | Adult | Anterior | 0.20 sec |
| | | Posterior | 0.27 sec |
| | | Bite Wings | 0.29 sec |
| | Child* | Anterior | 0.15 sec |
| | | Posterior | 0.22 sec |
| | | Bite Wings | 0.24 sec |
| Film | Adult | Anterior | 0.50 sec |
| | | Posterior | 0.65 sec |
| | | Bite Wings | 0.68 sec |
| | Child* | Anterior | 0.31 sec |
| | | Posterior | 0.50 sec |
| | | Bite Wings | 0.55 sec |

Note: Film Sensors generally require a longer exposure time when compared to digital sensors or phosphor plates

7.3 Exposure Process

- 1) Before attempting to capture an image set the desired exposure time.
- 2) Align the collimator cone with the area you want to get an image of.
- 3) Push the "Ready" button to disable the safety lock.
- 4) "Ready indicator light" will turn to green to notify the operator that the equipment is prepared to capture an image.
- 5) If the exposure button is not pressed in 30sec, the XR-3800 will go back to safety lock mode and the green ready light turns off.
- 6) Once you are ready to start exposure. Press and Hold down the "X-Ray Exposure Button" to start exposure process.
- 7) When the "X-Ray Exposure Button" is pressed, the exposure warning light turns on and a buzzer will beep.
- 8) 3 seconds after the "X-Ray Exposure Button" is pressed, the XR-3800 will start generating X-Rays for the length of the set exposure time.
- 9) Press and Hold down the "X-ray Exposure Button" until the end of exposure period (to avoid an E003 error code). Once the Exposure Button has been released, the exposure will stop immediately.
- 10) When the X-ray exposure is completed, the yellow LED turns off and the buzzer stops beeping.
- 11) After exposure a cooling time is required and an orange light will turn on. It takes a multiple of 30 times of exposure time + 5 seconds (i.e. Anterior teeth for an adult is $\{30 \times 0.2s\} + 5s$) to cool down the tube assembly. The operator cannot undergo another exposure until the cooling process is finished.

7.4 Recharging the Battery and Operation Times

 **WARNING !**

Use of any adapter other than the one supplied by Flight Dental Systems may damage the battery and will void the warranty.

 **WARNING !**

The battery provided is exclusive for the X-Vision Portable X-Ray. Do not use any other battery for this equipment. When the life span of the battery is finished, you must replace it with the same battery supplied by Flight Dental Systems or the warranty will be voided. .

7.4.1 Specification of Battery

This Lithium-Polymer battery has been specifically designed for Flight Dental Systems and is very safe. Its specification will not be altered after long periods of not being used.

7.4.2 Operation Time

The battery life is shown on the right-upper side of the Main Display. If the battery is insufficient, the operator will not be able to acquire the best images. To avoid this, remember to keep the battery charged at least with 1 bar of power on the indicator. When the remaining life of the battery is lower than the minimum required for an exposure, the power will automatically shut off to prevent damage to the unit. The complete charging time (from empty to full) is about 4 hours.

Please charge the battery for about 12 hours before using the equipment for the first time as the 12 hour charge will help to extend the battery life of the unit. After the first initial charge of the battery, you will only need to charge the battery for 4 hours to get a full charge. It is recommended to fully recharge the battery every three months regardless of use while in long-term storage to ensure that a low battery does not damage the equipment when it does ultimately get used.

7.5 Periodic Check

We recommend checking this equipment annually. Only qualified technicians can check this equipment according to the Regulations of the country.

VIII. Maintenance Plan

8.1 Daily and Routine Maintenance

1. Review this user's manual periodically to ensure the operator's complete understanding of its intended use.
2. Routine cleaning of the X-Vision X-Ray System is essential. Use non-acetone based disinfectants to wipe the exterior surface of the XR-3800.
3. Establishing a periodic review process of personnel training is essential. Make sure that the process meets local and national regulatory requirements.
4. Periodically review section 3.4 to maintain sufficient awareness of radiation protection protocol.

8.2 Battery Maintenance

1. Battery must be charged before initial use.
2. Battery's capacity decreases naturally over its lifespan which is usually between ~1-2 years depending on usage.
3. For long-term storage of the battery, as the battery would naturally lose power over time, recharging the battery every 3 months is strongly recommended.
4. Remove the charger from the unit after it is fully charged.

8.3 Annual Maintenance

1. Power on the device to ensure the power button is working properly and the green power indicator and four orange indicators at the top left side of the main display are illuminating properly.
2. Check the "increase" and "decrease" buttons are working properly by pressing them and seeing if the exposure time setting changes accordingly.
3. Set exposure time as 1.00 sec and press "READY". Verify that the button moves freely. Verify that your X-Vision X-ray unit can enter the READY state (READY LED illuminates). Initiate an exposure by pressing the "X-ray exposure button" on the front of the unit and release it to verify that the exposure terminates right away.
4. Verify an audible beep is heard during the exposure time.
5. Verify the backscatter shield is not cracked and firmly attached to the collimator cone.

8.4 Calibration check (optional)

1. XR-3800 is calibrated according to strict standards. All parameters are set in factory and don't need to be adjusted by the operator. However, calibration checks performed by a qualified and experienced technician are required in some countries/locations. Please refer to your local and national regulatory bodies regarding the need to calibrate the equipment in your area.

Help Message

2. Test items and descriptions

| Test Description | Acceptance Limits | Timer Settings and Corresponding Acceptable Ranges | | | | |
|------------------|--------------------------|--|----------|-----------|------------|--------------|
| | | 10 ms | 20 ms | 100 ms | 500 ms | 2000 ms |
| kVp Accuracy | 60kV \pm 10% | 54 to 66 | 54 to 66 | 54 to 66 | 54 to 66 | 54 to 66 |
| Timer Accuracy | Setpoint \pm 10%, +1ms | 8 to 12 | 17 to 23 | 89 to 111 | 449 to 551 | 1799 to 2201 |

8.5 Maintenance Log sheet

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 |
|--|--------|--------|--------|--------|--------|--------|
| | Date | Date | Date | Date | Date | *1 |
| 1. Power button | | | | | | |
| 2. Time selection buttons | | | | | | |
| 3. X-ray exposure button | | | | | | |
| 4. READY state | | | | | | |
| 5. Exposure termination | | | | | | |
| 6. Exposure warning signal | | | | | | |
| 7. Exposure termination | | | | | | |
| 8. Calibration check (if needs) | | | | | | |
| *To ensure Flight Dental System's X-Vision X-Ray System works properly. Scheduling yearly inspections/preventative maintenance by Flight Dental Systems is strongly recommended. | | | | | | |

IX. HELP MESSAGE

9.1 Error Code

If any error occurs on this equipment, it will show the following error codes.

| Error Code | Class of Error | Action plan |
|------------|--|---|
| E00 | Low Battery The battery power is insufficient to generate X-Ray | Recharge Battery |
| E01 | Filament Fails The filament is broken Unable to heat up the filament | Contact Flight Dental Systems |
| E02 | Temperature of Unit is too high The inner temperature of the tube assembly is over 60°C or 140°F | <ol style="list-style-type: none"> 1. Stop operating 2. After 2 hours, check again 3. If same message appears, contact Flight Dental Systems |
| E03 | Insufficient Exposure Time Exposure terminates if the operator releases the depressed exposure button prematurely. | <ol style="list-style-type: none"> 1. Check the exposure parameters 2. Reinitiate the exposure. |

X. DISPOSAL



In the EU the "crossed-out wheeled bin" symbol indicates that this product shall not be disposed of as unsorted waste and must properly be disposed of according to local regulations. In accordance, this will satisfy the European Directive 2002/96/EC and 2003/108/EC. XR-3800 system is made of materials including iron, aluminum, lead, copper, plastics, electronic components and dielectric oil in the x-ray tube assembly tank. Hence, it must be disposed of according to local requirements. DO NOT dispose of any part of XR-3800 without verifying with your local regulations.

XI. TECHNICAL DATA

11.1 Basic Technical Specifications

Classification / Specifications

| | |
|--|--|
| Compliance Electrical classification (Battery) | Internally Power Type B Class II |
| Electrical classification (AC/DC Adaptor) | Type B |
| MDD(93/42/EEC):Annex IX | Class IIb |
| IPX specification | IP0; do not operate under wet conditions |

Mode of operation

Intermittent operation

For use in environments where no flammable anesthetics and/or flammable cleaning agents are present; Cleaning only with non-alcohol based disinfectant wipes or cloth dampened with liquid/spray

Complied Standards

| | |
|------------------------|---|
| -IEC/EN60601-1 | - IEC/EN60601-1-2 |
| -IEC/EN60601-1-3 | - IEC/EN60601-1-6 |
| - IEC/EN 60601-2-65 | |
| X-Ray Exposure Control | |
| Exposure time range | 0.01sec~2.0sec manually adjustable (0.01s / steps) |

X-ray Tube Assembly

| | |
|-----------------------------------|--|
| kV range | 60kV(fixed) |
| mA range | 2.0mA(fixed) |
| Exposure duty cycle | 1:30 + 5sec |
| Total filtration | 1.6mmAl (1mm glass, 0.2mm Al, 0.4mm plastic cap and oil) |
| Maximum output power | 120W |
| Maximum Leakage technique factors | 60kV X4mAs |

Beam Limiting Device

| | |
|-------------------------|------------|
| Type | Round Type |
| Source to Skin Distance | 20cm |
| X-ray field size | Ø60 |

Battery

| | |
|-----------------|----------------------------|
| Model Name | 7S1PXR001(Li-Polymer Type) |
| Manufacturer | HR Dental Products Inc. |
| Nominal Voltage | 25.2Vdc |
| Capacity | 2900mAh |

AC/DC Adaptor

| | |
|--------------|--------------------------------|
| Model Name | GST60A24-P1J |
| Manufacturer | Mean Well Enterprises Co.,Ltd. |
| Rated Input | 100~240Vac, 50~60Hz, 1.4~0.7A |
| Rated output | 24Vdc/2.5A, 60WMax |

Dimension(Unit : mm) and Weight

| | | |
|---|-----------------|---------------------------|
| Main Body with Beam Limiting Cone | 174 x 178x257 | 2.7kg±10% or 5.9lbs±10% |
| Main Body without Beam Limiting Cone | 174 x 178x150 | 2.5kg±10% or 5.5lbs±10% |
| AC/DC Adaptor | 121 x 48 x 30 | 280g±10% or 0.62lbs±10% |
| Backscatter Shield (Fixed) (0.30 pb equivalent – 6” diameter) | 145 x 145 x 8 | 0.4kg±10% or 0.88lbs ±10% |
| Carrying Box | 455 x 260 x 197 | 1.2kg±10% or 2.6lbs±10% |

Environmental requirements

Operation

| | | |
|----------------------------|-------------------|----------------------------|
| Temperature | Relative humidity | -5°C ~ 40°C or 23°F ~104°F |
| Atmosphere | | 35% ~75%RH |
| Storage and transportation | | 700 ~1060hPa |

| | |
|-------------------|-----------------------------|
| Temperature | -10°C ~ 70°C or 14°F ~158°F |
| Relative humidity | 10% ~ 90%RH |
| Atmosphere | 500 ~ 1060hPa |

11.2 X-Ray Tube Specifications and Characteristics

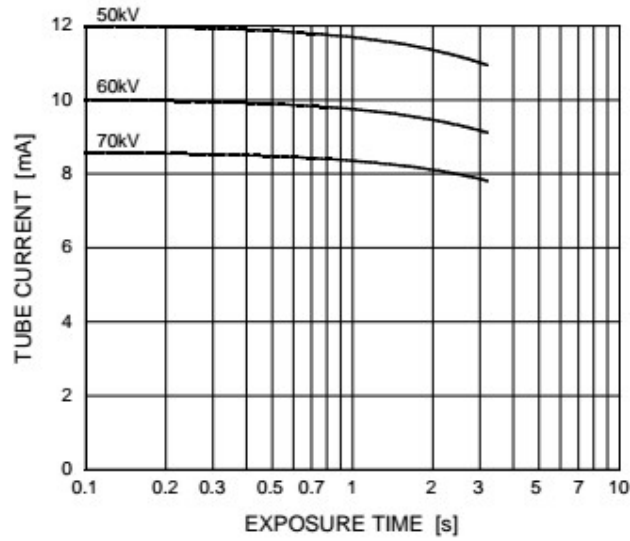
| | |
|-------------------------------------|-------------------|
| (1) Manufacturer | Canon(D-045) |
| (2) Type | Stationary |
| (3) Focal Spot | 0.4mm |
| (4) Target Angle | 12.5° |
| (5) Target Material | Tungsten |
| (6) Inherent Filtration | 1mmAl |
| (7) Cooling Method | Oil cooling |
| (8) Input Energy(see rating chart) | 585W(at1.0s) |
| (9) Maximum Tube Voltage | 70kV |
| (10) Minimum Tube Voltage | 50kV |
| (11) Maximum Tube Current | 2mA ± 10% nominal |
| (12) Maximum Line Current | 10A |
| (13) Maximum Input Volatage | 29.4V |
| (14) Filament Voltage | 4.0V |
| (at the maximum filament current) | |
| (15) Maximum Filament Current | 3.0A |
| (16) Thermal Characteristics | |
| Anode Heat Storage Capacity | 4.3kJ |
| Maximum Anode Heat Dissipation Rate | 100W |

(13) Rating Chart

Maximum Rating Charts (Absolute maximum rating charts)

Constant Potential High-Voltage Generator

Nominal Focal Spot Value: 0.4

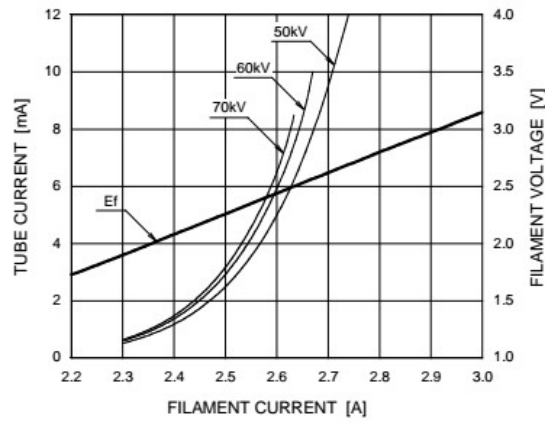


Refer to IEC60613:2010

Emission & Filament Characteristics

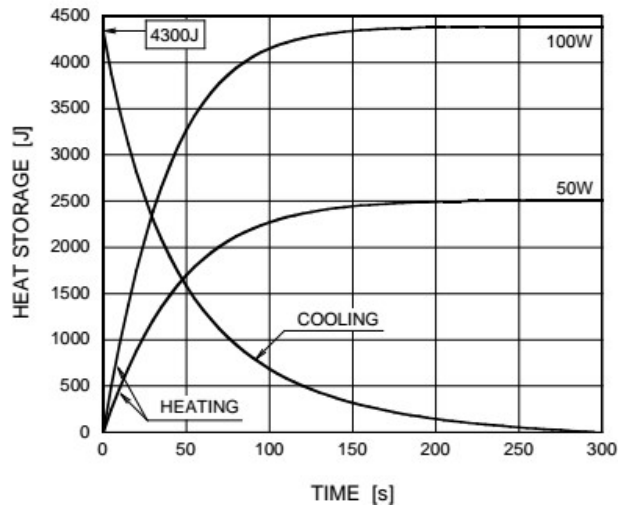
Constant Potential High-Voltage Generator

Nominal Focal Spot Value: 0.4



Note1) This graph indicates typical characteristics.
Note2) Refer to IEC60613:2010

Anode Heating / Cooling Curve

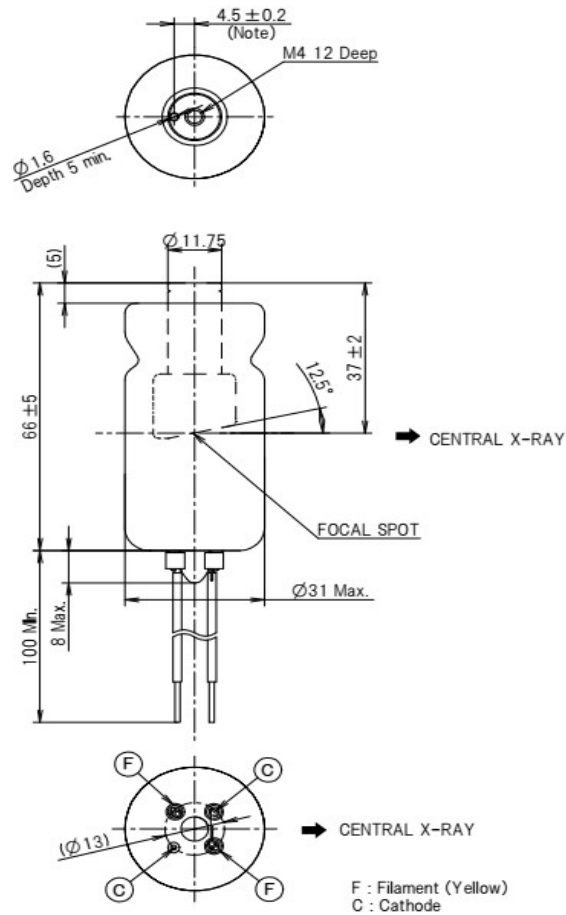


The X-ray source assembly heating and cooling curves are equivalent to the anode heating curves shown here. Flight Dental System's X-ray assembly has the protection of a 60°C thermal sensor to prevent overheating.

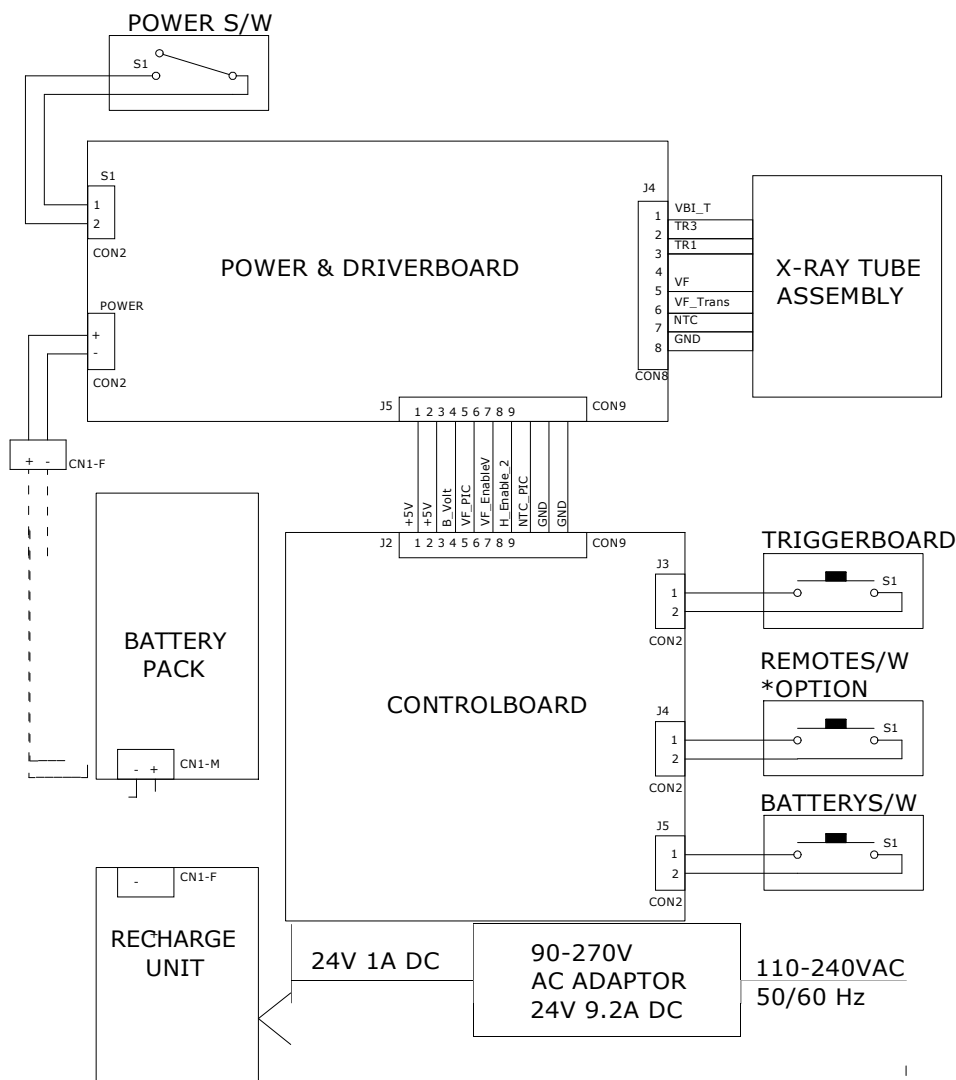
(14) Dimensional Outline of X-ray Tube(D-045)

Dimensional Outline

Unit: mm



11.3 Wiring Diagram



NOTE:

When the battery is charging, the X-Ray unit will not be functional i.e. an exposure cannot be done during the recharging phase.

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