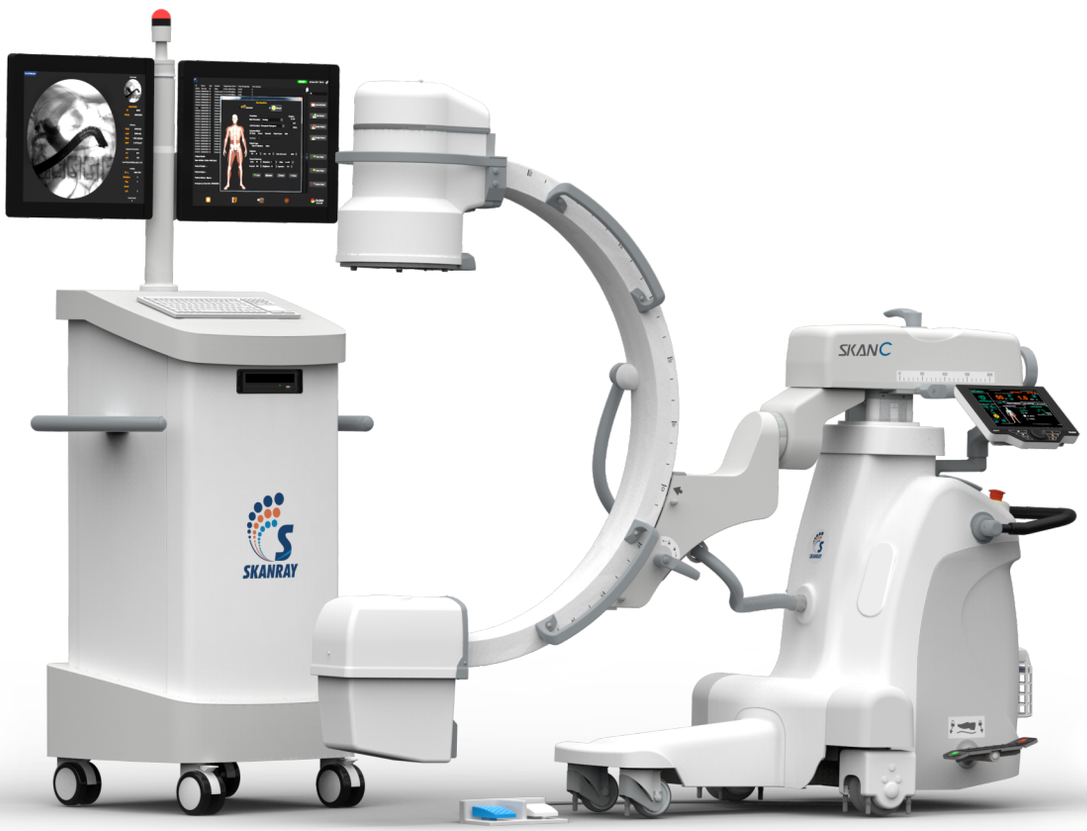
SKANRAY



SKAN C

High Frequency Mobile Surgical C-Arm

USERS' MANUAL

General Information

Document Number	UMN-000187-3-20
Part Number	515-001853-2
Document Revision	03
Release Date	27 - JULY - 2020

User Responsibility

This product is designed to perform its intended function when operated in accordance with the instructions provided in this manual, other accompanying labels, accessories (Cone & power cord) and when assembled as per the instructions provided. A defective unit should not be used. Parts that are broken, plainly worn, missing, incomplete, distorted or contaminated should be replaced immediately.

There are no user repairable components / modules used as a part of this product. In case of a defective or malfunctioning unit the repair should be carried out by a trained technician authorized by SKANRAY. The user shall have the sole responsibility of any outcome originating from this product resulting from improper use, faulty maintenance, damage or use of accessories (cone & power cord) / replacements parts not approved by SKANRAY.

While using the Skan C Mobile C-ARM X-Ray System, the user must ensure its application, prescribed operator qualifications, operating specifications and continued compliance of the equipment. Systems should only be used in designated use areas with approved AC receptacles. Unauthorized changes or modifications to any part of the system could have hazardous consequences. Changes or modifications must not be made unless specifically authorized by SKANRAY. To achieve satisfactory results and safely use Skan C Mobile C-ARM X-Ray System, it is important that the operator of Skan C Mobile C-ARM X-Ray System must read and understand this manual before operating the equipment.

CAUTION

Use of Accessories (Cone & power cord) / replacement parts that are not recommended by SKANRAY could compromise the performance of the unit if not compromise operator / patient safety.

SKANRAY will not be able to honour warranty, if any unauthorized accessories or changes done in the system. Additionally SKANRAY shall not be liable for any losses incurred due to the usage of any such non-recommended Accessories (cone & power cord) / replacement parts.

SKANRAY Responsibility

It is the responsibility of SKANRAY to provide system performance and safety as mentioned in the user's manual, conforming to regulatory requirements.

If the system does not operate properly or fails to respond for the intended operation/s as described in this manual, contact SKANRAY or your nearest authorized dealer.

Limited Warranty Statement

This warranty does not cover damages caused by any combination of

1. Handling during shipping (where applicable) or
2. Deviation from usage instructions while handling, maintaining or operating the unit as prescribed in this manual or
3. Alteration or repair attempted by user or by a personnel other than SKANRAY authorised service personnel or
4. Accidents including natural disasters.

If a product or accessory covered under this warranty is found to be defective because of defective material, component or workmanship and the warranty claim is made within the warranty period as described above, SKANRAY will, at its discretion, repair or replace the product or accessories (Cone & power cord) free of charge.

NOTE

For improving product quality and customer experience, we at SKANRAY are dedicated to upgrading the technology and processes used in our product. The information provided in this document is subject to change without prior notice.

Please contact SKANRAY for latest updates on the product and services.

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CHAPTER 1

Introduction

1.1 About Skan C

Skan C is a Mobile Diagnostic X-ray Unit with both Radiographic and Fluoroscopic system and is designed for medical use during surgical and/or imaging purpose. This User's Manual details the operational procedures and guidelines required for the safe and effective use of the Skan C Mobile C-ARM X-Ray System .

User of this device is advised strongly to go through this manual before using Skan C for its intended purpose. The operator is responsible for the use of the system in compliance with the applicable standards concerning installation and use.

It is not designed to replace or substitute for certified training in the radiological or medical field.

This manual describes necessary safety requirements and precautions to be taken by the user, while using this device for the intended purpose.

1.2 Conventions Used

In this manual following typographic & symbol conventions are used to facilitate the easy understanding of instructions.

- Cross references are important notes.
- Procedural steps or set of instructions are preceded by • or numerical indications.
- Safety symbol with Warning, Caution and Note used in this manual is as indicated below.

CAUTION

Indicates a Hazardous situation which, if not avoided, may result in death or serious injury.

WARNING

Indicates a hazardous situation which, if not avoided, may result in serious injury or permanent disability.

NOTE

Indicates improper functioning or may lead to risk if not used/followed as instructed.

1.3 System Compatibility

Skan C should be used only with Workstation provided along with the unit.

Skan C should not be used in conjunction or combination with any other devices unless such compatibility is declared explicitly safe to use by SKANRAY. When used with other devices and its compatibility is uncertain, it is the responsibility of user to ensure with SKANRAY on use of such device. Any changes or additions to the Skan C to be done only by SKANRAY authorized personnel.

CAUTION

Any use if unauthorized changes or use of unauthorized accessories will have an impact on safety and regulatory compliance. Please contact SKANRAY before making any such changes.

1.4 System Interfaces

Skan C does not recommend any interaction with devices for medication.

It is possible to interface the unit with certain devices such as DVD recorder, thermal printer, network (DICOM System). Such devices must be in full compliance with the safety requirements specified by 93/42/EEC directive. The liability of the interface, if it has not been evaluated and authorized by SKANRAY, shall lie with user/operator and/or of the person who has performed this interface.

1.5 Continued Compliance

Skan C User is responsible for verifying continued compliance with all applicable regulations and standards. Consult local or international regulatory agencies regarding any specific requirements applicable to use of this device, Skan C Mobile C-ARM X-Ray System.

Skan C is designed to conform to national and international regulations. This includes the conformance to electromagnetic emission levels and immunity levels as prescribed by IEC 60601-1-2.

Skan C confirms to IEC 60601-1 and is classified as Class 1.

NOTE

For details refer "Annex 5: Guidance and Regulatory Information"

CHAPTER 2

Intended Use

The Skan C, a mobile surgical C-Arm X-Ray System, is intended to provide fluoroscopic and radiographic images of the patient during diagnostic, surgical and interventional procedures. Skan C is used by qualified radiologists in the hospital OT's for surgery.

Examples of clinical applications may include orthopaedic, GI Procedure like endoscopy and cholenography, neurology, urology procedures, vascular, critical care and emergency room procedures. Skan C is not recommended for cardiac applications.

Skan C surgical C-Arm is indicated for visualization in real time and/or recording of surgical region of interest and anatomy, using X-ray imaging technique.

NOTE

Use of Skan C for unintended/ not indicated and/or improper/ incorrect use of Skan C, shall be under user's/operator's risk and SKANRAY shall not be held or take up responsibility of such mishaps or damages or injury.

NOTE

Skan C, is not designed for continuous use. It is not intended to make contact with patient. Accidental contact can only be non-invasive nature. User contact is only for operating the Skan C, under normal intended use.

2.1 Contraindications

Prior to all diagnostic and fluoroscopic exposures in women, it is recommended to check the pregnancy status and if found to be positive, evaluate the risks and benefits of radiation to the patient and to her unborn foetus.

WARNING

Prolonged radioscopically guided interventional procedures may increase the risk of deterministic effects.

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CHAPTER 3

Safety Information

3.1 General Safety Tips

- The Skan C Mobile C-ARM X-Ray System, is designed to meet all relevant safety requirement. However, a proper operation and maintenance needs to be exercised to maintain human safety.

WARNING

Ensure recommended user routine checks are performed and are satisfactory and planned maintenance are conducted, before using Skan C for any application. Failure to do so may lead to untoward incidence or failure of intended function.

Do not use the device, if there are any damages to the cables or any other mechanical damages.

CAUTION

Federal law restricts this device to sale by or on the order of a licensed radiologist or physician.

- User should understand and follow all safety guidance and instructions under the heading safety information.
- User should observe the safety instruction under Warnings, Cautions and Notes, which is provided under all topics as and when found relevant.
- User should understand and observe Intended use and Contraindications provided in Chapter 2 "Intended Use".
- User should go through all operational requirements for patient positioning to avoid any accidental injury and/or damage to the equipment.

NOTE

Refer section "Understanding Mechanical Movements" for the proper use of controls and brakes.

3.2 Protection Against Ionizing Radiation

1. Skan C Mobile C-ARM X-Ray System, is an X-ray (Ionizing Radiation) Medical device. It should be used only in the designated areas as per the local or international radiation safety norms.

WARNING

Skan C complies to the radiation limits as per international regulations. However, ionizing radiations are hazardous to the user and patient. It is advised to have appropriate protection

2. The exposure of the patient must be kept to a minimum level, consistent with clinical objectives and without loss of essential diagnostic information. To achieve this, available techniques appropriate to the equipment may be used.
3. The X-ray beam must be well collimated to restrict it as much as is practicable to the area of diagnostic interest.
4. The X-ray beam size is to be confined to the region of interest.
5. The X-ray beam should not be directed towards the gonads unless it is absolutely essential, in which case gonad shielding must be used whenever the value of the examination is not impaired by such use.
6. Shielding should be used where appropriate and practicable to limit the exposure of body tissues. It is particularly important that special effort to be made to protect the blood-forming organs, gonads and thyroids.

3.2.1 Radiation Safety to User / Staff

Follow time-distance-shield principle for radiation protection and safety

1. Optimize exposure time duration
2. Maintain distance from primary beam as far as possible during exposures
3. Use of shields to protect from scattered radiations
4. Use of appropriate lead apron and other protective clothing
5. Use of ceiling suspended, lateral shield and table curtains
6. Use of protective eye wear from ionizing radiations
7. Keep hands outside the primary beam as far as possible
8. Monitor radiation exposure on user and staff by using TLD or film badge or similar, at.
   - One inside the apron at chest level
   - One outside the apron at neck or eye level
   - Additional finger ring dose sensor, if required
9. Use normal fluoroscopy where ever possible instead of high dose fluoroscopy
10. Skan C provides virtual collimation, use appropriate collimation technique only for the required region of interest.
11. Try to keep the source under table as much as possible, this reduces the effect of scattered radiations

3.2.2 Radiation Safety to Patient

Observe following safety measures to reduce radiation hazard to the patient.

1. Maximize distance between the X-ray source and patient, to the maximum extent possible.
2. Minimize the distance between patient and the image intensifier.
3. Use of collimator to collimate the X-ray beam area within the region of interest.
4. Minimize fluoroscopy time. Keep records of fluoroscopy time for every patient.
5. Use pulsed fluoroscopy with lowest frame rate if possible to obtain images of acceptable quality.
6. Avoid exposing the same area of the skin in different projections. Vary the beam entrance port by rotating the tube around the patient.
7. Larger patients or thicker body parts trigger an increase in Entrance Surface Dose (ESD).
8. Oblique projections also increase ESD. Be aware that increased ESD increases the probability of skin injury.
9. Avoid the use of magnification. Decreasing the field of view by a factor of two increases dose rate by a factor of four.
10. Minimize number of frames and cine runs to clinically acceptable level. Documentation should be performed with last image hold whenever possible and not with cine images.
11. Observe radiation protocol suggested for pregnant women.
12. Do not allow operator for any non-prescribed exposure/s
13. The X-ray beam should not be directed towards the gonads unless it is absolutely essential, in which case gonad shielding must be used whenever the value of the examination is not impaired by such use.
14. In case of paediatrics, use of special devices, as recommended by the clinical procedures should be used.
15. International regulation recommends a minimum source-skin distance of 30cm, except for specific surgical applications. However, 20cm at a minimum is mandatory. Skan C, maintain a source to skin distance of 20cm by design. A skin spacer is provided along with machine, which can be used to increase the distance to 30cm.

CAUTION

Use of equipment and exposure settings designed for adults of average size can result in excessive radiation exposure for a smaller patient. Studies have shown that pediatric patients may be more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for paediatric patients.

CAUTION

It is recommended to follow the FDA guidance on paediatric X-ray imaging resources and image gently practices by referring to the below links

http://www.imagegently.org/About-Us/Resources

https://www.fda.gov/RadiationEmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm

3.2.3 Deterministic Effect

Skin-Dose level	Effect
Skin Erythema/Necrosis/Epilation: Erythema occurs 1 to 24 hours after 2Sv have been received. Breakdown of the skin surface occurs approximately four weeks after 15Sv have been received. Epilation is reversible after 3Sv but irreversible after 7Sv and occurs three weeks following exposure.	SkinErythema/ Necrosis / Epilation
Cataract: Cataract occurs due to accumulation of damaged or dead cells within the lens, the removal of which cannot take place naturally. Cataract occurs after 2 to 10 Gy have been received, but may take years to develop.	Cataract
Sterility: Radiation can impair oocyte function, leading to impaired or non-fertility. The radiation dose required to have this effect decreases with age due to falling total oocyte numbers. Similarly, radiation exposure to the testes can result in temporary or permanent azoospermia. Permanent sterility occurs after 2.5 to 3.5 Gy have been received by the gonads.	Sterility
Radiation Sickness: Radiation sickness (correctly termed acute radiation syndrome) involves nausea, vomiting, and diarrhea developing within hours or minutes of a radiation exposure. This is due to deterministic effects on the bone marrow, GI tract, and CNS.	Radiation Sickness
IUGR/Teratogenesis/Fetal Death : Deterministic radiation exposure effects during pregnancy depend not only on the radiation dose received but also on the gestational age at which it occurred. The embryo is relatively radio-resistant during its preimplantation phase but highly radiosensitive during its organogenesis (two to eight weeks) and neuronal stem cell proliferation phases (eight to 15 weeks). Fetal radiosensitivity falls after this period. High levels of radiation exposure in pregnancy can lead to growth retardation, in particular microcephaly. The threshold dose for this effect is high (>20Gy) with other deterministic effects (hypospadia, microphthalmia, retinal degeneration, and optic atrophy) having a lower threshold level of >1Gy.	IUGR/ Teratogenesis/ Fetal Death

3.2.3.1 Continuous Fluoroscopy Exposure Dose parameters

1. For time limits, it was assumed that it was usual to use different orientations of the X-ray beam and that only 50 percent of the total time would use the same orientation with the X-ray beam entering the patient at approximately the same location [Relative Time at Skin Location (RTSL)].
2. Serial image recording could produce an additional radiation dose equivalent to the fluoroscopic dose [Image Recording Factor (IRF)].
3. The image intensifier is at 950mm.
4. The beam entrance point is at 560mm.
5. A backscatter factor (BSF) of 1.2 is used to include radiation backscatter from the body to the skin.

Sl no	Procedure	Typical Dose Rate (R/min)	Average exposure (Sec)	Effective Dose(mR)	Cumulative time for 100 R DOSE (min)
1	Urology Procedure	0.16	55	300	333
2	Upper GI Series	0.22	85	600	235
3	Small bowel series	0.17	90	500	300
4	Barium enema	0.12	78	300	433
5	Endoscopic retrograde	0.23	110	800	228
6	Cholangiopancreatography	0.21	60	400	250
7	Lumbar Spine	0.14	40	180	366
8	Thoracic Spine	0.09	35	100	580
9	Extremities	0.04	35	50	1160
10	Cervical spine series	0.05	55	85	1033

WARNING

Unlike cardiovascular and angiographic procedures, dose effect on patient were found to be minimal. However, dose management of a particular patient to be carried out as per the international dose management report, by the user.

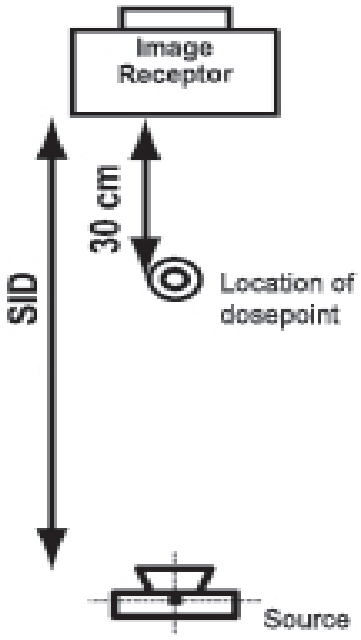
3.2.3.2 RAD Exposure Dose parameters

WARNING

Giving radiation exposure without Skin Spacer shall increase skin active radiation level, if source to skin is lower than 30cm.

Sl no.	Body Part	Medium patient				
		Adult M/F				
		kV	mAs	Dose	Airkerma in mGy	DAP Gy/cm²
1	PA Hand	60	2.00	105.86	0.29	0.12
2	PA Wrist	60	2.00	105.86	0.29	0.12
3	AP Forearm	50	2.00	38.23	0.19	0.02
4	AP Elbow	50	2.00	38.23	0.19	0.02
5	AP shoulder	70	10.00	225.57	1.88	0.9
6	AP Clavicle	60	2.00	105.86	0.29	0.12
7	PA Chest	110	5.00	358.38	2.39	0.98
8	AP Abdomen	80	20.00	456.36	5.32	2.18
9	AP pelvis	80	20.00	456.36	5.32	2.18
10	AP Femur	80	12.50	330.58	3.31	1.36
11	AP Knee	80	6.25	330.5	2.2	0.9
12	AP Ankle	60	4.00	66.79	0.45	0.19
13	AP Foot	60	2.00	45.38	0.23	0.09

3.2.3.3 Reference Location for AKR and Cumulative dose measurement



For U.S & non U.S, the AKR and cumulative dose measured from dose point to image receptor is 30cm.

3.3 Protection Against Electrical Hazard

Observe following safety measures to reduce electrical shock hazard to user and patient

1. Skan C to be used in environments specified in the product technical information "Annex 6: Technical Information".
2. Use only recommended cleaning and disinfecting agents, to avoid explosion or surface degradation of device.
3. Confirm the electrical inlet rating before connecting the unit to hospital power socket
4. It is strongly suggested not to attempt open covers for service or repair. There are no user repairable/replaceable parts. Do not attempt to open any of the covers unless otherwise authorized by SKANRAY.

CAUTION

Skan C internal circuits contain high voltage. Do not attempt to open covers without explicit authorization and training.

Disconnect from mains power before attempting the removal of covers.

5. User should take care of ground impedance quality of hospital supply outlet.

WARNING

Do not touch Skan C electrical/conductive parts and patient simultaneously. This can introduce hazardous leakage current through the patient.

6. Always Isolate Skan C system electrically before attempting any cleaning or disinfecting procedure.
7. Ensure there are no liquid of any conductive nature, to be spilled on the internal parts of Skan C.

WARNING

The Skan C Mobile C-ARM X-Ray system is not totally waterproof. Water, soap or other liquids, if allowed to drip into the equipment, can cause electrical short circuits leading to electric shock and fire hazards. Ensure no liquid is draped in to the system, before switching ON.

8. Skan C is classified as CLASS I under the electrical safety classification with "Mandatory protective earth conductor".

WARNING

To avoid electrical shock hazard, always ensure the integrity of the ground connection before plugging in and powering on the system.

3.4 Mechanical Safety

Figure 1: Trapping Zone

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 any mechanical movements.

Skan C Mobile C-ARM X-Ray System is mounted on casters and it is designed for lot of user initiated movements during or after the procedures. Ensure that no part of your body/patient are trapped in between. Pay attention to the labels where trapping zones are marked with.

1. While moving take care to avoid colliding with/or over-run on objects and/or persons. The user/operator must be familiar with all movement controls and brake mechanisms before attempting to move Skan C system.

NOTE

Refer section "Understanding Mechanical Movements" for mechanical movement controls.

2. Skan C X-ray system weights more than 270-300 kg and the workstation weights 80-100 kg. Generally a force of 80 kg may be required while manoeuvring over ramp or threshold.
3. While moving/transporting Skan C, it should be configured in transport position.

WARNING

Two people should maintain control of the equipment when moving up or down an incline.

Never attempt to move the system up or down steps or on an incline greater than 10 degrees to avoid injuries caused due to instability

NOTE

Refer Section "5.1 Mechanical Brakes and Movements" for the details on bringing Skan C main unit and Workstation for transport configuration.

4. User should go through and understand various mechanical movement for patient position within confined area and should observe following safety principles during normal use.

WARNING

Do not attempt to move Skan C if any of mechanical parts are found defective

*Ensure **locks** and **brakes** are properly locked once patient position is achieved*

Please, ensure none of the parts collide with patient or objects while attempting patient positioning. Handle mechanical movement with care. Keep patient within the sight of view

3.5 EMI / EMC

This equipment is in compliance with the standard IEC 60601-1-2 that defines the maximum allowed emission levels from electronic devices and the required immunity from interference caused by externally generated electromagnetic fields.

NOTE

Refer "Annex 5: Guidance and Regulatory Information" *for conformance report.*

Using any conductors or cables and accessories (Cone & power cord), other than recommended or supplied by SKANRAY may increase electro-magnetic radiation or reduce immunity towards electro-magnetic radiation.

Any transmissions by mobile radio equipment must be avoided. Mobile phones must be switched off in zones close to the unit. These must be observed while Skan C is under intended use.

Avoid use of mobile phones & mobile radio devices with in the vicinity. This may interfere with the device functionality. Refer "Annex 5: Guidance and Regulatory Information" for more specific information related to EMI / EMC compliance levels.

3.6 Laser Targeting Devices Safety

1. Do not stare in to the output window of laser system. Keep minimum distance of 100mm from eye.
2. It is advisable to keep away all reflecting materials for laser to reduce its hazards due to reflection.
3. Do not attempt to service or repair laser system.

NOTE

Laser Aimer in Skan C is used with the aim to reduce the dose to the patient. It is not considered as an absolute means of centring

WARNING

***LASER RADIATION:** Do not stare in to beam or view directly with optical instruments. Viewing within 100mm may induce eye hazard.*

Observe provision provided in IEC 60825-1, Section 3 "User Guide" for operating laser positioning device.

Class II laser product (in accordance with FDA 21CFR, Sub chapter J, Section 1040.10-11).

3.7 Installation and Service

Ensure that your X-ray unit is installed inside a hospital building, which complies with all applicable laws and recommendations concerning electrical safety. Installation should be done by an authorized service engineer only. Consult the factory or your dealer for installation of the unit. Take the services of qualified personnel when relocating the unit.

WARNING

Improper Installation and configuration may lead to failure and serious injuries to the user or patient. Installation should be done by qualified or trained personnel from SKANRAY or its authorized dealers to use the system. Please contact SKANRAY or its dealers for user training.

Skan C may be used by another user in other locations. Contact SKANRAY or its dealers in case the system is to be transported and installed at another location.

WARNING

*SKANRAY shall not take any responsibility of Skan C system failure or risks introduced by the system, which is transferred and installed without registering the **new user** with SKANRAY and not installed by SKANRAY Authorised Personnel. This may create serious Technical, Legal and Documentation Issues*

3.8 Fire / Explosion Safety

This equipment is not intended to be used in presence of flammable or potentially explosive disinfecting gases or vapours, which could ignite, causing personal injury and/or damage to the equipment. If such disinfectants are used, the vapour must be allowed to disperse before using the equipment.

WARNING

Skan C is non-anesthetic proof. Do not use it in presence of anaesthetic or similar gases which are explosive in nature.

Tips in case of fire

1. Disconnect electrical power supply connected to the C-Arm system.
2. Evacuate personnel from the area
3. Use fire extinguisher that is approved for use on electrical fires.

WARNING

Do not use water and other liquids to extinguish fire. Use only capable fire extinguisher for electrical fire.

3.9 Operator Qualifications

Operator of this unit should have received or trained adequately on its safe and effective use before attempting to use this equipment.

It is the responsibility of the owner to ensure that the system is operated only by properly trained, qualified personnel who have obtained necessary qualification criteria to operate Skan C, in accordance with local regulations and laws.

3.10 Burns & High Temperature

High temperature exists inside the unit on power circuits. The X-ray source may attain higher temperature. Skan C Has a safety feature to limit this temperature below 60°C. Ensure that this is not touched immediately after any prolonged procedures.

WARNING

Do not open covers and touch heat sinks and power components. During prolonged operations, heat sink may reach a temperature which can inflict burns.

Continuous exposure with high dose deLivery, may cause X-ray tube assembly to reach temperature, which may not be comfortable for the user to touch. However, Skan C system, beyond temperature 60 °C is not achieved.

WARNING

During prolonged, use with high dose deLivery, HV tank may attain a warm temperature range around 60 °C.

Avoid touching HV tank assembly during long high dose deLivery procedure.

3.11 Environmental Hazards

Skan C should be used under the specified environmental conditions specified in technical specification for the intended use.

NOTE

Refer operating environmental conditions in "Annex 6: Technical Information"

WARNING

Using Skan C outside the specified environmental conditions, can lead to device failure.

3.12 Waste Hazard Management

Skan C complies with RoHS requirement as per the European directive.

However, Skan C may contain some hazardous material as allowed by regulatory, which could pose a risk to the environment.

It is the responsibility of user/owner of this device to dispose OFF, considering local regulations and procedures.

WARNING

Some parts of Skan C Mobile C-ARM X-Ray System contains hazardous material like Lead, Oil etc. It is the responsibility of user/owner of Skan C to properly dispose the system as per the local or international regulation on hazardous waste management or re-cycling process.

3.13 Biological Hazards

Infected or contaminated body fluids or tissue residues over the Skan C parts may lead to cross contamination always use drapes and sterile cover to cover relevant parts of the system during use. Always disinfect the system after every use.

WARNING

USe of Drapes or similar sterile covers during surgical procedures is recommended, to avoid or reduce the cross-infection.

The X-ray source assembly consist of oil inside. Contact service team imminently if there are any oil leak and do not use the system.

3.14 Malfunction and/or Break Down

1. In case of malfunction or for any unintended behaviour of Skan C Mobile C-ARM X-Ray System, it should be switched OFF, mains to be disconnected and inform customer service department of the same.
2. In case of malfunction and if any service code is notified on the monitor, inform the error code/message to customer service department.

WARNING

In case of malfunction or unintended behaviour of Skan C Mobile C-ARM X-Ray System, do not attempt to open the covers and service the device without prior authorization and proper training. This may lead to injury.

3.15 Patient Environment

In the US the patient Environment is defined by NFPA 99 and UL 2601-1.

In areas in which patients are normally cared for, the patient environment is the space with surfaces likely to be contacted by the patient or an attendant who can touch the patient. This encloses a space within the room, 1.8m (6 ft). beyond the perimeter of the bed (examination table, dental chair, treatment booth, etc.) in its intended location, and extending vertically 2.3m (7.5 ft). above the floor.

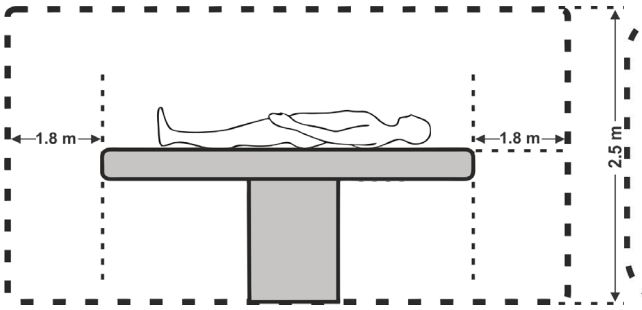


Figure 2: Patient Environment- Side view

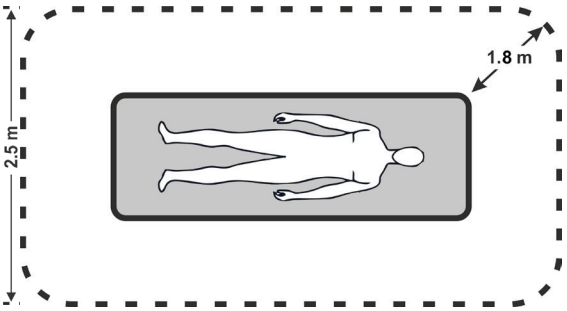


Figure 3: Patient Environment- Top view

Outside the United States

Outside the US the patient environment is defined by IEC 60601-1-1. In areas in which patients are normally cared for, the patient environment is the space with surfaces likely to be contacted by the patient or an attendant who can touch the patient. This encloses a space within the room 1.5m (5 ft) beyond the perimeter of the bed (examination table, dental chair, treatment booth, etc.) in its intended location, and extending vertically 2.5m (8ft) above the floor.

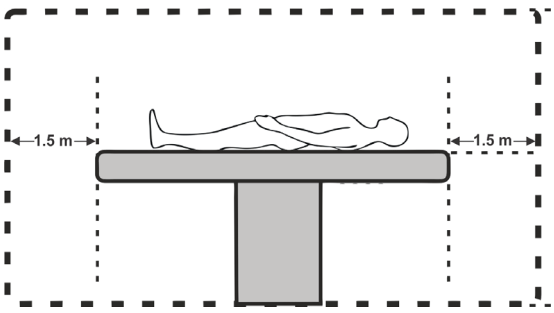


Figure 4: Patient Environment- Side view

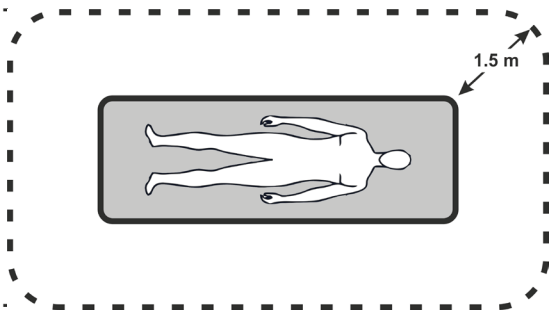


Figure 5: Patient Environment- Top view

3.16 Safety Symbols

WARNING

Warning statements describe conditions or actions that may result in personal injury or loss of life.

CAUTION

Caution statements describe conditions or actions that may result in damage to the equipment or software.

NOTE

Refer operating environmental conditions in "Annex 6: Technical Information"

	General Caution Symbol	ISO 7000-0434A
	General Warning Symbol	ISO 7010-W001
	Warning: HOT SURFACE	ISO 7010-W017
	Warning: Trapping Zone	ISO-7010-W024
	Warning: X-Ray Warning: 'Ioninzing Radiation'	ISO 7010-W003
	Warning: Electricity	ISO 7010-W012
	Dangerous voltage present	IEC 60417-5036
	Protective Earth Ground	IEC 60417-5019
	Refer to User Manual	ISO 7010-M002
	Alternating current	IEC 60417-5032

	FOCAL SPOT	IEC 60417-5325 IEC 60336
	WEEE Symbol Indicates that the unit conforms to WEEE Directive 2002/96/EC and must be disposed of only at the appropriate facilities for recovery and recycling.	
	Note Symbol	

There are no user repairable components / modules in this product. In case of a defective or malfunctioning unit, repair should be carried out by a trained technician authorized by SKANRAY.

SKANRAY will not bear responsibility for any outcome originating from this product resulting from improper use, faulty maintenance, damage and use of accessories/replacement parts not approved by SKANRAY.

CHAPTER 4

Know Your Skan C

4.1 Overview

WARNING

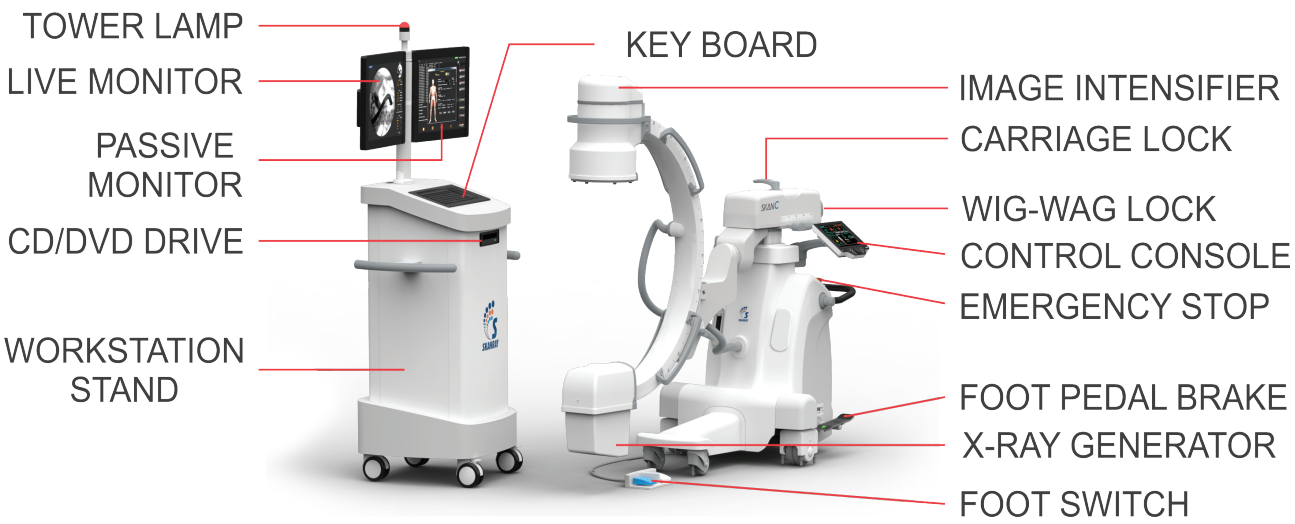
Do not start and use Skan C unless you have read and understood and implemented all safety instructions, detailed in Section "Safety Information"

Failing to observe Safety Instructions may lead to serious injury to you and your patient and possible misdiagnosis or mistreatment of patient.

Your Skan C, is a Mobile Surgical C-Arm intended for diagnostic purpose, using X-ray imaging technology. It is designed for medical use on humans, to assist surgical procedures.

Skan C is comprised of two main sub-systems

- Mobile C-Arm Unit
- Mobile Workstation



NOTE

If the user needs calls for standing for more than 4 hours in a stretch, he can have body movement to reduce the effect of standing for long time.

Product image colour & parts may change based on the configurations.

4.2 Configuration: Mobile C-Arm Unit

4.2.1 Tube-head X-ray Generator

X-ray generator is compact, housing all high voltage components along with the X-ray tube. Generator enclosure is designed for leak proof and explosion resistant. It houses a dual focal spot stationary X-ray tube, for both fluoroscope and radiography exposures. Generator is designed to withstand longer exposure period with excellent designed heat capacity.

This generator makes use of high frequency & state of the art technology, for efficient generation and control of X-ray Exposures.

For your Safety, this generator uses, the SKANSHIELD® patented technology, which is recognized for its lowest leakage radiation in the field.

NOTE

Measured ISO-DOSE is included in this manual in ISO-DOSE AIRKERMA Measurement graph, as per IEC requirement

4.2.2 Motorized Collimator

Collimator, is one of the essential component in achieving "ALARP- As Low As Reasonably Practicable".

- This collimator is completely motorize and you will have following collimation technique to adjust the primary X-ray beam to the Region Of Interest(ROI).
- Hard Shutter(Hard Blade), blocks the X-ray in unwanted region.
- Soft Shutter(Transparent Blade), improves the visibility of soft tissues, when used in combination with hard shutter.
- Perfect circular collimation(Under Patent), reduces the leakage radiation through edges.
- Orientation of both hard and soft shutters to the desired position, by rotating them together. This will help to align the region of interest to the desired anatomical view, without changing the position of patient.

NOTE

Collimation and restriction of primary beam to the region of interest, reduces the scattered radiation exposure to user and staff and improves image quality

4.2.3 Image Intensifier & Camera System

Image Intensifier provided to you is of 9"(23 cm), high DQE and high resolution. This has triple field view option for 6" and 4.5" and is selectable from C-Arm Console.

CMOS/CCD Camera provided with 1K x 1K resolution for acquisition keeping the image information intact, using GIGE-VISION Technology

Camera incorporates aperture iris control, for finer image quality and contrast depth.

4.2.4 Foot Switch

Skan C System is provided with "Dual Pedal Foot Switch", which has IPX7 rating. This provides two different coloured foot pedals, for fluoro/rad snapshot and fluoro continuous exposures.

Figure 6: Foot switch

Blue pedal actuation will enable fluoro continuous exposures.

Grey Pedal actuation will enable snapshot exposure in fluoroscope and initiate radiographic exposure in radiography.

Foot switch system is light weight, rugged and reliable. When not in use, can be easily be placed in its hanger.

Foot switch system is provided with sufficient length of cables, so that it enables you to use either at OT table or at console.

4.2.5 Hand Switch

Hand-Switch, is provided separately which has an extendible length up to 5m distance and Two separate actuation keys.

SNAP/RAD: During Fluoroscope, it is used to get a SNAPSHOT. During Radiography, it is used to initiate Radiographic Exposure.

FLUORO: During Fluoroscope, it is used to get Continuous exposures.

When not in Use, can be easily placed in its Hanger.

Figure 7: Hand Switch

4.2.6 C-Arm Console

Your C-Arm console is designed ergonomically with back-lit functions and at your eye level, reducing the strain on your neck and also keep the patient position in the same line of sight. Console consists of number of keys and an LCD, to display required information. Functions of keys are described in the Chapter 7 "C-Arm Unit Console Functions".

Display provides following information.

- Radiation Details
- Information and Exposure Status (X-ray ON)
- Radiation Details includes,
- Technique Parameter/s Selection (kV, mA or mAs)
- Cumulative Fluoroscopy Time for the procedures in mm:ss format
- Selected Mode of Operation

You can rotate the console and set it to the desired direction for your convenience.

Provision has been made to control the Live side of Workstation from console, like image rotate, image flip, image reverse, contrast/brightness adjust with auto-brightness controls.

Up/down keys are provided to control vertical movements of C-Arm, with patient in sight.

4.2.7 C-Arm Patient Positioning Mechanism

- Your C-Arm comes with all possible patient positioning options.
- It includes orbital rotation for under scan and over scan operation.
- C-rotation for full circle for angulation and to facilitate under and over table procedures
- A carriage movement up to 200mm is provided to ease the finer anatomical positioning
- A wig-wag movement of complete C-Arm up to 12.5° on either side
- All the above movements have brakes/locks, which are manually controlled and are easy to operate.
- Electrically controlled vertical movement, to adjust the C-Arm height for the desired procedural requirement is provided with fail safe mechanism by the use of emergency switch.
- A steerable handle to control the direction of C-Arm unit movement in desired direction is provided. This includes single actuation dual braking system, for safer and user friendly operation.
- All wheels are provided with cable deflector mechanism, which eases your movement within OT avoiding cables getting trapped under the wheels.
- Details on each operation and brake systems, are mentioned in Chapter 5 "Understanding Mechanical Movements".

4.2.8 Emergency Switch

An Emergency switch is provided to stop the vertical movement as a safety precautionary system, in case console control becomes ineffective or non-operational.

Figure 8: Emergency Switch

4.2.9 Power inlet and Interface Panel

Mains power inlet is provided behind the workstation with MCB for Safety. The mains MCB, when operated, electrically isolate both Live and neutral lines from hospital power line. Interface panel connects your hand-switch, foot-switch and interfaces to Workstation.

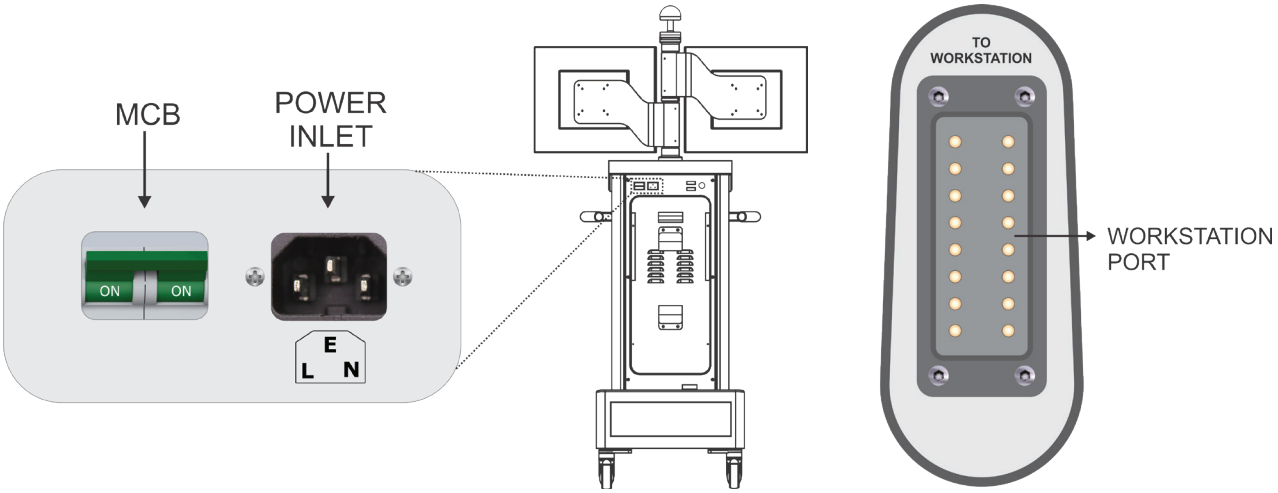


Figure 9: Power inlet and Interface Panel

4.2.10 Laser Aimer

Refer Section "3.6 Laser Targeting Devices Safety" for safety precautions.

A laser aimer is provided on the image intensifier system.

Laser can be switched ON/OFF using the console or on the laser assembly (battery operated). Laser light generates a cross hair on the region of interest. Centre of the cross hair normally corresponds to the centre of X-ray beam. This is one of the dose reduction technique to reduce the radiation exposure on patient.

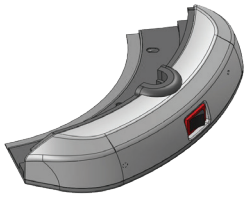


Figure 10: Laser Aimer

4.2.11 Detachable Skin Spacer (Optional)

An optional detachable Skin Spacer is provided maintain a distance of 30cm from X-ray source to skin. However, for the safety of reducing the intensity of skin irradiation, a minimum distance of 20cm is maintained from the X-ray source, even without Skin Spacer.

CONE EXTENSION LABEL - SKAN C	
PART No. REF	211-002207-0
SSD	20cm + 1cm

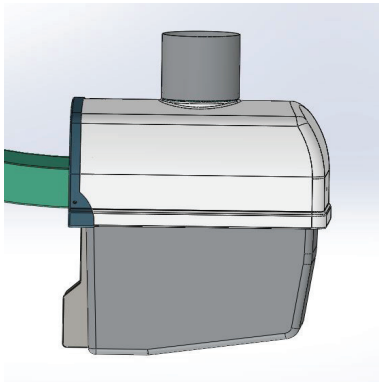


Figure 11: Skin spacer

4.2.12 Detachable Cassette Holder

To take radiographic exposure on the film, a detachable cassette holder is provided, as an option. This holder can accommodate 24cmx30cm size cassette.

However, X-ray exposure made on the film is circular and limited to 23cm diameter.

Figure 12: Detachable Cassette holder

4.2.13 Detachable Copper Filter (Optional)

For the safety of reducing the dose to paediatric patients, Skan C is provided with a detachable copper filter, to reduce the low intensity irradiation to the patient.

Thickness of filter is set to 0.1mm of Cu or 2.5mm of aluminium equivalent.

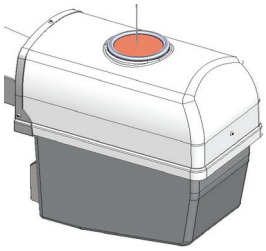


Figure 13: Detachable copper filter

4.2.14 Spring Clasp for Sterile Drape (Optional)

A spring clamp to hold the sterile drape either disposal or reusable is provided with the system. This can be used over the C-structure to hold the sterile material over the C, without hindering the C-arm movement

However, reusable green coloured sterile drapes can be procured from SKANRAY against order.

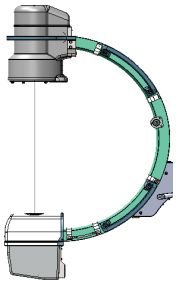


Figure 14: Sprint clasp

4.2.15 Detachable Anti scatter grid

Anti-scatter Grid with an attenuating factor less than equivalent of 1.2mm Al is provided, to help medical professionals make accurate diagnoses, by dramatically improving image contrast. This is achieved by absorbing scattered rays while maintaining the optimum transmission of primary radiation

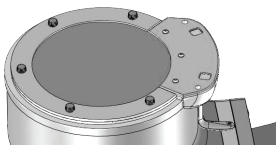


Figure 15: Anti-scatter Grid

4.3 Configuration: Mobile Workstation

Workstation is provided with the following configuration for your ease of use.

Figure 16: Workstation

4.3.1 Twin Monitors

Workstation is equipped with two monitors.

Live monitor displays the Live images captured which includes DSA, ROAD-MAP and Last Image Hold (LIH).

Passive monitor to be used for post processing, patient registration and other off line features.

You can adjust monitor viewing angle to your convenience.

4.3.2 Workstation Controls

Workstation is provided with a keyboard and a pointing device, to control the examination from Workstation side.

4.3.3 Exposure Status Indicator

An Exposure lamp, indicating the exposure status, is placed above the monitors. It is visible from all angles and from at a distance. Since, you will be observing the monitor during examination, an indication just above on status can be visualized without taking off your eyes from examination monitor.

4.3.4 DVD Writer

A DVD writer is provided with Workstation to facilitate storage of images and data on external storage media.

4.3.5 Mobility

Castors are provided with wheel lock facility, can be moved around for your convenient viewing position.

4.3.6 Cable Holder

Cable holder at the rear can be used for retaining cable while unplugged from Skan C Unit.

4.3.7 Standard DICOM Package

Workstation provides DICOM 3.0 compliant interface. It can be exported to a network storage device or sent to a network printer for output.

There is also image configuration facility available to configure images to be sent or printed.

CAUTION

It is recommended to format the removable media before plugging into the workstation to erase any traces of malware that could be present

CHAPTER 5

Understanding Mechanical Movements

The user/operator of Skan C should be familiar with and has understood all the safety instructions mentioned in Chapter 3 "Safety Information".

Setting up and use of Skan C, normally includes following work flow

- Mechanical movement and handling procedure for transportation and patient positioning
- Controls available and their use at Skan C unit
- Controls available and their use at Workstation
- Emergency procedures

WARNING

Do not start and use Skan C unless you have read and understood and implemented all safety instructions, detailed in Chapter 3 "Safety Information". Failing to observe safety instructions may lead to serious injury to you and your patient and possible misdiagnosis or mistreatment of patient

5.1 Mechanical Brakes and Movements

Skan C, is provided with various movement, to achieve required exposures as per the need of various surgical procedures. It can be virtually moved in any plane. For every movement an individual brake is provided.

WARNING

All Brakes shall be in locked condition always. Unlock during movement and relock after positioning. Use handles provided for various movements, this avoids fingers coming in the way C-guide rays.

CAUTION

During patient position or parking, make sure no person or objects are in the C-Arm path.

NOTE

Braked and Locked are the terms used to indicate a particular movement is being arrested, using a mechanical lever provided.

Following brakes and movements are available with Skan C, C-Arm unit.

- Orbital Movement and Brake
- C-Arm Rotation Movement and Brake (Sometimes referred as Yoke Rotation)
- Wig-Wag Movement (Panning) and Brake
- Horizontal(Carriage) Movement and Brake
- Steering and Foot Pedal Brake

Identify and locate movements, handles and brake/locks for a particular movement/s.

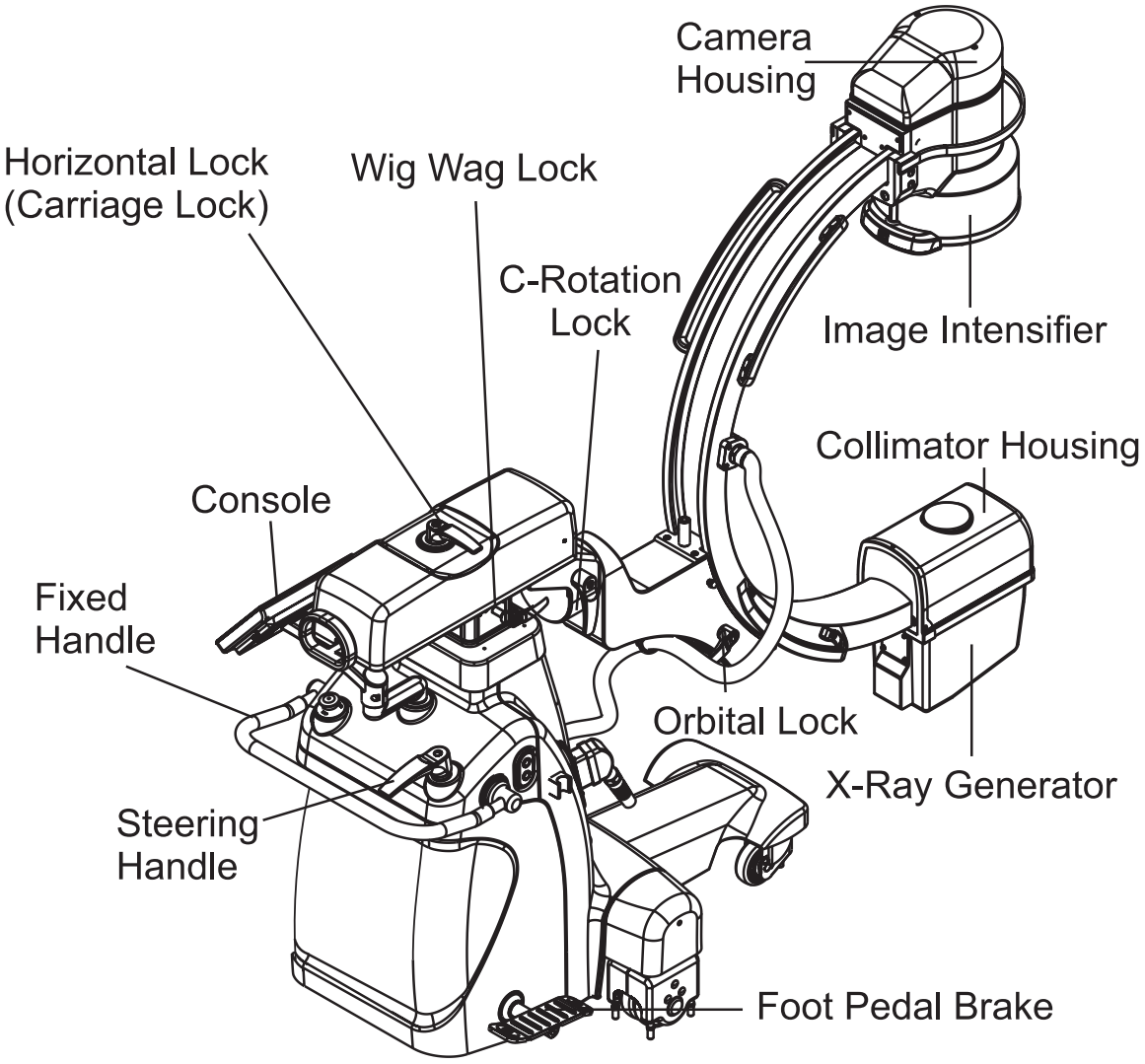


Figure 17: C-Arm parts

CAUTION

Do not use any other surface/part of the system for positioning. They are not designed to be operated for positioning. Use only specified handles.

5.1.1 Orbital Rotation: C-Arm Unit

1. Unlock orbital brake lever to unlock position
2. Use C-Arm handle and move C to desired position. You can achieve up to 90° under scan or 35° over scan position, for better reach
3. Lock orbital brake lever in to lock position
4. There are two graduated labels in degree on either side of C indicating the orbital angle
5. Normal position is mentioned as generator in the bottom, and position is read as 0° on the orbital scale.(Shown in "Figure 18")

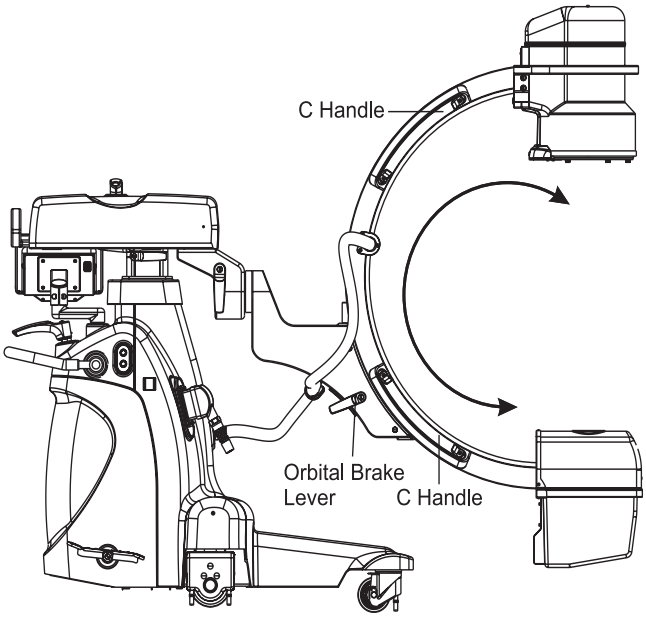


Figure 18: Orbital Movement

5.1.2 Wig-Wag (Panning): C-Arm Unit

Wig-Wag, also called as Panning, Where C-arm can be moved on either side of the C vertical plane.

1. Unlock Wig-Wag brake lever to unlock position
2. Use C-Arm Handle or Carriage handle to position in desired direction. You can move C on either side
3. Lock Wig-Wag brake lever in to lock position

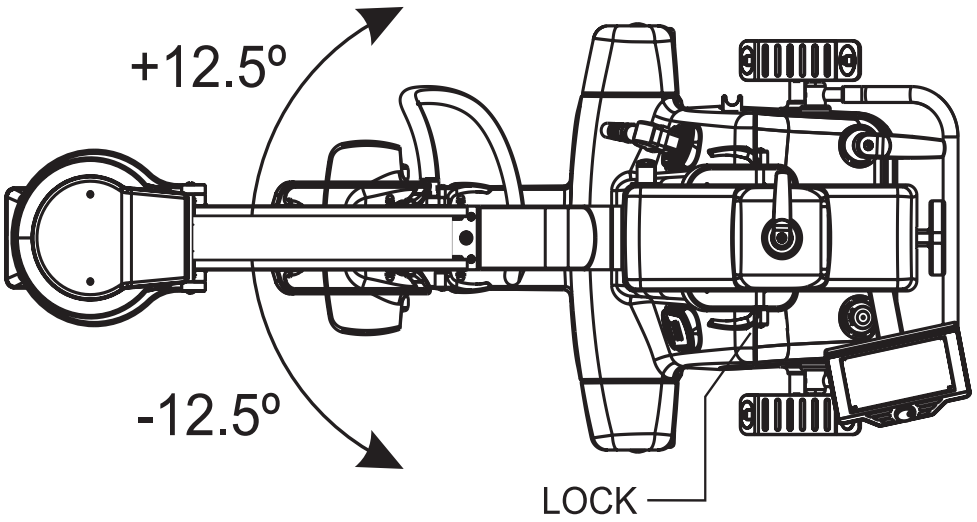


Figure 19: Wig-Wag movement

5.1.3 Horizontal (Carriage) Movement: C-Arm Unit

Horizontal movement also referred as carriage movement, can be adjusted as mentioned below.

1. Unlock horizontal (carriage) brake lever to unlock position.
2. Use C-Arm handle or carriage handle in forward or reverse direction.
3. Lock horizontal(carriage) brake lever in to lock position.
4. There is a graduation scale of 200mm length. You can indent or register locations on this scale, with respect to the pointer provided.

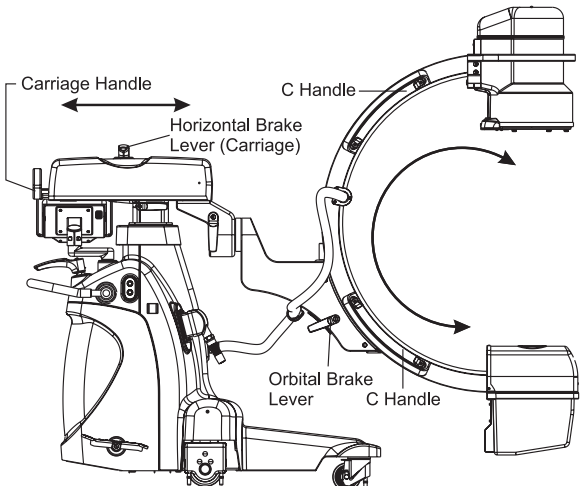


Figure 20: Horizontal Carriage movement

5.1.4 C-Rotation (Yoke Rotation): C-Arm Unit

C-Rotation is also referred as yoke rotation.

1. Move yoke brake lever to unlock position.
2. Use C-Arm Handle to position in desired orientation. You can rotate C-Arm in clockwise or anti-clockwise.
3. Move yoke brake lever in to lock position.
4. When X-ray generator is in the bottom, this position is known as 0° position(Normal Position).
5. You can rotate up to 180° on either side for better patient positioning.

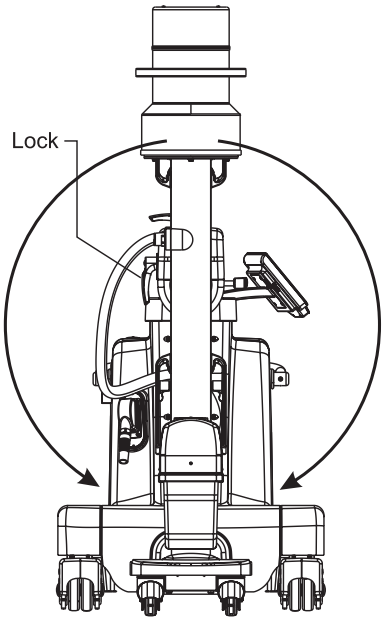


Figure 21: C-Arm Rotation

5.1.5 Steering Control and Floor Movement: C-Arm Unit

Steering handle can be used to move C-Arm in straight or transverse directions.

1. Rear wheel steering handle is labelled with graduation indicating the orientation of wheel. Steering handle direction also indicates the movement direction.
2. Single actuation-dual braking system is provided with your system. Actuation on any one pedal will apply brake on both wheels. If pedal is horizontal, brake is applied. Unit will not move. If pedal is at an angle, system is in un-braked condition.
3. Use rear wheel steering along with fixed handle while moving the system.

5.1.6 Vertical Movement Control: C-Arm Unit

1. C-Arm vertical movement, this is an electrically actuated electronically controlled system.
2. To move Up or Down movement of c-arm for c height adjustment, three buttons on the console are used for the purpose, represented with vertical movement activator, Up and Down symbols.
3. Electronic movement controls will be locked by default. To unlock the controls, vertical movement activator must be pressed and released.
4. As long as Up or Down Buttons is pressed, Electronic controls the Up or Down movement, once released, movement will stop.
5. Once vertical movement locking system is unlocked, if upward or downward movement button are not operated and is in idle state for a duration of five seconds, then vertical movement controls will be re-locked.

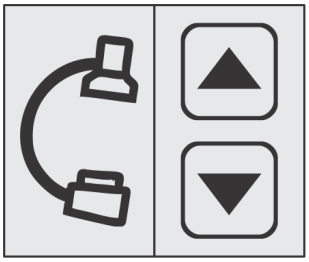


Figure 22: C-Arm vertical movement unlocked

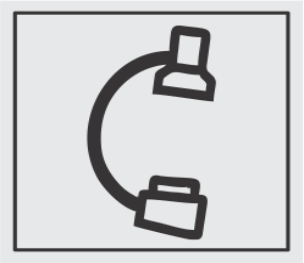


Figure 23: C-Arm vertical movement locked

5.1.7 Monitor Swivel: Workstation

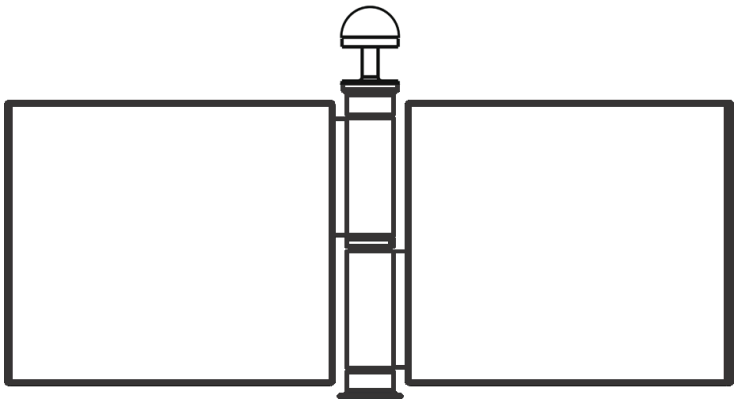


Figure 24: Open

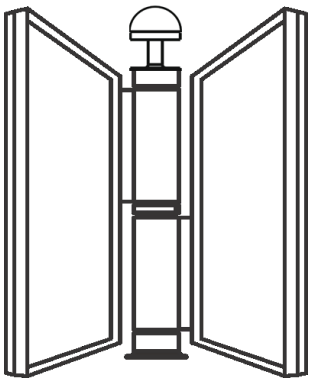


Figure 25: Closed

5.2 Transport Position

If Skan C and Workstation are to be moved to different location within the hospital, it should be brought under transport configuration.

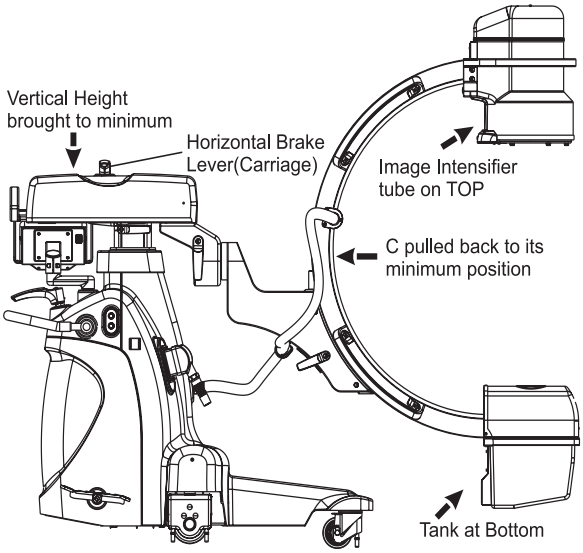


Figure 26: C-Arm Transport Position

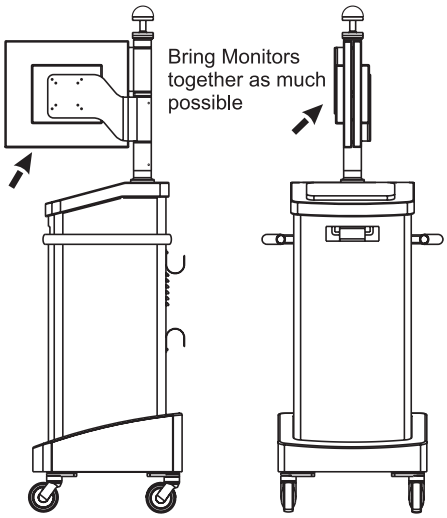


Figure 27: Workstation Transport Position

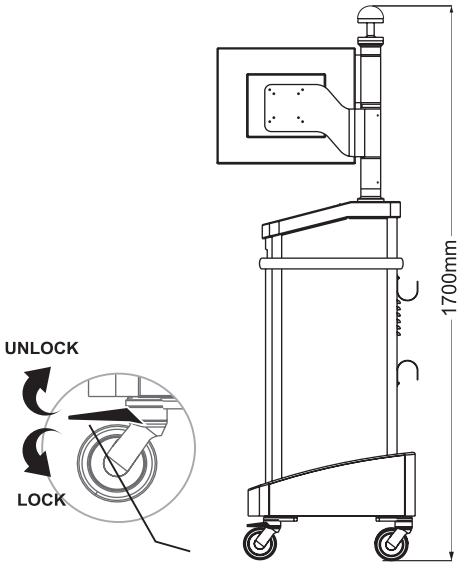


Figure 28: Workstation Brake

5.2.1 Preparing for TRANSPORT

Before transporting within hospital, observe following guidelines

1. Bring down vertical height to minimum position.
2. Power OFF Skan C: Refer Section "6.3 Powering OFF".
3. Switch OFF the Skan C C-Arm Unit.
4. Remove power flux cable from the buggy.

5.2.2 Transport Position Guide for C-Arm Unit

1. Bring C-Rotation to 0°, where Image Intensifier above the generator (X-ray source). Lock C-Rotation
2. Bring Orbital Rotation to 0°, you will find overall length is minimized. Apply orbital brake lever.
3. Bring Wig-Wag (Panning) to Centre position, to 0°. Lock Wig-Wag Brake Lever
4. Pull Carriage to its minimum position, to 0mm reading on the Scale. Lock horizontal movement.
5. Steering control and brake pedal to be used cautiously while moving.

NOTE

Observe instruction in Section "3.4 Mechanical Safety", while moving the unit.

5.2.3 Transport Position Guide for Workstation

1. Twin Monitors are moved towards the centre.
2. Workstation is provided with braking levers on front two wheels. By pressing the levers, brakes are applied. Lever has to be lifted to un-brake the system.

CAUTION

During transport, monitors may freely move and accidentally may hit any person or object, resulting in injury or damage.

LEFT BLANK INTENTIONALLY

CHAPTER 6

Setting UP for Powering ON

6.1 Interconnecting Workstation and C-Arm Unit

1. Move C-Arm unit and Workstation to the desired working position.
2. Ensure all brakes are properly locked and secured

WARNING

Do not connect any device which is not recommended by SKANRAY.

3. Ensure Mains ON/OFF button on Workstation is switched OFF.
4. Unroll Workstation interface cable from its hanger. Select proper cable layout on the floor for best convenience.
5. Connect power/signal cable to rectangular connector. This is a polarized connector. Lock using the provided lever.
6. Foot-Switch connector is a polarized round connector. Insert gently and secure the connector by threading the locking heads.
7. Hand-Switch Connector is a polarized round connector. Insert gently and secure the connector by threading the locking heads.

NOTE

Though both Hand and Foot switch connectors are of same connector type, but they can not be interchanged. The mating types are not the same.

8. All cables from Workstation Interface cable along with its cable manager(a protective flexible casing) and power cable are pulled lightly and secured with cable secure belt provided in the front, fastened to C-Arm cable gland.
9. Depress the emergency switch down and ensure it is locked. This will disable any vertical movement of the system.

CAUTION

Cables from interface and power panel should be properly secured without a SAG, such that, it shall not hinder the foot brake operation.

WARNING

X-ray exposure and image display functions may not work properly for any improper interface of cables between Workstation and C-Arm Unit

6.2 Powering ON

After successfully completing the interconnecting procedure of C-Arm Unit and Workstation, as mentioned in Section "6.1 Interconnecting Workstation and C-Arm Unit", you can proceed with following powering on sequence.

WARNING

Ensure free access to the plug and the power panel.

1. Switch ON C-Arm Unit by depressing ON/OFF power switch on the power interface board near workstation back panel.
   1.1. Console system display will lit and system performs a system initialization and a self-test.
   1.2. Console will display status and default settings. Loading factor field will be blank.
   1.3. For any errors, it will be displayed, else the error field will be blank.
2. Switch ON Workstation by pressing the ON switch of the UPS device located on the back side of the Workstation Unit.
   2.1. Power monitor display will lit and indicate the power ON status.
   2.2. Monitors ON status are indicated by the Power LED on the monitors. If power LED's on the monitor are not ON, ensure the power switch of monitors are switched ON.
   2.3. Workstation will establish communication link with the C-ARM unit. If there are any errors, the error message is displayed on the monitor.

CAUTION

Skan C may not function properly if ERROR messages are neglected

NOTE

It is recommended to switch ON C-Arm unit first and later followed by workstation switching ON procedure both of which are present at workstation side.

3. It will display a Login screen "Figure 44" and system software versions are displayed after successful Login.
4. Now, your Skan C is ready for use.

6.3 Powering OFF

After successfully completing the procedures of use of Skan C for the intended purpose, to power it OFF, follow below mentioned procedure.

NOTE

Click is the terminology used to indicate that if you are using pointing device(mouse), move the pointer to desired operation(function) and press left button on pointing device.

If you are using keyboard, use "Tab" to highlight desired operation(function) and press "Enter"

WARNING

Ensure to shut-down workstation before switching OFF the Skan C from mains power.

1. Follow normal shut down process of workstation. You have two options to achieve this. Either through "Patient Browser" screen or from "Log- In Screen".
   1.1. Shutting down from activities menu,click sub menu shutdown system or from Login screen, click shutdown icon within Login window
   1.2. Message will appear "Are you sure, you want to shut-down the system?" in a child window. Click on the "YES" radio button.
   1.3. System will close all open files, stores the current system configuration and initiates a systematic shutdown procedure.
2. Switch OFF power button on the workstation. Ensure, display blanks out.
3. Turn OFF power switch on the power console panel on C-Arm workstation side.
4. Follow procedure mentioned in Section "6.1 Interconnecting Workstation and C-Arm Unit", to detach all cables from both the systems and store/place them in their appropriate location.

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CHAPTER 7

C-Arm Unit Console Functions

Console in the C-Arm Unit has several functions, ergonomically laid our for easy understanding and use.

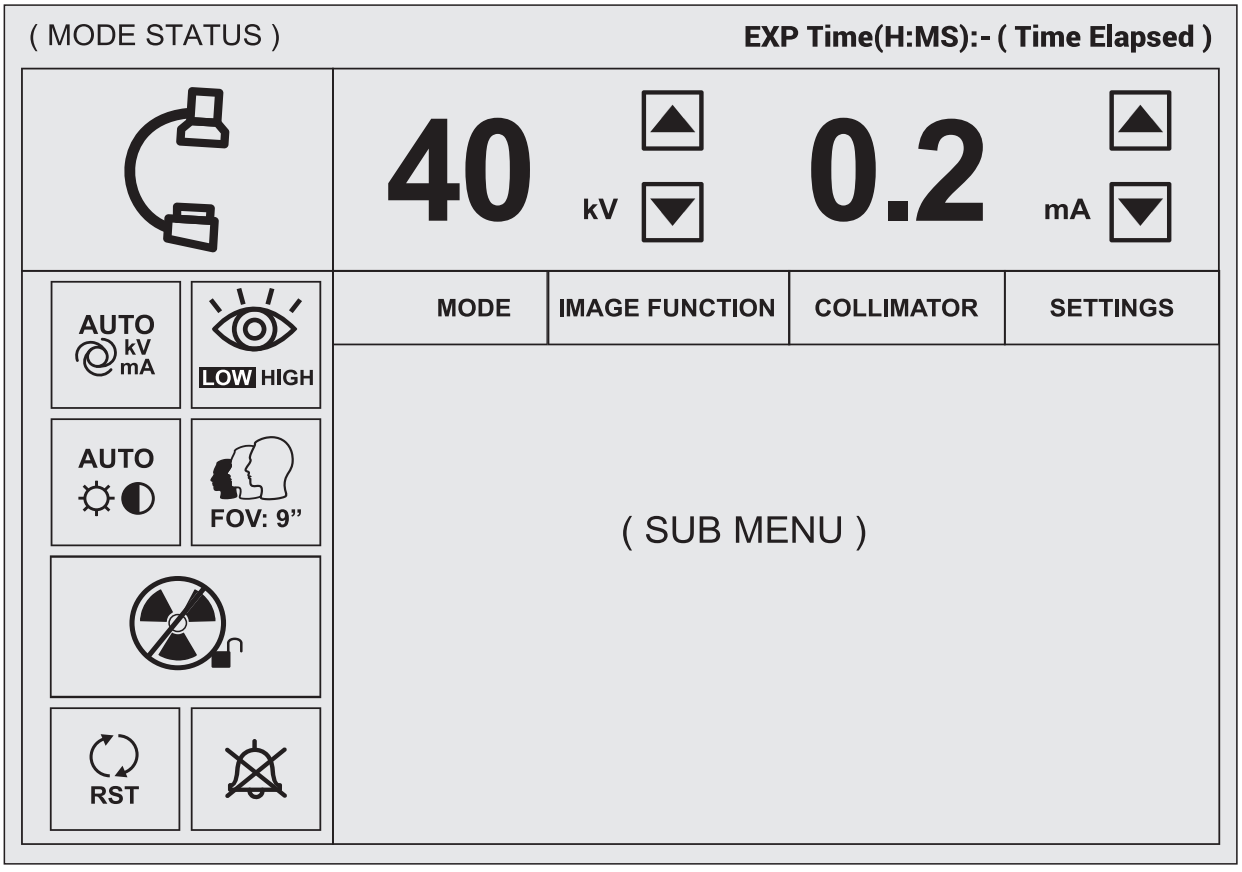


Figure 29: User Interface

7.1 Button Description

7.1.1 Vertical Column Movement UP and DOWN

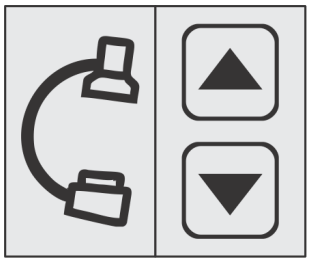


Figure 30: C -Arm UP/Down

1. Vertical movement activator button is used to lock or unlock the C-Arm Movement controls.
2. UP arrow button is used to control vertical travel of C-Arm in upward direction. C-Arm will move in upward direction, as long as the button is pressed, until the upper limit is reached.
3. Down arrow button is used to control vertical travel of C-Arm in downward direction. C-Arm will move in downward direction, as long as the button is pressed, until the lower limit is reached.

WARNING

Vertical movement control do not have automatic anti-collision system, it is manually controlled. User is advised to ensure the patient is in the line of sight while doing vertical movement.

Unintended operations of vertical movement may induce injury to personnel and damage to C-Arm. Always lock vertical movement control by depressing emergency switch

7.1.2 Active Radiation Switch

- *This is operational in all modes of exposure.*
- *In case of any unintended radiation occurs, this switch can be used to control the exposure to OFF condition.*
- *Press again to activate exposures.*

WARNING

Active radiation switch is used under all emergency conditions where unintended or uncontrolled exposure occurs.

7.1.3 RESET

Reset command functionality is determined by the state of exposure, if orientation of image is changed and image processing features(except brightness and contrast operation) are used and a new exposure is not initiated the reset feature will reset image to acquired state.

If orientation of image is changed and image processing features(except brightness and contrast operation) are used and a new exposure is initiated the reset feature shall reset the image processing features(except brightness and contrast operation) and shall not reset the image orientation.

7.1.4 Collimator Functions

Collimation of X-ray beam is achieved through Hard Shutter, Soft Shutter, Collimator Rotation and Iris Control. These controls are electrically operated and position of these can be visualized after the operation by viewing it in the workstation collimator control screen.

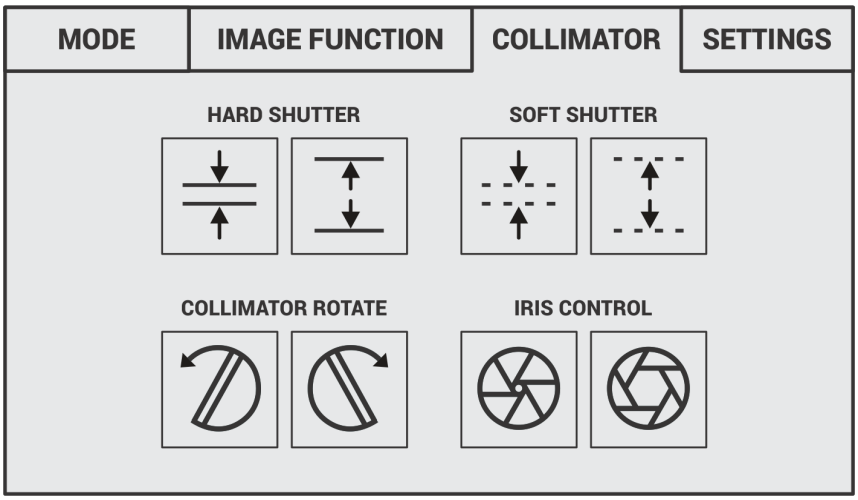
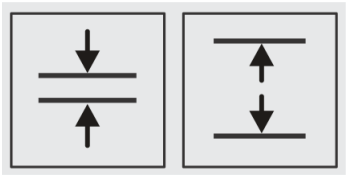


Figure 31: Collimator Functions

7.1.4.1 Hard Shutter Open and Close

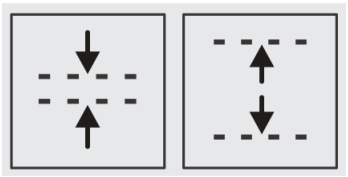


Hard Shutter is used to allow X-ray beam only to the Region Of Interest (ROI).

This is a leaded shutter to block the passage of X-ray.

Two buttons are provided for the open and close operations. The target opening or closing can be set viewing virtual collimation of hard shutter operation on the Live Monitor.

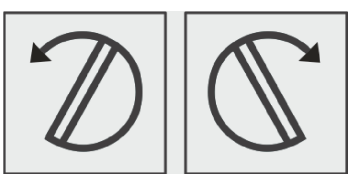
7.1.4.2 Soft Shutter Open and Close



Soft Shutter is used to allow X-ray beam only to the Region Of Interest (ROI). This is a semi transparent shutter to attenuate the passage of X-ray.

Two buttons are provided for the open and close operations. The target opening or closing can be set viewing virtual collimation of soft shutter operation on the Live Monitor

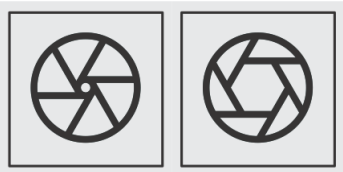
7.1.4.3 Collimator Rotate



Collimator rotation is used to align the shutters to the anatomy of interest.

Two buttons are provided for the rotate clockwise & anti-clockwise operations. The target orientation can be set viewing virtual collimation of rotate operation on the Live Monitor

7.1.4.4 IRIS Control



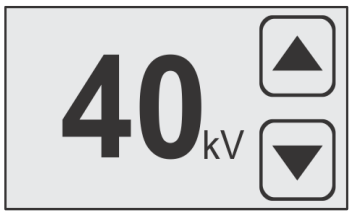
IRIS control is used to allow X-ray beam only to the selected area of Region Of Interest (ROI). This is lead covered and will block X-ray in unwanted region.

Two buttons are provided for the open and close operations. The target opening or closing can be set viewing virtual collimation of iris operation on the Live Monitor

7.1.5 Exposure Parameters Setting

Exposure parameters like kV and mA or mAs are available for exposure control.

7.1.5.1 kV Setting



Tube voltage is set by pressing increase or decrease arrow buttons and value is displayed on the LCD in selected kV window.

Setting range is from 40kV to 110kV. Voltage increment or decrement is in steps of 1 kV in all fluoroscopic modes and in steps of 5kV in radiography mode.

During auto-technique mode, this value is taken as start up value and is changed as per the image quality received as per the auto mode control algorithm.

7.1.5.2 mA or mAs Setting

Fluoroscopic Modes of Operation.
Tube current is set by pressing increase or decrease arrow buttons and resultant value is displayed on the LCD in selected mA window.

Setting range of mA is from 0.2mA to 8mA with an incremental value of 0.1mA for all fluoroscopic modes.

Radiography Mode of Operation.
During radiography Mode, Current time product (mAs) is displayed on the display.

NOTE

In fluoroscope mode, the deLivered current is limited as per the intended operation of particular foot switch or hand switch. Refer fluoroscopy operation for details.

7.1.5.3 Auto-Technique (Auto kV/mA)

Auto-technique operation controls independently the loading factors like kV and mA during fluoroscope mode for the optimized image quality.

This operation is indicated by "AUTO-MODE" in console display, where MODE is user set procedure i.e, Fluoro OR Vascular OR Pulse.

7.1.5.4 H-L Fluoro

H-L fluoro operation limits the loading factor mA during Fluoroscope Mode for the Dose Control.

In MANUAL mode: If H-L Fluoro is set to "LOW" then loading factor mA will be limited to 3mA.

To command a loading factor higher than 3mA, H-L Fluoro needs to be set to "HIGH".

In AUTO mode: If H-L Fluoro is set to "LOW" the loading factor mA will be limited to 5mA.

To allow AUTO mode for commanding loading factor higher than 5mA, H-L Fluoro needs to be set to "HIGH".

This operation will be disabled in PULSE, AUTO-PULSE and RAD modes

7.1.6 Modes Of Operation

Following Modes of operations are available from Console

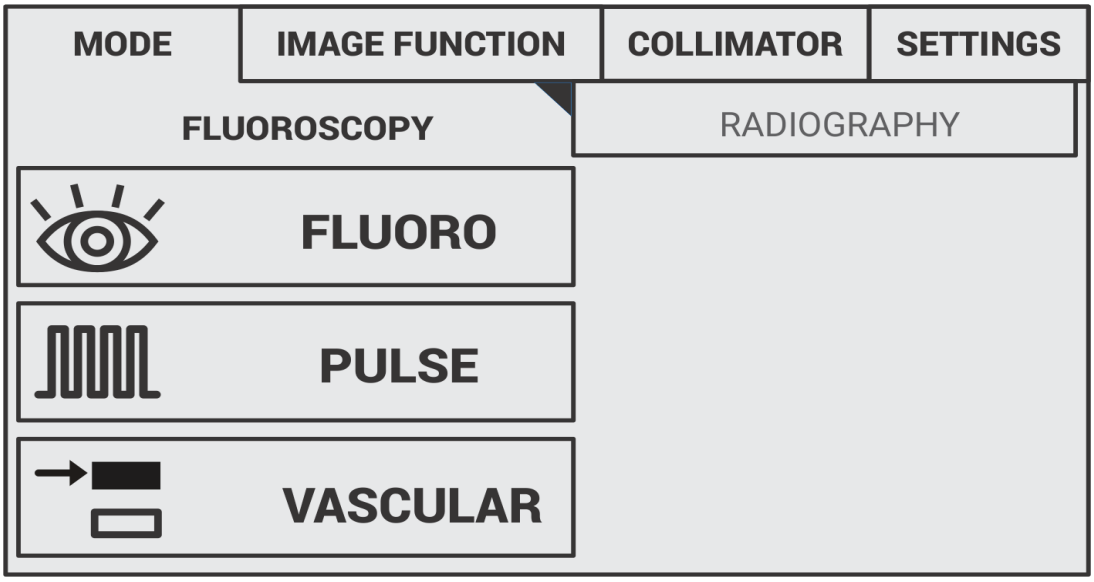


Figure 32: Modes

7.1.6.1 Pulsed Fluoroscope (PULSE MODE)

This button will select pulsed fluoroscopy procedures. Once "PULSE" mode is selected all other modes of operations are deselected.

Figure 33: PULSE MODE (UNSELECTED)

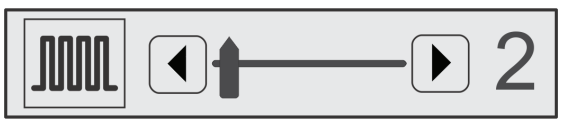


Figure 34: PULSE MODE (SELECTED)

In "Pulse" Mode, X-ray exposure is 2,4,6 or 8 frames per second instead of continuous to reduce radiation hazard to the patient. Slider or left/right buttons can be used to select the pulse.

7.1.6.2 Vascular Fluoroscope (VASCULAR MODE)

This button will select vascular procedures. When selected, all other modes of operations are deselected.

Figure 35: VASCULAR MODE (UNSELECTED)

DSA(SUB),PIXEL SHIFT, LANDMARK, ROADMAP, PEAK and MASK functions are available only under the "Vascular" procedure.

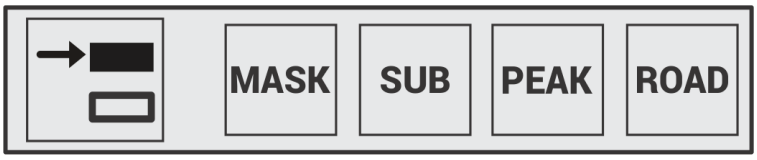


Figure 36: VASCULAR MODE (SELECTED)

7.1.6.2.1 MASK

This function is used for both DSA and road map functions.

On "Mask" function selection from console control panel, the current image displayed on the Live monitor is set as a Mask Image in Vascular Mode operation for "DSA". If "Peak" command is already enabled, then "Mask" command sets mask image from the peak image for "Road Map".

This Function is available only during Vascular Mode.

7.1.6.2.2 SUB (DIGITAL SUBTRACTION ANGIOGRAPHY (DSA))

DSA is used clinically for diagnostic and therapeutic applications of vessel visualization throughout the entire body. This is achieved by real-time subtraction of pre and post contrast (of injected material) images. The mask image selected before function will be subtracted from the Live Image frame when "Sub" button is selected to get image.

It supports AUTO-DSA, wherein if user operates "Sub" button before setting MASK Image, MASK Image will be automatically set for DSA.

7.1.6.2.3 Peak (PEAK PLOTTING)

"PEAK" function when enabled shows the flow of liquid and movement of organ or tissue as long as foot-switch is pressed.

7.1.6.2.4 Road (ROAD MAP)

"Road" function when enabled outlines the existing peak plotting. Software will overlap this outline on the fluoroscopy images to enable or guide the movement of objects and liquid or tissues.

It supports AUTO-ROADMAP, wherein if User operates "ROAD" button before setting PEAK & MASK Image.

Once mask and sub is enabled / DSA Function is Enabled, PIXEL SHIFT and LANDMARK Feature will be made avaliable for activation.

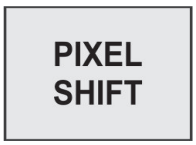
NOTE

PIXEL SHIFT and LANDMARK features is available only for DSA Application.

NOTE

If Auto-DSA is activated then PIXEL SHIFT and LANDMARK features will not be available

7.1.6.2.5 PIXEL SHIFT



"PIXEL SHIFT" function will help to move the set MASK image from current position in case of patient movement.

Once "PIXEL SHIFT" is activated, directional arrow buttons will be displayed on Console.

With the help of directional arrow buttons the set MASK image can be moved in the direction. "PIXEL SHIFT" function will be only available for DSA procedure.

7.1.6.2.6 LAND MARK

"LAND MARK" function will help to visualize the underneath anatomy during DSA procedure. "LAND MARK" function will be only available for DSA procedure.

7.1.6.3 Continuous Fluoroscope (FLUORO MODE)

This button will select fluoroscopic procedures. When selected, all other modes of operations are deselected.

Figure 37: FLUORO MODE (UNSELECTED)

Figure 38: FLUORO MODE (SELECTED)

In "Fluoro" mode, software will start continuously displaying the acquired images on start of X-ray exposure.

In "Fluoro" mode, kV and mA values are manually adjustable. However, deLivery limit of mA values is dependent on the activation foot-switch used.

In "Fluoro" mode, NORMAL FLUORO, BURST FLUORO and ENHANCED FLUORO options are available.

7.1.6.4 Radiography (RAD MODE)

This menu will select Radiography procedure and selecting the anatomy under this menu will enable RAD mode.

There are "13 Anatomical procedures listed". The technique parameters are automatically set based on patient selection as thin or medium or thick. Once "RAD" mode is selected all other modes of operations are deselected.

For better user interface user can touch and select the anatomy on the skeleton shown on the screen and further detailed procedure under it can be selected from drop down box.

On X-ray exposure, the Live monitor on the workstation will display blank frame with patient information. User need to use the film with cassette holder to capture image and there will be no image displayed on the monitors during the process.

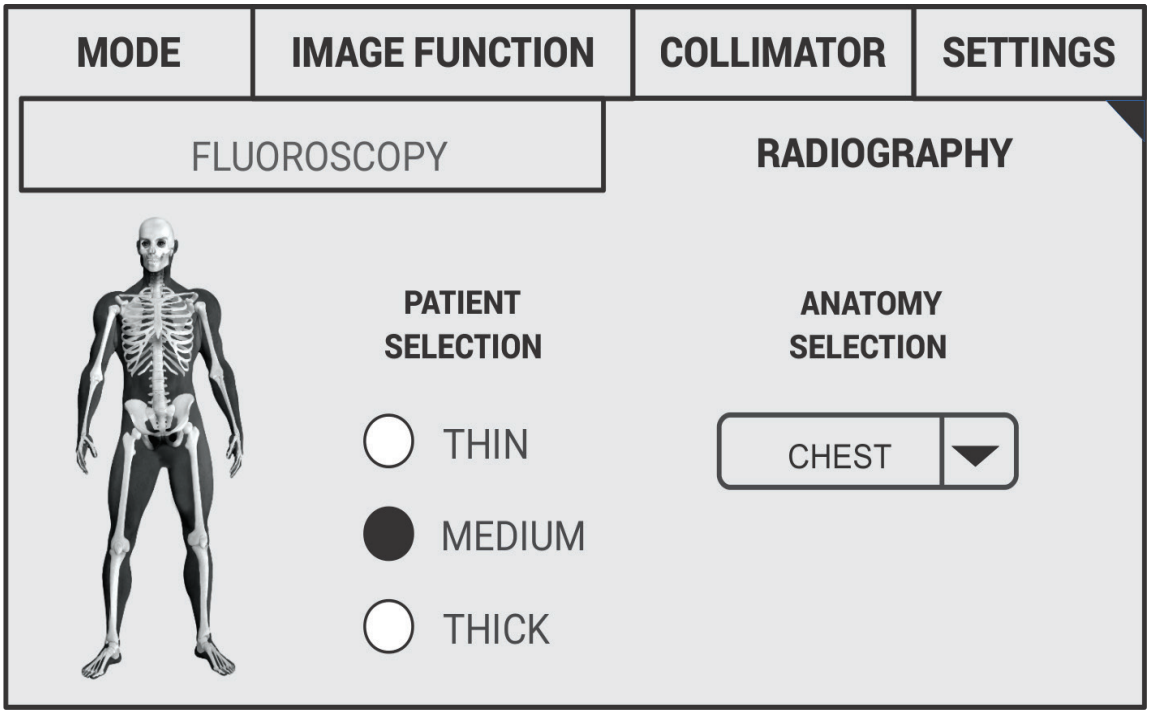


Figure 39: RAD Mode

7.1.7 Digital Image Processing Features

Following functions are available from console control panel to control image displayed on the Live screen of workstation.

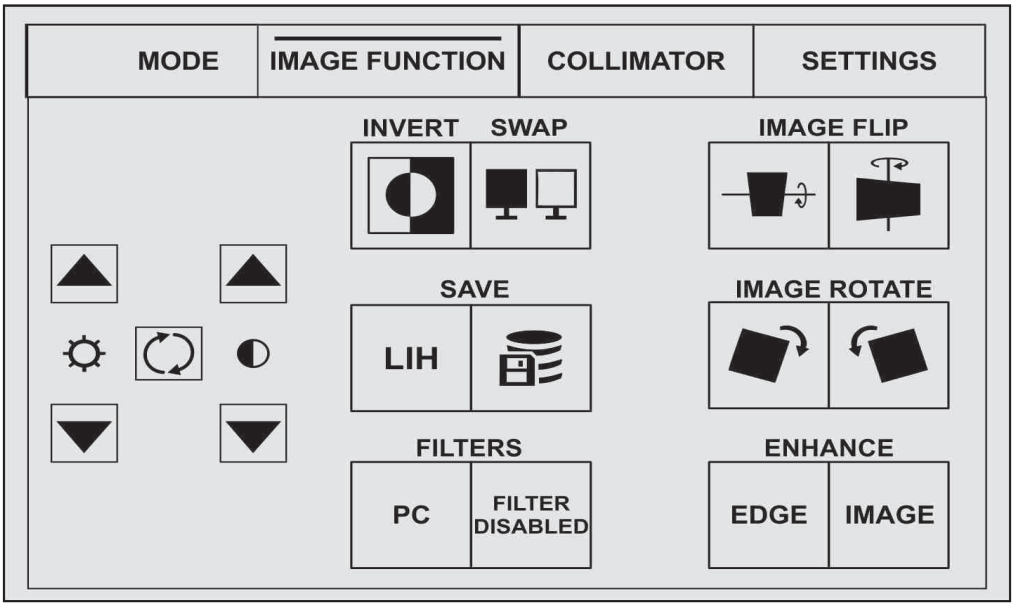
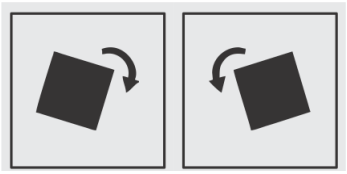


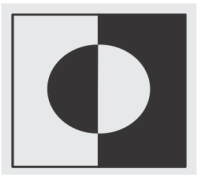
Figure 40: Image Functions

7.1.7.1 Image Rotation



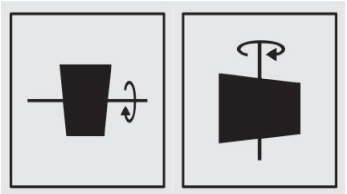
These buttons enables the rotation of the image Clockwise / Anticlockwise. The rotation can be seen on the Live Monitor.

7.1.7.2 Image Invert



INVERT function inverts the image on the Live Monitor.

7.1.7.3 Image Flip



These buttons enable the image flip on the Live screen in vertical or horizontal direction.

Left side button press will flip or mirror the image on the Live monitor and toggles between flip vertical ON and OFF.

Right side button press toggles between horizontal flip and normal.

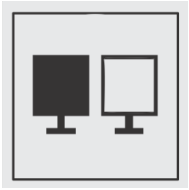
NOTE

Virtual collimator sync will be done only from Live collimator control operation i.e from console collimator window. The workstation Passive side rotation or flip operation will not reflect on the collimator window.

Whenever image flip or rotation operation is performed from console then application will rotate/flip the virtual collimator internally and display only when collimator operation is called.

Virtual Collimator rotation and flip will be in sync with image orientation on Live side.

7.1.7.4 Monitor Swap



SWAP function swaps the images between Live monitor and Passive Monitor. Live Monitor is on the left side of View, in the normal use.

7.1.7.5 Save (Image save series)

When this button is pressed, acquired image series is saved to the hard-disk and displayed on the Passive Monitor after release of Foot/ Hand Switch.

The saved image is marked as restricted file to avoid accidental deletion of image file.

7.1.7.6 Save (Image save LIH)

When this button is pressed, acquired LIH image is saved to the hard-disk and displayed on the Passive Monitor after release of foot/ hand switch.

The saved image is marked as restricted file to avoid accidental deletion of image file.

7.1.7.7 Edge Detection

When this button is pressed, LIH on the Live monitor is applied with edge detection filter.

7.1.7.8 Image Enhancement

When this button is pressed, LIH on the Live monitor is applied with image enhancement filter.

7.1.7.9 Camera Filter

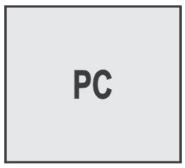
NOTE

The Camera Filter is **NOT** *recommended to be used in case of patient movements.*

When this button is pressed, Image on the Live monitor is applied with camera filter.

On pressing this button, Filter will cycle to "Filter Disable", "2F", "4F" & "8F".

7.1.7.10 PC Filter



When this button is pressed, Image on the Live monitor is applied with PC Filter.

On activation of the PC Filter, this button will be highlighted.

7.1.7.11 Contrast Control

Upward button is pressed to increase the contrast on the Live monitor Image.

Downward button is pressed to reduce the Contrast on the Live monitor Image.

Application will display the contrast effect on the LIH but will not modify current series/image.

The contrast variation will affect the whole series /image only for next exposure.

The variation will be saved to the DCM file and the DCM file with the contrast effect will be viewable in Passive window .

7.1.7.12 Brightness Control

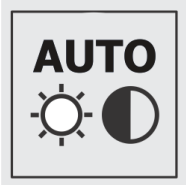
Upward button is pressed to increase the brightness on the Live monitor Image.

Downward button is pressed to reduce the brightness on the Live monitor Image.

Application will display the brightness effect on the LIH but will not modify current series/image.

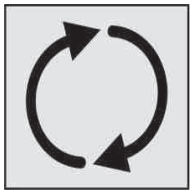
The brightness variation will affect the whole series /image only for next exposure.

The variation will be saved to the DCM file and the DCM file with the brightness effect will be viewable in Passive window .



The Live image brightness will be adjusted automatically for the optimum image. The auto brightness effect will affect the whole series/image only for next exposure. The same shall be saved to the DCM file so that auto brightness effect is viewable in Passive window.

7.1.7.13 Brightness and Contrast Reset



The brightness and contrast on Live monitor will be reset for each brightness and contrast reset console command received. Application shall display the image which was obtained before contrast and brightness variations on the LIH and it will not save the effect on current series/image. The next exposure will not have contrast and brightness effect.

Brightness and contrast will be reset when new study/ emergency operation is performed.

7.1.7.14 Magnification

Image Intensifier provides magnification to 4.5", 6" and 9" Image capture.

Pressing magnification button selects one of three selections as Magnification.

WARNING

Higher Magnification increases DOSE to the Patient.

7.1.7.15 Exposure control

Operation of the switch enables / disables exposure.

7.1.7.16 Mute

During Fluoroscopic Procedure, continuous tone will be generated during the OVER DOSE period, this tone is silenced by pressing "Mute" button.

7.2 Rotatory knob and Hot-Keys

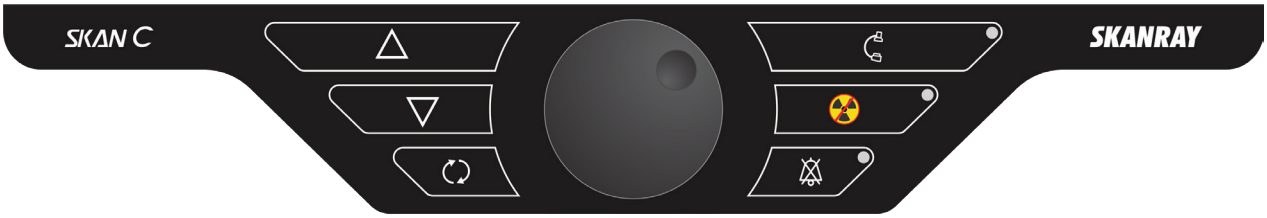
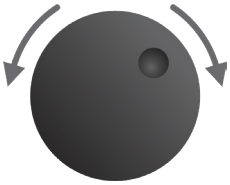


Figure 41: Console keypad with rotatory knob

	This Hot-key will be enabled only on enabling C-Arm Button/ Hot-key. This will move the C-Arm in upward direction.
	This Hot-key will be enabled only on enabling C-Arm Button/ Hot- key. This will move the C-Arm in downward direction.
	This Hot-key will reset Errors/warnings and all image operation except SWAP and CAMERA FILTERS.
	This Hot-key will enable/disable the vertical movement of C-ARM. The key status is indicated by the LED in it.
	This Hot-key will enable/disable the X-RAY radiation. The key status is indicated by the LED in it.
	This Hot-key will enable/disable the alarms. The key status is indicated by the LED in it.
	This is a Rotatory knob provided as an alternative User Input Device. User need to press on the knob once to switch the User Input Device from Touch-screen device to Rotatory knob device. Upon activation of rotatory knob device a selection window is displayed always at the start from top left button (i.e. AUTO-kVmA). Clockwise rotation follows selection from left-right and top-bottom rule. Anti-Clockwise rotation follows selection from right-left and bottom-top rule. User needs to press the knob to confirm the operation of selection window.

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CHAPTER 8

Fluoroscopic Operations

8.1 Overview

Workstation provides user with twin monitors, showing Live images in left Live monitor (Refer "Figure 42: Live monitor") and review images on the right Passive Monitor. Keyboard and mouse (graphic pointer device) is for user commands.

Workstation is run by either Mains or UPS.

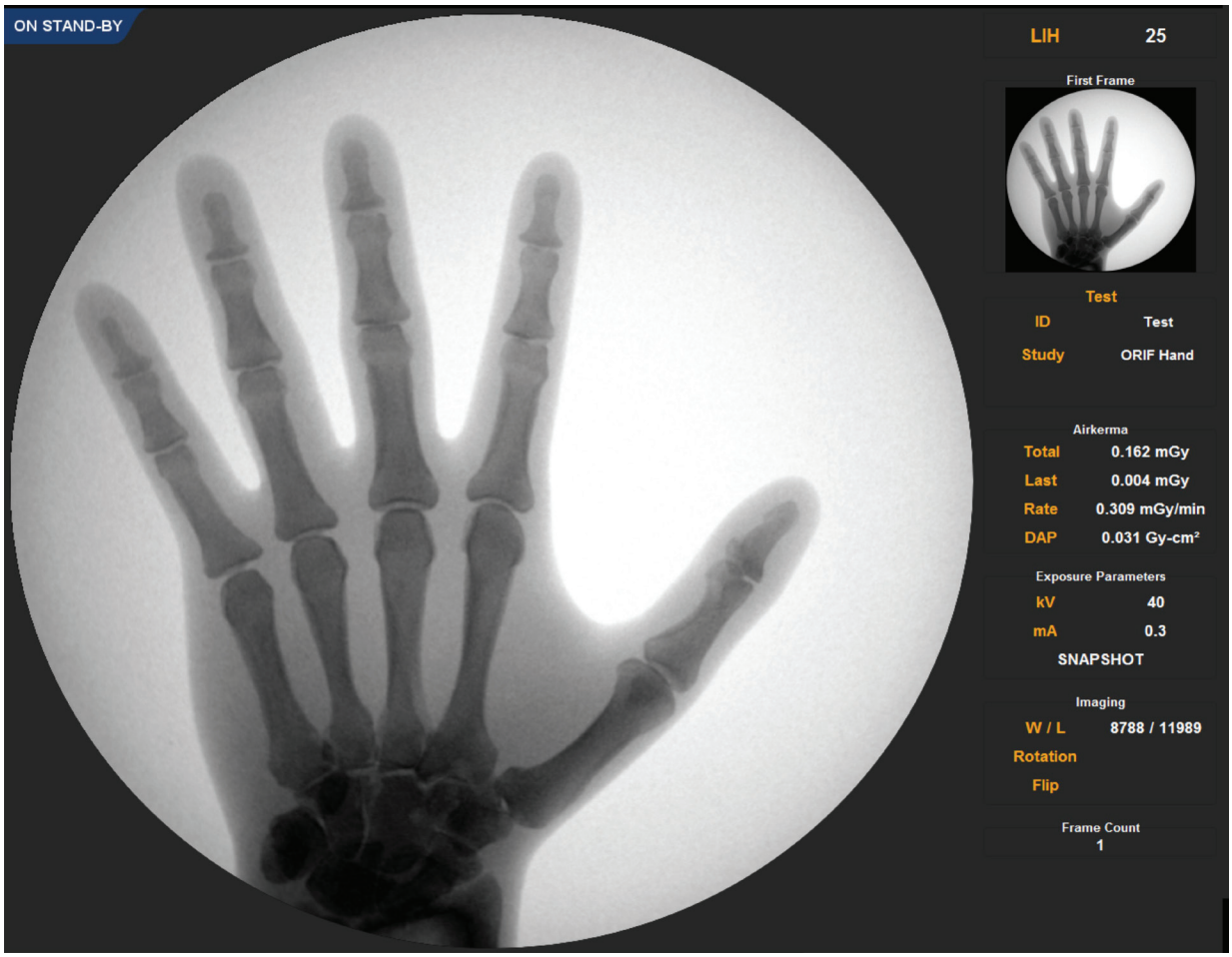

Figure 42: Live monitor

8.1.1 Live Monitor

Live Monitor displays Live Fluoroscopic Images and static snapshot image

At the end of every Fluoroscope operation, Last Image Hold (LIH) is performed to facilitate the last image viewing.

The Patient Name, Patient ID, Study(Procedure Name), AIRKERMA (Total, Last, Rate & DAP) values Exposure Parameters such as kV and mA, Imaging information such as W/L, Rotation, Flip, LIH and frame count are displayed on the right side of the Live Monitor.

The First frame of the current captured series is displayed on the thumbnail right side of the LIH image.

Image rotate, brightness control and image flip operations from console control panel, are seen on the Live Monitor.

CAUTION

When MAIN power goes OFF Workstation still runs with UPS and this is Indicated by a message "C-UNIT IS OFFLINE. Please Wait for C-UNIT to Power ON" in the Live Monitor. The application will be ready for exposure within 40 Seconds after the MAINS power is ON.

WARNING

If X-ray ON Indicator (Over Head Lamp) is still ON even after releasing "FLUORO" on Foot/Hand switch, under such circumstances, User has to click "Refresh" button of Communication Component displayed at System Status Window. Refer "Figure 43".

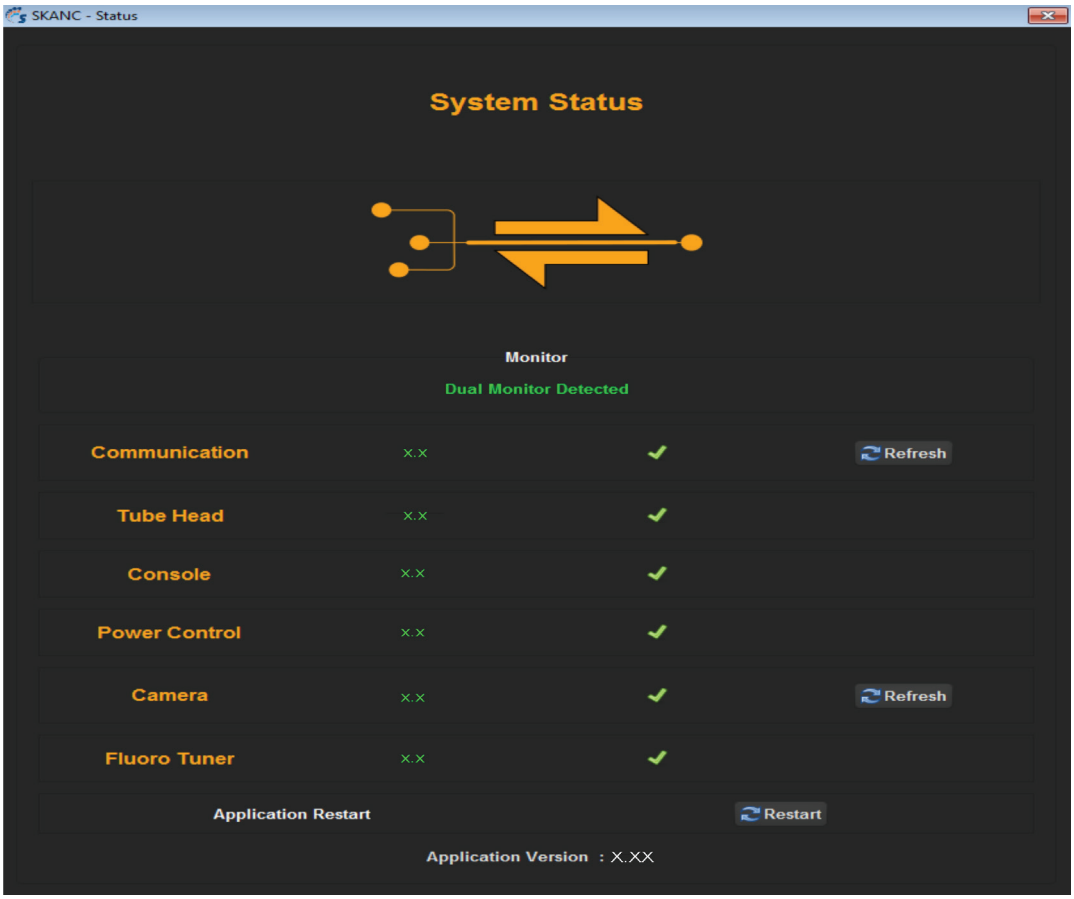

Figure 43: System Status

8.1.2 Passive Monitor

Passive Monitor is provided to display the stored image only in Passive mode or when exposure is not in progress. The Passive Monitor automatically displays the latest acquired image as soon as soon as acquisition is stopped (If Enable image viewer is enabled in configuration settings). This is active as long as stopped by the user or new exposure starts on the Live Monitor.

During the Passive Mode, this Monitor will be used to Login, Register new patients, Initiate new X-ray procedures, change Setup and review already acquired Image series with necessary image manipulation features.

The User Interface or GUI is menu driven and self guiding to perform the necessary function. The Help function can be accessed from the Activites menu (Refer "Figure 53: Activities Menu"). Help Window can be used when ever more information is needed to perform the needed function.

8.2 Login Process

The first time use of Workstation application will need User set up with all the mandatory inputs for the subsequent authorized usage of the software. The Admin User will register other valid users with passwords.

The Admin User will be created by the software with standard admin password. Admin shall change password using the Login setup which will be explained later in the section.

If Login option is NOT needed, direct Login option is provided under application settings.

8.2.1 Login Window

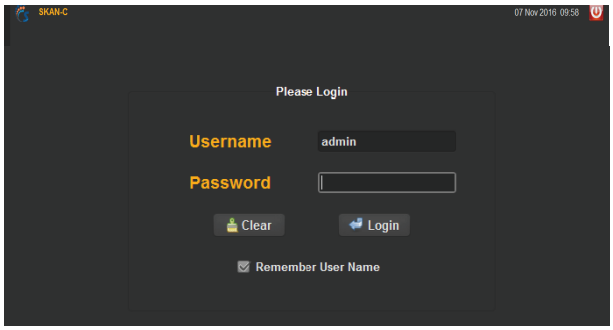

Figure 44: Login WINDOW

When Workstation is powered ON, Login window as shown in "Figure 44: Login WINDOW" will appear on Passive Monitor.

When user enters the valid User Name and Password in their respective fields and press the Login button, Dashboard/Home window as shown in "Figure 46: Dashboard Layout" will open as the Main window in the Passive Monitor. Login feature can be avoided by disabling the option from application settings (Refer "General" Under Section"8.2.3.19 Activities List").

When user press the Clear button, it will clear the contents of the User Name, Password fields and remember User Name check box.

After entering the user name and password, if user selects the remember user name check box, in subsequent sessions the application will display by default the previously entered user name only on successful login.

Apart from this, the application enforces strict control with Login. If the user fails to provide correct credentials for 5 consecutive times, it allows the user to Login, but in a restrictive mode. In this mode(during the session), the user is presented with an empty dashboard(Old patient data hidden to protect patient data), but allow him/her to add new patients and do all normal activities without hampering the intended operation. While in this mode the user won't be able to disable the Login feature(normally possible from Application Settings after a successful Login) and no external backups are allowed.

Also the patients added during a particular session(under this mode), will not be available during the next session if its restricted again. However, they will be available if the correct credentials are provided in subsequent sessions.

8.2.2 Login Failure

The application enforces strict control with Login. If the user fails to provide correct credentials for 5 consecutive times, it allows the user to Login, but in a restrictive mode. In this mode(during the session), the user is presented with an empty dashboard(Old patient data hidden to protect patient data), but allow him/her to add new patients and do all normal activities without hampering the intended operation. While in this mode the user won't be able to disable the Login feature(normally possible from Application Settings after a successful Login) and no external backups are allowed.

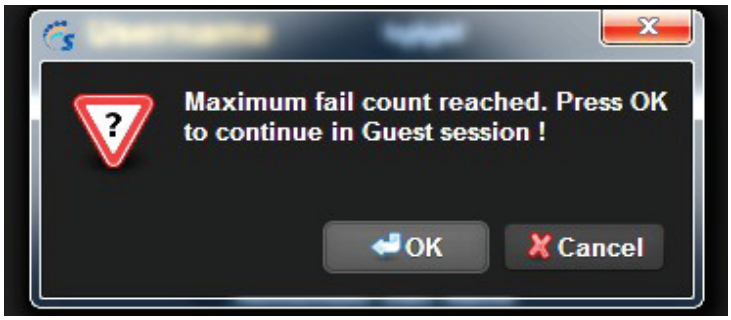

Figure 45: Login Failure

Also the patients added during a particular session(under this mode), will not be available during the next session if its restricted again. However, they will be all available if the correct credentials are provided in subsequent sessions.

8.2.3 Dashboard

Dashboard/Home window will be the first window displayed in Passive Monitor on successful Login.

It displays all the previously registered Patients details stored in the database. All the patients list will be sorted according to recent acquired dates.

Search and Sort facility will be provided on the Patient List to select the specific Patient ID.

The patient list table displays Patient ID, Patient First name, Age, Gender, Registration Date, Total Dose, Total number of Studies in the tabular form. Scrolling down feature will be used to view remaining patient list.

Sum of current series dose for a patient in mGy is stored in the data base and is displayed under Total Dose column.

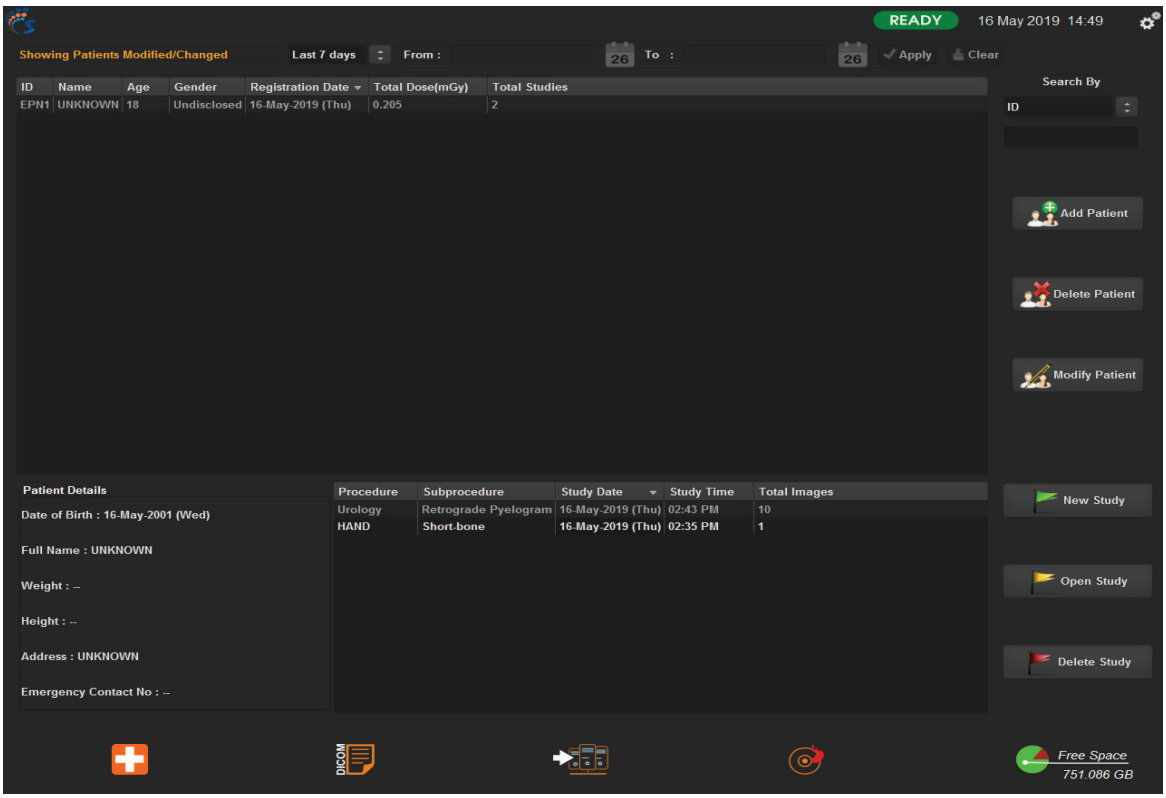

Figure 46: Dashboard Layout

8.2.3.1 Search Filter

Search filter will have the below mentioned options in a drop down menu. The user can select any one of the below mentioned options.

1) Last 7 Days : This feature will display all the patients registered within last 7 days.

2) Last 30 Days : This feature will display all the patients registered within last 30 days.

3) Today : This feature will display all the patients registered today.

4) Range : This feature will provide the user with two calender options to select FROM & TO date. After selecting the From & To date the user can select Apply button to display patients registered within the given date,

5) All : This feature will display all the patients registered.

By default the application will display the patient registered within Last 7 days.

8.2.3.2 Search By

Search By option will provide two options to search a particular patient by the below mentioned options.

1) ID : Search a patient by the entered patient ID

2) Name : Search a patient by the entered Name

The user has to enter the Details either Patient Name/ID in the Search Box.

8.2.3.3 Add Patient

Application allows the user to register/Add patient by entering the details in the available registration form. When a new patient is added the patient details will appear in the top most row of the browser. The details entered will be saved in the database for access at a later period of time.

- Option is provided to register a new patient before capturing X-ray images.
- The patient registration window is split into two tabbed windows namely "Patient information" and "Additional Information".
- Fields which are marked with (*) are mandatory information and others are kept as optional information to enable quick registration.

8.2.3.4 Delete Patient

Application allows the user to delete the selected patient. Only one patient can be deleted at a time. When a patient is deleted, all the studies/images owned by that particular patient will be deleted only from the users' view.

8.2.3.5 Modify Patient

Application allows the user to modify/update the patient information which has already been registered.

8.2.3.6 System status Indicator

This feature is present on the top bar of the Passive Monitor where the system status is shown. Status will be refreshed every 20 seconds. When user clicks on the System status icon as shown in *"Figure 43"* this will pop up system status window which will show the health condition of the whole System. If any of the system component fails, the same shall be highlighted on the status window and the status Icon will change to "ERROR" in Red color. When the failure of all components is resolved then Status Icon will change to normal state(Ready in Green color).

- **Camera Re Initialization**

  This feature is used to reinitialize the camera. Click on Refresh button of Camera component displayed on System Status window to reinitialize the camera Refer "Figure 43: System Status".

  Success: display "Connected" and "tick mark symbol" on the Camera Component of System Status Window.

  Failure: Display "NA" and "cross mark symbol" on the camera component of System Status Window.

The application shall allow the user to forcefully restart the application in extreme cases, where system behaviour is uncertain. The user can exercise this option by clicking the application restart button present in status window. In case of force restart, the application will not store the previous state.

8.2.3.7 New Study

From patient browser of the Passive Monitor, user can select any of the patient and initiate image scan through procedure selection window.

By default the application shall select Auto mode in procedure selection window. However the user will have an option to select manual mode.

The following points discuss the requirements on the workstation software for console commands.

1. The application shall by default enable auto brightness control (ABC) for all modes except for vascular mode.
2. Acquisition of images starts on "FLUORO" on Foot/Hand switch press which will initiate the X-ray exposure and hence capture and display image / images (Fluoro or RAD mode) based on mode of capture selected from the console. In Fluoro mode of capture, the latest captured 300 frames of current series can be saved in the hard disk with corresponding DICOM header information. Pulse Mode acquire images in frame rate of 2, 4, 6, 8.

   2.1. If Denoise Fluoro is enabled in service window, it shall perform Denoising. In this mode PC and 4F recursive filtering shall not be turned ON.

NOTE

When denoise fluoro mode is enabled, the cine rate in the Dicom Tag/frame rate shall be in the range of 12-15 frames per second. When denoise fluoro mode is disabled, the frame rate shall be in range of 9-10.

3. Vascular Mode used for DSA / Road map functions.

   3.1. Steps for DSA:

   3.1.1. Switch ON the Skan C unit and UPS on Monitor cart.

   3.1.2. Register new patient details. After successful registration Anatomy window will be displayed

   3.1.3. Select the EXPOSURE MODE - VASCULAR

   3.1.4. Select Patient Type, Procedure Type, Exposure Parameters

   3.1.5. Go To SCAN

   3.1.6. Acquire an image using "FLUORO" on Foot/Hand Switch.

   3.1.7. Press MASK Key from Console during the acquisition or after the acquisition for Mask image

   3.1.8. Press SUB Key from Console during acquisition to subtract Live frames from Mask image to obtain DSA.

   3.1.9. After completion of procedure press SUB key again to disable DSA.

   3.1.10. Repeat the steps 6 to 9 to repeat new DSA.

   3.2. Steps for ROAD MAP

   3.2.1. Switch ON the Skan C unit.

   3.2.2. Register New Patient details. After successful registration, Anatomy window is displayed.

   3.2.3. Select the EXPOSURE MODE – VASCULAR

   3.2.4. Select patient type, procedure type, exposure parameters.

   3.2.5. Go to SCAN

   3.2.6. Acquire an image using "FLUORO" on Foot/Hand Switch.

3.2.7. Press PEAK key from Console during the acquisition or after the acquisition.

3.2.8. Press MASK Key from Console during the acquisition or after the acquisition for Mask image.

3.2.9. Press ROAD Key from Console during the acquisition to obtain Roadmap.

3.2.10. After completion of procedure press ROAD key from console to disable Roadmap.

3.2.11. Repeat the steps 6 to 9 to repeat new Roadmap

3.3. Steps for PIXEL SHIFT

3.3.1. Switch ON the Skan C unit and UPS on Monitor cart.

3.3.2. Register New Patient. After successful registration Anatomy window will be displayed

3.3.3. Select the EXPOSURE MODE - VASCULAR

3.3.4. Select Patient Type, Procedure Type, Exposure Parameters

3.3.5. Go To SCAN

3.3.6. Acquire an image using "FLUORO" on Foot/Hand Switch.

3.3.7. Press MASK Key from Console during the acquisition or after the acquisition for Mask image

3.3.8. Press SUB Key from Console during acquisition to subtract Live frames from Mask image to obtain DSA.

3.3.9. In case of patient movement or change in Mask Image, select the pixel shift button on the console. The console will display Directional buttons.

3.3.10. Select the direction in which the Mask Image has to be shifted.

3.3.11. The Pixel shift operation can be performed only 8 times in one direction.

3.3.12. The change in the Mask image can be checked in Passive monitor.

3.3.13. Give a exposure to start DSA with the changed/modified MASK image.

NOTE

Pixel shift option is available only for DSA procedure

3.4. Steps for LANDMARK

3.4.1. Switch ON the Skan C unit and UPS on Monitor cart.

3.4.2. Register new patient details. After successful registration anatomy window will be displayed

3.4.3. Select the EXPOSURE MODE - VASCULAR

3.4.4. Select Patient Type, Procedure Type, Exposure Parameters

3.4.5. Go To SCAN

3.4.6. Acquire an image using "FLUORO" on Foot/Hand Switch.

3.4.7. Press MASK Key from console during the acquisition or after the acquisition for mask image

3.4.8. Press SUB Key from console during acquisition to subtract Live frames from mask image to obtain DSA.

3.4.9. Press the land mark button in the console to view the underlying anatomy during the subtraction procedure.

NOTE

LAND MARK option is available only for DSA procedure

4. In RAD mode, single image is acquired on film and film is placed near detector using film holder. Image information can be saved in workstation if needed(For RAD values Refer "Annex 11: APR Table – Radiography").

5. Burst mode (normal fluoro with high frame rate) acquire and display minimum of 25 frames per second. However during this mode, use of display manipulation commands will slow down the frame rate.

5.1. If Denoise Burst is enabled in the service window, it shall perform Denoising where the 2F recursive filter shall be turned off.

1. Snapshot

Snapshot is single frame image and is saved in the hard disk with corresponding DICOM header information. "SNAP/RAD" on Foot/Hand Switch is used to initiate the X-ray exposure. During acquisition process, snapshot message "CAPTURING – SNAPSHOT" gets displayed on Top left corner and also "Press & Hold Hand Switch SnapShot In-Progress" message is displayed in Live Monitor. Once this message is displayed release the "SNAP/RAD" on Foot/Hand Switch. If the "SNAP/RAD" on Foot/Hand switch is released immediately "Hand Switch released early, command aborted!!" message gets displayed on the Live Monitor indicating snapshot command failed. For completion of the snapshot image user should hold the "SNAP/RAD" on Foot/Hand switch in pressed condition until the "press & hold Hand Switch Snap Shot In-Progress" message (based on the configuration in service window) disappears from the Live monitor.

In case the "SNAP/RAD" on Foot/Hand switch is released early before processing then the message "Released Early, Processing Incomplete" will be displayed & the displayed image will not be fully processed.

NOTE

The goal of Snapshot mode is to obtain high quality static image therefore it is NOT *recommended to be used in case of patient movements.*

2. Procedure Selection

In this window, selection of anatomy related options like Exposure Mode, Body Part, Patient Type (Thin, Normal, Thick) and Main Procedure and Sub-Procedure are provided.

Based on the options selected, the X-ray exposure parameters kV, mA/mAs, Auto set value, Gain, Enhanced Fluoro, Sharpness, Contrast, Brightness, Aperture are set.

Options to set Image sharpness is also provided before initiating Image Scan. For Fluoroscopic procedures, suggested kV and mA will be shown based on the procedure selected. There is option to save the kV and mA values for subsequent selections by pressing the update button.

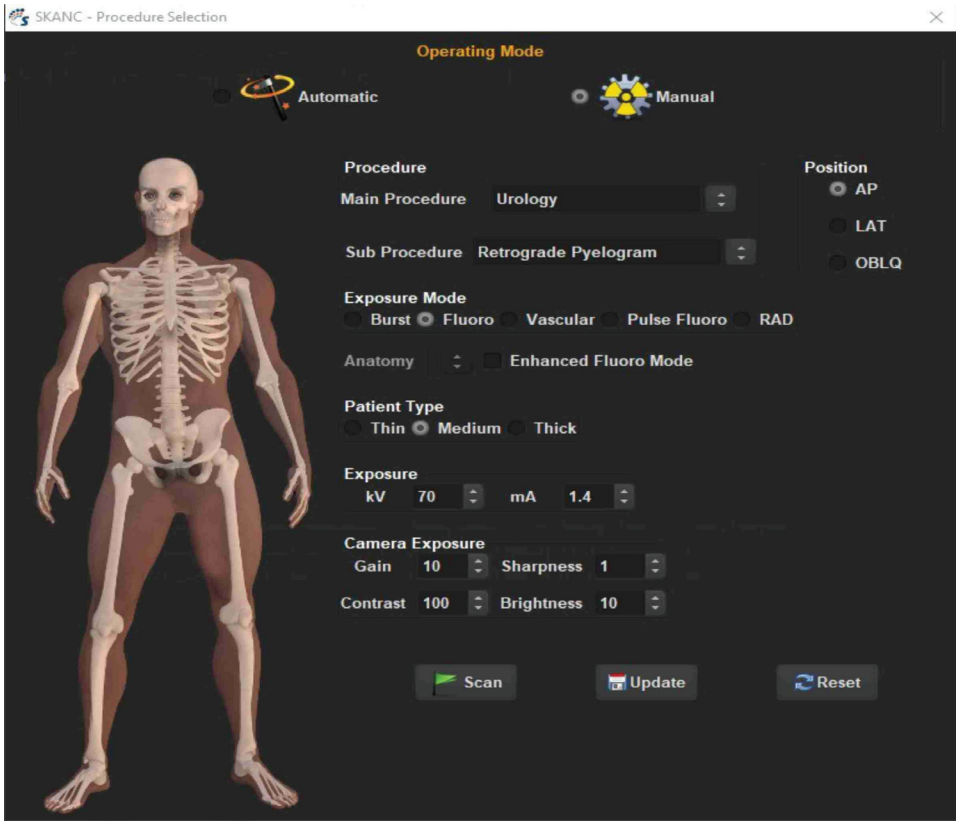

Figure 47: Anatomy for Fluoro

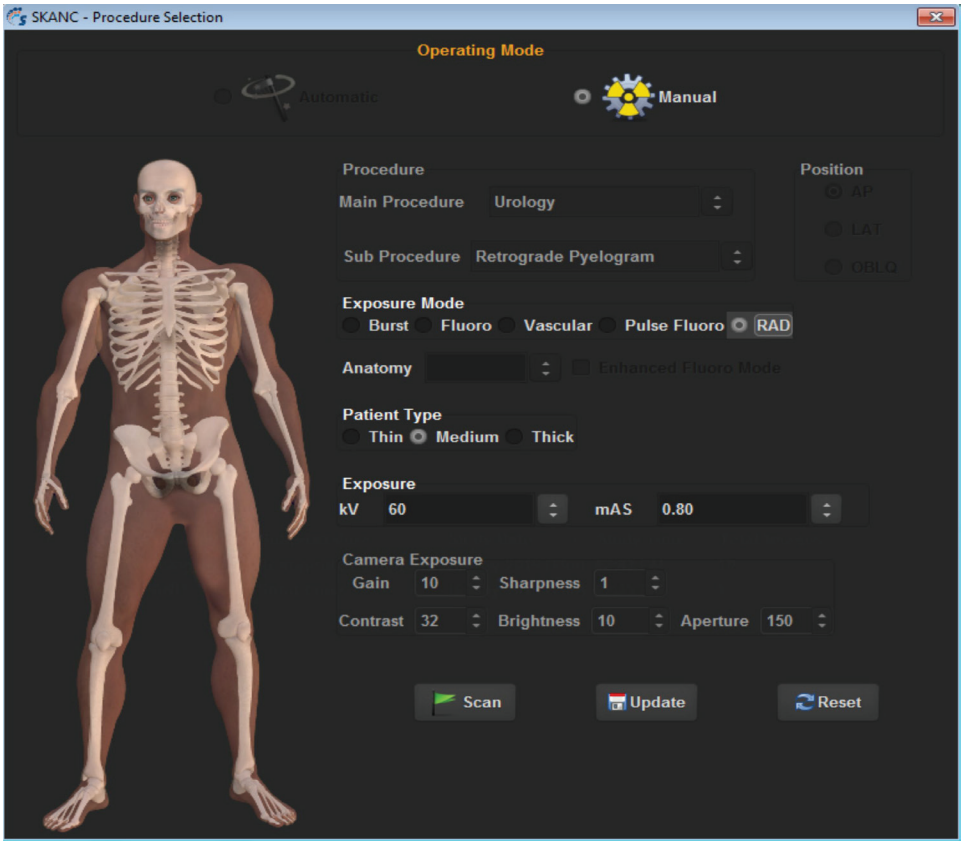

Figure 48: Anatomy for Rad

8.2.3.8 User selectable region for image optimization On Live Window

User selectable region for image optimization feature highlights region that is selected. This feature will improve the brightness and contrast of the anatomy without disturbing the actual data.

NOTE

This feature is deprecated.

- **Enabling:** Software will enable this feature on left mouse double click on the Live window after the Live window initialization. Once this feature is enabled software will display a square box (orange color)when mouse is moved as shown in "Figure 49".
- **Tracking**: Software will move the orange color box when there is movement in the mouse inside the viewing circle of the LIH on Live window. Which will help the user to track and select the region of anatomy. This will be visible only when this feature enabled.
- **Selection:** Software will display a green color box once the right mouse button is clicked on LIH of Live window. This will indicate that this feature has been selected. After selecting the area of interest take an exposure to change the brightness and contrast of the image. This will be visible only when this feature enabled as shown in "Figure 50".
- **Save:** After applying this feature on the image, software will save same to the DCM file and thumbnail. So that the same brightness and contrast will be viewed in Passive window by double clicking on the Passive window thumbnail.
- **Disable:** Software will disable this feature on double click of left mouse button.
- **Exposure:** Software will hide the square boxes during the exposure. And then again it will be displayed after the end of the exposure.

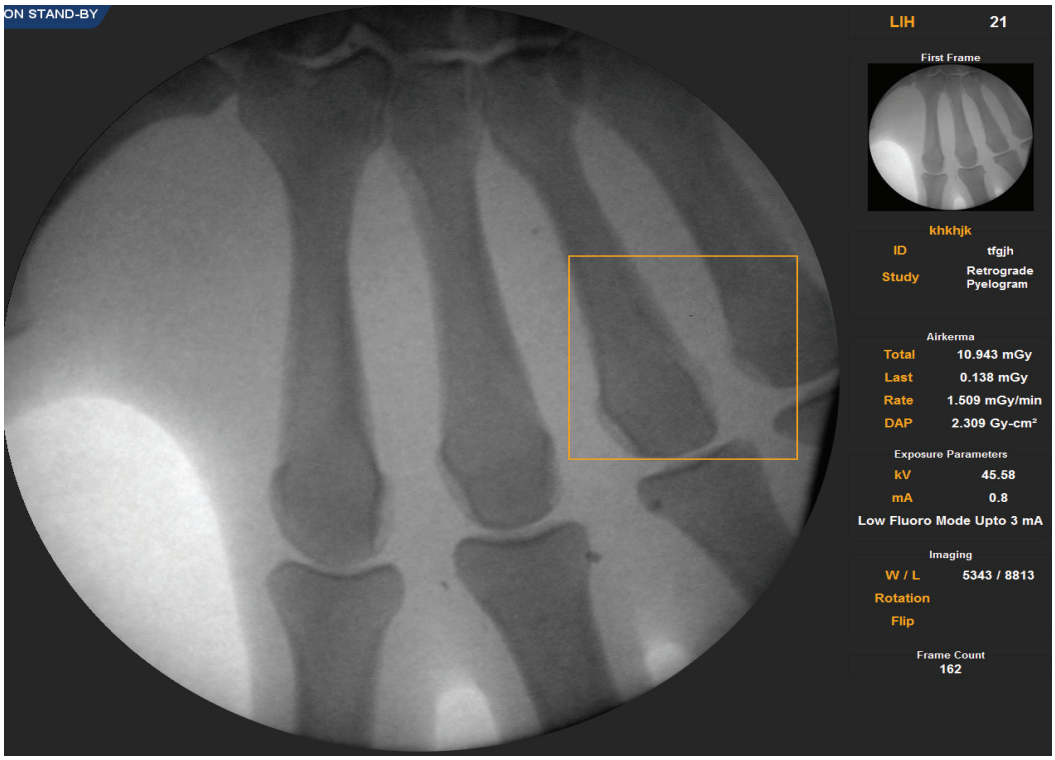

Figure 49: User selectable region for image optimization selection

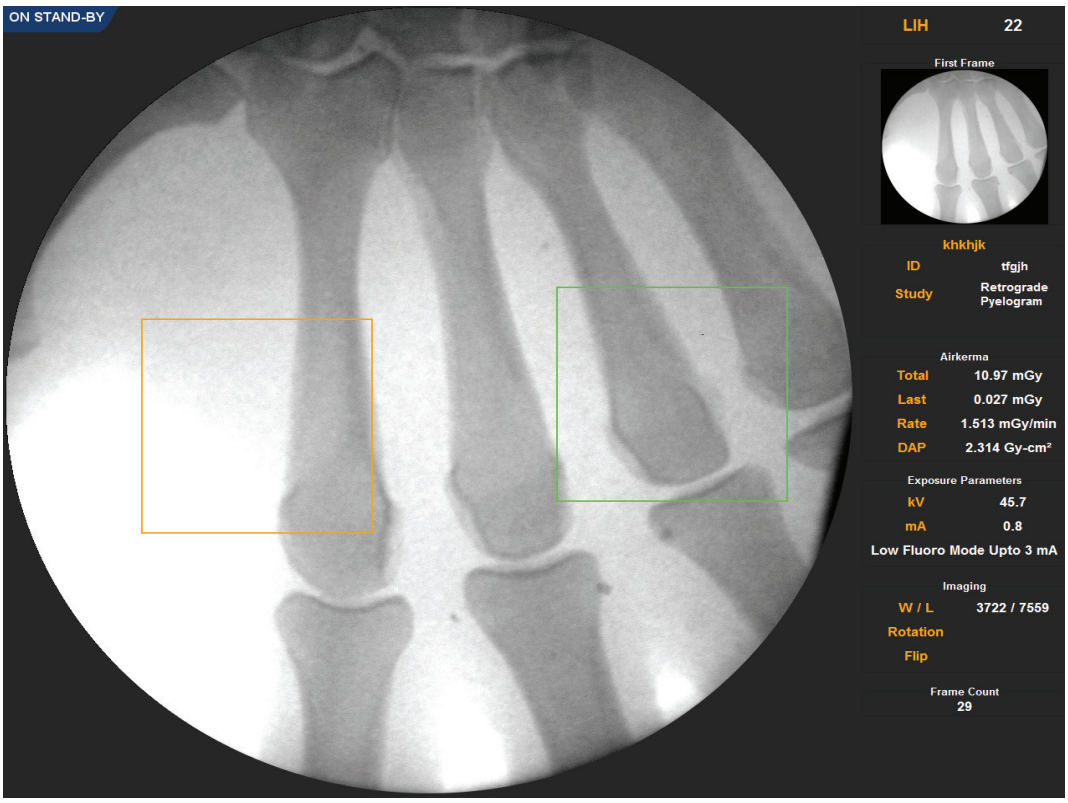

Figure 50: Outcome of ROI

8.2.3.9 Open Study

Open study button shall open passive window to display the last saved image on the passive monitor for the selected study. If images are not present for that study then the message "DCM/JPEG File not found" shall get displayed. "Figure 51: Passive Monitor (Image Viewer & Control Panel)" Image Viewer displays the selected Image in RUN mode. The Image manipulation buttons located on right side of the image viewer can be used as needed by user. Double click of the mouse in thumbnails displays the selected image.

Number of frames will be displayed on left bottom corner of the thumbnail image.

Image series number is displayed on right bottom corner of the thumbnail image.

Some of the features on the Passive monitor are

- **Overlay texts:** Images have overlay texts related to the Patient and Image acquired on each corners of the image.
- **FREEZE:** Clicking on FREEZE button shall freeze the viewer window(Freeze Mode). Upon clicking on UNFREEZE button it shall allow to perform all normal operations. Freeze mode shall allow all Passive window operations except loading subsequent frames in one/all of the window/(s) in any window configuration. When freeze mode is enabled the application shall display "FROZEN" and when mode is disabled the message shall be removed.
- **Run Mode Play/Pause:** In case of Multiple Frames, image frames will be displayed in continuous display Mode (Cine mode) or slide show mode. The image frames will be displayed at a preset speed (frames per second) at which the images were acquired in the Live Mode. Clicking the Pause button shall stop the Run mode and clicking the Play button shall restart the Run mode. The

application shall display the subsequent frame(from the available frames in the current DICOM file) until the end. Based on the click(Right/Left) the frames will be displayed in order.

- **Local Print:** The Local Print will print the current image displayed on Image viewer to the configured local printer.

NOTE

When the print operation is initiated, exposure will be disabled, to re-start the exposure the user needs to initiate a new study or emergency patient operation.

- **Save Image:** Saves the current image in Joint Photographic Experts Group (JPEG) format to local disk.
- **Reset to Original Image:** current image displaying on image viewer after applying manipulation feature can be reset to its original image.

Control panel includes total five tabs such as:

1. Common
2. Light-Room
3. Imaging Filters
4. Studies
5. Media

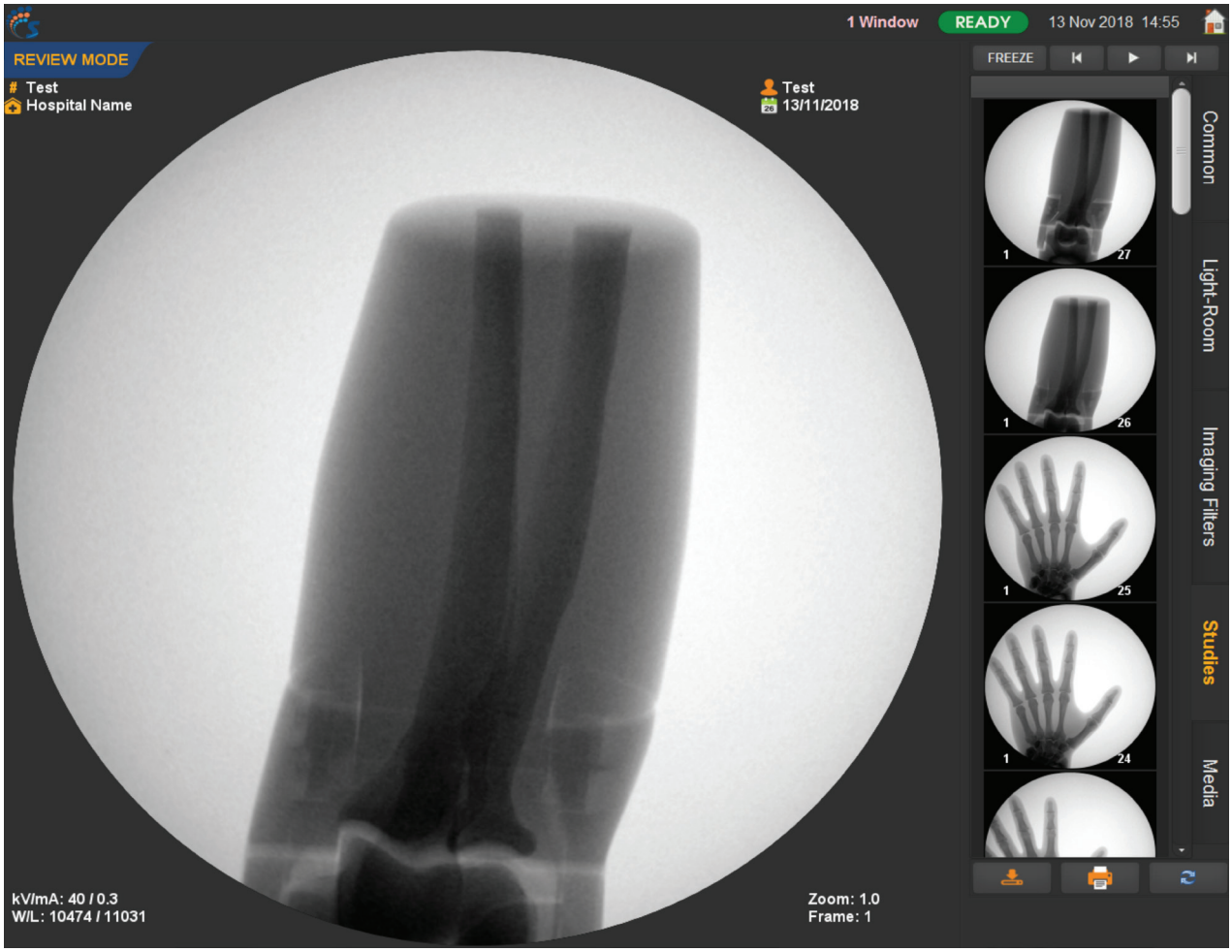

Figure 51: Passive Monitor (Image Viewer & Control Panel)

1. Common

It includes the following functionality

Rotate: Rotates the image in clockwise or anti clockwise direction.

Flip: Flips the image in horizontal or vertical plane.

Image Zoom in/Out: It allows the user to Zoom in/out on a selected image.

Line measurement: Measure the distance between two points.

Angle Measurement : Measures the angle between two lines drawn.

Trace: Highlights the region of Interest/ Mark on the displayed image.

Annotation: Write text on image.

Enable Panning: Provides option to move the image within the boundary area.

Magnification: It provides a small circular area of the image as magnified for better viewing. The user shall move around the mouse pointer on the Image display, where the user wants to magnify the part of the image.

NOTE

Measuring function is not the intended function of Skan C

NOTE

Virtual collimator sync will be done only from Live collimator control operation i.e from console collimator window. The workstation Passive side rotation or flip operation will not reflect on the collimator window.

Whenever Image flip or Rotation operation is performed from console then application will rotate/flip the virtual collimator internally and display only when collimator operation is called.

Virtual Collimator rotation and flip will be in sync with image orientation on Live side.

2. Light Room

It includes the following functionality

Histogram equalization: It provides Histogram equalized image.

Torch: A small portion of the displayed image around the cursor position is enhanced using histogram equalization.

Brightness: To set brightness required for user to view the image

Contrast: To set contrast required for user to have a better contrast of image.

3. Imaging Filters

It includes the following functionality

Invert Filter: Inverts the grey scale of the selected image. It displays the complement of original image.

Median Filter: It allows the user to apply the median filter on a selected image.

Edge detection: An image processing technique used to find the boundaries of objects within images

Edge Enhancement: *Used to highlight the edges of image and sharp contours of image to give enhanced clinical representation.*

Enhance Filter: It allows the user to apply the Enhance filter on a selected image.

4. **Studies**

It displays the series of images of the selected patient with a thumbnail scroll able to switch between images by double clicking on the thumbnail.

Export: The application allows the user to export DCM(from Study Tab) and JPEG/Video(from the Media Tab) files to an External Drive or Device. This is facilitated to the user through the right click menu on the thumbnail available on the Study/Media Tab. It shall also allow the user to export RAW image data from individual DICOM files.

Export as RAW: The application shall allow the user to export only the RAW image data of the saved DCM image. The RAW exports shall be saved with the same name as the parent DICOM files to a user selected drive/path.

NOTE

Export is allowed only to removable drives

Create Video: The application shall allow the user to create a video file out of the DCM images available in the current study. A single video file can be created with multiple DCM images. A minimum of 30 frames is required for Video Creation.

During Video creation **in progress** message is shown in the status-bar. The files later may be exported to external device (Pen Drive, External hard disk) for further use.

Delete: The application shall allow the user to delete the selected image by right clicking on the thumbnail and selecting delete option. A confirmation message will be displayed before deleting the image.

5. **Media**

It allows the user to view both the saved JPEG image and Video files from Media tab. Video file shall be identified by a video symbol in the bottom right corner of the thumbnail. Double clicking on the video file from the Media tab shall open the player and shall play the video.

8.2.3.10 Delete Study

The application allows the user to delete all the images of the selected study.

8.2.3.11 Emergency scan

This is a special function used only during emergency scan requirement. The Patient name and other mandatory fields are taken with default values for immediate X-ray procedure. The default fields are expected to be updated with Patient Update function after the procedures. This feature is to be used only when there is no time to enter Patient data before the X-ray procedure. It is shown in "Figure 52: Emergency Scan(with AutoTech feature)"

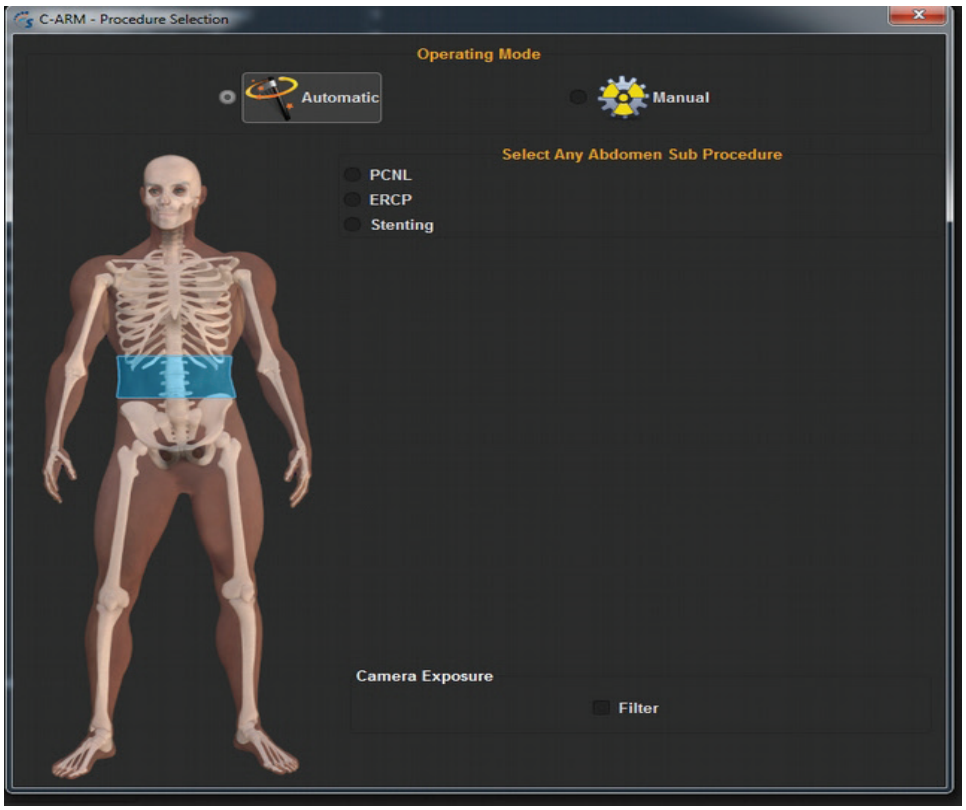

Figure 52: Emergency Scan(with AutoTech feature)

8.2.3.12 DICOM MWL Query

DICOM Worklist Manager is a feature (incorporated as requirement for DICOM Compliance) that allows communication between the RIS and modalities like the X-ray machines. The DICOM Worklist Manager closes the gap between the modalities and the RIS, enhancing the system's ability to manage the daily work flow. In DICOM MWL Query the user shall query the RIS for patients scheduled to the machine for that particular date. All the details entered in the DICOM MWL Query window shall be processed and queried to the RIS.

8.2.3.13 Modalilty Performed Procedure Step (MPPS)

MPPS is a feature (incorporated as requirement for DICOM Compliance) that allows communication between the RIS and modalities like the X-ray machines.

8.2.3.14 Send To PACS

This function sends all the selected image files to any specific REMOTE AE selected. After completion of the transfer, success or failed message is displayed. Option is provided to select individual file or all image files for the selected Patient ID.

8.2.3.15 DICOMDIR

DICOMDIR option shall allow the user to Burn/Export the images in DICOMDIR format either to CD/DVD or Pendrive respectively, DICOMDIR function shall open a new window with all the image files for the selected patient study in the form of thumbnails. DICOMDIR write option will allow the user to Burn/Export patient's particular study images only. First the user has to detect the media next has to select the images & press Burn/Detect button.

8.2.3.16 Display Free Space Message

Application shall display the free disk space of system at all time on the dashboard. Since image sizes can go up to several mega bytes per procedure, there shall be continuous display of free space available. This feature shall help user to monitor and control free space before any long fluoroscopic procedure.

8.2.3.17 Study Browser

Study browser shall have a list displaying all the studies for the selected patient. Multiple selection of studies shall not be allowed for any operation.

It shall display the following details about the study.

- Procedure
- Sub Procedure
- Study Date
- Study Time
- Total Images

8.2.3.18 Additional Patient Info/Patient Details

It shall display the following details about the selected patient.

- Date of Birth
- Weight
- Height
- Address
- Emergency Contact number

8.2.3.19 Activities List

The application shall allow the user to perform certain activities as shown below

1. Application Settings
2. Service Access
3. Restart Application
4. Help
5. Trash Bin
6. Shutdown System

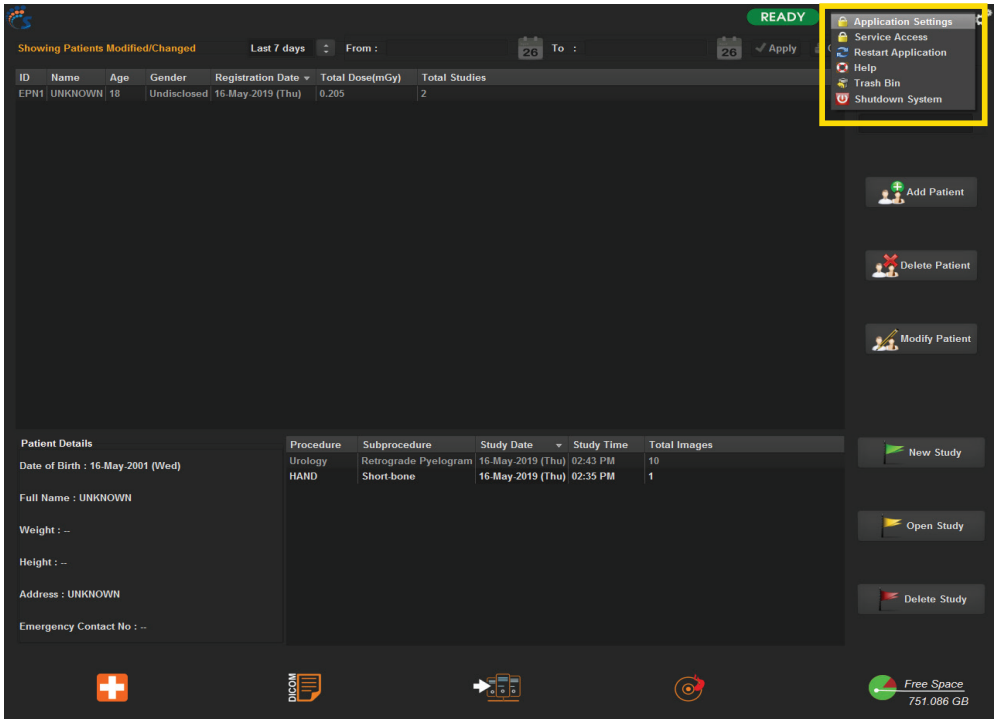

Figure 53: Activities Menu

8.2.3.19.1 Application Settings

The software enables the user to set and edit the user changeable parameters. User will be able to change the default parameters depending on the requirement. The changes made by the user will be saved in the database, so that it can be loaded next time the application starts. Default button shall be given which shall set all the settings to default parameter.

Live Navigation setting is only for that session.

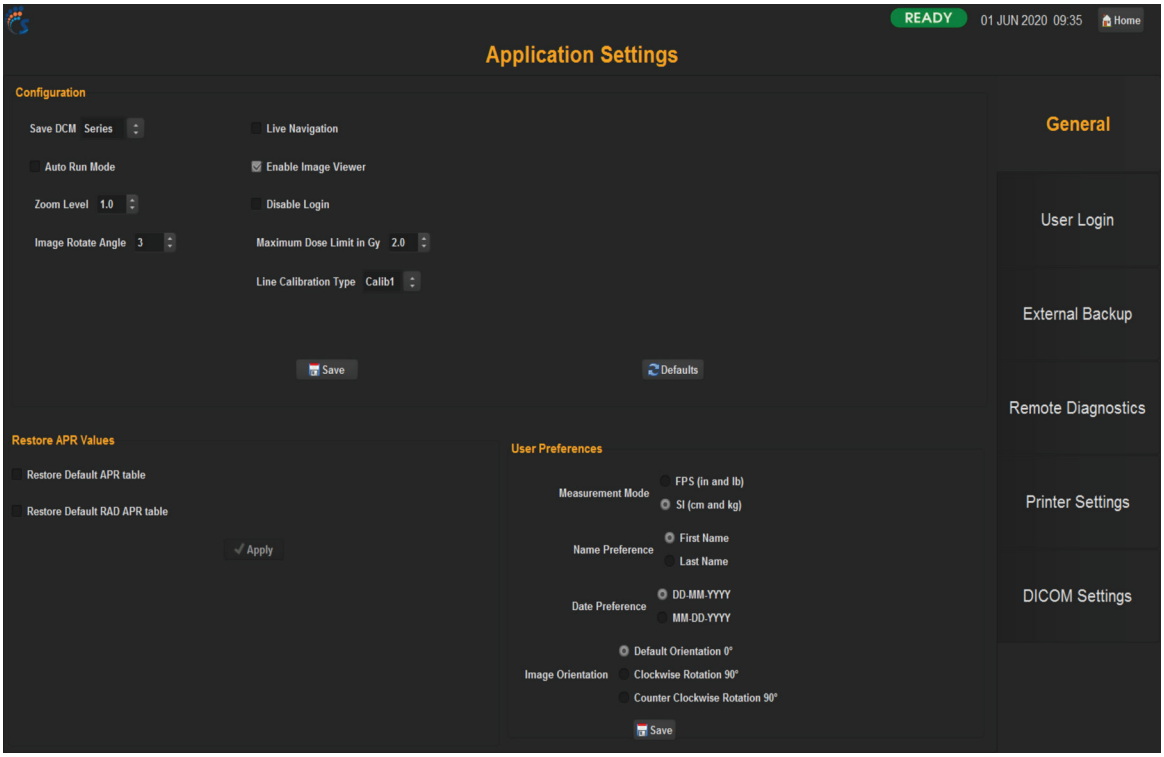

Figure 54: Configuration

- **General**

1) Configuration -This feature helps to change few default parameters after installation as per the requirement of the user.

The parameters available are

- Save Each Series
- Live Navigation
- Auto Run Mode
- Enable Image Viewer
- Zoom Level
- Disable Login
- Angle of Image Rotation
- Maximum Dose Limit (in Gy)

2) Restore APR values - This feature helps to restore the default APR value of Fluoro & RAD mode. The below mentioned options are available for the user.

- Restore Default APR Tables
- Restore Default RAD APR Tables

3) User Preferences - This feature helps user to set preferences for the below mentioned settings

- **Measurement Mode -** It allows the user to select either SI or FPS as measurement mode.
- **Name Preference -** It allows the user to select either First Name or Last Name as the mandatory field
- **Date Preference -** It allows the user to select the date format either in DD-MM-YYYY or MM-DD-YYYY format.
- **Image Orientation** - This feature allows the user to rotate the Image in the desired Orientation, based on the selection.
  - **Default Orientation 0°:** No rotation will be done in Live Window by default.
  - **Clockwise Rotation 90°:** In the Live window image will be rotated in 90° by default.
  - **Counter Clockwise Rotation 90°**: In the Live window image will be rotated in 270° by default.

NOTE

- *Application restarts when there is a change in Measurement Mode, Name preference or Date Preference. However if only Image Orientation is changed there will be no restart.*

- **User Login**

This window has New User(Create new user), Save, Delete and Reset options. Creating new user feature is available only for ADMIN user.
Only valid users created with this function will be able to Login and use Workstation software during Power ON.

- **Skan C External Backup**

This feature is used to copy data that is present in VAULT folder to external device or hard disk to free disk space.

- **Remote Diagnostics**

This function is used to communicate to SKANRAY host(server) from individual client unit. It allows the user to communicate with SKANRAY server machine by transferring the error-log/JPEG/DICOM/Any other status files to remote host server from client unit. There is a feature to download software from Server.

User will be able to do the Server Configuration by specifying the Server URL/IP address and port number before connecting to the server. Once the connection is established with the server user can select any one of the following options at a time as shown below and as depicted on "Figure 55: Remote Diagnostic" and click on "Run" to send the selected information/file to server and also user will be able to get the Skan C software setup file from the server by selecting Software Setup file option and click on **get** button.

- System Information
- Log File
- Jpeg file
- DICOM file
- Other file

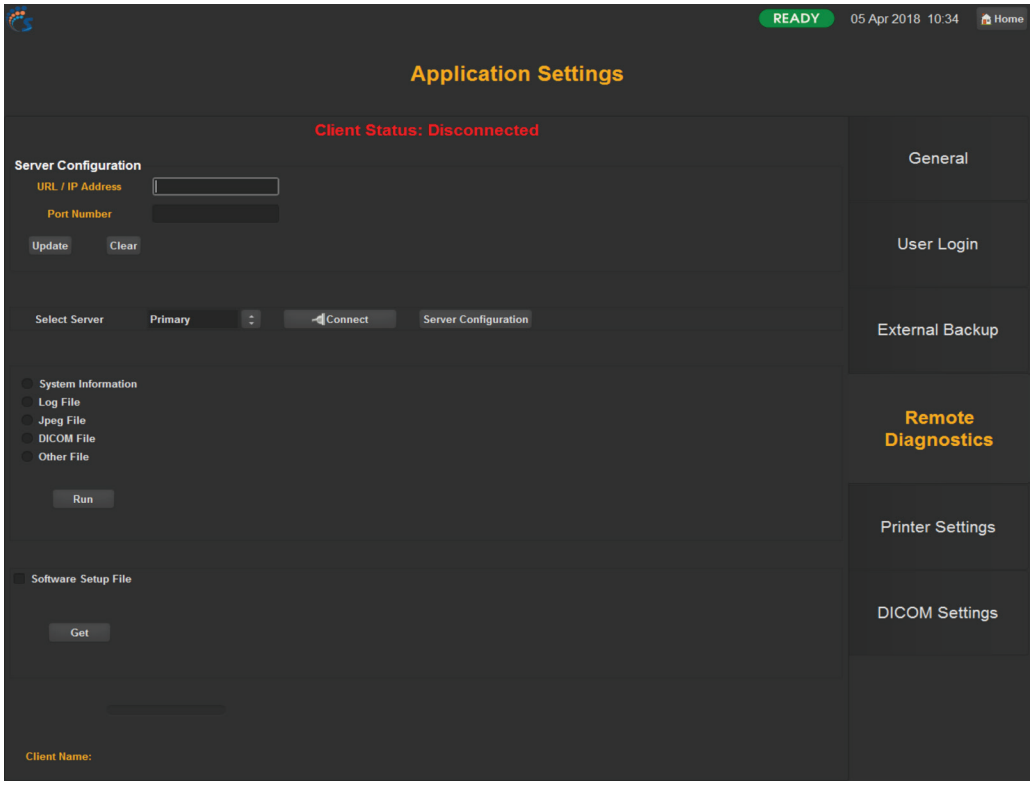

Figure 55: Remote Diagnostic

- **Printer Settings**

It displays all the DICOM printer settings field which will have standard options for each field which can be saved in database. The print module also provides setup for DICOM printer configuration and normal image display manipulation functions before printing in DICOM printer. Maximum of 4 Images can be printed in 2×2

matrix with image manipulation functions applied to each image independently.

Print set up shall select film type, printer type and other settings except window matrix, which shall be based on the window the user has selected.

Before printing, there shall be option for basic image manipulation features like rotate, flip, zoom, pan, invert and contrast adjustment.

- **DICOM Settings**

The image series in Skan C Mobile C-ARM X-Ray System are DICOM complaint and will be able to send to other DICOM Listener Hosts.

- **Configuration**

In order to send any image to PACS or DICOM Printer, Remote AE and Local AE details needs to be provided from Configuration function.

Local AE

This window displays Local IP address, Port and AE title. Port and AE title is editable but local IP address is un-editable. The window has update option.

Remote AE

This window has Add, Update, and Delete options. More than one remote entries are allowed to be stored to the data base and update feature is provided to change the data as necessary. User will be able to store REMOTE AE details with Remote IP Address, Port No and Title Name.

- **Start Receive From SCP**

Start Receive From SCP shall acts as a server and waits for incoming connections by DICOM Storage SCUs. Whenever a connection is established, the images are stored in the directory "D:/DICOM_Received_Images". It gives the provision to display the IP Address and Port Number, for which the receiver is configured.

8.2.3.19.2 Service Access

This function is only for service functions and restricted to support staff with valid service password. This feature is restricted to normal user.

8.2.3.19.3 Restart Skan C Application

This feature is used to restart the workstation application to re-establish the communication with camera and console. This happens when workstation is on UPS and power failure is on C-Arm X-Ray Unit. When the **Restart Application** button is pressed, it shall backup the following values and restore these values after restart completion.

- Patient ID/ Patient Name
- kV
- mA
- Main Procedure, Sub Procedure
- Study
- LIH Value

8.2.3.19.4 Help

Help button shall provide basic help to perform Skan C Mobile C-ARM X-Ray System software functionality. Using mouse click user can drill down to specific function details and usage.

In Help window left side has the functions and the help information will be displayed on the right side.

8.2.3.19.5 Trash Bin

The Trash bin displays the Patient ID and Patient name of a particular patient of whose images/study or the patient itself is deleted. User can select any of the patient (listed in trash bin) and click on **Restore** button to restore that selected patient. User can select any of the patient (listed in trash bin) and click on Delete button to delete the files permanently.

NOTE

The trash bin window shall display only the patient ID, even if a single image/ study/patient is deleted. So if the user deletes a patient from the trash bin, it deletes only the earlier deleted image/study/patient permanently.

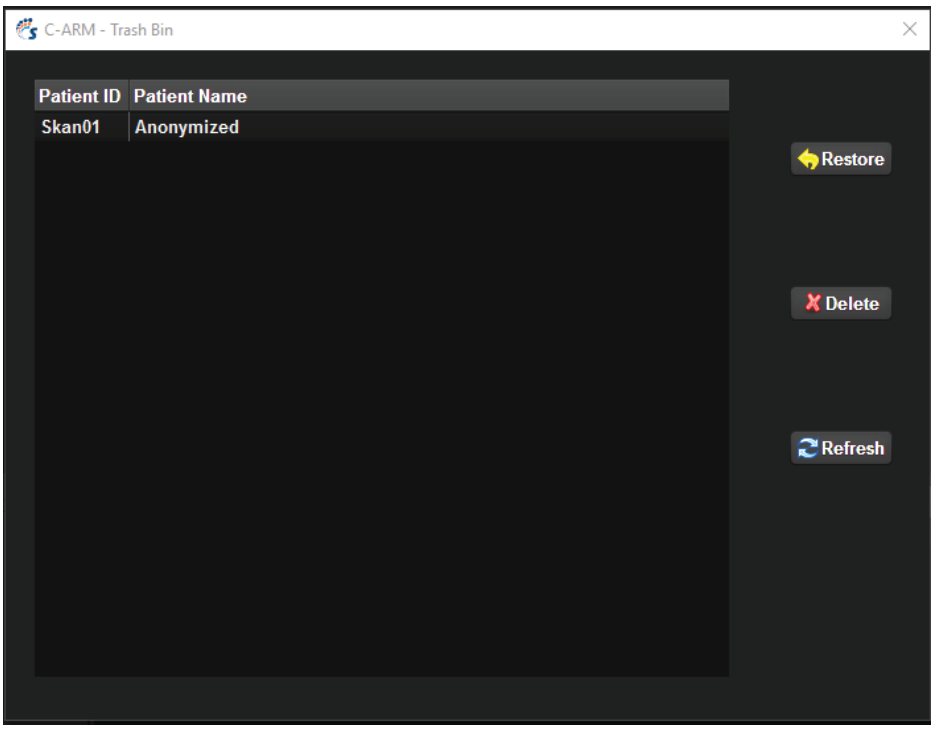

Figure 56: Trash

NOTE

If there are no patient displayed, please use the refresh option on the screen to get all the patients which were deleted.

8.2.3.19.6 Shutdown System

It allows the user to shutdown the system in which Skan C application software is running.

8.3 Image Processing and manipulation Tools

The following features are functional only on Passive Monitor on the currently displayed Image frame.

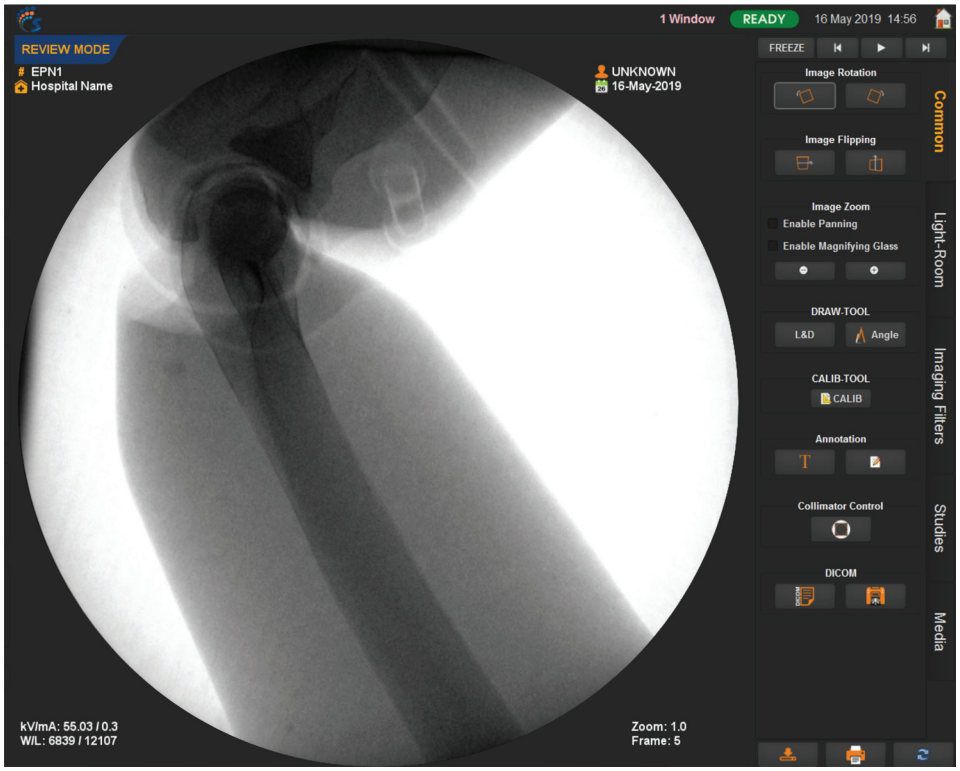

Figure 57: Image Processing and Manipulation Tools

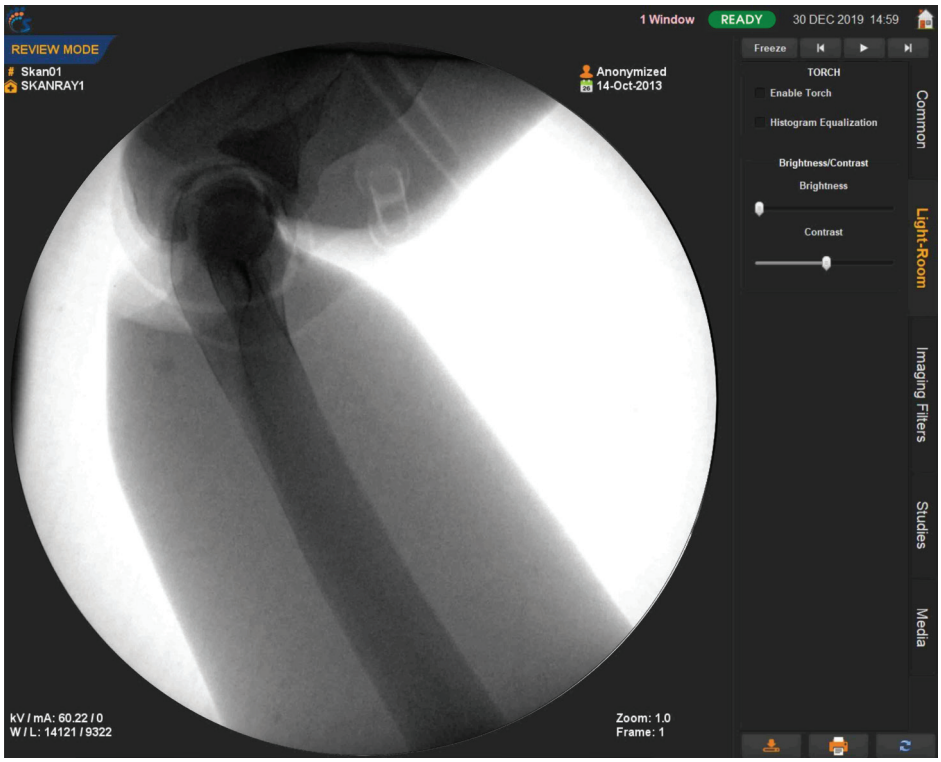

Figure 58: Image Processing (Light-Room)

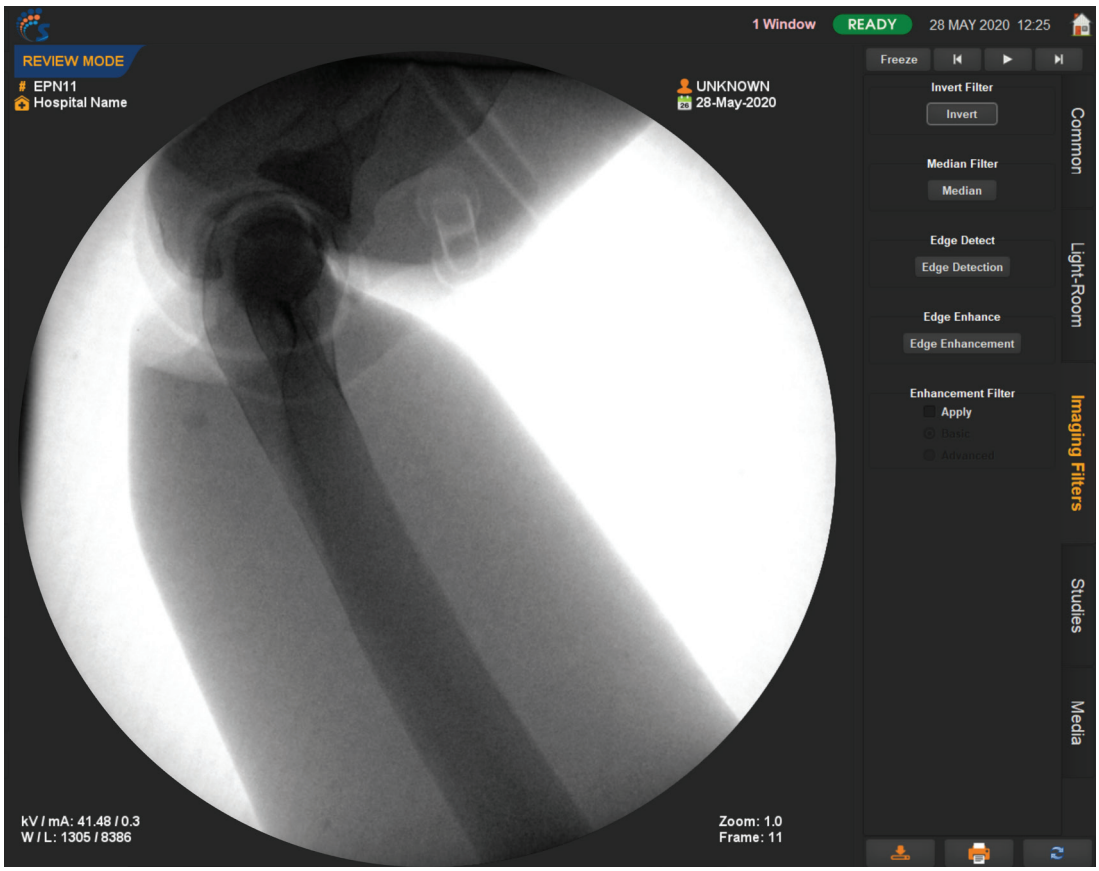

Figure 59: Image Processing(Imaging Filters)

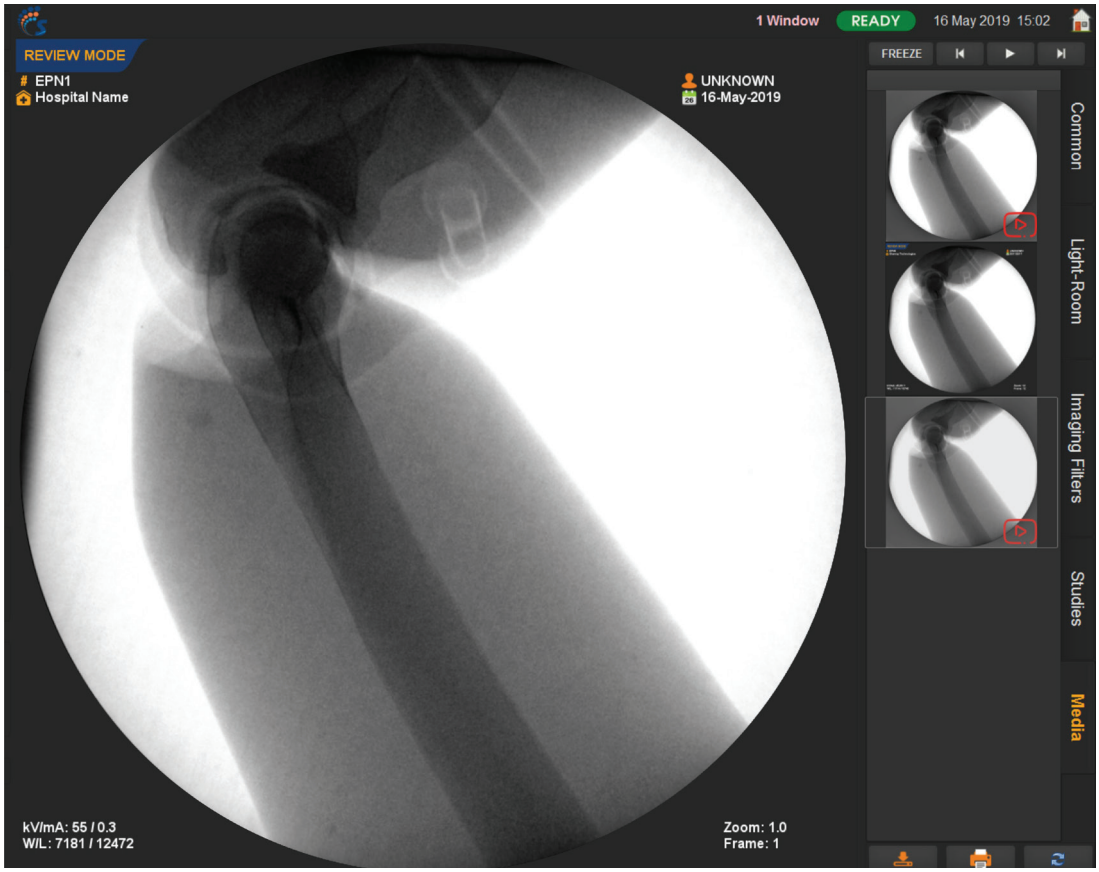

Figure 60: Image Processing (Media)

8.3.1 Image Rotation and Flipping

Mouse click on the buttons to perform the desired function on the displayed image. At any time, applying Reset icon button shall restore the original Image.

8.3.2 Enable Panning

This feature is used to move the image by pressing **Enable Panning** check button.

After clicking Pan check button left click on image and move the image to desired location. This feature finds better use on zoomed image which are outside the viewing area.

8.3.3 Image Magnifying Glass

This feature is enabled by clicking **Enable Magnifying Glass** button.

It provides a small area of the image as magnified or zoomed for better viewing. The user can move the mouse pointer on the image display, where the user wants to magnify the part of the image. The magnification factor is 2 times the current image.

8.3.4 Line Draw

This function enables the user to measure the distance between two points on the image.

- Distance measurement shall be marked as approximate distance due to possible inaccuracy during exact point selection.
- Length units shall be in mm or as per selection done in application settings.
- Line calibration should be done before the line draw with an object for exact measurement.
- Enter the height of object (Range 1 to 75 cm) for calibration in line calibration window for exact measurement. If the object height is not entered default height is taken as 25 cm.
- Line calibration is valid only for current series in the image viewer. If the height is changed then, re-calibration is necessary.

8.3.5 Angle measurement

This function enables the user to measure the angle between two lines on the image.

- The user should select the Angle measurement button.
- Draw a line by left clicking on the image & drag the mouse cursor when the user needs to terminate the first line the user has to again left click. Then drag the mouse cursor to the other end and press left click again to terminate the line.
- This will show the angle between the two lines drawn.

NOTE

To **delete** the angle and the lines associated with it,user needs to right click on the **first digit** of angle(lines will be highlighted) and then select **OK** button. If **Cancel** button is clicked then there will be no changes.

8.3.6 Trace Draw

The trace function enables the user to make a mark and region of interest on the image. Use left mouse button press and move mouse on image to have desired marking.

8.3.7 Annotation (Text Annotation)

This function enables the user to write text on image. Annotation can be edited by double clicking the left mouse button with cursor on the text.

8.3.8 Collimator Control

This function is used to control the Collimator- IRIS, Hard Shutter, Soft Shutter, Rotate Collimator selection through mouse scroll movement / Page UP/DOWN from the keyboard. The effect is displayed on Passive Monitor Image display and the same effect can be seen during the next exposure. (Virtual Collimation).

There is an option to reset the collimator to its original position by clicking on the reset button.

8.3.9 DICOM Tags

It displays the DICOM header for the displayed Image series in a new text window to review the parameters like Patient Info(Patient ID, Patient's name, DOB, Doctor name, institute name), procedure details (Study date, Study time, Study description, Series description), image series details (number of frames, Kvp, X-ray tube current, Exposure time), Modality type ("RF" for Fluoro and "RG" for RAD) etc.

8.3.10 Save Image (Local Save)

This feature saves the image frame displayed on the screen as JPEG file in patients folder as per the name given by the user.

If the user wants to export the image, an external device (Removable media) has to be connected.

8.3.11 Torch

The Torch function provide enhanced view of the selected area.

When this button is selected and mouse pointer is placed on the image, a small area (128×128 pixel) enhanced to get better display.

8.3.12 Histogram Equalization

This feature applies histogram equalization on the image frame displayed to provide histogram equalized image for better contrast.

8.3.13 Brightness

To set optimum brightness required for user to view the image. User can use the slider control available as displayed on "Figure 58: Image Processing (Light-Room)" by sliding left/right within the control.

8.3.14 Contrast

To set optimum contrast required for user to have a better contrast of image. User can use the slider control available as displayed on "Figure 58: Image Processing (Light-Room)" by sliding left/right within the control.

8.3.15 Invert Filter

This feature displays image with negative effect by reversing pixel data from white to black and vice-versa. This feature makes the image display complement of original display.

8.3.16 Median Filter

It allows the user to apply the median filter on a selected image.

8.3.17 Edge detection Filter

It allows the user to apply the Edge filter on a selected image to detect edges.

8.3.18 Edge Enhancement

It allows the user to enhance the edges of the selected image.

8.3.19 Enhancement Filter

It allows the user to enhance the selected image for a enhanced view.

There are 2 levels of enhancements, Basic and Advanced. User should be able to select either Basic or Advanced.

8.3.20 Reset

Reset operation enables the user to reset the values changed to default original values. By using RESET all the local image manipulation functions performed on the current image frame is reverted back to the original form. This is applicable only to the image frame on display.

Reset image shall clear the image from all applied Rotate, Invert, Flip, Zoom, Pan, Line, Enhance, filter, virtual Collimation and other Image manipulation operations.

8.3.21 Multiple Window

The Live images that are captured is displayed in quad window in clockwise direction/ order. User can also select any window to load the image from thumbnail. There will be an option for user to "Freeze" a window for reference and not to load an image in that window and "Unfreeze" is to disable the window from freeze. When the freeze option is utilized, the application shall display "Frozen" on the image/window where it is applied.

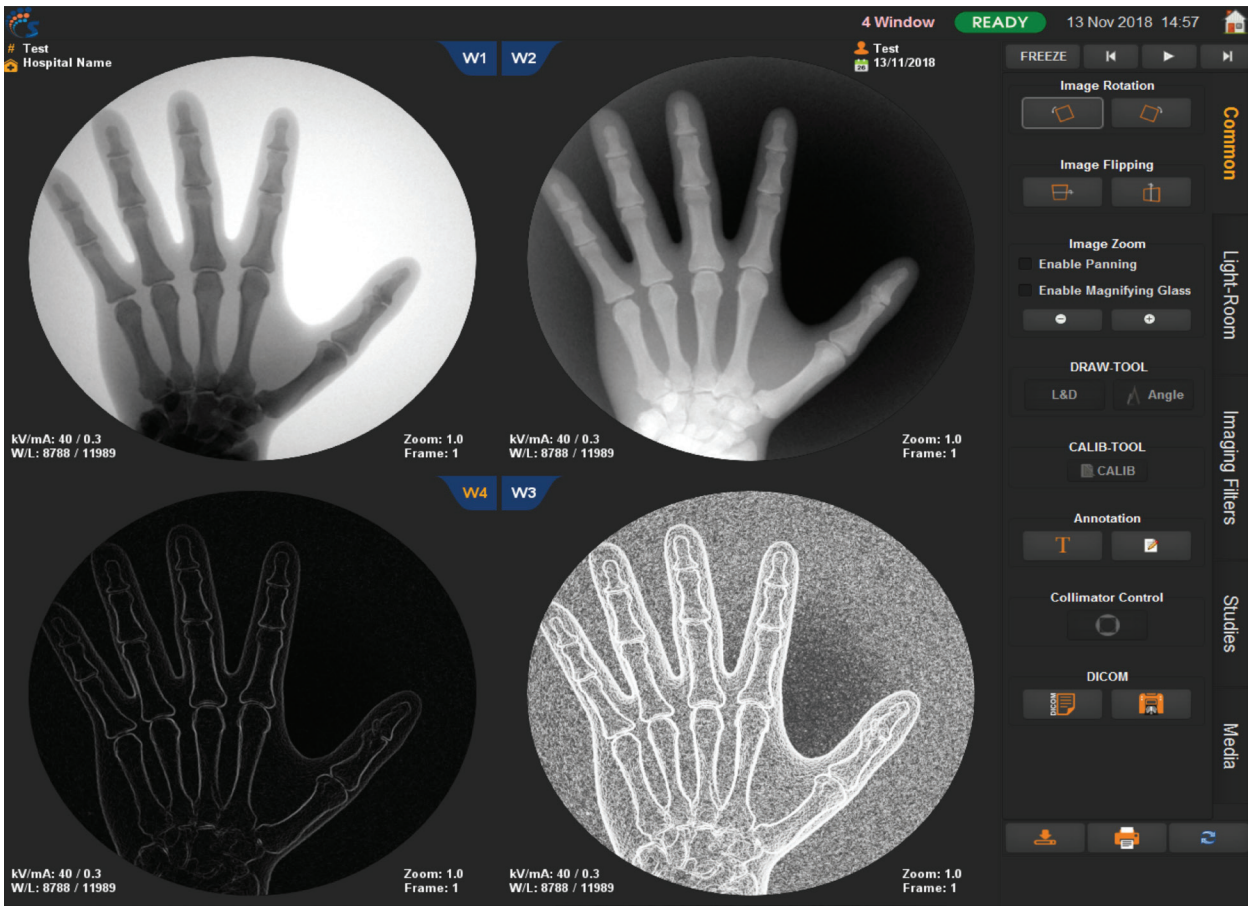

Figure 61: Multiwindow

8.4 Status Bar

Status Bar shall display one line message at the top of Passive Monitor. The message shall remain for 5 sec or until another message is displayed on it. The status message shows only the text for the user to take necessary action.

8.5 Database Restore

This feature is used by software during start up in case there is a database corruption or if database is file not found. Software shall restore the data base from one of the previous back up. If primary backup fails the application will internally select the alternative backup to restore. If both the database restore fails, the system will prompt the user to select from one of the options below,

- Continue without modification
- This will create a fresh database of the current application.
- Continue with Patient Data Recreate from DICOM files (This may take longer time based on the number of files available)

NOTE

This will create a fresh database and fill the database with patient data.

8.6 Live Navigation

This feature is provided for enabling the transfer of images to the Neurosurgery Navigation systems. Using video splitter.

8.6.1 Disk Full Message

User will get warning message when the free Disk space is less than 1 GB so that User can backup old Patient Data to free more disk space. "Image Saving" process is disabled if the disk free space is less than 1GB.

8.7 Troubleshooting

1. If there is no display of frames even after Exposure is ON (Lamp on Workstation is ON). Kindly do power recycle on the C-side.
2. If collimator operation is not in sync with the virtual collimator, Use collimator reset from virtual collimator/ Perform a New study for the same patient. NOTE : Performing this will reset all the collimator to original positions.
3. After performing Live Navigation operation if Live screen monitor is extended to Passive side then press Swap from Console.

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CHAPTER 9

Radiography Operation

User can use SCAN button to set Exposure Parameters and to initiate X-ray procedure session after selecting the Patient or after Patient Registration. First, User needs to select X-ray mode as RAD, Patient size and desired Procedure. Based on the selection, Suggested X-ray exposure parameters are displayed. The kV and mAs values can be changed by the User if necessary. Use Hand-Switch To give Exposure. Exposure Indicators like Audible sound and "Exposure Lamp" will be ON for a brief period, for the exposure duration. Single image is acquired in Film/Casette and the Film/Casette should be placed near detector using film holder. Image information can be saved in Workstation if needed (For RAD values refer "Annex 11: APR Table – Radiography").

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CHAPTER 10

Cleaning / Disinfection

WARNING

Indicates a hazardous situation which, if not avoided, may result in serious injury or permanent disability.

This section describes routine performance checks that needs to be performed to ensure that the system is operating correctly. The performance checks listed are not intended to substitute for scheduled periodic maintenance.

If problems are found during these checks, contact a qualified service engineer to troubleshoot and repair the system. In addition to performance checks, safe cleaning practices are included and a description of periodic maintenance that should be performed. All periodic maintenance should be performed by SKANRAY or a qualified service engineer.

Observe safety operations before performing any maintenance and cleaning procedures

The performance checks should be performed as often as equipment use and circumstances warrant. Extensive use warrants increasing the frequency of performance checks. In addition, circumstances such as accidents during transport or exposure to excessive fluids may warrant that performance checks be performed to verify operation of the equipment.

10.1 Cleaning and Disinfection

1. Use a mild detergent, if necessary to remove scuffs and stains.
2. Use damp cloth or sponge to clean the surface.
3. Do not use excess liquid to clean as liquid may seep inside the unit
4. Do not use any solvents which may damage surface or plastic components

WARNING

Remove power connection to Skan C Mobile C-ARM X-Ray System and switch off all mains, before attempting a cleaning procedure.

CAUTION

Skan C Mobile C-ARM X-Ray System is not water proof. Avoid spilling or splashing liquids on the surface.

To Avoid any Cross-Infection due to nature of procedure, where possibility of spillage of fluids and/or bodily fluids, it is recommended to use DRAPES for Tube-head and Detector Assemblies.

CAUTION

During OT Sterilization using formaldehyde vapors, it is strongly recommended to move Skan C outside the environment, where it is not possible to move, it recommended to cover units so vapors do not come in contact with sensitive parts of Skan C.

CHAPTER 11

Maintenance

To maintain Skan C for Safe, effective and reliable operation, it requires:

User Maintenance on Regular Basis as referred in section "11.1 User Maintenance"

Scheduled Maintenance by the Authorized Personnel as referred in section "11.2 Maintenance"

CAUTION

Skan C should be used in accordance with this user manual. Do not misuse or abuse the system and its accessory usage/function

Do not use any sharp objects other than finger tip to operate console keys, else may lead to system Failure

All mechanical movements should be used cautiously. Avoid forced and over-speed operations.

11.1 User Maintenance

User has to check the possible malfunction or defects or deterioration of system, periodically or as mentioned below.

No	Item	Inspection type	Schedule
1	Brakes, Locks and Steering	Check by operating individual brakes/Locks	Daily
2	During Power ON	Check for any Error Message	Daily
3	Hand-Switch	Check for any damage and functional check	Daily
4	Foot-Switch	Check for any damage and functional check	Daily
5	Workstation Functioning	Check for Boot-up screen and Monitors	Daily
6	Laser Aimer	Check for Laser Operation	Daily
7	Connectors and Cables	Check for any deterioration or damage	Weekly
8	X-ray Exposure	Check for X-ray Functional Check	Daily
9	Collimator	Check for Shutters and Iris operation	Weekly
10	Beep Test	Check for audible sound during key press and X-ray exposure	Daily
11	Lamp Indicator Status	Check for Lamp ON during Exposure	Daily

No	Item	Inspection type	Schedule
12	Surface Cleanliness	Clean and keep surface free of dirt and liquids	Daily
13	Backup Power Workstation	Check for Backup Charging Status and function	Daily
14	UP and DOWN movement	Check for its slowness or any unusual noise	Daily
15	Castors and Wheels	Check and if required clean	Daily
16	Information Labels	Check for Legibility and Deterioration	Monthly
17	Emergency Switch	Check for its functionality	Daily

11.1.1 Mechanical Checks

11.1.1.1 Foot brake operation

1. Lock Wig-wag Brake, Carriage Brake, yoke brake, Orbital Brake and emergency switch and unlock foot Brake.
2. Check for C-Arm device movement for ease of movement by operating through Steering Handle.
3. Now lock the foot Brake.
4. There shouldn't be any device movement unless an undesirable large amount of force being applied.

11.1.1.2 Wig Wag brake operation

1. Lock foot brake, yoke brake, carriage brake, orbital brake and emergency switch and unlock Wig Wag brake.
2. Check for C-Arm wig-wag angular movement for ease of movement by operating through C-Handle.
3. Now lock the Wig-wag Brake.
4. There shouldn't be any swivel motion unless an undesirable large amount of force being applied.

11.1.1.3 Carriage brake operation

1. Lock foot brake, Wig Wag brake, yoke brake, orbital brake and emergency switch and unlock carriage brake.
2. Check for C-Arm Carriage horizontal travel for ease of movement by operating through Carriage rear handle.
3. Now lock the carriage Brake.
4. There shouldn't be any travel observed.

11.1.1.4 Yoke brake operation

1. Lock foot brake, Wig Wag brake, carriage brake, orbital brake and emergency switch and unlock Yoke brake.
2. Check for C-Arm wig-wag angular movement for ease of movement by operating through C-Handle.
3. Now lock the Yoke Brake.
4. There shouldn't be any angular movement unless an undesirable large amount of force being applied.

11.1.1.5 Orbital brake operation

1. Lock foot brake, yoke brake, carriage brake, Wig Wag brake and emergency switch and unlock orbital brake.
2. Check for C-Arm orbital rotation for ease of movement by operating through C-Handle..
3. Now lock orbital brake.
4. There shouldn't be any orbital motion unless an undesirable large amount of force being applied.

11.1.1.6 Vertical movement control check

1. Lock Foot brake, Wig Wag brake, carriage Brake, yoke brake and Orbital Brake and release the emergency switch for operating the vertical movement.
2. Bring the system into normal position with detector on the top and C-Arm is in vertical position.
3. Normally the height of the C-Arm is in fully retracted position (at zero indication on label).
4. Press UP or DOWN movement key and observe the movements in respective direction.
5. While in motion, activate "Emergency Switch". Movement should be stopped immediately.
6. Release of "Emergency Switch" requires to rotate in particular direction. This should restore the movement control.

CAUTION

A 9 minute interval should be ensured for every continuous 1 minute vertical movement operation to avoid any damage to the Electro-Mechanical Circuits.

If upward movement is not stopped after the 450mm scale, Skan C Mobile C-ARM X-Ray System may become unstable. Stop immediately, bring down height and call service to fix the problem.

If downward movement is not stopped at 0 mm scale, column may hit bottom and may damage the system. To avoid risk, stop immediately, bring up little height and call service to fix the problem.

11.1.2 Electrical Test Procedure

Check for following for

- Power Inlet Cable
- Foot Switch and Hand Switch cables
- Signal/Power cable connecting to Workstation
- Signal/Power Cable connecting between Bucky and C-Structure
- Check for any wetness or body fluid or other fluids on the cables and connectors.
- Check for any wetness or other fluids on keyboard and mouse
- Check for any wetness or other fluids on Console Panel
- If observed, follow cleaning procedure mentioned.
- Ensure All connectors are properly connected as indicated the User Manual
- Switch ON the unit. Ensure Console Panel lights up and Workstation completes Power Up Sequences.
- Create a Test Patient with default settings in Normal Fluoroscope Mode.

11.1.3 C-Vertical Movement Control Check-up

WARNING

This procedure mechanically moves in Vertical Direction. Take Appropriate Protective Measures.

- Press and Hold Vertical Movement in the desired direction. Observe a smooth movements
- During the above Step, Press "Emergency Switch".
- Observe Vertical Movement should STOP.
- If Vertical Movement does not stop, Switch OFF the Mains Power Switch.
- Inform inform authorized personnel.
- DO NOT USE Skan C until the Problem is fixed.

NOTE

Follow Power UP sequence once C-Arm Mains Power Switch is Switched OFF

It is recommended to contact SKANRAY to perform the below imaging performance test. If user still wish to do these tests, below is the procedure

11.1.4 Fluoroscope Mode Performance Check-up

WARNING

This procedure generates X-ray. Take Appropriate Protective Measures.

- Create a Test Patient with default settings in Normal Fluoroscope Mode.
- Position the C-Arm such with Image Intensifier in DOWN position, Place a test object over the Image Intensifier surfaces

NOTE

Weight of the test object shall be less than 100gms OR Position the C-Arm in under table position.

Place the Test Object in the Beam Path.

1. **For Normal Fluoroscopy**
   - Press the foot switch for a short period of time, until the image is displayed on the Live Monitor.
   - Keeping the foot-switch pressed, check for image rotation and magnifications N, M1 and M2.
   - Once the foot switch is released, the Image will be retained and LIH is displayed on the Monitor.
   - During the exposure time exposure indicators like Audible sound and Exposure Lamp will be ON.
2. **For Auto-Technique**
   - Enable Auto-Technique, Press the Foot Switch for a short period of time, until the image is displayed on the Live Monitor.
   - Once the foot switch is released, the Image will be retained and LIH is displayed on the Monitor.
   - During the Exposure time Exposure indicators like Audible sound and Exposure Lamp will be ON.
3. **For Snapshot**
   - Disable Auto-Technique and Press the Hand-Switch Until the Image is displayed on the Live Monitor.
   - Once the Hand switch is released, the Image will be retained and LIH is displayed on the Monitor..

11.1.5 Radiography Mode Performance Check-up

WARNING

This procedure generates X-ray.Take Appropriate Protective Measures.

- Create a Test Patient with default settings in Normal Radiography Mode.
- Position the C-Arm such with Image Intensifier in DOWN position, Place a test object over the Image Intensifier surfaces
- Attach the cassette holder to the image intensifier

NOTE

Weight of the Test Object shall be less than 100 gms OR Position the C-Arm in Under Table Position

- Place the test object in the beam path.
- Set a Technique Parameter of Lower DOSE level with a test object in the X-ray path
- Give Exposure using the Hand Switch
- You will hear a brief sound and X-ray Status Lamp briefly turns ON indicating the Exposure
- Film can be developed for Imaging performance

11.2 Maintenance

Maintenance shall be carried by the authorized personnel. Preventive maintenance is recommended once in a year, after the first year from the date of installation. It is the responsibility of the user to assist in maintenance carried out by the competent and authorized personnel, done as per the company's service & maintenance policy and procedures.

11.2.1 Spatial (high contrast) resolution

This is a visual assessment of a resolution test object imaged with solid state image intensified system, commonly used to assess spatial resolution.

Recommended Testing Tool: Line Pair Phantom

Procedure:

1. Line Pair shall be placed close to the Input surface of II tube and at the centre.

2. Set kV to 40-44 and mA to 0.2-0.5 range for the acceptable image.

Resolve the visible line pair

Acceptance Criteria: For 9" FOV, minimum identifiable resolution shall be at least 1.6 lp/mm

11.2.2 Spatial uniformity

Convex detection surfaces leading to spacial distortion and non-uniformity of intensity response. Conduct the following test to identify imaging anomalies.

Recommended Testing Tool : Measuring scale or similar mesh objects

Procedure:

1. Test object shall be placed close to the Input surface of II tube and at the centre.

2. Set kV to 40-45 and mA to 0.2-0.8 range for the acceptable image quality.

Acceptance Criteria:

a) Visual contrast distribution and with contrast measurement on the system shall not vary all along the mesh lines by more than 10%.

b) Straight lines shall not have any linear distortion more than 10% throughout the length.

11.3 Tube Seasoning

If for some reason, Skan C is not used for its intended use and regular maintenance was not carried out for more than 90 days, HV Tank requires seasoning before using it on the patient along with regular checks mentioned in Sections "11.1 User Maintenance"

1. Interface Workstation and C-Arm unit as described in Section "6.1 Interconnecting Workstation and C-Arm Unit"
2. Connect Skan C Mobile C-ARM X-Ray System to power and switch on system. Keep the system in stand-by position for 60 minutes.
3. Perform fluoroscope procedure and rad procedures as follows.

11.3.2.1 Fluoroscope Procedure:

Step	Settings	Remark
1	Set kVp to 40 and mA to 0.5	Exposure for 5 Seconds Wait for 20 seconds
2	Set kVp to 60 and mA to 0.5	Exposure for 10 Seconds Wait for 20 seconds
3	Set kVp to 80 and mA to 0.5	Exposure for 10 Seconds Wait for 20 seconds
4	Set kVp to 95 and mA to 0.5	Exposure for 5 Seconds Wait for 20 seconds
5	Set kVp to 110 and mA to 0.5	Exposure for 5 Seconds Wait for 20 seconds

11.3.2.2 Radiography Procedure:

Step	Settings	Remark
1	Set kVp to 40 and mAs to 0.5	Wait until "cooling Period" disappear from the console.
2	Set kVp to 60 and mAs to 10	Wait until "cooling Period" disappear from the console.
3	Set kVp to 80 and mAs to 20	Wait until "cooling Period" disappear from the console.
4	Set kVp to 90 and mAs to 1	Wait until "cooling Period" disappear from the console.
5	Set kVp to 110 and mAs to 1	Wait until "cooling Period" disappear from the console.

11.4 External Device Interface

- To ensure patient safety, connect only SKANRAY approved devices. All Equipment attached to the external interface connections must meet the requirements of IEC 60601-1 when operated within patient environment.
- When used outside of patient environment, such devices must comply with relevant IEC/ISO requirements for that device.
- However, in all combinations, leakage current of any device used within the patient environment will not exceed limits specified in IEC 60601-1.

11.5 Optional Device

Following accessories have been tested with Skan C.

- Detachable Cassette Holder
- Detachable Copper Filter
- Spring Clamp for Sterile Drape
- Detachable Skin Spacer

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Annex 1: Error and Alert Messages

Error codes & suggested solutions and Alert Messages displayed on Workstation.

Error Codes

Error No	Error Description	Suggestion
ECN1	Over kV Fault	Clear fault by pressing RESET key, If Error is repeated Restart System, if error persists then Shut Down the System. Do not USE. Inform Service Support.
ECN2	Over mA Fault	
ECN3	Cathode Arc Fault	
ECN4	Anode Arc Fault	
ECN5	Tube Arc Fault	
ECN6	Collimator motor over current fault	Clear fault by pressing RESET key, if error is repeated then Calibrate collimator and restart the system.
ECN7	Improper/Invalid of Hand Switch Operation	Hand switch pressed in vascular mode or during foot switch operation. Do not use hand switch in vascular mode and clear fault by pressing RESET key.
ECN8	Filament Limit Fault/ Filament OC Fault	Clear fault by pressing RESET key, If Error is repeated restart system, if error persists then Shut Down the System. Do not USE. Inform Service Support.
ECN9	Low mA Fault	
ECN10	kV Regulation Fault	
ECN11	Improper/Invalid of Foot Switch Operation	Foot switch is pressed in RAD Mode or during Hand switch operation. Do not press foot switch in RAD mode and clear fault by pressing RESET key.
ECN12	Tube head Temperature Warning	Tank temperature is high. Wait until it is cooled down and clear fault by pressing RESET key.
ECN13	Collimator Fault	No feed back from collimator. Calibrate collimator and restart the system.
ECN14	Tube Temperature Fault	Wait until it is cooled down.
ECN15	Tube-Head Reset Fault	Restart System. If Error is repeated, Shut Down the System. Do not USE. Inform service support.
ECN100	Keypad Operation Error	Use keypad as instructed in the user manual and clear fault by pressing RESET key.
ECN101	CAN Communication Failure	Check Signal Cable interface between Workstation and C-Arm. Restart system. If error is repeated, shut down the system. Do not use. Inform service support.
ECN102	Measurable Performance	Feedback error. Restart system. If error is repeated, shut down the system. Do not use. Inform service support.

ECN111	Magnification key short error	Try pressing gently again. If problem is not resolved restart system. If error is repeated, shut down the system. Do not use. Inform service support.
ECN50	Actuator Motor Overload	Press RESET Button if error persist press UP if previous movement is DOWN, press DOWN if previous movement is UP.
ECN51	Heat Sink Over Temperature	Press RESET and wait for 1 minute.

Alert Messages displayed on Passive monitor

Message ID	Message Text
1.	Are you sure, you want to shutdown ?
2.	Alpha Numeric Characters are accepted
3.	Valid field shall have minimum of 4 characters,Maximum of 30 characters
4.	Correction required in the highlighted field(s)
5.	Invalid Credentials, Please try again
6.	Please select files for saving in Video format
7.	File already exists!, Click OK for overwriting. Cancel for Creating new file
8.	Please select a minimum of 30 frames to create a Video file
9.	Video Creation in Progress
10.	Successfully created Video file
11.	Failed to Create Video
12.	Unable to Save Printer Settings
13.	Printer Settings Successfully Saved
14.	No Printer Selected
15.	Database Migration is in progress.. Can't Close the window.
16.	Logger Configuration failed
17.	Logger Configured
18.	Are you sure you want to close the Application and return to Desktop ?
19.	<FLUORO/RAD/COLLIMATOR > Calibration is in Progress
20.	<FLUORO/RAD/COLLIMATOR > Calibration Aborted
21.	Query successful
22.	Dose File is Empty
23.	This Operation has not implemented
24.	Camera Operation Successfully
25.	Camera Operation Failed
26.	Operation Failed Please check Camera Connection
27.	Receiver is not Enabled to STOP

Message ID	Message Text
28.	<FLUORO/RAD/COLLIMATOR > Calibration Completed Successfully
29.	<FLUORO/RAD/COLLIMATOR > Calibration is in Progress <...>
30.	Workstation will shutdown after the Operation. Are you sure to continue..?
31.	Updated Failed
32.	Workstation shall Shutdown after the Operation. Are you sure to continue ?
33.	Airkerma Module Update Failed
34.	Airkerma Module Updated successfully..
35.	Database Migration in progress..
36.	Update to Database failed
37.	Values Updated Successfully
38.	Are you sure, you want to restore Default Settings ?
39.	Unable to apply Default Settings
40.	Unable to Read Configuration settings
41.	Default Settings Applied
42.	Not a valid Port Number
43.	Not a valid AE Title
44.	Local AE details updated successfully
45.	Please select a Remote AE to Delete
46.	Receiver is Enabled
47.	Are you sure you want to close the Settings Window ?
48.	Are you sure, want to Restore default APR table(s) ?
49.	Default APR table restored successfully
50.	Restoring Default APR table failed
51.	Are you sure, want to delete the User Login information?
52.	Sorry, You Can not delete ADMIN account
53.	User Information deleted successfully
54.	User Information Update failed
55.	Only registered Username's can be Updated
56.	Alpha Numeric Characters are accepted"
57.	Valid field shall have Minimum of 4 characters, Maximum of 30 characters
58.	Alphabets are accepted
59.	Password Mismatch
60.	Loading Login User data failed
61.	Correction required in the highlighted field(s)
62.	User Already Exists

Message ID	Message Text
63.	User Information Saved Successfully
64.	Save option can be used to Save a new User only !, Try Using Update option
65.	Not a Valid IP address
66.	Not a Valid Port Number, only numbers allowed
67.	Only alphabets allowed
68.	Please select an WLM Target AE Title
69.	Please select an Mpps Target AE Title
70.	No Patient is Selected for Importing
71.	Camera is Offline, Please wait for Initialization
72.	CAMERA Connection Failed , Restart Application !!
73.	SnapShot Aborted !!
74.	Fluoro Aborted !!
75.	Vascular Fluoro Aborted !!
76.	Pulse Fluoro Aborted !!
77.	LOW mA FAULT
78.	Database is restored from last saved copy since Database is corrupted
79.	Database is restored from last saved copy since Database is not found
80.	Database is restored from last saved copy since Database path is not found
81.	Are you sure, you want to shutdown ?
82.	Are you sure, you want to Re-initialize the Camera ?"
83.	Are you sure, you want to Restart Application ?
84.	Are you sure, you want to Re-Initialize Serial Communication ?
85.	SCAN disabled, Please Check CAN/CAMERA Communication
86.	Unable to update Dose into DB
87.	MASK is set for DSA
88.	MASK is set for Road-Map
89.	DSA is Enabled
90.	DSA is Disabled
91.	Peak is Enabled
92.	Peak is Disabled
93.	Road-Map is Enabled
94.	Road-Map is Disabled
95.	Not enough Space in the Disk. Please take the Backup Soon
96.	Disk is full not able to save Series
97.	Collimator is Disabled in Live Navigation Mode

Message ID	Message Text
98.	DCM file is Saved and Marked as Restricted Image
99.	Delete is in Progress please don't perform any action
100.	Deletion Successful
101.	Delete Aborted
102.	Collimator is Disabled in Live Navigation Mode
103.	DCM/JPEG File not found
104.	Unable to load DCM file
105.	JPEG file already exists, Please enter new name !!
106.	JPEG files can be viewed in 1 Window mode only !
107.	No Image is selected
108.	Error While Printing"
109.	Print Operation Successful
110.	Print Operation Canceled
111.	Print Operation In Progress
112.	File Not Found
113.	Please wait, File Save is in Progress
114.	Please save the file from console
115.	Unable to Parse the DICOM file
116.	Are you sure you want to close ?
117.	DICOM Print is in progress...
118.	Image sent to DICOM printer
119.	Unable to send to DICOM printer
120.	Please select a file for exporting
121.	Can't Export to the selected Drive
122.	Export Successful
123.	Export failed with <windows error message>
124.	DCM File created successfully
125.	Unable to play the video file
126.	Video file doesn't exist in path
127.	Do you want to Exit Shutter Window ?
128.	Collimator Operation Timeout
129.	Unable to Stop Camera
130.	N Create response sent
131.	Sending N Create response failed
132.	N Set response sent

Message ID	Message Text
133.	Sending N Set response failed
134.	Selected Study will be removed from the Live WINDOW
135.	Are you sure, you want to Delete ?
136.	Please select the Image to be Deleted
137.	Please select the row to be Modified
138.	Please select a patient !!
139.	No study is selected for delete
140.	Please select a patient
141.	Are you sure you want to delete?
142.	Patient not Found Please add Patient to Proceed
143.	Please select the Image
144.	Please Select The Remote AE Title
145.	Select one of the Remote AE title available from the list
146.	Echo Failed
147.	Echo Successful
148.	Echo Failed to the selected AE Title. Sending to PACS Aborted
149.	Images Sent Successfully
150.	Sending of 1 image failed out of 1 image
151.	Sending of X images failed out of Y images
152.	Please insert CD/DVD and retry !!
153.	No Images Selected for Burning/Export
154.	Please Insert a Full Formatted Disk! File system is invalid!
155.	Selected files size exceeds Media-disk capacity!
156.	No Disc is present
157.	Please insert an empty disk
158.	Burning/Export Failed
159.	Please Enter From and To Date
160.	The Selected Date is greater than the Current Date
161.	PACS Sending is in Progress...
162.	Preparing
163.	Burning / Export
164.	Finished
165.	Are you sure you want to abort this study ?
166.	The Allowed Maximum mA is <Depends on mA >
167.	Values Added successfully

Message ID	Message Text
168.	Duplicate Sub Procedure not allowed
169.	Sub Procedure can't be empty !
170.	Anatomy can't be empty !
171.	Maximum allowed Age is 110
172.	Please enter all the mandatory fields
173.	Emergency Patient Registered
174.	Image Sending Failed
175.	Unfreeze to Load Image
176.	Are You sure, want to stop DICOM print process?
177.	Virtual Collimation Disabled, Please Check the CAN Communication
178.	Are You sure, want to restore selected Patient?
179.	Selected Patient is restored Successfully
180.	Proceed with Deletion? Deletion shall remove the files permanently
181.	Selected Patient is deleted Successfully
182.	Are you sure, you want to Restore the Default Table
183.	Not enough space in the external drive
184.	Backup Successfully Completed
185.	Are you sure, want to delete the selected Remote AE?
186.	Remote AE deleted successfully
187.	Records are saved in the Database
188.	Receiver is Already Enabled, Cannot Enable again
189.	Receiver is Stopped
190.	Patient has to be atleast 1 year old
191.	Warning! QA Mode – Not for Clinical Use
192.	Are you sure, you want to Stop DVD/Export Burning?
193.	Are you sure you want to stop calibration?
194.	Migration Failed!! Please Restart the Application
195.	QA mode enabled
196.	QA mode disabled
197.	Query dose failed
198.	Emergency string(EPN*) not allowed
199.	Patient will be removed from Live window. Do you wish to continue ?
200.	Database Migration successful. Please Restart the Application
201.	Maximum fail count reached, press ok to continue in Guest session
202.	Default Database copied/created. Select additional option if required from below

Message ID	Message Text
203.	Continue without modification
204.	Continue with Patient Data Recreate from DICOM files (This may take longer time based on the number of files available)
205.	Are you sure, you want want to continue to Print ?
206.	Log File Sent Successfully
207.	File Sending Failed
208.	File Transfer is Cancelled
209.	Image File Sent Successfully
210.	DICOM File Sent Successfully
211.	File Sent Successfully
212.	Updated Successfully in the Database
213.	Request for Setup File Sent Successfully
214.	File ("filename") received Successfully from Server
215.	Server Started successfully
216.	Backup Cancelled on Request
217.	Snapshot Configured Successfully
218.	Snapshot Configuration Failed
219.	Are you sure you want to do a force restart ? The current state of the machine won't be preserved after the restart.
220.	Released Early, Processing Incomplete
221.	Auto DSA is Enabled
222.	Auto DSA is Disabled
223.	Auto RoadMap is Enabled
224.	Auto RoadMap is Disabled
225.	Video Creation already in progress, Try Again later!
226.	User Login Information is restricted in Guest session
227.	External Backup is restricted in Guest session
228.	Unable to Flash
229.	Invalid/Corrupt Flashed Binary on Target
230.	Time out/Unable/No Response from host
231.	Time out/Unable/No Response from target
232.	Secure Key Incorrect
233.	Binary size Invalid
234.	Binary data transfer Invalid
235.	Database migration not supported for database version <...>
236.	LandMark is Enabled

Message ID	Message Text
237.	LandMark is Disabled
238.	Other Activities will be blocked to execute the flash operation. Are you sure you want to Flash the Target?
239.	Please Wait Flashing is in Progress
240.	Please Select the Target
241.	Please Select the bin file
242.	Flashing failed due to target response time out
243.	Identify the Tank type(8Layer/10Layer) before selecting binary file.\n\r Hint: One can see the etching on Tube Head to make sure which tank is being used.
244.	Make sure to remove Hand Switch & Foot Switch connection before Flashing
245.	Flash operation is going on. Are you sure you want to abort the Flash operation and return to Desktop?
246.	Only Alphanumeric allowed
247.	Not a valid input character
248.	Bin file is not matching with selected target.\n\r Please select bin file based on Target selection
249.	Re-establishing camera connection
250.	Invalid Date Format input in (DD-MM-YYYY)
251.	Camera Filter: Disabled
252.	Camera Filter: 2F
253.	Camera Filter: 4F
254.	Camera Filter: 8F
255.	User Preferences Changed application needs to restart
256.	Please wait Collimator operation is in progress...
257.	Maximum Brightness
258.	Minimum Brightness
259.	Maximum Contrast
260.	Minimum Contrast
261.	Trash Bin is restricted in Guest session
262.	Restoring of patient failed
263.	Please Select a Patient to restore
264.	Are you sure you want to Exit calibration ? **Note:** 1) Exiting calibration mode will exit the application to Windows 2) Restart the C-Unit
265.	Brightness/Contrast adjustment not allowed in Vascular Mode

Message ID	Message Text
266.	**Note:** **Collimator Control**: Choose Collimator operation and Scroll the middle mouse button or page up/down keys to move Hard/soft shutter, IRIS, and Rotate
267.	**Note:** 1) **Virtual collimator** : Choose Collimator operation and Scroll the middle mouse button or use page up and page down to move. 2) **Physical collimator** : Press Arrow UP/Down key on key board to move Hard /soft shutter, IRIS, and Rotate
268.	Please wait until Export is complete
269.	Only Numbers allowed
270.	Not a Valid Date
271.	Invalid Date Format input in (MM-DD-YYYY)
272.	Patient Not Found
273.	Default Orientation 0°
274.	Clockwise Rotation 90°
275.	Counter Clockwise Rotation 90°
276.	Image Orientation
277.	Unable to create JPEG file, Please try again
278.	JPEG saved to disk.\n No removable device found, Cannot Export!
279.	Export JPEG failed
280.	Export JPEG Successful

Alert Messages displayed on Live monitor

Message ID	Message Text
1.	Preparing ....
2.	Hand Switch released early, command aborted!!
3.	Foot Switch released early, command aborted!!
4.	Unable to Start Camera Exposure
5.	Press & Hold Hand Switch SnapShot In-Progress"
6.	Brightness/Contrast adjustment not allowed in Vascular Mode
7.	OVER kV FAULT
8.	OVER mA FAULT
9.	CATHODE ARC FAULT
10.	ANODE ARC FAULT
11.	TUBE ARC FAULT
12.	COLLIMATOR MOTOR\n OVER CURRENT FAULT

13.	IMPROPER / INVALID OPERATION OF HAND-SWITCH
14.	FILAMENT LIMIT FAULT/ FILAMENT OVER CURRENT FAULT
15.	kV REGULATION FAULT
16.	IMPROPER / INVALID OPERATION OF FOOT-SWITCH
17.	TUBEHEAD TEMPERATURE WARNING
18.	COLLIMATOR FAULT
19.	TUBEHEAD TEMPERATURE FAULT
20.	TUBEHEAD RESET FAULT
21.	ACTUATOR OVERLOAD
22.	HEAT SINK OVER TEMPERATURE
23.	KEYPAD MALFUNCTION
24.	BREAK IN CAN COMMUNICATION
25.	MEASURABLE PERFORMANCE
26.	MAGNIFICATION KEY SHORT ERROR
27.	FATAL FAULT
28.	Mask is not set\nPlease do Vascular Fluoro
29.	C-UNIT IS OFFLINE\nPlease Wait for C-UNIT to\n Power ON
30.	Restart the C-Unit due to\n Camera Error
31.	CAN communication issue \n Please Check Connection
32.	Please Initiate SCAN \nfor Live Image
33.	Ready for Exposure
34.	Exposure Switch is ON\nCheck Hand/Foot Switch !!\n \nPlease initiate a new SCAN
35.	C-UNIT IS ONLINE\nPlease wait for C-UNIT to\nInitialize
36.	C-Unit Power Trip
37.	Camera port is down
	Please Wait Camera is \n Initializing...

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Annex 2: Emergency Procedure

List of steps to be followed during emergency are as listed below. Copy of the instruction is also tagged to the machine.

In Case Of Exposure Control Failure

Use RADIATION STOP button on the CONSOLE, labelled as 

Once Problem is solved, by depressing this button again, Exposure can be initiated.

Power Failure Emergency Procedure

In case of Power Failure Only to C-Arm and Workstation Connected Backup Supply

1. User Powering UP sequence as mentioned earlier to continue with the procedure. The Workstation will be ready with in 30 sec after C-Arm unit is powered Up.

In case of TOTAL POWER Failure of SYSTEM during the Procedure

1. Use Normal Powering Up Sequence.
2. System indicate acceptance of recovery if required. Give consent for the same.
3. System re establish the data base and bring Login Screen.
4. Continue with further procedure as indicated in rest of Power up Sequence

Camera Link Failure

In case of Communication Failure with Camera

1. Select Status icon on the top bar on Passive Monitor on Right Side using Pointing Device(Mouse)
2. Select Refresh button of Camera sub system. Check the status for success or failure information.
3. In case of Success, Camera sub system status shall be shown as "Connected" and tick mark symbol.
4. In case of Failure, Initiate "Restart Application" from Activities Menu.
5. If Camera Re Initialization Fails, as indicated, a power recycling(restart C Unit) may be necessary.

In case of repeated errors like "Exposure Abort"

The user can refresh the camera connection from the Status Window. In a situation when the issue still persists after a refresh, the user should do a power refresh of the C side followed by an application restart.

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Annex 3: Significant Zone of Occupancy

Procedures like Urology, Spine and GI Diagnostics, may introduce large scattered radiation due to higher body mass in the path of X-ray.

Distribution of Scattered Radiation in the Significant Zone of Occupancy

Exposure Condition: 90kV to 110kV / 200W Average

Distance Source to Phantom: 45 cm

Phantom: PMMA 25cm x 25cm x 30 cm, Equivalent to Large Patient

NOTE

Graph represent the highest value measured. Values indicated are applicable for both horizontal & vertical directions.

User need to exercise care specially in Urology, Spinal and Chest, Fluoroscopy & Radiography.

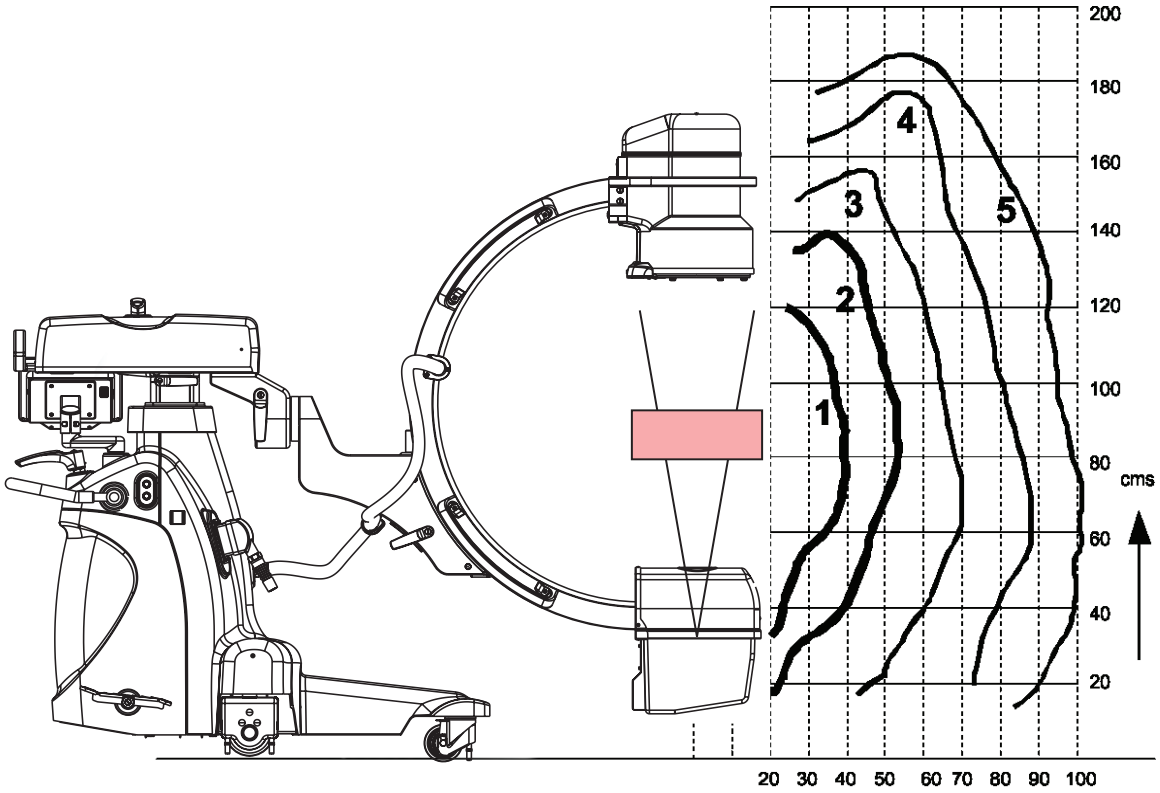

Figure 62: Scattered Radiation

Curve No's	1	2	3	4	5
Dose	< 10mGy/hr	< 5mGy/hr	< 2mGy/hr	< 0.5mGy/hr	< 0.3mGy/hr

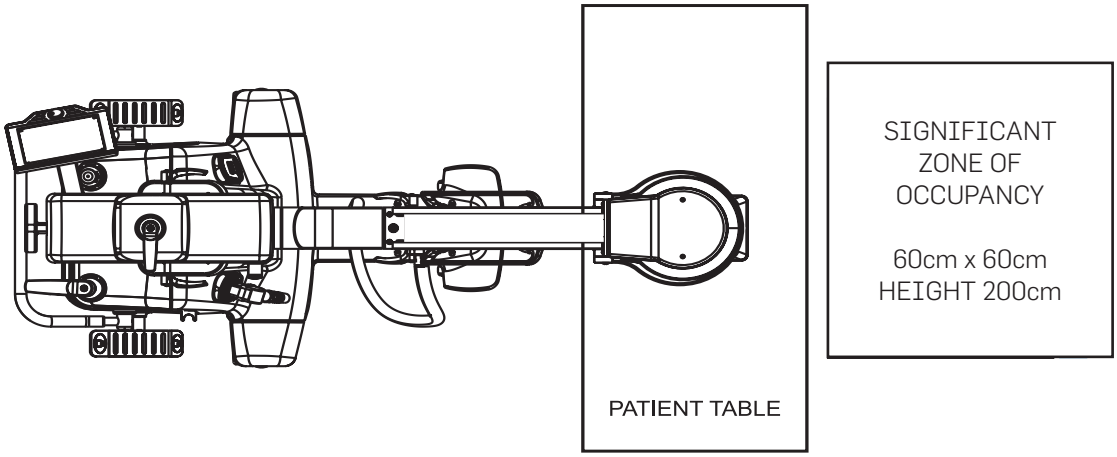

Figure 63: Scattered Radiation

Horizontal Position

Exposure Condition: 90kV to 110kV/ 200W Average

Distance Source to Phantom: 45 cm

Phantom: PMMA 25cm x 25cm x 30 cm - Equivalent to Large patient

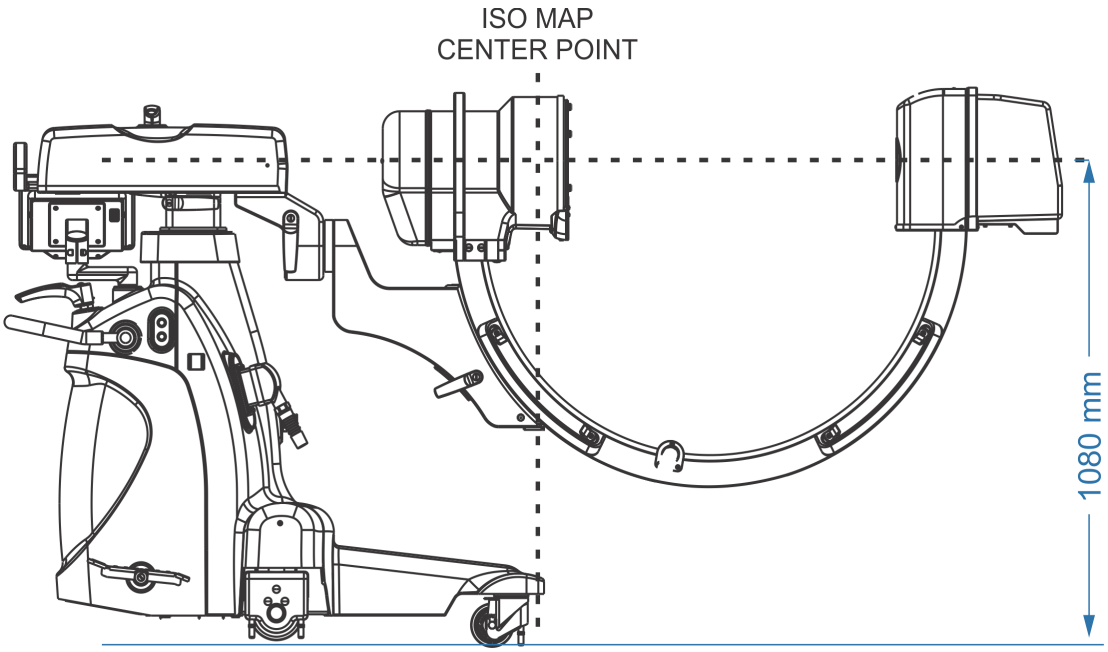

Figure 64: Horizontal Position

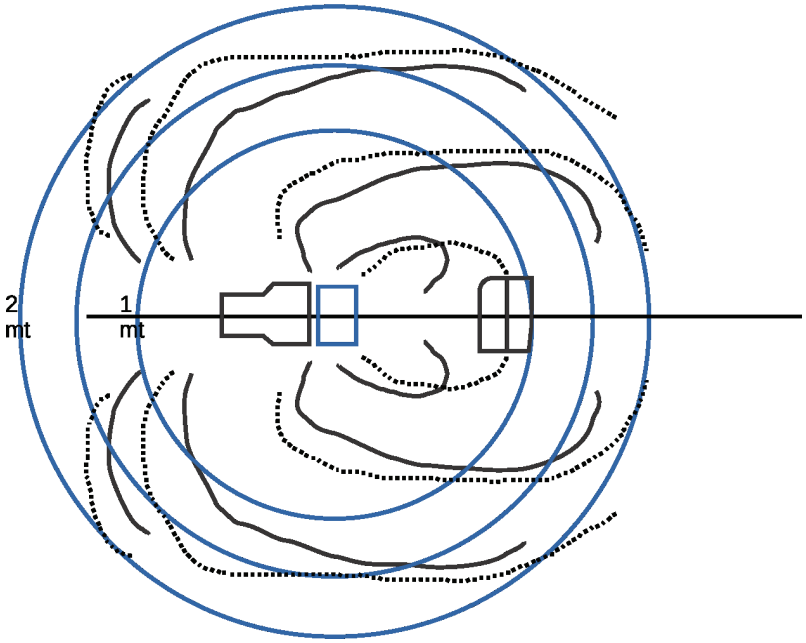

Figure 65: Scattered Radiation

Curve No's	1	2	3	4
Dose	< 10 mGy/hr	< 3 mGy/hr	< 1 mGy/hr	< 0.5 mGy/hr

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Annex 4: Labelling Information

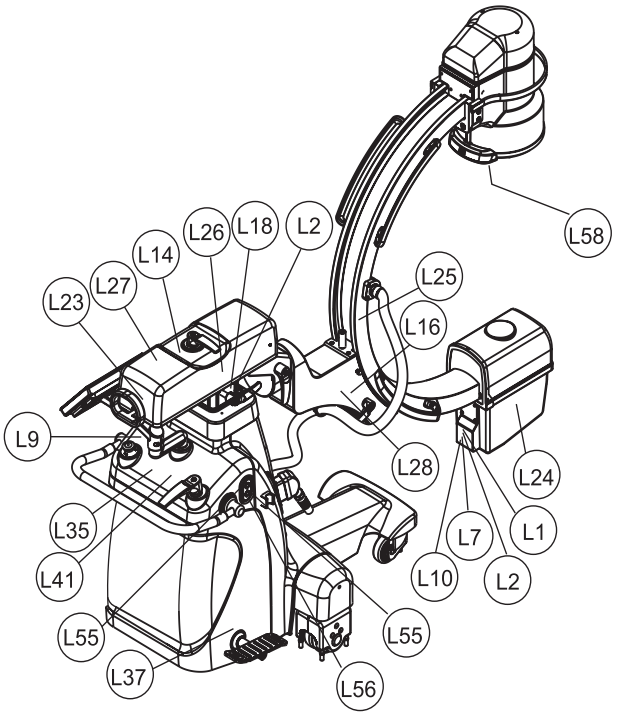

Figure 66: Location 1

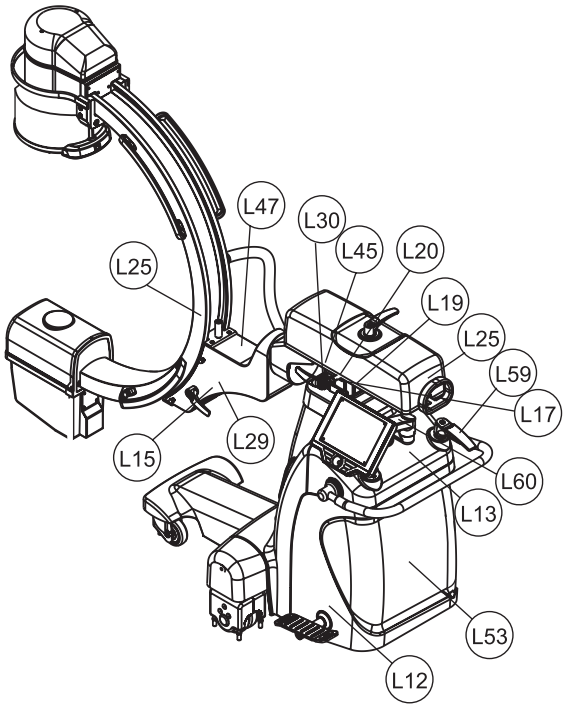

Figure 67: Location 2

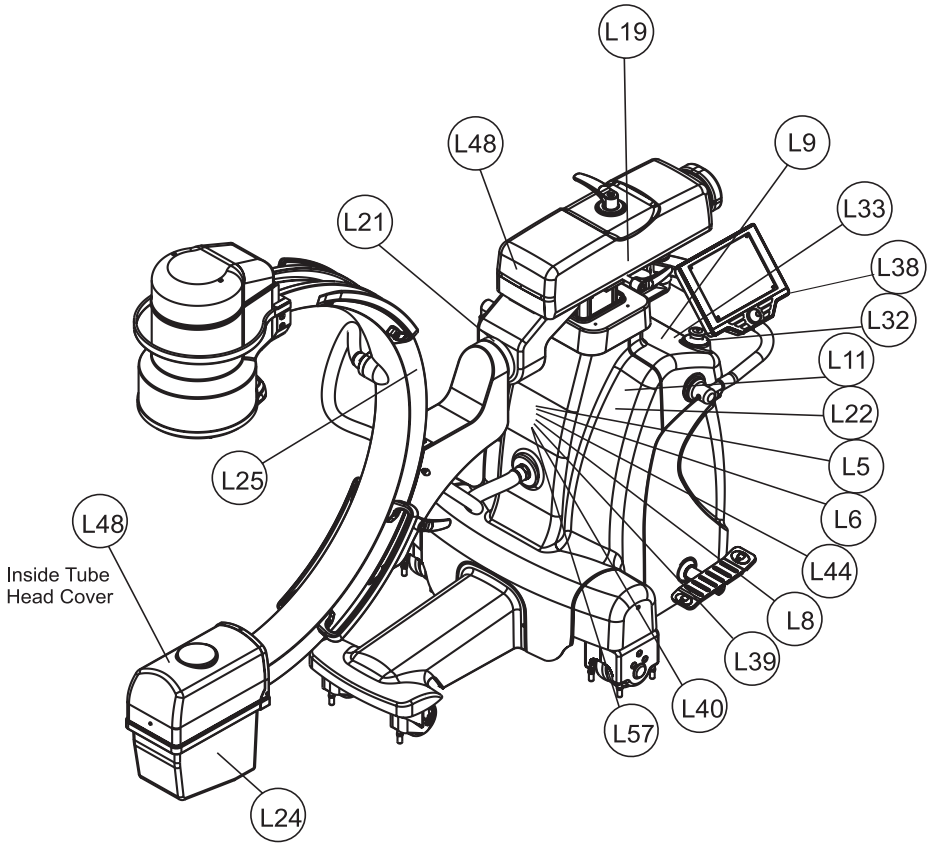

Figure 68: Location 3

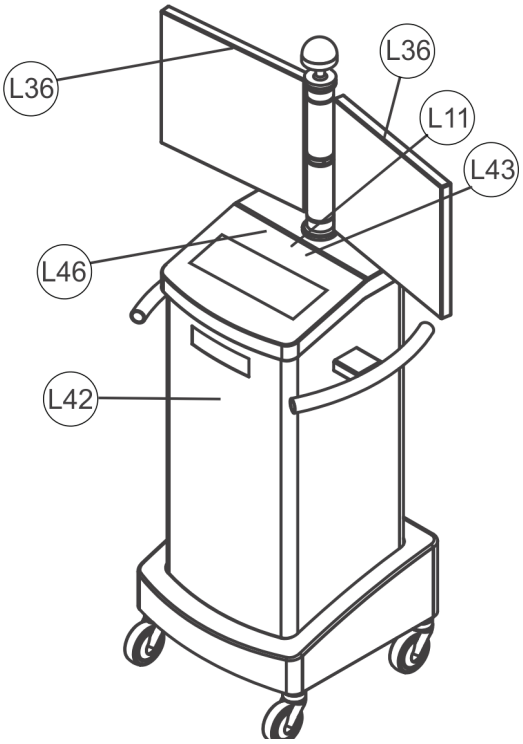

Figure 69: Location 5

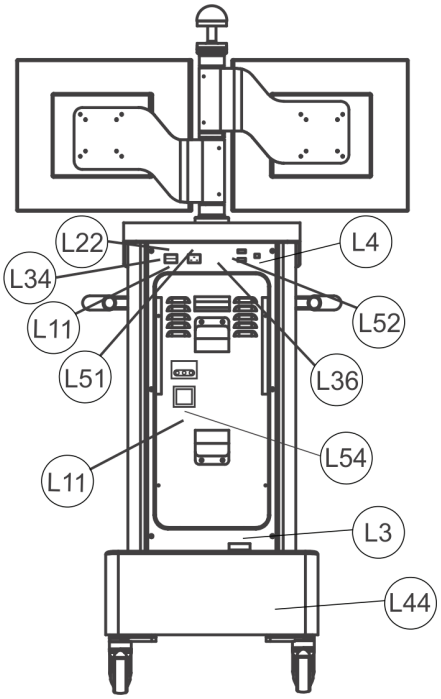

Figure 70: Location 6

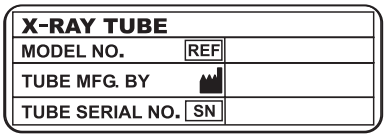

Figure 71: X-Ray Tube Label[L1]

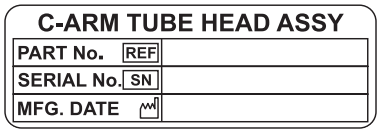

Figure 72: Tube Head Assembly[L2]

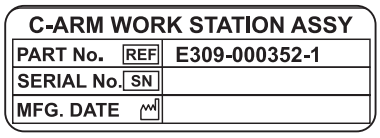

Figure 73: Workstation Label[L3]

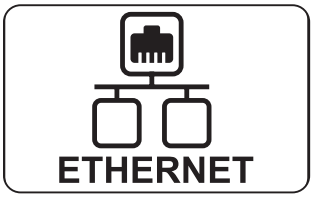

Figure 74: Ethernet Label[L4]

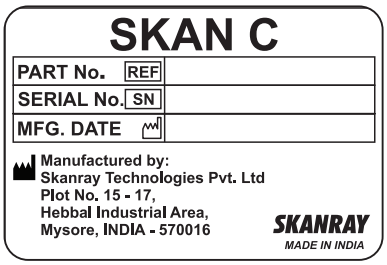

Figure 75: System,Manufacturing location and Business place Label[L5]

Figure 76: AERB Label[L6]

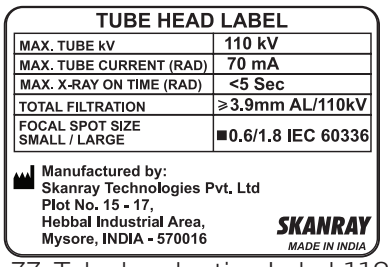

Figure 77: Tube head rating Label 110V[L7]

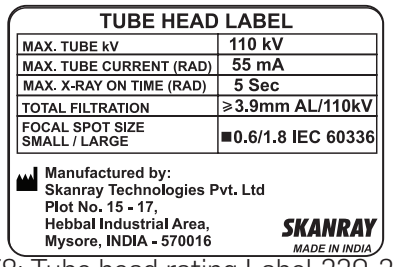

Figure 78: Tube head rating Label 220-240V[L7]

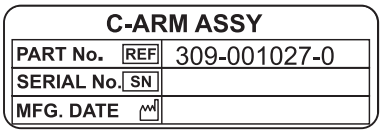

Figure 79: C-ARM Assembly Label [L8]

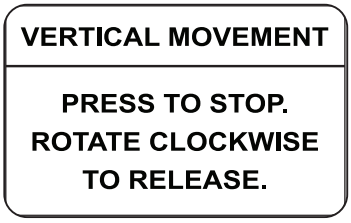

Figure 80: Emergency Switch Label [L9]

Figure 81: Warning Label [L10]

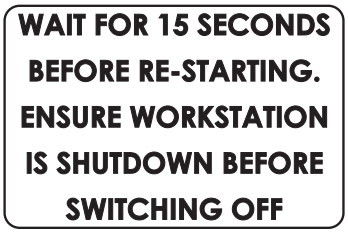

Figure 82: Restart Warning Label [L11]

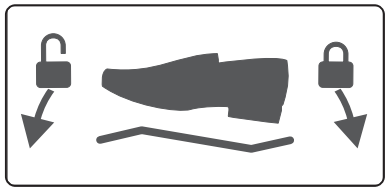

Figure 83: Foot Break Label(L12)

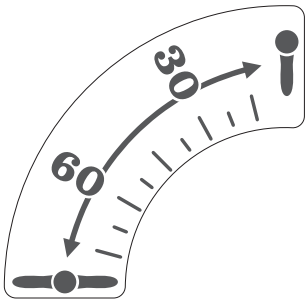

Figure 84: Graduation Label: Steering Handle [L13]

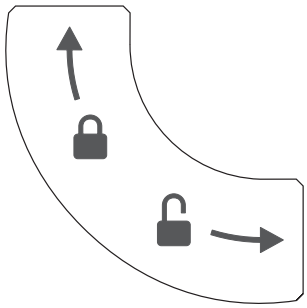

Figure 85: Lock-Unlock symbol: Yoke & Carriage Brake [L14]

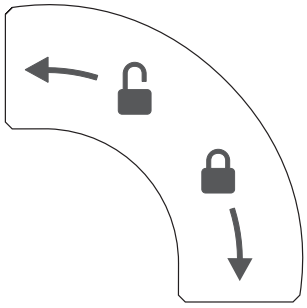

Figure 86: Lock-Unlock symbol: Orbital Brake LH[L15]

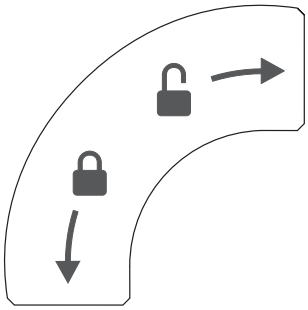

Figure 87: Lock-Unlock symbol: Orbital Brake-RH [L16]

Figure 88: Lock - Unlock Symbol: Wig Wag Brake LH [L17]

Figure 89: Lock - Unlock Symbol: Wig Wag Brake RH [L18]

Figure 90: Carriage Movement [L19]

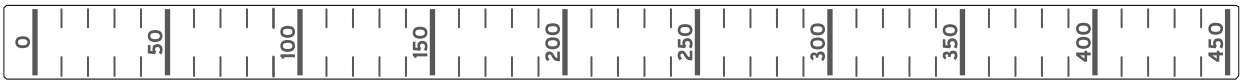

Figure 91: Vertical Movement [L20]

Figure 92: Graduation Label: C Rotation [L21]

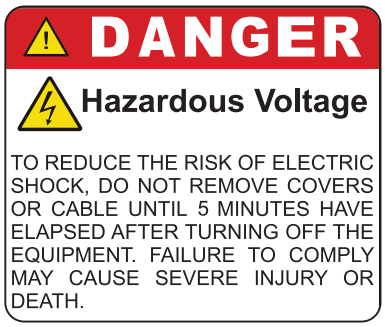

Figure 93: Danger Label [L22]

Figure 94: Warning Label [L23]

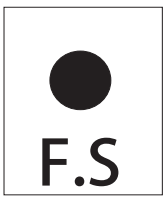

Figure 95: Focal Spot Label [L24]

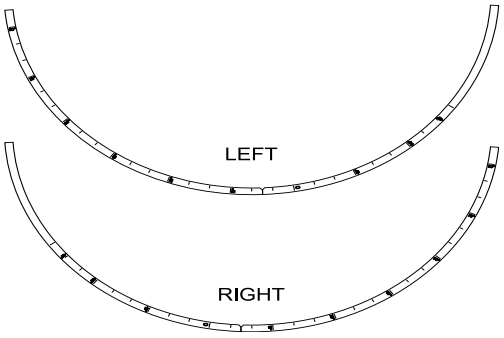

Figure 96: Graduation Label: C-Arm [L25]

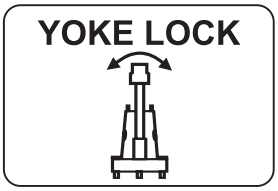

Figure 97: Yoke Label (L26)

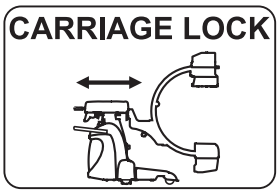

Figure 98: Carriage Label (L27)

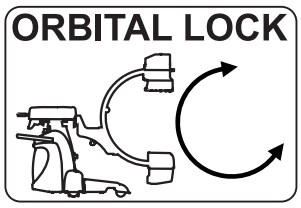

Figure 99: RH Orbital Lock Label (L28)

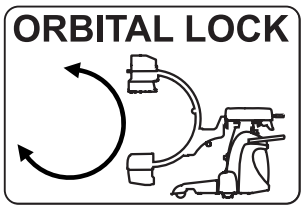

Figure 100: LH Orbital Lock Label (L29)

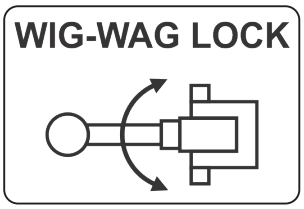

Figure 101: LH Wig Wag Lock Label (L30)

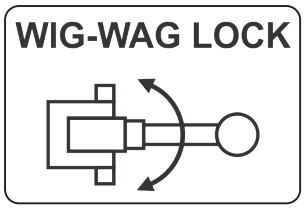

Figure 102: RH Wig Wag Lock Label (L31)

Figure 103: Emergency Stop Label [L32]

Figure 104: Emergency Stop Label [L33]

Figure 105: ON/OFF Label [L34]

Figure 106: Weight Caution Label- C Arm [L35]

Mobile C-Arm	
INPUT VOLTAGE	220-240V ~
INPUT FREQUENCY	50-60 Hz
MOMENTARY CURRENT	30A
LONG TERM CURRENT	16A
MAX MAINS IMPEDENCE	0.2Ω
INGRESS PROTECTION	IP X0-system IP X7-foot switch

Figure 107: Rating Label (220-240VAC) [L36]

Mobile C-Arm	
INPUT VOLTAGE	110V ~
INPUT FREQUENCY	50-60 Hz
MOMENTARY CURRENT	40A
LONG TERM CURRENT	16A
MAX MAINS IMPEDENCE	0.1Ω
INGRESS PROTECTION	IP X0-system IP X7-foot switch

Figure 108: Rating Label (110VAC) [L36]

INPUT VOLTAGE	220-240V ~
INPUT FREQUENCY	50-60 Hz
MOMENTARY CURRENT	30A
LONG TERM CURRENT	16A
MAX MAINS IMPEDENCE	0.2Ω

SKANRAY
Manufactured by:
Skanray Technologies Pvt. Ltd
Plot No. 15 - 17,
Hebbal Industrial Area,
Mysore, INDIA - 570016

IS 7620
Part 1
CM/L-6200023781

Figure 109: Rating Label (220-240VAC) [L36] (Optional)

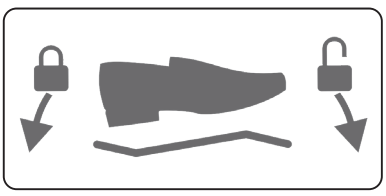

Figure 110: Foot Brake -RH [L37]

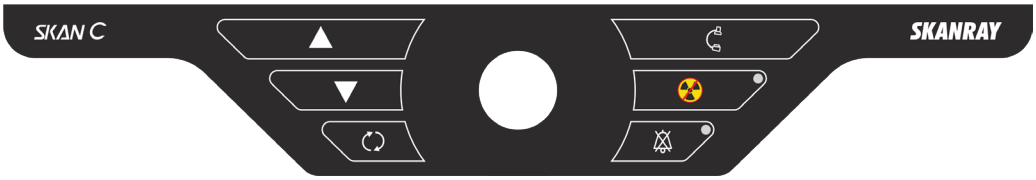

Figure 111: Console Keypad Sticker [L38]

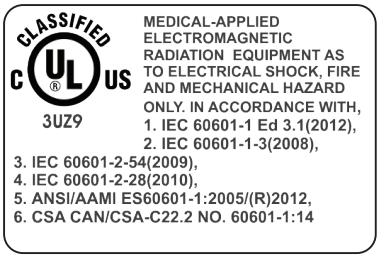

Figure 112: UL Label (Optional) [L39]

Figure 113: CE Label (Optional) [L40]

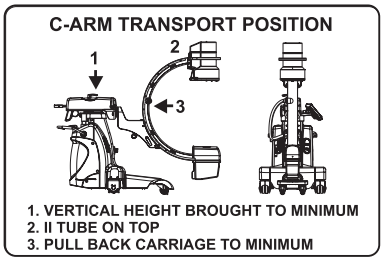

Figure 114: C-Arm Transport Position[L41]

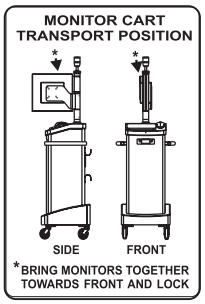

Figure 115: Monitor Cart Transport Position [L42]

Figure 116: Weight caution label Workstation[L43]

Figure 117: Customer Support Label [L44]

Figure 118: Pointer Label [L45]

Figure 119: Warning Label [L46]

Figure 120: Trapping zone Label [L47]

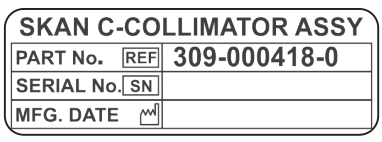

Figure 121: Collimator Assy[L48]

Figure 122: Disinfection Attention Label [L49]

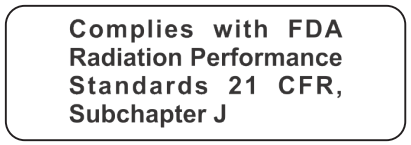

Figure 123: FDA Compliance Label [L50]
(for 110V Variant)

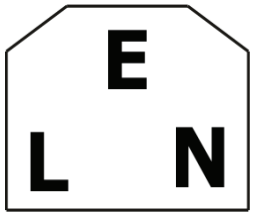

Figure 124: Input Connector Label [L51]

Figure 125: USB Label [L52]

Figure 126: Foot switch holder Label [L53]

Figure 127: ON/OFF Label [L54]

Figure 128: Hand switch Label [L55]

Figure 129: Foot switch Label [L56]

Figure 130: UDI Label [L57]

Figure 131: No Sitting Label [L58]

Figure 132: Do not lift steering handle [L59]

Figure 133: Do not lift console [L60]

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Annex 5: Guidance and Regulatory Information

According to: IEC 60601-1-2: 2014(4th Edition) Skan C is classified as Group 1, Class A for use in Hospital. However it is not a Life Supporting Device

Skan C is tested as per applicable IEC standards, to be used under electromagnetic environment specified below.

Table 1: Guidance and manufacturer's declaration – electromagnetic emissions – for all equipment and systems

Emissions test	Compliance	Electromagnetic environment – guidance
Radiated emissions CISPR 11:2010	Group 1, Class A	Skan C 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.
Conducted emission CISPR 11:2010	Group 1, Class A	Skan C is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2:2009	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3:2013	Complies	

Table 2: guidance and manufacturer's declaration – electromagnetic immunity – for all equipment and sysTEMS

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2:2008	± 8 kV contact-Direct ± 8 kV contact-Indirect ± (2, 4, 8, 15) kV air	± 8 kV contact-Direct ± 8 kV contact-Indirect ± (2, 4, 8, 15) kV air	Floors should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4: 2012	± 2 kV for power supply lines (100kHz repetition frequency). ± 1 kV for Signal lines (100kHz repetition frequency).	± 2 kV for power supply lines (100kHz repetition frequency). ± 1 kV for Signal lines (100kHz repetition frequency).	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5: 2005	± 0.5 kV Differential & Common mode ± 1 kV Differential & Common mode ± 2 kV Common mode	± 0.5 kV Differential & Common mode ± 1 kV Differential & Common mode ± 2 kV Common mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11: 2004	For voltage dips: 0 % UT ; 0,5 cycle at 0° , 45°, 90° ,135°, 180°, 225°, 270° & 315° 0 % UT ; 1 cycle & 70 % UT ; 25/30 cycles single phase at 0° For Voltage interruptions: 0% UT ; 250/300 cycles	For voltage dips: 0 % UT ; 0,5 cycle at 0° , 45°, 90° ,135°, 180°, 225°, 270° & 315° 0 % UT ; 1 cycle & 70 % UT ; 25/30 cycles single phase at 0° For Voltage interruptions: 0% UT ; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Skan C requires continued operation during power mains interruptions, it is recommended that the Skan C be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8: 2009	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3: guidance and manufacturer's declaration – electromagnetic immunity – for all equipment and systems that are not life-supporting

Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6: 2013	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150kHz and 80 MHz 80% AM at 1kHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150kHz and 80 MHz 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Skan C, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Radiated RF IEC 61000-4-3: 2010	3 V/m 80 MHz to 2.7 GHz 9 V/m, 27V/m, 28 V/m Enclosure port immunity to RF wireless communications equipment	3 V/m 80 MHz to 2.7 GHz 9 V/m, 27V/m, 28 V/m Enclosure port immunity to RF wireless communications equipment	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a) should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol b): 

Note 1: At 80 MHz and 800 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 Skan C is used exceeds the applicable RF compliance level above, the Skan C should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Skan C.

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

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Annex 6: Technical Information

X-ray Tube / Tube Head Specifications	
X-ray Tube Type	Fixed Anode
Nominal Focal Spot Value	0.6/1.8 as per IEC60336
Target Angle	15°
Nominal X-ray tube Voltage	120kV
Maximum Anode heat Content	56 kHU
Maximum Housing heat content	1150 kHU
Inherent Filtration	0.5 mm Al Equivalent
Added filter	2 mm Al
Total Filtration	> 2.5 mm Al Equivalent
Removal filter	0.1mm copper in case of paediatric
Image intensifier field size	230mm dia. Nominal, programmable to 160 & 120mm

X-ray Generator Specifications	
Generator Type	HF Generator – Processor Controlled
Maximum X-ray Generator output in large Focus	3.5kW (220-240VAC Input) 2.2kW (110VAC Input)
Maximum continuous X-ray Generator output in Small Focus	500W for 10min limited by X-ray tube characteristics 60W continuous limited by Tube Head Temperature
kV Range	40-110kV
Maximum Tube Current (Large Focus)	70mA @50kV,32mA @110kV (220-240V Input) 55mA @40kV,20mA @110kV (110V Input)
Frequency	80 – 250 kHz

Continuous Fluoroscopy (Small Focus)	
kV Range	40-110kV in Steps of 1 kV
mA Range for Normal Fluoroscopy	0.2mA to 3mA
mA range for High-level Fluoroscopy	0.2mA to 8mA
Fluoro timer	Digital totalizer timer for 5 minutes

Pulsed Fluoroscopy (Small Focus)	
kV Range	40-110kV in Steps of 1kV
mA Range for Pulsed Fluoroscopy	0.2mA to 12mA
Pulse rate(PPS)	2,4,6 and 8

Digital Radiography-Snapshot (Small Focus)	
kV Range	40-110kV in Steps of 1 kV
mA Range for Snapshot	0.2mA to 10 mA

Radiography Mode (Large Focus)	
kV Range	40-110kV in Steps of 5 kV
mA Range	10-70mA (220-240VAC Input) 10-55mA (110VAC Input)
mAs range	0.5mAs-240mAs (220-240VAC Input) 0.5mAs-200mAs (110VAC Input)
Radiographic X-ray Power	3.5kW for 100 mS (220-240VAC Input) 2.2kW for 100 mS (110VAC Input)

Accuracy of Loading factors	
Accuracy of kVp	±5%
Accuracy of mA	±(5%+0.02mA) for mA ≤ 0.5mA and ±5% for mA>0.5mA
Accuracy of mAs	±(5%+0.2 mAs) for mAs ≤ 1mAs and ±5% for mAs>1mAs
Ripple factor of kV	≤ 4%

Input Power Specifications	
Input Voltage Range	220-240VAC RMS, 50-60Hz Single Phase / 110VAC RMS, 50-60Hz, single phase
Maximum mains impedance	0.2 Ohm for 220-240VAC 0.1 Ohm for 110VAC
Input Current maximum	Long term current - 16A Momentary current – 30A(220-240VAC Input) Momentary current – 40A(110VAC Input)
Input protection	MCB, 25A
Impedance	Earth pin in the appliance inlet and any part that is protectively earthed shall not exceed 100mΩ
Earth leakage	2.5 mA in normal condition and 5 mA in single fault conditions.
Electrical classification	Class I ME Equipment
Medical Device Directive Classification	Class II B ME Equipment
Mode of Operation	Continuous: Fluoroscopy, Intermittent: Radiography

Collimator Unit Specifications	
Collimation Type	Circular Iris Collimator
Hard Shutter & Soft Shutter	Available, Electrically operated from Full Open to Close
Collimator Blade Rotation	0-360° in configurable steps
Total Filtration	>2.5 mm Al Equivalent

Mechanical Specifications	
Overall Width	850mm Max.[Wheel aligned to 90°] & 800 mm Max [wheel aligned to 0°]
Overall Length	2700 +200 mm Max.
Overall Height	1800+400 mm Max.
Source to image distance	970 ±20 mm
Immersion Depth	680 mm Max
Clear space (free space)	770 ± 10 mm
Vertical Travel	450 mm Max.
Horizontal Travel	200 mm Max.
Orbital Motion	-40° to +90° Max.
Angulation (C- Rotation)	±180° Min.
Wig-Wag Motion (Swivel range)	±12.5° @ Min.
Steering	Rear wheels

X-ray MODES	
Snap Shot Digital Exposure Mode	For Radiographic quality Fluoro application
Film Mode	For Film Application
Low Dose Fluoroscopic Mode	For reduced dose application
High Dose Fluoroscopic Mode	For high definition diagnostic images
Reduced Pulsed Fluoroscopic Modes	2,4,6 and 8 PPS
Vascular Fluoroscopy Mode	Reduced dose and contrast media with reusable mask Peak Opacification / subtracted image of vasculature. Road Map imaging techniques

Image Processing Features	
Last Image Hold	Hold the last image on the screen after every procedure during Fluoroscopy
Random Noise Filtration	White Noise compression
Virtual Collimation	Alignment and adjustment of X-ray field with image available on the monitor
Edge Enhancement	Edge Enhancement for clearer and enhanced edge of the selected image
Edge Detection	Edge detection for detecting the edges of the selected image
Annotation	User interface for overlaying the required text or symbols on the image
Noise Integration/reduction	Adoptive Temporal Recursive filter for both Live and static images
Measurements	Tool to measure length and angle of image under study
ZOOM and PAN	ZOOM and PAN facility on the selected images during pre and post processing
Invert Function	Inverting tool to invert the image under study
Image Math Processing	Image subtraction and/or addition used during the vascular and road map procedures.
DICOM	Image processing supports DICOM format
Image Save/Backup	Image backup in DICOMDIR format on CD/DVD
Image FLIP – Horizontal and Vertical	Mirror-reversal of image in horizontal or vertical direction during or post processing procedures

Workstation Specification	
Monitors	Active and Passive monitors: LCD 1280x1024 Adjustable viewing angles: ±45º
Image Capture Resolution & Frame-rate	1024 X 1024 at maximum frame-rate 30 per sec
Acquired Image Processing Resolution	8 -14 bit
User Interface	Keyboard for alphanumeric and special functions a pointing device
Peripheral Interface	Printer Interface, DVD Drive & additional display port like HDMI and optional composite video.
Workstation Mobility	Swivel casters with caster lock feature
X-ray Status Indication	Overhead Lamp
C-arm Vertical Height Adjustment	Motorized vertical control mechanism using console

Console Specifications	
Console Display	10.4 inch, 800 x 600 TFT-LCD, Anti-glare color display with resistive touch screen
Number of Key Functions	More than 40 functions with menu driven
Pixel Pitch	0.264 x 0.264 with 16.2M (RGB 8-bits)

Console Functions	
C-Arm UP/Down motion	Vertical motion control up to 450mm
Hard Shutter	Hard Collimation from Full open to 100% close
Soft Shutter	Soft Collimation from Full open to 80% close
Collimator blade rotation	Blade Rotation 360°
IRIS control	Adjustable 9 sizes perfect circular collimation
kV setting	Increase/Decrease functions at 1kV step
mAs /mA setting	Increase/Decrease function at 0.1mA in Fluoroscopic and fixed steps in Rad mAs
Auto kV/mA (Auto Technique)	Enabling and Disabling Exposure Control Parameters for Optimized Image Quality
Radiography	Radiography Mode Selection
Fluoroscopy	Continuous Fluoroscopy Mode Selection
Vascular	Vascular Fluoroscopy Mode Selection
Pulsed Fluoroscopy	Pulsed Mode Selection for 2,4,6 and 8 Pulses/Sec
Mask	Instant Mask Capture for Vascular Procedure
Digital subtraction angiography	Enable/Disable Digital Subtraction Function for DSA procedure
Peak Plotting	Enable/Disable Peak Opacification Procedure
Road map	Enable/Disable Road Map function
Pixel shift	Enable/Disable Pixel shift function
Land mark	Enable/Disable Land mark function
Normal Fluoro	Selects Normal Fluoro in Continuous Fluoroscopy Mode
Burst Fluoro	Selects Burst Fluoro in Continuous Fluoroscopy Mode
Enhanced Fluoro	Selects Enhanced Fluoro in Continuous Fluoroscopy Mode
Image rotation – Clockwise / Anticlockwise	Image Rotation at selected/Configured angle of Live image
Image Flip -Vertical / Horizontal	Image Flip on Live monitor
Image Swap	Exchange current Live and Passive monitor functions
Image Save	Image Save function of Live Monitor

Brightness control – Increase / Decrease	Brightness Increase and Decrease function of Live monitor
Auto B/C	Auto Control Function of Brightness/Contrast Levels on Live Monitor
Magnification	Image Magnification functional selection for Normal(9") and Magnified area of 6" and 4.5" of captured image
Edge Enhancement Filter	Edge Enhancement Filter of LIH on Live Monitor
Image Enhancement Filter	Image Enhancement Filter of LIH on Live Monitor
Filters	Change Filters from 2F/4F/8F to reduce noise in images
Exposure control	Shall inhibit exposure in-case of emergency
Reset	Resets, Rotation, Flip, Inverse to default levels on Live monitor
Alarm Silence	Audible Alarm Silence Function
Laser	Turns ON/OFF Laser Guide from Detector side

Safety	
Over Voltage Protection	Hardware limit 120kVp±5% Software limit set value +10%
Over mA protection	13mA±5% for small focus 80mA±5% for large focus
Shielding and leakage radiation	≤1mGy (115mR) in 1 hr at a distance ≥ 1m for 110kV ,3.2mAs protocol(220-240VAC) and 110kV, 2mAs protocol(110VAC)
Short circuit – Fire Prevention	Suitable MCB to isolate mains power

Environmental Specifications	
Operating Temperature	10 °C to 40 °C
Storage and transport temperature	-10 °C to +55 °C
Operating Humidity Range	20% to 80% Non-Condensing
Storage & Transport Humidity Range	20% to 65 % Non-Condensing
Protection Class – User Console System	IPX0
Protection Class – X-ray Source & Detector	IPX0
Protection Class – Foot Switch	IPX7

Annex 7: Measurement Basis for Technique Factors

kVp	The peak value of Tube Voltage measured after the instant once mA is settled.
mA	Average value of Tube Current after the instant once mA is settled.
mAs	The Time integral of mA over the duration for which Tube Voltage is greater than 75 % of its peak value.

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Annex 8: Storing

Temporary Storage (Less than 60 days)

1. To prepare the C-Arm for storage, bring the system to the transport position.
2. Cover the C-Arm with a dust cover. Refer to the Technical Specifications for the range of environmental conditions in which the C-Arm can be safely stored.

Long Term Storage (More than 60 days) or Shipment Preparation

To prepare the C-Arm for long term storage or shipment, observe the following recommendations,

1. Move all mechanical assemblies into their most compact positions except intensifier parked on the Yoke, set all locks and brakes and remove all power.
2. Wrap the image intensifier, X-ray tube assembly, high voltage cable, and the control panel housing with bubble wrap.
3. Cover the C-Arm and Accessories (Cone & power cord). Attach each to a solid supportive shipping base and enclose in a protective container adequate for shipment or storage. For the range of environmental conditions in which the C-Arm can be safely stored.

Unpacking

The materials used to pack Skan C Mobile C-ARM X-Ray System are recyclable. They must be collected and processed in accordance with the regulations in force for the country where the machines or Accessories (Cone & power cord) are unpacked.

Disposal Of The Unit

1. Do not dispose this unit as general waste. It contains elements that could be toxic.
2. Do not attempt to dispose this unit as scrap.
3. Do not open the unit. The unit can be refurbished only by a SKANRAY qualified technician.
4. Local governments would have rules and regulations on waste disposal of electronic goods. Please follow the local guidelines.
5. Your distributor could also buy back the unit to be disposed off.
6. Contact the factory for shipping.

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Annex 9: X-ray Tube Information

Tube characteristics – small focal spot 0.6mm

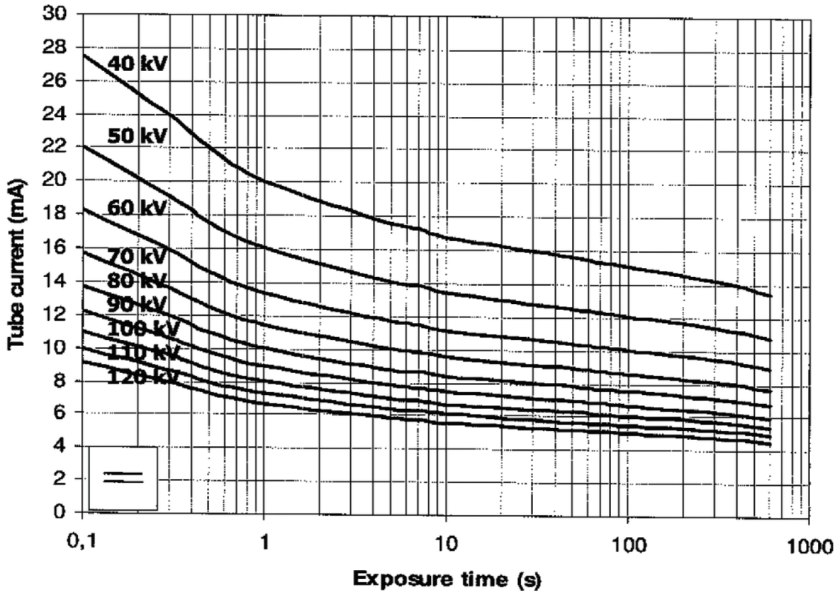

Figure 134: Tube characteristics – Small focal spot 0.6mm

Tube characteristics –Large focal spot 1.8mm

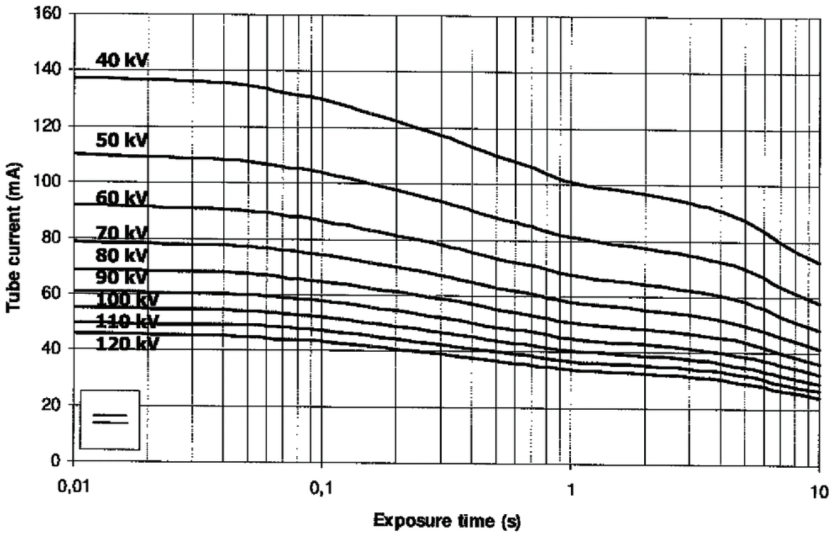

Figure 135: Tube characteristics –Large focal spot 1.8mm

Thermal Curves

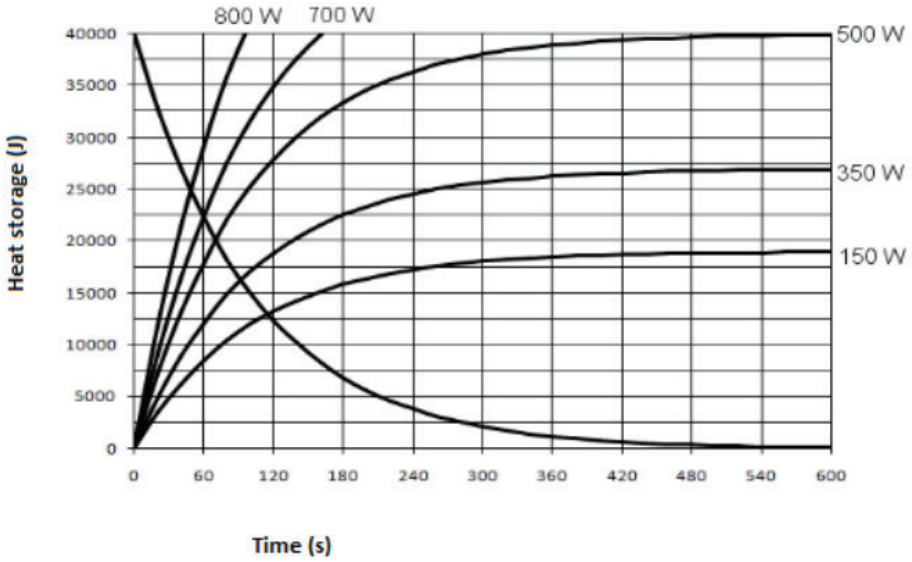

Figure 136: Thermal Curves

X-Ray Tube Dimension

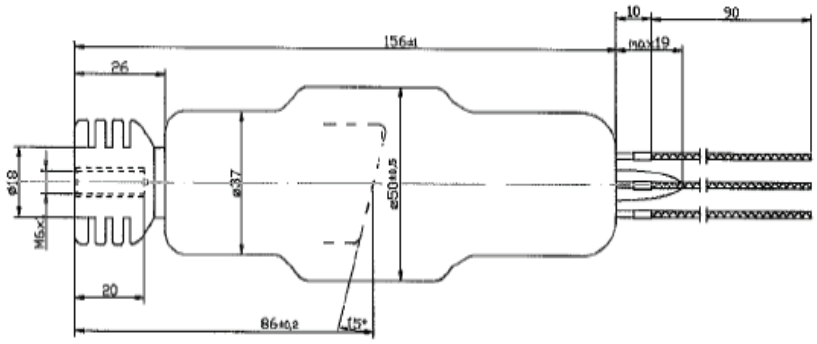

Figure 137: X-Ray Tube Dimension

Annex 10: Powering ON/OFF – A Short Note

1. Ensure Monitor Cart Interface cable, Foot Switch and Hand Switch are connected.
2. Power ON the system, switch is provided on the back side of workstation.
3. System will undergo self check and you will see LOG IN screen. Use Mouse and Keyboard for desired operation.
4. If there are any errors during the self check, it will be displayed on the Passive Monitor. User is recommended to resolve the error and restart again for the normal Usage.
5. Select existing patient OR Create a New Patient OR create Emergency patient.
6. Select Add Patient displayed at the right side of the Passive Monitor pops up the Procedure Selection Window to select Patient Anatomy and exposure parameters.
7. Select Exposure MODE and Technique Parameters and other details as required and select Scan button at bottom of the Procedure Selection Window.
8. Use Foot Switches either HIGH or NORMAL fluoroscope or Hand-Switch for Snapshot or RAD Exposure.
9. If required, Technique Parameters can be changed using C-Arm Console.
10. For Fluoroscope, images are displayed on the Live monitor, for Radiography, exposure is made on the FILM placed.

NOTE

Please note if the RADIOGRAPHY mode is misused on purpose by the OPERATOR for real-time imaging, there shall be no image display on the Live monitor.

Normal Shutdown:

1. Initiate shutdown procedure from Workstation. Wait until Workstation Monitors are switched OFF.
2. Initiate Switch OFF of Power Switch Provided at the rear side of workstation to power OFF C-Arm unit.

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Annex 11: APR Table – Radiography

	Thin		Dose Rate	Normal		Dose Rate	Thick		Dose Rate
	Adult/ Paediatric			Adult M/F			Adult M/F		
Body Part	**kV**	**mAs**	**mGy/min**	**kV**	**mAs**	**mGy/min**	**kV**	**mAs**	**mGy/min**
PA Hand	50	1.25	4.74	60	2	11.28	70	4	29.93
PA Wrist	50	1.25	4.74	60	2	11.28	60	4	22.57
AP Forearm	40	1.25	3.02	50	2	7.59	60	4	22.57
AP Elbow	40	1.25	3.02	50	2	7.59	60	4	22.57
AP shoulder	60	6.25	35.28	70	10	74.84	80	16	168.8
AP Clavicle	50	1.25	4.74	60	2	11.28	70	4	29.93
PA Chest	90	3.2	39.29	110	5	83.82	110	10	167.64
AP Abdomen	70	12.5	93.55	80	20	211.008	90	25	306.99
AP pelvis	70	16	119.97	80	12.5	131.88	90	25	306.99
AP Femur	70	8	59.87	80	12.5	131.88	90	20	245.59
AP Knee	70	2.5	18.711	80	6.25	65.94	90	10	122.796
AP Ankle	50	2	7.59	60	4	22.57	70	8	59.87
AP Foot	50	1	3.79	60	2	11.28	70	4	29.93

NOTE

The above values are for indicative purpose. However, it is the responsibility of the user to select approximate values depending on the patient condition.

Also the above values needs to be changed based on change in camera settings like Brightness, Contrast & Gain etc..

NOTE

Body mass index	Weight classification	Popular description
<18.5	Underweight	Thin
18.5 – 24.9	Medium	Normal
25 – 29.9	Overweight	Thick
30 and above	Obese	Thick

CAUTION

For Paediatric patients it is recommended to use the detachable copper filter provided along with the unit. Refer Section "Detachable Copper Filter (Optional)".

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Annex 12: kV & mA Relation in Fluoroscope

Procedure		NORMAL						THICK						THIN						
		AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	Enhanced Fluoro Mode
Pain Management	Gasserian ganglion Block	65	2	12.33	70	3	17.3	70	3	17.3	75	3	24.05	70	2	13.84	70	3	17.3	Check
	Sphenopalatine Block	65	2	12.33	70	3	17.3	70	3	17.3	75	3	24.05	60	2	7.74	65	2	12.33	Check
	Stellate Block	65	3	15.41	70	3	20.76	70	3	17.3	75	4	28.06	60	2	10.32	65	3	15.41	Check
	Splanchnic Block	80	4	37.5	90	5	60.8	85	5	50.4	90	5	60.8	75	3	24.05	80	4	32.86	Check
	Celiac Plexus Block	80	4	37.5	90	5	60.8	85	5	50.4	90	5	60.8	75	3	24.05	80	4	32.86	Check
	Superior Hypogastric Block	80	4	37.5	90	5	60.8	85	5	50.4	90	5	60.8	75	3	24.05	80	4	32.86	Check
	Ganglion Impar Block	75	4	28.06	85	5	50.44	80	4	37.5	85	5	50.4	70	3	17.3	75	3	24.05	Check
	Cervical Facet Block	65	2	12.33	70	3	17.3	70	3	17.3	75	3	24.05	60	1	5.16	65	2	9.24	Check
	Lumbar Facet Block	80	4	37.5	90	5	60.8	85	5	50.4	90	5	60.8	75	3	24.05	80	4	32.86	Check
	SI Joint Injection	80	3	23.4	85	3	33.62	85	3	33.62	90	4	42.56	75	2	16.03	80	3	23.47	Check
	Transforaminal Epiolenal	80	4	37.5	85	5	50.44	85	5	50.4	90	5	60.8	75	3	24.05	80	4	32.86	Check
	Caudal Epidural	80	4	37.5	85	5	50.44	85	5	50.4	90	5	60.8	75	3	24.05	80	4	32.86	Check
	Lumbar Sympathetic Block	80	4	37.5	90	5	60.8	85	5	50.4	90	5	60.8	75	3	24.05	80	4	37.5	Check
	Knee Genicular Branch Block	60	3	12.9	63	3	16.26	65	3	18.49	70	4	24.2	55	2	6.26	60	3	12.9	Check
	Cervical Epidenal Injection	65	3	15.41	70	3	20.76	70	3	20.7	75	4	28.06	60	2	7.74	65	3	15.41	Check
	Line Placement	90	4	48.64	95	5	58.48	95	5	58.4	100	5	69.9	85	3	33.62	90	4	42.56	Check
	Transjugular Biopsies	90	4	48.64	95	5	58.48	95	5	58.4	100	5	69.9	85	3	33.62	90	4	42.56	Check
	TIPS Stent	90	4	48.64	95	5	58.48	95	5	58.4	100	5	69.9	85	3	33.62	90	4	42.56	Check

Procedure		NORMAL						THICK						THIN						
		AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	Enhanced Fluoro Mode
Gastro Intestinal	Barium Swallow	70	1	5.53	70	1	6.92	67	1	6.35	70	1	8.99	60	1	4.12	65	1	6.16	Uncheck
	Small Bowel Enema	75	1	8.01	80	2	14.08	80	2	16.89	85	2	16.81	60	1	5.16	65	2	9.24	Uncheck
	Upper - GI	75	2	12.02	75	2	12.02	75	2	16.03	75	2	16.03	70	1	6.92	70	1	6.92	Uncheck
	Selenography	70	1	8.3	70	2	10.38	75	1	9.62	75	2	12.02	65	1	6.16	65	1	6.16	Uncheck
	ERCP	70	4	27.68	75	5	36.08	80	5	42.24	80	5	46.94	65	3	18.49	70	3	20.76	Uncheck
	Dilation	70	4	27.68	75	5	36.08	75	5	40.9	80	5	46.94	80	5	46.94	70	4	27.68	Uncheck
	FREKA	70	4	27.68	75	5	36.08	75	5	36.08	80	5	46.94	65	4	21.58	70	4	27.68	Uncheck

Procedure		NORMAL						THICK						THIN						
		AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	Enhanced Fluoro Mode
Gynaecology	HSG	70	3	17.3	75	3	24.05	80	3	28.16	85	4	44.83	65	2	12.33	70	3	20.76	Uncheck
Neurology	Nephrology Vascular Peripheral	65	1	6.16	65	1	4.93	65	1	6.16	65	1	6.16	60	1	2.58	60	1	5.16	Uncheck

Procedure		NORMAL						THICK						THIN						
		AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	Enhanced Fluoro Mode
Orthopedic	CRIF Tibia	60	1	6.19	62	2	8	62	1	7.46	65	2	9.24	65	1	6.16	58	1	4.9	Check
	CRIF Foot	50	1	3.17	55	1	5.01	52	1	3.96	58	2	7.48	45	1	2.17	50	1	2.85	Check
	CRIF Humerus	55	1	3.76	58	1	4.99	58	1	4.99	60	1	6.19	50	1	1.9	53	1	3.62	Check
	CRIF Forearm	55	1	3.76	58	1	4.99	58	1	4.99	60	1	6.19	50	1	2.53	53	1	3.22	Check
	ORIF Hand	52	1	2.64	55	1	4.17	55	1	4.17	58	1	5.98	50	1	1.9	50	1	2.53	Check
	ORIF Wrist	50	1	1.58	52	1	2.31	53	1	3.22	55	1	3.76	45	0	0.816	50	1	1.58	Check
	Clavicle	70	3	20.76	70	3	20.76	75	4	28.06	75	4	28.06	65	3	15.41	65	3	15.41	Check
	Cervical	70	3	17.3	70	4	24.22	75	3	24.05	75	4	32.07	65	2	12.33	65	3	18.49	Check
	Lumbar	80	4	37.55	90	5	60.8	85	5	50.44	95	6	71.47	75	4	28.06	85	5	50.4	Check
	Thoracic	75	4	28.06	80	5	42.2	80	4	37.5	85	5	50.4	70	3	20.76	75	4	32.07	Check
	Hip Joint	80	4	37.55	90	5	60.8	85	5	50.4	95	6	71.4	75	4	28.06	85	5	50.44	Check
	Long Bone Ortho	65	2	12.33	70	3	17.3	80	4	32.8	85	4	44.83	85	3	33.62	90	4	42.56	Check

Procedure		NORMAL						THICK						THIN						
		AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	AP kV	AP mA	Dose Rate in mGy/ min	LAT kV	LAT mA	Dose Rate in mGy/ min	Enhanced Fluoro Mode
Urology	PCNL	70	4	24.22	70	4	27.68	75	5	36.08	75	5	40.09	65	3	15.41	65	3	18.4	Uncheck
	URSL	65	4	24.66	75	4	32.07	70	5	31.14	80	5	42.24	60	3	15.48	70	4	24.2	Uncheck
	RIRS	70	4	24.22	73	4	28.87	75	4	32.07	80	5	42.24	65	3	18.49	68	4	23.53	Uncheck
	STENTING	70	4	24.22	75	4	32.07	75	4	32.07	80	5	42.24	65	3	18.49	70	3	20.76	Uncheck
	PCN	70	4	24.22	73	4	28.87	75	4	32.07	77	5	37.04	65	3	18.49	68	4	23.53	Uncheck
	RGP	70	4	24.22	73	4	28.87	75	4	32.07	77	5	37.04	68	3	20.17	68	4	23.53	Uncheck

NOTE

1. *NA- Not Applicable*
2. *The above values are for indicative purpose. However, it is the responsibility of the user to select approximate values depending on the patient condition.*

NOTE

Body mass index	Weight classification	Popular description
<18.5	Underweight	Thin
18.5 – 24.9	Medium	Normal
25 – 29.9	Overweight	Thick
30 and above	Obese	Thick

CAUTION

For Paediatric patients it is recommended to use the detachable copper filter provided along with the unit. Refer Section "Detachable Copper Filter (Optional)".

Annex 13: Exposure Time & mA list for selected kV & mAs

Exposure Time & mA list for selected kV & mAs (220-240VAC)

KV	Set kV
mAs	Set mAs
Exp-Time (mSec)	Calculated X-ray ON time for set mAs, in milliseconds
mA	Calculated mA for set mAs

40 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	20	40
4	1.00	20	50
5	1.25	30	41.67
6	1.60	30	53.33
7	2.00	40	50
8	2.50	40	62.5
9	3.20	50	64
10	4.00	50	80
11	5.00	60	83.33
12	6.25	60	104.17
13	8.00	60	133.33
14	10.00	60	166.67
15	12.50	60	208.33
16	16.00	60	266.67
17	20.00	60	333.33
18	25.00	60	416.67
19	32.00	60	533.33
20	40.00	60	666.67
21	50.00	60	833.33
22	62.50	50	1250
23	80.00	50	1600
24	100.00	50	2000
25	125.00	50	2500
26	156.00	50	3120
27	195.00	50	3900
28	240.00	50	4800

50 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	20	40
4	1.00	20	50
5	1.25	30	41.67
6	1.60	30	53.33
7	2.00	40	50
8	2.50	40	62.5
9	3.20	50	64
10	4.00	50	80
11	5.00	60	83.33
12	6.25	60	104.17
13	8.00	70	114.29
14	10.00	60	166.67
15	12.50	60	208.33
16	16.00	60	266.67
17	20.00	60	333.33
18	25.00	50	500
19	32.00	50	640
20	40.00	50	800
21	50.00	50	1000
22	62.50	40	1562.5
23	80.00	40	2000
24	100.00	40	2500
25	125.00	40	3125
26	156.00	40	3900
27	195.00	40	4875

60 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	20	40
4	1.00	20	50
5	1.25	30	41.67
6	1.60	30	53.33
7	2.00	40	50
8	2.50	40	62.5
9	3.20	50	64
10	4.00	50	80
11	5.00	58	86.21
12	6.25	58	107.76
13	8.00	50	160
14	10.00	50	200
15	12.50	50	250
16	16.00	50	320
17	20.00	50	400
18	25.00	50	500
19	32.00	50	640
20	40.00	40	1000
21	50.00	40	1250
22	62.50	40	1562.5
23	80.00	40	2000
24	100.00	40	2500
25	125.00	40	3125

70 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	20	40
4	1.00	20	50
5	1.25	30	41.67
6	1.60	30	53.33
7	2.00	30	66.67
8	2.50	40	62.5
9	3.20	40	80
10	4.00	50	80
11	5.00	50	100
12	6.25	40	156.25
13	8.00	40	200
14	10.00	40	250
15	12.50	40	312.5
16	16.00	40	400
17	20.00	40	500
18	25.00	40	625
19	32.00	30	1066.67
20	40.00	30	1333.33
21	50.00	30	1666.67
22	62.50	30	2083.33
23	80.00	30	2666.67
24	100.00	30	3333.33
25	125.00	30	4166.67

80 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	20	40
4	1.00	20	50
5	1.25	30	41.67
6	1.60	30	53.33
7	2.00	30	66.67
8	2.50	40	62.5
9	3.20	40	80
10	4.00	43	93.02
11	5.00	43	116.28
12	6.25	40	156.25
13	8.00	40	200
14	10.00	40	250
15	12.50	40	312.5
16	16.00	40	400
17	20.00	40	500
18	25.00	40	625
19	32.00	40	800
20	40.00	30	1333.33
21	50.00	30	1666.67
22	62.50	30	2083.33
23	80.00	30	2666.67
24	100.00	30	3333.33

90 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	10	80
4	1.00	20	50
5	1.25	20	62.5
6	1.60	20	80
7	2.00	30	66.67
8	2.50	30	83.33
9	3.20	38	84.21
10	4.00	38	105.26
11	5.00	30	166.67
12	6.25	30	208.33
13	8.00	30	266.67
14	10.00	30	333.33
15	12.50	30	416.67
16	16.00	30	533.33
17	20.00	30	666.67
18	25.00	30	833.33
19	32.00	30	1066.67
20	40.00	30	1333.33
21	50.00	30	1666.67
22	62.50	30	2083.33
23	80.00	30	2666.67
24	100.00	30	3333.33

100 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	10	80
4	1.00	20	50
5	1.25	20	62.5
6	1.60	20	80
7	2.00	30	66.67
8	2.50	30	83.33
9	3.20	35	91.43
10	4.00	35	114.29
11	5.00	30	166.67
12	6.25	30	208.33
13	8.00	30	266.67
14	10.00	30	333.33
15	12.50	30	416.67
16	16.00	30	533.33
17	20.00	30	666.67
18	25.00	30	833.33
19	32.00	25	1280
20	40.00	25	1600
21	50.00	25	2000
22	62.50	25	2500
23	80.00	25	3200
24	100.00	25	4000

110 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	10	80
4	1.00	20	50
5	1.25	20	62.5
6	1.60	20	80
7	2.00	30	66.67
8	2.50	32	78.12
9	3.20	32	100
10	4.00	30	133.33
11	5.00	30	166.67
12	6.25	30	208.33
13	8.00	30	266.67
14	10.00	30	333.33
15	12.50	30	416.67
16	16.00	30	533.33
17	20.00	30	666.67
18	25.00	30	833.33
19	32.00	25	1280
20	40.00	25	1600
21	50.00	25	2000
22	62.50	25	2500
23	80.00	25	3200
24	100.00	25	4000

Exposure Time & mA list for selected kV & mAs (110VAC)

40 kV				50 kV				60 kV			
Sl. no.	mAs	mA	Time (ms)	Sl. no.	mAs	mA	Time (ms)	Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50	1	0.50	10	50	1	0.50	10	50
2	0.62	10	62	2	0.62	10	62	2	0.62	10	62
3	0.80	20	40	3	0.80	20	40	3	0.80	20	40
4	1.00	20	50	4	1.00	20	50	4	1.00	20	50
5	1.25	30	41.67	5	1.25	30	41.67	5	1.25	30	41.67
6	1.60	30	53.33	6	1.60	30	53.33	6	1.60	30	53.33
7	2.00	40	50	7	2.00	40	50	7	2.00	37	54.05
8	2.50	40	62.5	8	2.50	40	62.5	8	2.50	37	67.57
9	3.20	50	64	9	3.20	44	72.73	9	3.20	37	86.49
10	4.00	50	80	10	4.00	44	90.91	10	4.00	37	108.11
11	5.00	55	90.91	11	5.00	44	113.64	11	5.00	35	142.86
12	6.25	55	113.64	12	6.25	40	156.25	12	6.25	35	178.57
13	8.00	50	160	13	8.00	40	200	13	8.00	35	228.57
14	10.00	50	200	14	10.00	40	250	14	10.00	35	285.71
15	12.50	50	250	15	12.50	40	312.5	15	12.50	35	357.14
16	16.00	50	320	16	16.00	40	400	16	16.00	35	457.14
17	20.00	50	400	17	20.00	40	500	17	20.00	35	571.43
18	25.00	50	500	18	25.00	40	625	18	25.00	35	714.29
19	32.00	50	640	19	32.00	40	800	19	32.00	35	914.29
20	40.00	50	800	20	40.00	40	1000	20	40.00	35	1142.86
21	50.00	50	1000	21	50.00	40	1250	21	50.00	35	1428.57
22	62.50	50	1250	22	62.50	40	1562.5	22	62.50	35	1785.71
23	80.00	50	1600	23	80.00	40	2000	23	80.00	35	2285.71
24	100.00	50	2000	24	100.00	40	2500	24	100.00	35	2857.14
25	125.00	50	2500	25	125.00	40	3125	25	125.00	35	3571.43
26	156.00	50	3120	26	156.00	40	3900				
27	200.00	50	4000	27	200.00	40	5000				

70 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	20	40
4	1.00	20	50
5	1.25	30	41.67
6	1.60	30	53.33
7	2.00	30	66.67
8	2.50	30	83.33
9	3.20	32	100
10	4.00	30	133.33
11	5.00	30	166.67
12	6.25	30	208.33
13	8.00	30	266.67
14	10.00	30	333.33
15	12.50	30	416.67
16	16.00	30	533.33
17	20.00	30	666.67
18	25.00	30	833.33
19	32.00	30	1066.67
20	40.00	30	1333.33
21	50.00	30	1666.67
22	62.50	30	2083.33
23	80.00	30	2666.67
24	100.00	30	3333.33
25	125.00	30	4166.67

80 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	20	40
4	1.00	20	50
5	1.25	28	44.64
6	1.60	28	57.14
7	2.00	28	71.43
8	2.50	28	89.29
9	3.20	28	114.29
10	4.00	25	160
11	5.00	25	200
12	6.25	25	250
13	8.00	25	320
14	10.00	25	400
15	12.50	25	500
16	16.00	25	640
17	20.00	25	800
18	25.00	25	1000
19	32.00	25	1280
20	40.00	25	1600
21	50.00	25	2000
22	62.50	25	2500
23	80.00	25	3200
24	100.00	25	4000

90 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	10	80
4	1.00	20	50
5	1.25	20	62.5
6	1.60	20	80
7	2.00	20	100
8	2.50	25	100
9	3.20	25	128
10	4.00	25	160
11	5.00	25	200
12	6.25	25	250
13	8.00	25	320
14	10.00	25	400
15	12.50	25	500
16	16.00	25	640
17	20.00	25	800
18	25.00	25	1000
19	32.00	25	1280
20	40.00	25	1600
21	50.00	25	2000
22	62.50	25	2500
23	80.00	25	3200
24	100.00	25	4000

100 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	10	80
4	1.00	20	50
5	1.25	20	62.5
6	1.60	20	80
7	2.00	20	100
8	2.50	22	113.64
9	3.20	20	160
10	4.00	20	200
11	5.00	20	250
12	6.25	20	312.5
13	8.00	20	400
14	10.00	20	500
15	12.50	20	625
16	16.00	20	800
17	20.00	20	1000
18	25.00	20	1250
19	32.00	20	1600
20	40.00	20	2000
21	50.00	20	2500
22	62.50	20	3125
23	80.00	20	4000
24	100.00	20	5000

110 kV			
Sl. no.	mAs	mA	Time (ms)
1	0.50	10	50
2	0.62	10	62
3	0.80	10	80
4	1.00	20	50
5	1.25	20	62.5
6	1.60	20	80
7	2.00	20	100
8	2.50	20	125
9	3.20	20	160
10	4.00	20	200
11	5.00	20	250
12	6.25	20	312.5
13	8.00	20	400
14	10.00	20	500
15	12.50	20	625
16	16.00	20	800
17	20.00	20	1000
18	25.00	20	1250
19	32.00	20	1600
20	40.00	20	2000
21	50.00	20	2500
22	62.50	20	3125
23	80.00	20	4000
24	100.00	20	5000

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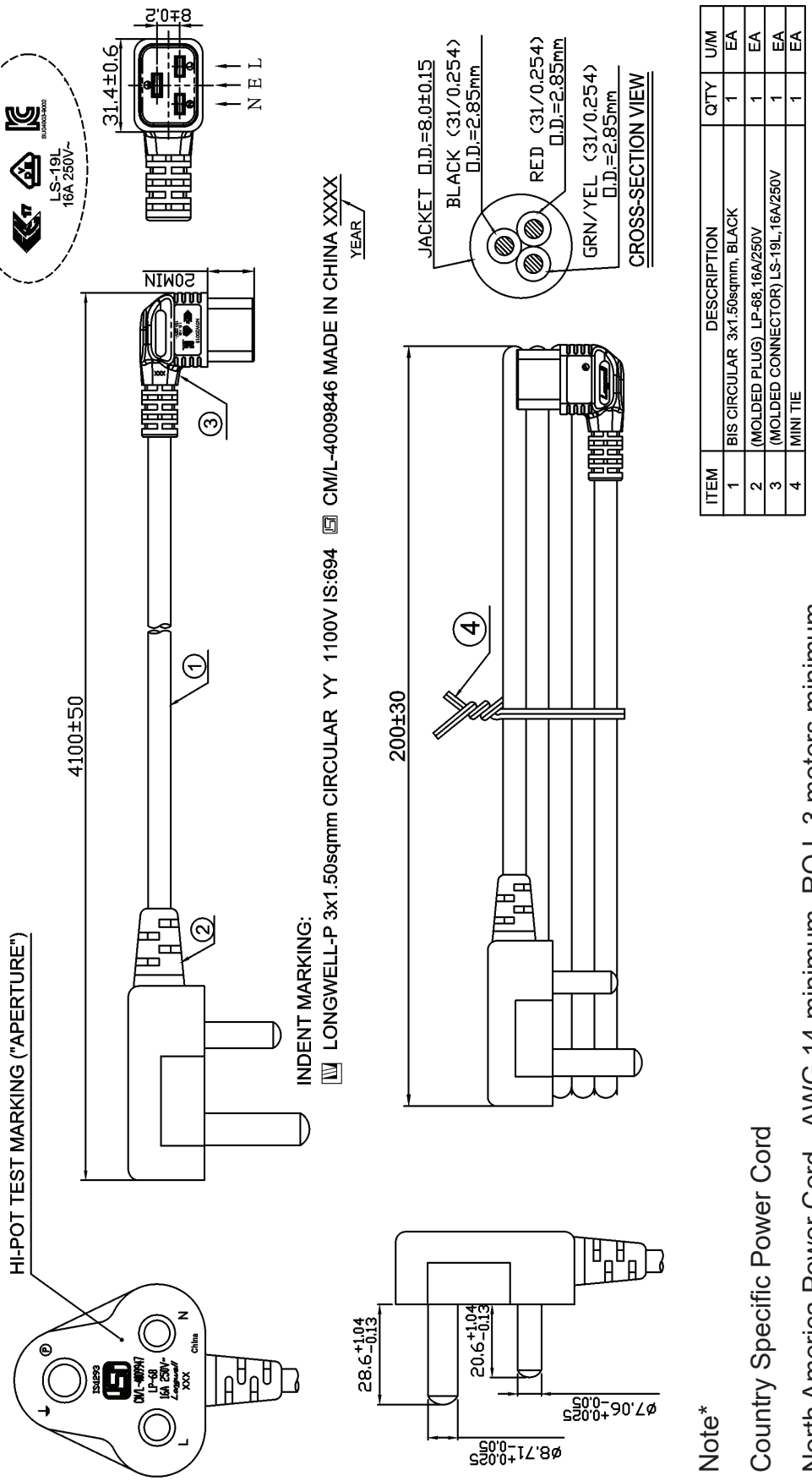
Annex 14: Power cord Details



ITEM	DESCRIPTION	QTY	U/M
1	BIS CIRCULAR 3x1.50sqmm, BLACK	1	EA
2	(MOLDED PLUG) LP-68,16A/250V	1	EA
3	(MOLDED CONNECTOR) LS-19L,16A/250V	1	EA
4	MINI TIE	1	EA

Note*

Country Specific Power Cord

North America Power Cord - AWG 14 minimum, ROJ, 3 meters minimum

International Power Cord - 1.5 Sqmm minimum, ROJ, 2.5 meters minimum

Or and other country specific Power Cord can be used.

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Annex 15: Safety Declaration

The product described herein conform to the following regulatory markings

UL safety marking (Optional):

CE marking (Optional):

Competent Authority Address

The chairman, Radiological Safety Division, Atomic Energy Regulatory Board, Niyamak Bhavan, Anushakthi Nagar, Mumbai – 400 094

Declaration

SKANRAY Technologies Private limited declares that the products described herein meet all the applicable Essential Requirements of the EC Medical Device Directive 93/42/EEC in Annex I, For Class IIb products described herein, the product is manufactured, inspected, tested, and released in accordance with the approved quality assurance system established in accordance with ISO 9001:2015, ISO 13485:2016

Annex II of the EC Medical Device Directive under the supervision of the UL INTERNATIONAL (UK) LTD, a Notified Body carrying the Notified Body No. 1434.

Authorized Representative & Notified body

Europe Authorized Representative	Notified Body
SKANRAY Europe s.r.l Via Della Tecnica, 3- San Lazzaro di Savena (40068), Bologna, Italy. E mail: SKANRAYeu@legalmail.it	**Polish Centre for Testing and Certification** 23 A Ktobbucka street,02-699, Warsa Poland Telephone : 48 22 46 45 200 E-mail : pcbc@pcbc.gov.pl

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Annex 16: Contact details

Registered Office & Radiology Division	Skanray Technologies Pvt. Ltd. Technology Division #15-17, Hebbal Industrial Area, Mysore 570 016, Karnataka, INDIA Phone : +91 821 2415559 Fax : +91 821 2403344 Email : enquiry@skanray.com Web : www.skanray.com
24 Hour Hotline Number **[Customer complaints & Incident reporting only for Radiology products]**	+91 9901144411
Healthcare Division	Skanray Technologies Pvt Ltd Healthcare Division Plot # 360, KIADB Indl. Area, Hootagalli, Mysore 570 018, Karnataka, INDIA Phone : +91 821 2407000 Fax : +91 821 2407001 Email : enquiry@skanray.com Web : www.skanray.com
Customer Interaction Centre [Toll-free: Monday to Saturday: 10:00 AM to 6:45 PM]	Email : cic@skanray.com Toll Free: 1800 425 7002

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भारत सरकार
परमाणु ऊर्जा नियामक परिषद्

GOVERNMENT OF INDIA
ATOMIC ENERGY REGULATORY BOARD

सत्यमेव जयते

अध्यक्ष
Chairman

Case File Number: KA-21000-MF-XRE-001 **Issuance Date:** 10/12/2018

Document Number: 99-TA-661 **Expiry Date:** 10/12/2021

TYPE APPROVAL FOR C-ARM EQUIPMENT MODEL SKAN C MANUFACTURED BY M/S. SKANRAY TECHNOLOGIES PRIVATE LIMITED, INDIA

In exercise of the powers conferred under Section-16 of the Atomic Energy Act, 1962 read in conjunction with Rule-3 of the Atomic Energy (Radiation Protection) Rules, 2004, the Atomic Energy Regulatory Board (AERB) hereby grants Type Approval to following medical diagnostic x-ray equipment from radiological safety view point:

Type of Equipment	C-Arm
Model Name	SKAN C
Name of Manufacturer	M/s. Skanray Technologies Private Limited, India
No. of x-ray tubes	1
Maximum operating voltage	110.000 kVp
Maximum operating current	70.000 mA

TERMS AND CONDITIONS

1. These Terms and Conditions to be read in conjunction with Terms and Conditions of Supplier's Authorization. A copy this Type Approval and Supplier's Authorization shall be provided to the prospective utility.
2. This Type Approval becomes invalid if any change is made in the design of above model.
3. The Type Approved Model shall be supplied only by Suppliers Authorised by AERB and to the user who has obtained requisite permission from AERB to procure the equipment.
4. Supplier shall provide duly signed and stamped installation report with Quality Assurance test report to utility after installation and commissioning of x-ray equipment.
5. The supply of above Model after expiry of this Type Approval is conditional upon its revalidation.

(Competent Authority)

MR. VISHWAPRASAD ALVA
SKANRAY TECHNOLOGIES PRIVATE LIMITED
PLOT NO 15 TO 17 HEBBAL INDUSTRIAL AREA, MYSORE, KARNATAKA-570017

शिव अभिलाष भारद्वाज / S. A. BHARDWAJ
अध्यक्ष / Chairman
परमाणु ऊर्जा नियामक परिषद
Atomic Energy Regulatory Board

परमाणु ऊर्जा नियामक परिषद्,नियामक भवन, अणुशक्तिनगर, मुंबई 400094 (महाराष्ट्र)
Atomic Energy Regulatory Board, Niyamak Bhavan, Anushaktinagar, Mumbai 400094 (Maharashtra)

An IS/ISO 9001:2008 Organisation

वेबसाइट/Website: www.aerb.gov.in दूरभाष/Tel: 91-22-2599 0604 फैक्स/Fax: 91-22-2599 0344

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SKANRAY

NOTHING IS OPAQUE

Skanray Technologies Pvt. Ltd.

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Skanray Europe S.R.L: Via Cicogna 36, 40068 San Lazzaro di Savena, Bologna, Italy.

PART NO.: 515-001853-2_REV. 03