
REVEAL 35C



USER MANUAL (EN)



CE 2862

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Content Review and Approvals

Submission Information		
Submitted by	Submitted to:	Submitted on:
Michael Behm	Ari Grohn, Basel Albahhal, Gary Allan, Juliet Opuni-Mensah	

Approval Sign-offs: MAN-00001 Reveal 35C EN.02		
Reviewer Name	Sign-off Date	Signature (E-signature accepted)
Ari Grohn		AG
Basel Albahhal		BA
Gary Allan		GA
Juliet Opuni-Mensah		JO

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INTRODUCTION

1

The Reveal 35C User Manual contains the following chapters:

Chapter 1	INTRODUCTION
Chapter 2	SAFETY PROCEDURES & PROTOCOLS
Chapter 3	REVEAL 35C DESCRIPTION
Chapter 4	REVEAL 35C HARDWARE SETUP
Chapter 5	REVEAL 35C SOFTWARE SETUP
Chapter 6	IMAGE ACQUISITION
Chapter 7	TROUBLESHOOTING
Chapter 8	MAINTENANCE
Chapter 9	SERVICE AND SERVICEABILITY



IMPORTANT

Ensure that all users and potential users are trained and qualified in all safety procedures before operating the Reveal 35C Flat Panel Detector.



All users, potential users, and technicians must **READ, UNDERSTAND, AND RETAIN ALL CAUTIONARY INFORMATION PROVIDED IN CHAPTER 2** before attempting to operate the Reveal 35C Flat Panel Detector.

Any serious incident that has occurred in relation to the device should be reported KA Imaging Inc. and the competent authority of the EU Member State or the regulatory authority of the country in which the user and/or patient is established.

Intended Use and Indications for Use

The Reveal 35C Flat Panel Detector (FPD), when used with a radiographic imaging system, is intended to generate radiographic images of human anatomy wherever a conventional screen-film, digital radiography (DR), or computed radiography (CR) detector is used for general purposes.

Reveal 35C is designed to retrofit into an existing X-ray system, and for integration into a complete X-ray system by a qualified system integrator.

When the dual energy subtraction function is enabled, it is intended to assist the physician through the visualization of anomalies by reducing the visibility of underlying or overlying anatomical structures.

This device is not intended for use in mammography applications.

Intended target patient groups: Reveal 35C is indicated for use on pediatrics to adult for general diagnostic radiographic examinations as prescribed by qualified healthcare professionals. Indicated use of this device is irrespective of gender, height, and weight.

Intended user(s) and use environment: The Reveal 35C is intended to be used by trained medical professionals in a hospital or clinical setting.

Clinical performance claim: When used with a radiographic imaging system, Reveal 35C is intended to generate radiographic images of human anatomy.

Clinical safety claim: The Reveal 35C is free from unacceptable clinical risks, when used with a radiographic imaging system according to its Instructions for Use to generate conventional radiographic images of human anatomy or dual energy subtraction images as intended for diagnosis. The Reveal 35C's clinical safety claim is enhanced Patient and Operator safety with less X-ray radiation exposure that produces good quality radiographic images (DQE = Typ. 65% @ 1 lp/mm).

Contraindications

This device is not intended for use as a primary barrier to X-rays.

Before using the X-ray system, refer to the regulations in force in your area concerning pediatric patients, pregnant women, and anyone with health issues that contraindicate the use of X-rays. Ascertain patient history and local regulations before starting the exposure.

Pediatric Use



Use special care when imaging patients outside the typical adult size range.

Special care should be exercised when imaging patients outside the typical adult size range, especially smaller pediatric patients whose size does not overlap the adult size range (e.g., patients less than 50 kg (110 lbs.) in weight and 150 cm (59 in.) in height, measurements that correspond to that of an average 12-year-old or a 5th percentile U.S. adult female.

Exposure to ionizing radiation is of particular concern in pediatric patients because: 1) for certain organs and tumor types, younger patients are more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher for younger patients); 2) use of equipment and exposure settings designed for adults of average size can result in excessive and unnecessary radiation exposure of smaller patients; and 3) younger patients have a longer expected lifetime over which the effects of radiation exposure may manifest as cancer.

To help reduce the risk of excessive radiation exposure, follow the ALARA (as Low as Reasonably Achievable) principle and seek to reduce radiation dose to only the amount necessary to obtain images that are adequate clinically.

The following resources, sourced from the FDA website, provide information about pediatric imaging radiation safety and/or radiation safety for general radiography devices.

1. Hermann, Tracy L., M.Ed., R.T.(R). 2012. Best Practices in Digital Radiography. Radiologic Technology, Volume 84, Number 1, September issue.
http://www.asrt.org/docs/whitepapers/asrt12_bstpracdigradwhp_final.pdf
[Best Practices in Digital Radiography](#)
2. Moore, Quentin T., MPH, R.T.(R)(T)(QM) et al. 2012. Image Gently: Using Exposure Indicators to Improve Pediatric Digital Radiography. Radiologic Technology, Volume 84, Number 1, September issue.
https://www.imagegently.org/Portals/6/Procedures/RADT12_SeptOct_v84i1_Q.Moore.pdf
[Best Practices in Digital Radiography](#)

Disclaimer

The owner is responsible for ensuring that all system users have read this manual and all other relevant literature, and that all users fully understand all information before using this equipment.

KA Imaging makes no representation, however, that the act of reading this manual qualifies the reader to operate, test and/or calibrate the system.

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In no event shall KA Imaging be liable for:

- Damage or loss arising from a fire, earthquake, or any intentional or negligent action by users.
- Damage or loss arising from any trial usage, or other usage under abnormal conditions.
- Personal physical harm or property damage that is sustained when the instructions of this manual are not followed.
- Direct or indirect consequential damages arising from the use of this product.
- Damage arising from moving, alteration, inspection, or repair by a person other than authorized service engineers.
- Loss of image data for any reason.

Image acquisition, image processing, image reading, and image data storage must be performed in accordance with the laws of the country or region in which the product is being used. The user is responsible for maintaining the privacy of image data acquired from this product.

It is the responsibility of the attending physicians to provide medical care services. KA Imaging is not liable for faulty diagnoses.

Specifications, composition, and appearance of this product may change without prior notice.

KA Imaging reserves the right to change this document at any time without notice and disclaims liability for editorial, pictorial, or typographical errors.

Product Disposal

Unlawful disposal of this product may have negative effects/impact on health and the environment. When disposing of this product, be certain to follow and conform to the laws and regulations applicable in your area.

Battery Disposal



The flat panel detector in this system contains batteries with more than 0.004% (40 ppm) lead. Disposal is regulated due to environmental considerations.



The lithium-ion/polymer battery can explode, leak, or catch fire if exposed to high temperature, water, or fire. Do not short-circuit, open, or disassemble the battery. Dispose of it properly.

Before discarding the battery, cover the terminals with adhesive tape or other insulators. Contact with other metal materials may lead to fire or an explosion.

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In Canada and the United States only, the lithium-ion battery is recyclable. Call local authorities for battery recycling instructions.



This symbol indicates that this product is not to be disposed of with your household waste, according to the WEEE Directive (2012/19/EU) and national legislation. This product should be handed over to a designated collection point, e.g., on an authorized one-for-one basis when you buy a new similar product or to an authorized collection site for recycling waste electrical and electronic equipment (EEE). Improper handling of this type of waste could have a possible negative impact on the environment and human health due to potentially hazardous substances that are generally associated with EEE. At the same time, your cooperation in the correct disposal of this product will contribute to the effective usage of natural resources. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, waste authority, approved WEEE scheme or your household waste disposal service. If collection systems are not available, contact KA Imaging for assistance.



Pb

This symbol indicates that the person who wishes to dispose of this product must send it to appropriate facilities for recovery and recycling of waste containing higher than 0.004% (40 ppm) lead.

If unsure of the correct procedure, defer to your institution's disposal guidelines or contact your city's waste disposal department for direction.

Copyright

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Trademarks

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Typographical Conventions

Text formatting conventions in this manual help you understand the information being shown. The conventions are explained below.

Textual Format	Convention Description
ALL CAPS	<ul style="list-style-type: none">• Indicate an OPERATING MODE or a power change; i.e., ON or OFF• Call attention to information that MUST BE READ for the purpose of safety
SMALL CAPS	<ul style="list-style-type: none">• Indicate an on-screen button or function key
Blue text	<ul style="list-style-type: none">• Indicates a cross-reference to related information
Numbered text	<ul style="list-style-type: none">• Numbered text is reserved for use in procedural text only, representing steps that must be performed in the order they are given
Bulleted text	Indicates: <ul style="list-style-type: none">• Items in a list• The task in a procedure that has a single step

Danger, **Warning**, and **Caution** messages precede the procedures to which they refer. **Notes**, providing more information or user 'tips' about a topic or a procedure, that are not concerned with operator or patient safety, appear wherever their use is relevant.

2 SAFETY PROCEDURES & PROTOCOLS

This chapter provides

- Danger, Warning, and Caution messages for all potentially hazardous system components, including but not limited to: X-ray detector, radiation exposure, battery and charger, and power supply.
- Important handling conventions.
- Proper responses to accidents and abnormal operations.
- All electromagnetic compatibility information.

IMPORTANT! PLEASE READ



ALL USERS, POTENTIAL USERS, AND TECHNICIANS MUST READ, UNDERSTAND AND RETAIN THE CAUTIONARY INFORMATION PROVIDED IN THIS CHAPTER BEFORE USING THE REVEAL 35C FLAT PANEL DETECTOR (FPD).



ALL USERS, POTENTIAL USERS, AND TECHNICIANS MUST READ, UNDERSTAND AND RETAIN THIRD-PARTY EQUIPMENT MANUALS AND COMPONENT OEM DOCUMENTATION BEFORE USING THE REVEAL 35C FLAT PANEL DETECTOR.

Symbol Definitions



The DANGER symbol preceding a procedure, an instruction, or information indicates that a potentially hazardous situation exists.

If a DANGER message is ignored, the situation may result in severe personal injury, death, or substantial product damage.



The WARNING symbol preceding a procedure, an instruction, or information indicates that a potentially hazardous situation exists.

If a WARNING message is ignored, the situation may result in serious to severe personal injury or substantial product damage.



The CAUTION symbol preceding a procedure, an instruction, or information indicates that a potentially hazardous situation exists.

If a CAUTION message is ignored, the situation may result in minor to moderate personal injury or product damage.



The ELECTRIC SHOCK HAZARD symbol preceding a procedure, an instruction, or information indicates that a potentially hazardous situation exists.

If an ELECTRIC SHOCK HAZARD symbol is ignored, a risk of moderate to severe personal injury, up to and including possible death, exists.

Instructions preceded by an ELECTRIC SHOCK HAZARD symbol should be performed by a certified electrician only.



The FIRE HAZARD symbol preceding a procedure, an instruction, or information indicates that a risk of fire exists should the flagged procedure not be performed according to safety regulations, by trained personnel.

It is vital to the safety of employees, and to safeguard against potentially catastrophic equipment damage, that only trained personnel perform procedures flagged by a FIRE HAZARD symbol.



The EARTH GROUND symbol preceding a procedure, instruction, or information, indicates that a risk of serious or potentially fatal injury exists if this warning is not heeded. Always use properly grounded electrical outlets and power cables, such as those supplied with the instrument. Never use an ungrounded outlet.



The INFORMATION label provides additional information regarding a process, description, or procedural step.



The ELECTROMAGNETIC RADIATION symbol preceding a procedure, instruction, or information, indicates possible interference between electrical devices.



The RADIATION symbol preceding a procedure, instruction, or information, indicates that a risk of a serious or potentially fatal injury exists if this warning is not heeded.

General Safety Warnings



Prior to Reveal 35C installation or use, all personnel should read and understand this manual and any third-party equipment manuals.

Knowledge of the safety risks, rules and regulations protects against personnel injury and equipment damage.



The Reveal 35C Flat Panel Detector should be operated only by trained and qualified professional personnel who are knowledgeable in the use of X-ray detectors, X-ray systems and electrical equipment.



The user is responsible for using and maintaining the Reveal 35C Flat Panel detector per prescribed installation, usage, maintenance, handling, and storage specifications.



X-ray imaging, image processing, image acquisition and data storage must be performed in accordance with applicable laws. The user is responsible for compliance to laws pertaining to the privacy of image data.

Radiation Warnings



Exposure of any part of the human body to X-radiation may be detrimental to health. Whenever X-ray equipment or radioactive sources are in use, appropriate safety precautions and measures must be taken.

It is the responsibility of the X-ray installer, operator, and user to comply with applicable requirements and ensure all regulatory requirements are met.



The X-ray detector is intended to be installed, maintained, and used by qualified professional personnel who are trained and certified in the installation, maintenance, and use of X-ray equipment. The X-ray system installer must provide the training necessary for operators to protect themselves, their patients, and all surrounding persons.



The X-ray detector does not contain a primary barrier for X-rays or Gamma rays.

The X-ray system installer must provide the necessary protection based on the intended use of the detector.

Power Supply (Power Unit, Cables, and Connectors) Precautions



Ensure the power to the Reveal 35C is OFF, the power supply is OFF, and the lithium battery pack is removed before servicing, maintaining, connecting, or disconnecting the power cables or any accessories.



Do not touch the power supply, lithium battery pack, the detector, cable, connector, or any other electrical component with wet hands. Ignoring this instruction may result in severe injury or death, or substantial product damage.



Do not disconnect cables by pulling on the cable itself; rather, pull on the connector.

Ignoring this instruction may cause an electric shock, which may result in severe injury, death, or substantial product damage.



Do not modify the cables or subject any cables to external stress. Avoid placing anything heavy on a cable. Do not step on or pull the cable or subject the cable to excessive bending or bundling. Do not use the detector with multiple portable socket-outlet or extension cords.

Ignoring this instruction may cause cable failure, resulting in electric shock, which may result in severe injury, death, or substantial product damage.



Do not turn ON the power supply or X-ray detector when condensation is formed on the system. Ignoring this warning may cause electric shock, which may result in severe injury, death, or substantial product damage.



Do not touch the power supply, lithium battery pack, the cable, connector, or any other electrical component and the patient at the same time when the device is operational or when it is charging.

Do not allow the patient to touch the power supply, lithium battery pack, the cable, connector, or any other electrical component.

Ignoring these warnings may cause electric shock or other unknown hazards, which may result in severe injury, death, or substantial product damage.

Handling Conventions



Do not disassemble, modify, or alter the X-ray detector, any of its components, the lithium battery pack, the battery charger, or any of its accessories. Do not connect any equipment not specified in this User Manual.



Ignoring this warning may cause electric shock, fire or other unknown hazards which may result in severe personal injury, death, or substantial product damage.



Do not hit or drop the equipment; a sudden strong jolt may cause damage that, if not repaired prior to next use, could result in fire or electric shock. If the detector is dropped, remove it from service immediately and inform your establishment's safety representative to verify and revalidate for proper function before resuming use.



If using the detector in an upright orientation, hold the detector securely. Ignoring these warnings may result in severe injury, death, or substantial product damage.



Do not place objects on the surface of the X-ray detector. Metal objects, such as needles or clips, may fall into the equipment or fall off the equipment and cause injury. Spilled liquids or chemicals can cause fire or electric shock. In cases where the patient is injured, protect the equipment with a disposable covering to prevent contact with blood or bodily fluids.



Ignoring these warnings may result in severe injury, death, or substantial product damage.



Never submerge the X-ray detector in water or other liquids.

Ignoring this warning may cause electric shock or unknown hazards which may result in severe injury, death, or substantial product damage.



Do not place weight over 150 kg/330 lbs. on the detector, as this could damage the internal image sensor and affect image quality. Likewise, use the detector on a flat surface to prevent any bending that may also damage the internal sensor.

Ignoring these warnings may cause electric shock or unknown hazards which may result in severe injury, death, or substantial product damage.



Exercise caution to prevent entanglement of the cable or entanglement of feet in the equipment's cable. Equipment malfunction may occur, or personal injury may result from a trip and fall.

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Battery Pack and Charger



Do not use the battery pack as a power source for any equipment other than the Reveal 35C Flat Panel Detector.

Similarly, use only the dedicated battery pack for the Reveal 35C Flat Panel Detector in this equipment.



Use only the battery charger designed for the Reveal 35C Flat Panel Detector, and do not use it to charge any equipment other than the Reveal 35C Flat Panel Detector.

Do not operate the battery charger using any type of power supply other than the one indicated on the rating label. Do not use in a patient environment.



Ignoring these warnings may result in a battery explosion or a battery leak, fire, or electric shock.



Do not handle the battery or the battery charger with wet hands.

Do not allow the battery pack or charger to come into contact with water or other liquids.

Do not attempt to disassemble, alter, or apply heat to either the charger or the battery.

Ignoring these warnings may result in a battery explosion or a battery leak, fire, or electric shock.



Do not drop the battery or subject it to impacts. If the battery is accidentally dropped and cracked, do not touch its internal parts.

Stop using the battery immediately if it emits smoke or a strange smell, or if it behaves abnormally in any way.

Do not attempt to clean the battery or any leakage from a cracked battery with substances containing organic solvents such as alcohol, benzene, thinner or other chemicals.

Ignoring these warnings may result in a battery explosion or a battery leak, fire, or electric shock.



Do not store the battery pack in the detector. If the detector is going to be out of use for an extended time, **store it with the battery pack removed.**

Not removing the battery pack may cause malfunction of the battery and/or the FPD and may lead to injury and/or equipment damage.

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Do not allow dirt, metal objects (such as keys, staples, or hair pins) to contact the battery terminals.

Do not place, leave, or store the battery or charger in locations near heat sources, or in places subject to direct sunlight, high temperature, high humidity, excessive dust, or dirt, or near mechanical equipment where a risk of shock exists.

Do not use a battery pack that has deteriorated.



Ignoring these warnings may result in a battery explosion or a battery leak, fire or electric shock and overheating/damage to the product.

If a battery leaks and electrolytes come into contact with your eyes, mouth, skin or clothing, immediately flush eyes and wash affected skin with water and seek medical attention.



Always keep the battery and the battery charger out of reach of children.

The battery pack is a consumable item and slowly discharges even if not in use.



The battery pack may have expired if it discharges immediately after being fully charged.

Purchase an optional battery pack and replace the pack if a fully charged battery is consumed quickly.

Be sure to charge the battery periodically (once a year) if it is not used for an extended time.



ONLY trained personnel should change lithium batteries or fuel cells for the purpose of safety and hazard prevention.

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Accident Response



In the event of fire, or if any abnormal conditions are noted during operation—such as the presence of smoke, fumes, or strange sounds—unplug the power supply immediately from the AC outlet.



Inform your establishment's safety representative and ask for instructions.

Do NOT continue to use the X-ray detector during abnormal conditions.

Failure to comply with these warnings may result in severe injury, death, or substantial product damage.

Electromagnetic Compatibility

CDRH Compliance

Reveal 35C complies with the Department of Health and Human Services radiation performance standards per Title 21 CFR, Chapter 1, Subchapter J.

Classification in Accordance with IEC 60601-1

Protection against electrical shock	Class I equipment/internally powered
Degree of protection against electrical shock	Type B
Mode of operation	Continuous with intermittent loading
Use regarding flammable anesthetics	Not suitable for use in the presence of flammable or mixed flammable with air/oxygen/nitrous oxide anesthetics

Conforming Standards

Classification in Accordance with IEC

USA	ANSI/AAMI ES60601-1:2005/A1:2012-08 – Medical Electrical Equipment Part 1: – General requirements for basic safety and essential performance
Canada	CAN/CSA-C22.2 No. 60601-1:2014-03 – Medical Electrical Equipment Part 1: – General requirements for basic safety and essential performance



EMC Statements: US and Canada

Changes or modifications not expressly approved by KA Imaging could void the user's warranty and ability/authority to operate this equipment.

This equipment has been tested and found to comply with the limits for Class A digital devices, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and radiates radio frequency energy. If not installed and used in accordance with this OM Manual, harmful interference to radio communications may result. Operation of this equipment in a residential area is likely to cause harmful interference, in which case, the user will be required to correct the interference at the user's own expense.

This device complies with part 15 of the FCC Rules under product FCC ID number PD98265NG. Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

This device complies with Industry Canada's license-exempt RSS standard(s) under product IC ID number 1000M-8265NG. Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

Electromagnetic Emissions/Immunity

Electromagnetic Compatibility Precautions

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Medical equipment must be installed and put into service according to the IMC information provided.

Communications Equipment

Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment EMC performance.

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Cable and Accessory Information for Reveal 35C

Replacement cables and accessories specified below are available from KA Imaging. Use no parts from other sources.

Port/Cable/Accessory	No.	Port/Cable/Accessory	No.
Battery Charger	1	AC/DC adapter	1
Battery Pack	1	FPD power cord	1
FPD Cable	1	Connector Adapter	1

Electromagnetic Emissions for Group 1, Class A Equivalent

Emissions Test	Compliance	Electromagnetic Environment - Guidance
Reveal 35C is intended for use in the electromagnetic environment specified below. The owner/operator of Reveal 35C should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 1	Reveal 35C uses RF energy only for internal functions. Therefore, its RF emissions are very low, and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	Reveal 35C 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 for domestic purposes.
Harmonics Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity for Equipment and Systems Fully Compliant with IEC 60601-1-2:2014, Edition 4.0


Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and variations on power supply lines IEC 61000-4-11	<5% U_T (95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Reveal 35C requires continued operation during power mains interruptions, it is recommended that the Reveal 35C be powered from an alternate AC power source.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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Electromagnetic Immunity for Non-Life Supporting Systems

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of Reveal 35C, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 v/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17 \sqrt{P}$ 80 MHz – 800 MHz $d = 2.33 \sqrt{P}$ 800 MHz – 2.5 GHz where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of the equipment marked with the following symbol: 

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 strength from fixed transmitters, such as base station 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 Reveal 35C is used exceeds the applicable RF compliance level above, observation must take place to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Reveal 35C.

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



Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and Reveal 35C

Reveal 35C is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of Reveal 35C can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and Reveal 35C as recommended below, according to the maximum output of the communications equipment.

Rated Maximum Output Power of Transmitter	Separation Distance According to Frequency of Transmitter		
	Watts	Meters	
	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.117	0.117	0.233
0.10	0.370	0.370	0.737
1.00	1.170	1.170	2.3300
10.00	3.700	3.700	7.3600
100.00	11.700	11.700	23.300

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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FCC Notice (USA)

Reveal 35C has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a commercial installation.

Reveal 35C generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television receptions, which can be determined by turning the equipment ON and OFF, the user should try to correct the interference using the following methods:

- Reorient the device.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into an outlet on a circuit different from the one to which the receiver is connected.
- Consult an experienced radio/TV technician for help.

REVEAL 35C DESCRIPTION

3

The Reveal 35C Flat Panel Detector (FPD) is shipped with these main components:

- Flat panel detector
- Battery pack
- FPD cable
- Connector adapter
- AC/DC adapter
- Power cord

These accessory components can be ordered and shipped with the main components:

- Battery charger (equipped with its own AC/DC adapter)
- Additional battery pack(s)

These auxiliary components are NOT part of Reveal 35C, but are required on-site:

- PC
- Ethernet cable
- Wireless access point
- Wi-Fi card

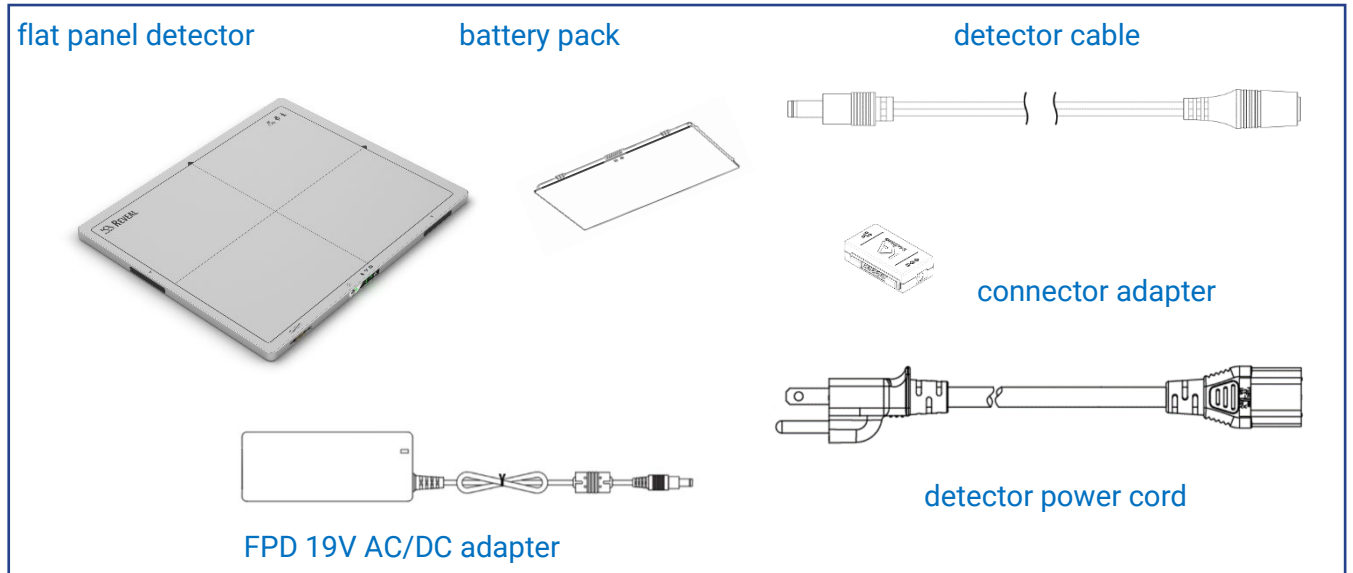
REVEAL 35C

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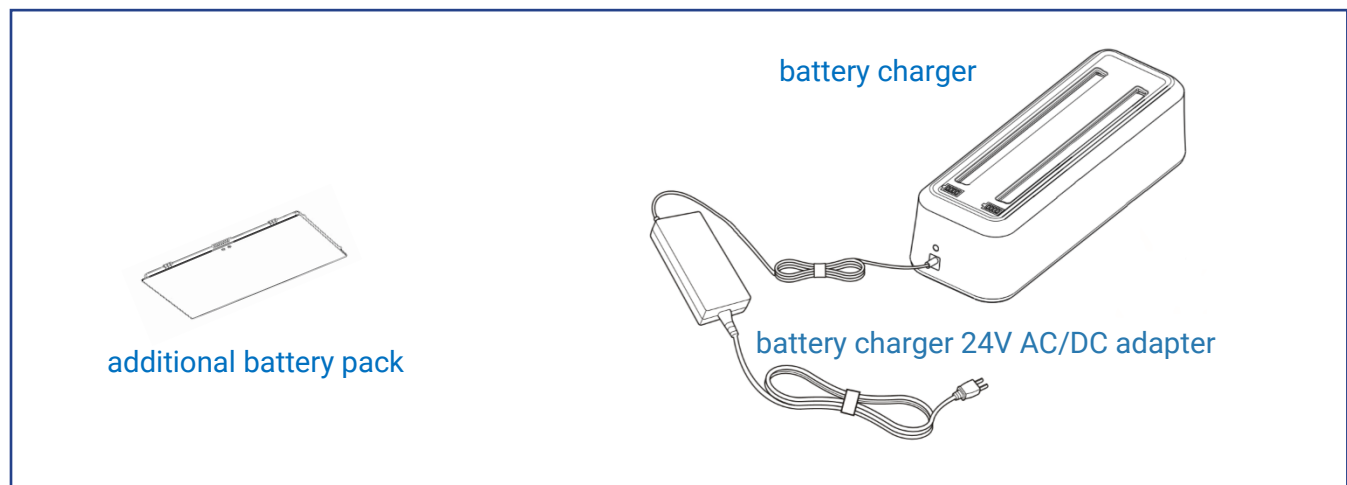


Product Components

Main Components



Accessory Components



The larger of the two AC/DC adapters is the FPD AC/DC adapter. The smaller AC/DC adapter is for the battery charger. Do NOT interchange these adapters; they are for use with their specific equipment ONLY.

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Auxiliary Components

The following auxiliary components are required to use Reveal 35C and its software but are not included.

- PC
- Ethernet cable
- Wireless access point

Minimum PC Requirements

CPU Intel Core i5 4th generation or newer

RAM At least 16 GB (16 GB+ recommended)

Drive Capacity

At least 100 GB application and temporary archiving

At least 500 GB for long-term image archiving

Network Card

100 Mbps or faster Wired Network Adapter Card

802.11n or newer Wireless Card for untethered operation

Graphics Card / Monitor

Minimum resolution of 1280×1024

A dedicated GPU, while not necessary, will speed up image processing

Operating System (OS)

Windows 10, 64-bit

Windows 11, 64-bit

Minimum Requirements for Accessories

Cat5e or greater Ethernet cable

802.11n or newer wireless access point

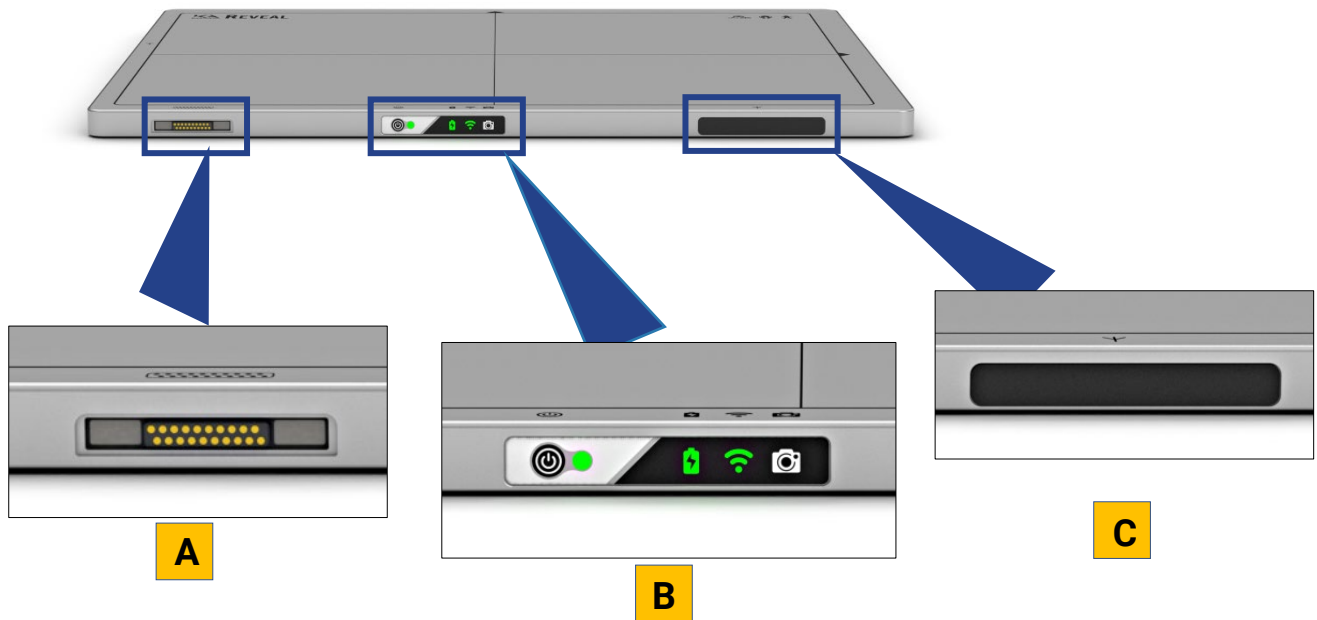
Cyber-Security Recommendations

- Use anti-virus software on the PC
- Do not connect the computer to the internet without a firewall
- If possible, keep the computer within the organization's intranet
- Always keep the FPD behind a firewall

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Flat Panel Detector Components



A	I/O Connector
B	Keypad
C	Wi-Fi Antenna (1)
D	Battery Pack Compartment

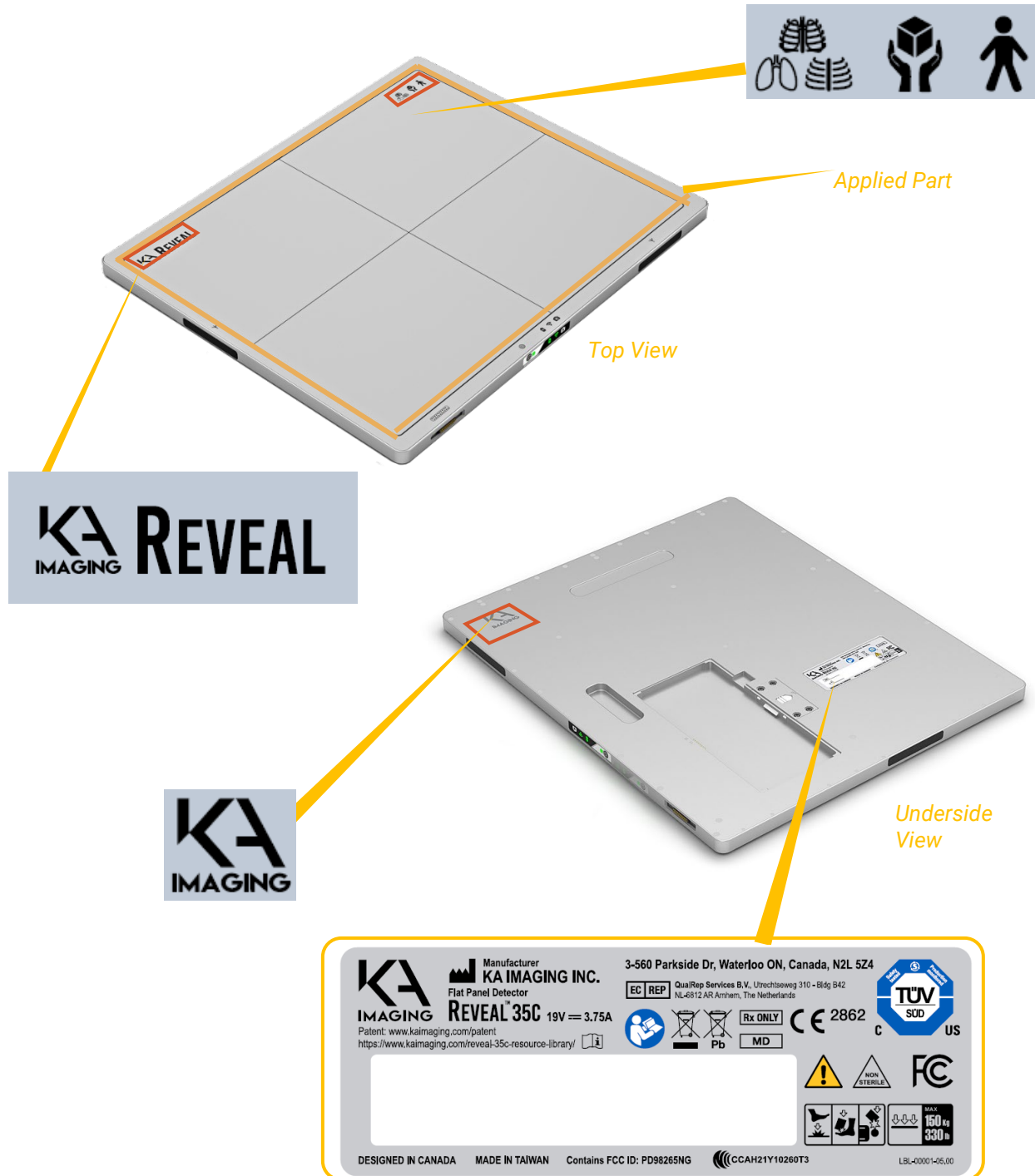


REVEAL 35C

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Flat Panel Detector Labels



REVEAL 35C

USER MANUAL (EN)



Label Descriptions

	<ul style="list-style-type: none"> KA Imaging company logo Product Trademark: Reveal
	<p>From left to right:</p> <ul style="list-style-type: none"> Dual-Energy X-ray device Handle with care Type B applied part
	<p>KA Imaging company logo (manufacturer's label)</p>
	<p>Product Rating Label Caution symbols and markings explained in the table below.</p>

	<p>Manufacturer's name and address</p>	<p>Rx Only</p> <p>MD</p>	<p>Prescription use only. Federal Law restricts this device to sale by or on the order of a radiologist or any other practitioners licensed by the law of the state in which that person practices to use or order the use of the device.</p>
	<p>Date of manufacture</p>		<p>Medical device</p>
	<p>Refer to Instruction Manual</p>		<p>Caution symbol</p>
	<p>Not to be disposed of with household waste per WEEE Directive (2002/96/EC)</p>		<p>Non-sterile</p>
	<p>Not to be disposed of with household waste per WEEE Directive (2002/96/EC) Contains lead</p>		<p>FCC marking</p>
	<p>TÜV SÜD certification mark</p>		<p>Caution for local load Do not drop the FPD on the user or patient.</p>
	<p>Do not place a load more than 150 kg/330 lbs on top of the FPD</p>	<p>SN</p>	<p>Serial number</p>



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EC REP	Authorized representative in the European Community		Consult instructions for use.
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Flat Panel Detector Technical Specifications

Item	Specification
Model Number	Reveal 35C
Sensor Arrays	a-Si photodiodes
X-ray Scintillator Type	CsI
Pixel Pitch	140 μ m
Active Area	347.76 \times 425.04 mm
Active Array	2484 \times 3036 pixels
Bit Depth	16 bit
X-ray Synchronization Control	AED (Auto Exposure Detection)
Rated Power Supply	DC +19 V, Max. 3.75 A
Power Consumption	Max. 63 W
Energy Range	40 ~ 150 keV
MTF (@1 lp/mm)	Min. 57% / Typically 64%
DQE (@1 lp/mm)	Min. 50% / Typically 65%
Defective Lines	\leq 9
Defective Pixels	\leq 3000
Dimensions (H x W x D)	14 x 17 x 0.6 in. (383.5 x 459.5 x 15 mm) ISO 4090
Weight	8 lbs. (3.6 kg) including battery
Data Transmission	Wired: Gigabit Ethernet (1000BASE-T) Wireless: IEEE802.11 ac/n
Data Transmission Rate (Wired)	Max. 1 Gbps
Data Transmission Rate (Wireless)	Max. 867 Mbps
Preview Time	Typically, 7 seconds
Cycle Time	Typically, 20 seconds

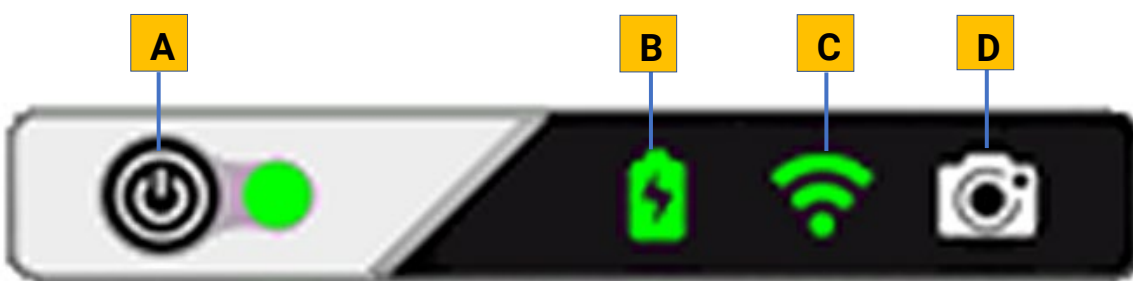


Flat Panel Detector Controls

The Reveal 35C flat panel detector is engineered for maximum strength at minimal product weight, promoting portability without sacrificing robustness. The mechanical housing is constructed using a magnesium alloy. The top frame, for product protection and for strength, is manufactured of a materials mix including carbon fiber.

Power Pushbutton and LED Indicators

The control area, located on the front, operator-facing edge of the detector panel, has a power button and four (4) multi-color LEDs.



A	Power Button with Power LED at right	C	Wi-Fi LED
B	Battery LED	D	Camera LED

- During the most common operations, when no user input is required, only green lights should be ON.
- Flashing indicates temporary states or those that require user input. For example, flashing yellow indicates a detector error that requires operator intervention. See [Flat Panel Detector States and Associated LED Indication](#) for details.

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Flat Panel Detector States and Associated LED Indication

This table summarizes all possible FPD states with associated LED indications. In instances where illumination color and type can have more than one meaning, both are provided.

LED color and state	POWER LED	BATTERY LED	Wi-Fi LED	CAMERA LED
OFF	Deep sleep mode/dead	Battery attached and fully charged; DC attached	Wi-Fi is OFF	No Capture
		Battery attached, no DC, charge level > 10%		
		DC attached, no battery		
Green Solid	FPD ON	Battery attached and charging	Connected to PC (either Wi-Fi or tethered)	FPD ready for exposure (AED mode)
Green Flashing	FPD powering up	N/A	Access point found and connecting to the AP	FPD Busy – (AED mode) Image being captured, transferring, or saving FPD busy – starting AED mode
	FPD powering down			
Yellow Solid	FPD error	Battery attached, no DC, charge level < 10%	Connected to AP through Wi-Fi or tethered; no connection to the PC	N/A
Yellow Flashing (once per second)	Standby mode	Battery error	Searching for the AP	Capture error
		No battery attached, no DC		
Yellow Slow Flashing (once per 3 seconds)	Sleep mode	N/A	N/A	N/A



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Blue Solid	N/A	N/A	N/A	FPD ready for exposure (AED calibration)
Blue Flashing	N/A	N/A	N/A	FPD busy (AED calibration) Image being captured/transferred/saved
				FPD busy – Starting STANDALONE mode
				FPD busy – Starting Calibration
Blue/Green Solid	N/A	N/A	N/A	FPD ready for exposure – STANDALONE mode
Blue/Green Flashing	N/A	N/A	N/A	FPD Busy – STANDALONE mode – Image being captured/saving

Power Button Actions

The POWER button is the only controller on the unit; all others are indicators. The POWER button performs different functions depending on the duration of the button press:

Button Press Duration	Result
Short press (<0.5 seconds)	<ul style="list-style-type: none"> In SLEEP mode, switches the FPD to READY-TO-CONNECT mode. In Standby mode, switches the FPD to CONNECTED mode. See Operating Modes for details. No result unless in Standby or Sleep modes.
Long press (>2.0 seconds)	FPD powers up or down (depending upon its current state).
Extended press (>12.0 seconds)	The FPD performs a hard reboot (forced reset).
Double press	Primary battery percentage temporarily displayed via front-panel LED indication. See Installing the Battery .
Triple press	Toggles the FPD between READY-TO-CONNECT mode and STANDALONE mode.



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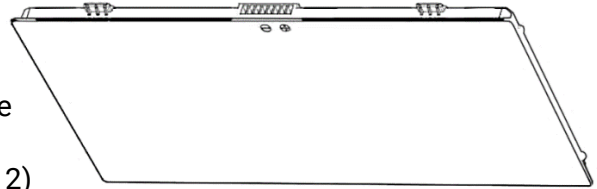


Accessory Component Specifications

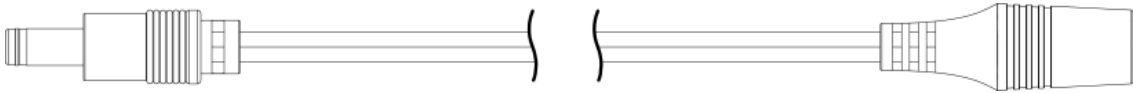
Battery Pack

The battery pack is a rechargeable Li-ion battery:

- 4212 mAh capacity
- 11.4V, Typically, 4212mAh/48Wh rating voltage
- ~260g weight
- UL certified (in accordance with IEC 62133:2012)
- UN 3481, PI 966
- KAI part number COS-00003



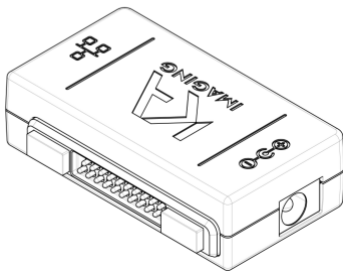
FPD Cable



The cable shown above connects to the connector adapter on the flat panel detector:

- KAI part number OTS-00057

Connector Adapter



The connector adapter accepts the FPD cable on one side and an Ethernet cable on the other.

- KAI part number CON-00004

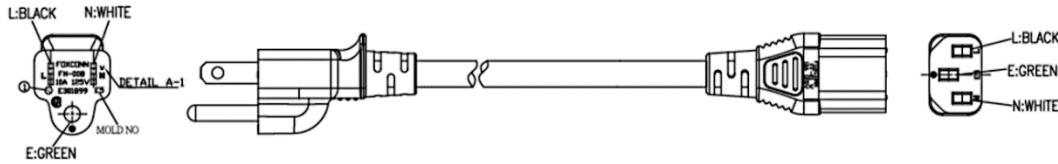
Note: The connector adapter replaces the break-out cable used on previous versions of Reveal 35C, but is cross-compatible with the break-out cable.

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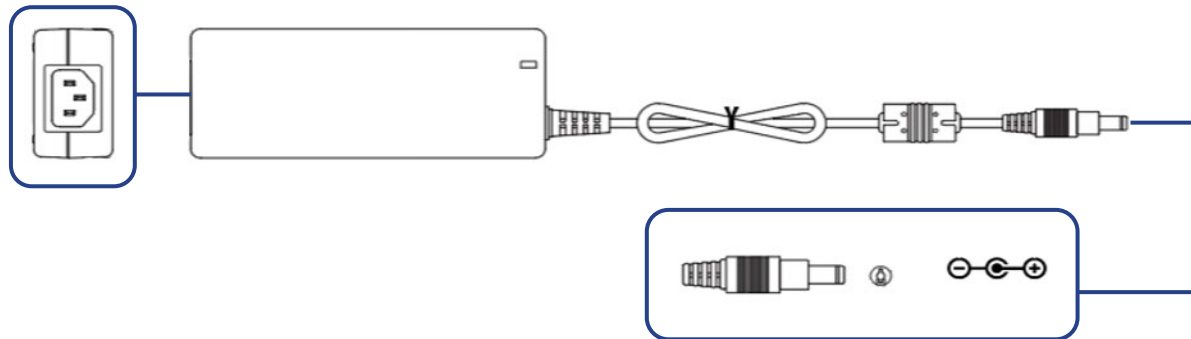
FPD Power Cord



The specifications for the power supply cord are:

- Plug, 10A/125V
- Connector, 10A/125V – Length 2.5M
- Weight 252 grams
- KAI part number OTS-00007

FPD AC/DC Adapter



The 19V medical grade FPD AC/DC adapter is used to provide power to the flat panel detector. The adapter is in accordance with IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012.

- Input 100-240V ~ 1.3–0.6A 50–60Hz
- Output 19V = 4.74A
- Length 1.2M
- Weight 270 grams
- KAI part number OTS-00008



IMPORTANT

The FPD AC/DC adapter and the battery charger AC/DC adapter (on the next page) **are not interchangeable**. Use the adapter cables **ONLY** with their intended equipment.

Using the 24V AC/DC battery charger adapter as a plug-in for the flat panel detector **damages the FPD**.

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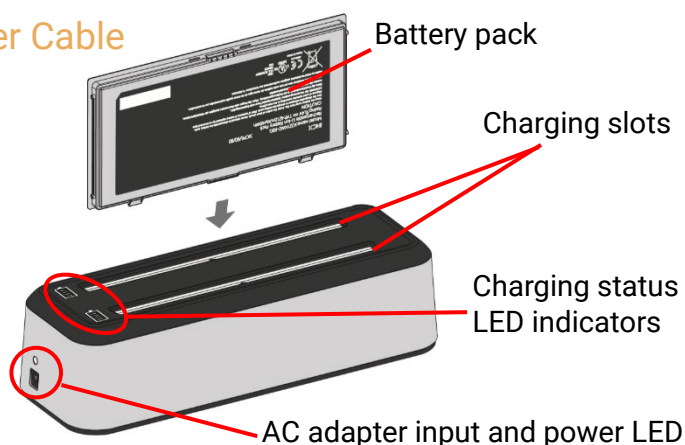


Battery Charger and AC/DC Adapter Cable



USE the charger-specific 24V AC/DC adapter ONLY.

Do not interchange the 24V charger adapter with the 19V detector adapter.



Charger and Adapter Specifications

Item	Specification
Dimensions (L x W x H)	278 x 98 x 75 mm (11 x 3.9 x 3 inches)
Weight	570 grams (1.25 lbs.) ±5%
Charging Channels	2
LED Display	Power / Charging
Battery Pack	X221AW2 B0G rechargeable lithium-ion battery pack UN 3481, PI 966
Adapter	AC Input 110–240 Volts, Output 24V DC (2.5 V) GST60A24-P1J
Charge Voltage	13.05 V
Charge Current	Maximum 2A per channel
Ambient Operating Conditions	0 ~ 35°C, 0 ~ 90% RH
Storage Environment	-20 ~ 55°C, 0 ~ 95% RH
Regulatory Safety Specifications	UL 62368-1, IEC 60950-1, IEC 62368-1, CSA C22.2 No. 62368-1, EN 55032:2015/AC:2016 Class B, EN 61000-3-2:2014 EN 61000-3-3:2013, EN 55024:2010/A1:2015
Regulatory Environment	RoHS, REACH, PFOS, DEHP, BPA, WEEE



Operating Modes

This section describes the available operating modes of the Reveal 35C Flat Panel Detector. The mode of the FPD determines which actions the FPD is allowed to perform. The modes are:

- READY-TO-CONNECT
- CONNECTED
- CONNECTED AED
- STANDALONE

Ready-to-Connect Mode

The default mode of the FPD after power-up is READY-TO-CONNECT. From READY-TO-CONNECT, the user can enter CONNECTED, CONNECTED AED or STANDALONE mode.



Do not start imaging with the FPD when the battery charge is **less than 10%** (battery LED is solid yellow).

Connected Mode

CONNECTED mode is the primary FPD operating mode and is entered by connecting the FPD to the UI.



Disconnecting the FPD from the UI returns the FPD to READY-TO-CONNECT mode.

In CONNECTED mode, the user can perform the following actions:

- Calibrate the FPD. Refer to [Calibration](#) on [page 64](#).
- Enter CONNECTED AED mode to capture X-ray images
- Change detector settings

Connected AED Mode

Connected AED mode is the mode the flat panel detector, when connected to the UI, enters for image capture. When the FPD is actively in CONNECTED AED mode, the camera LED on the FPD illuminates green.

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Standalone Mode

In STANDALONE mode, users can capture X-ray images without using the UI. An image captured in STANDALONE is saved to the FPD's internal storage and the last image acquires can be downloaded using the UI CAPTURE HISTORY feature.

STANDALONE mode can be activated from READY-TO-CONNECT mode (FPD is fully powered ON but not connected to the UI):

Action	Mode Indication
Press the POWER button 3 times consecutively from READY-TO-CONNECT mode.	The capture LED flashes blue for a few seconds to indicate the FPD is entering STANDALONE mode. The capture LED illuminates solid light blue (simultaneous illumination of the green and blue light) to indicate FPD readiness for image capture.
Expose the panel to perform an automatic capture.	The capture LED flashes blue.
Press the POWER button 3 times consecutively from STANDALONE mode to return to READY-TO-CONNECT mode.	The capture LED flashes blue for a few seconds to indicate the FPD is exiting STANDALONE mode.



The UI cannot connect to the FPD in STANDALONE mode until the user exits the FPD from STANDALONE.

Power Saving Modes

Power saving modes are NOT operating modes; they function to conserve power when the FPD is ON but not currently in use.

- STANDBY mode, which automatically occurs if the FPD is idle long enough to reach the Standby Idle Timer. This Power Saving mode—which maintains FPD connection to the UI—is indicated as active to the operator via yellow flashing of the power LED. Exit STANDBY either by pressing the POWER button, moving the FPD, or by using any UI function or command.
- SLEEP mode, which occurs automatically if the FPD is in STANDBY mode long enough to reach the Sleep Inactivity Timer. SLEEP mode disconnects the FPD from the UI.

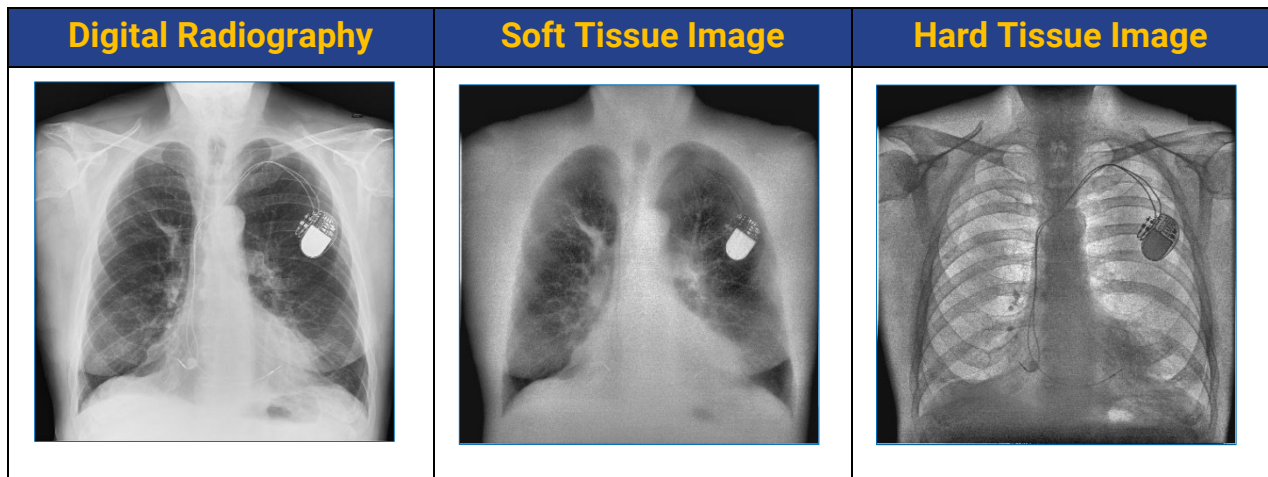
Captured Image Formats

Reveal 35C is designed to obtain dual-energy X-ray images from a single exposure using a conventional hospital X-ray source when the dual-energy subtraction function is enabled. The Reveal 35C Flat Panel Detector incorporates different energy levels to allow for advanced tissue differentiation in the diagnostic image by separating the X-ray energy spectrum.

The three image types possible in a single capture are:

- Digital Radiography
- Soft Tissue Image
- Hard Tissue Image

Captured image samples:



REVEAL 35C HARDWARE SETUP

4



The initial (first use) connection of the Reveal 35C Flat Panel Detector (FPD) must be wired, an Ethernet connection must be made, and the Wi-Fi must then be configured to allow for future wireless connection and use.

The software setup portion of setup is described in the next chapter, REVEAL 35C SOFTWARE SETUP.

Steps for Reveal 35C Hardware Setup: Process Overview

The steps for FPD setup in preparation for first use are as follows:

1. Charge the battery.
2. Install the battery.
3. Check the charge.
4. Connect the flat panel detector.

Precautions for Battery Charger Operation and Use



- Use only designated battery packs and cables with the battery pack charger.
- Do not disassemble, convert, or modify the battery pack(s) or the battery charger.
- Do not continue to use or attempt to repair faulty batteries or a malfunctioning battery charger.
- Do not cover the holes in the charger with foreign matter; avoid dust; avoid extraneous material ingress into the battery charger when inserting battery packs.
- Use a properly wired earth-ground socket outlet to plug in the battery charger.
- Do not step on, trip over, or drop the battery charger or battery packs.
- Do not charge the battery near heat sources or in strong sunshine. Built-in protection mechanisms are activated at high temperatures to prevent charging in dangerous conditions.
- Immediately stop charging a battery pack that does not charge inside a 3-hour timeframe. If this warning is ignored, the battery pack may overheat, emit smoke, explode, or ignite.
- Do not charge damaged or suspect battery packs.
- Do not use a damaged/abnormal battery charger or AC power adapter.

For more information, refer to the Reveal 35C Battery Charger manual supplied with the charger.

Charging the Battery



Use the recommended battery charger **ONLY** to charge the battery packs.
Failure to comply with this warning may result in battery damage.

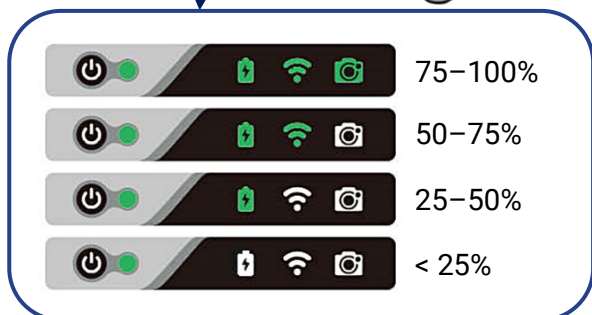
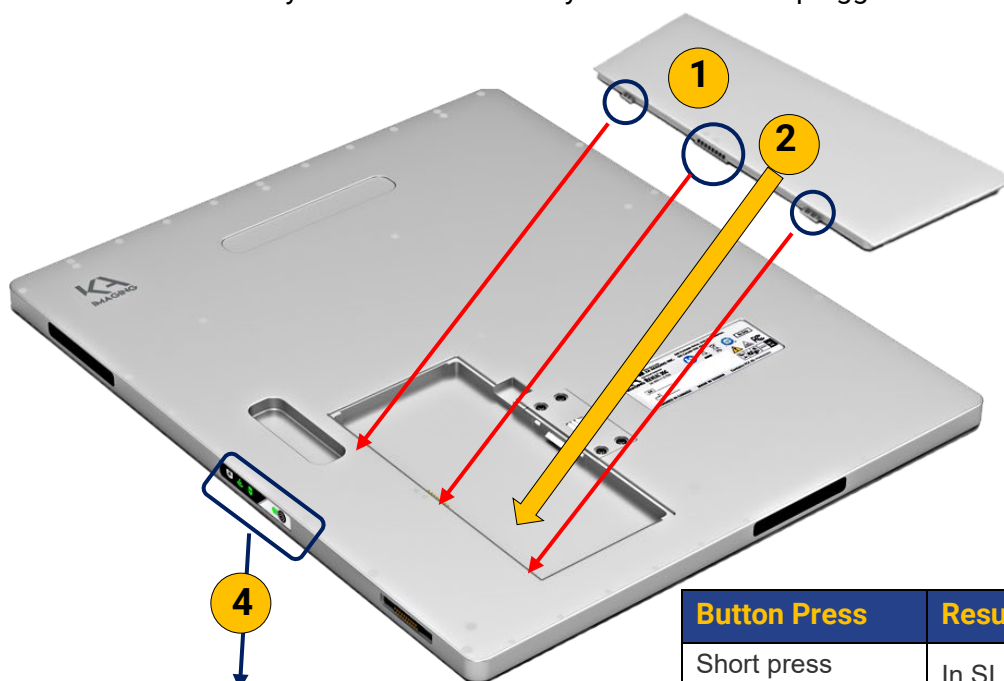
For charging instructions, refer to the Battery Charger UM supplied with the charger.

For battery maintenance instructions, refer to the [MAINTENANCE](#) chapter.

Installing the Battery

To install the battery:

1. Align the battery with the connectors on the flat panel detector as shown by the red arrows in the graphic.
2. Slide the battery into the compartment.
3. Press gently but firmly on the battery pack cover to ensure it is properly secured in place.
4. Double press the power button on the front panel of Reveal 35C to verify the charge. Use the chart below to determine the percentage charge remaining.
5. If the charge remaining is low, remove and charge the battery in the battery charger before using it. If the optional battery charger was not purchased, charging of the installed battery occurs automatically once the FPD is plugged into A/C power.

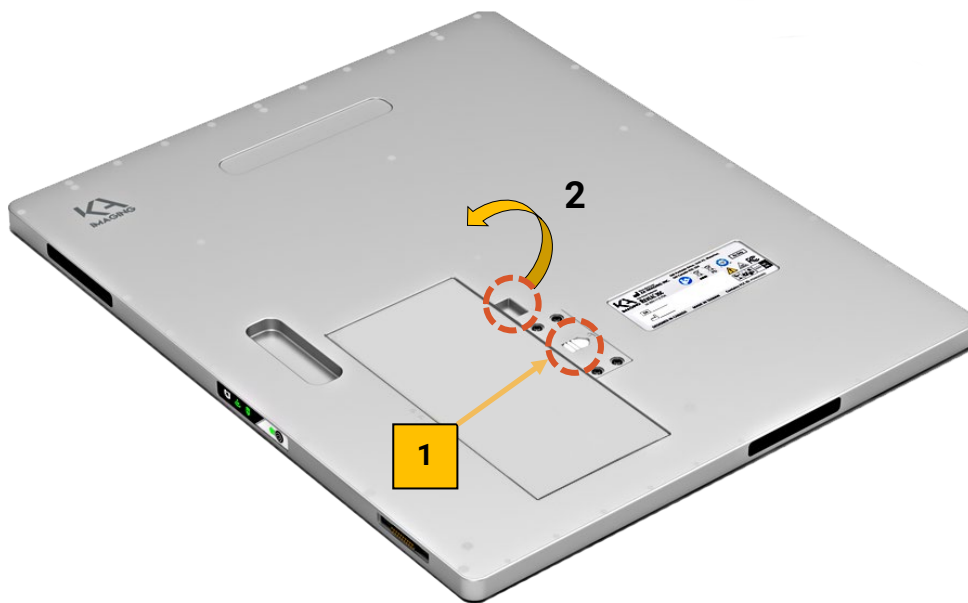


Button Press	Result
Short press (< 0.5 seconds)	In SLEEP mode, switches the FPD to READY-TO-CONNECT mode. In Standby mode, switches the FPD to CONNECTED mode.
Double press	Primary battery percentage displays via the LED illumination illustrated in the graphic at left
Long press (> 2 seconds)	Detector powers up or down, depending on its current state
Extended press (> 12 seconds)	Detector performs a hard shutdown (forced reset)

Removing the Battery

To remove the battery (in preparation for charging):

1. Slide the arrow switch as shown in the graphic and hold the switch to allow battery release from the compartment.
2. Use your other hand to lift an edge of the battery from the compartment as shown.
3. Remove the battery.



Environmental Requirements



Storage and use of the Reveal 35C FPD and power supply in environmental conditions outside of the specifications detailed below may cause fire, electric shock, and other unknown hazards.



Do not use this equipment in areas that fall outside of the parameters outlined in the Environmental Constraints for Use table.



Do not use this equipment in areas that fall outside of the restrictions defined in the Environmental Restrictions section.

Failure to comply with these warnings may result in severe injury, death, substantial product damage or reduced product lifetime.

Environmental Constraints for Use

Environment	Transportation/Storage	Operation
Ambient Temperature	-20°C to +40°C (-5°F to 105°F)	+15°C to +35°C (60°F to 95°F)
Relative Humidity	15% to 90%	15% to 90%
Atmospheric Pressure	50 to 106 kPa (15 in. to 30 in.)	70 to 106 kPa (20.6 in. to 30 in.)
Vibration (EN60068-2-6)	5 m ² /s ³ (10 Hz to 100 Hz) 1 m ² /s ³ (100 Hz to 2000 Hz)	0.5m ² / s ³ (10 Hz to 100 Hz) 0.1m ² / s ³ (100 Hz to 2000 Hz)
Shock (EN60068-2-27)	20g (.7 oz) duration: 11 ms	1.6g (.06 oz) duration: 11 ms

Environmental Restrictions

Failure to comply with these restrictions may result in severe injury, death, substantial product damage or reduced product lifetime.

Do not install or use Reveal 35C in any of these locations:

- Close to facilities where water is used
- Close to an electric heating appliance
- Close to air outlets of either air conditioners or ventilation equipment
- Close to electromagnetic interference (EMI) from telecommunication devices, transceivers, electronic devices, etc.
- In direct sunlight
- In environments that are dusty, saline, or sulphurous
- Where power supply is unstable
- Where temperature or humidity fall outside of the defined parameters

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- Where freezing or condensation occur
- In areas prone to vibration
- In areas where flammable anesthetics mix with air, oxygen, or nitrous oxide
- In areas where food or liquids are present, presenting a risk of short circuits
- On an incline or in an unstable area



Electromagnetic interference (EMI) may cause the FPD to malfunction.

To prevent electromagnetic waves from negatively influencing the Reveal 35C FPD, avoid proximity to EMI generators. Change the direction or position of the equipment or move it to a shielded place to reduce electromagnetic interference.



To avoid electric shocks and burns, ensure the onsite fire extinguisher is approved for use on electrical fires.

Ensure the battery charger is never used in the vicinity of a patient.

Considerations for Using Reveal 35C Outdoors

If the Reveal 35C FPD is being used outside (for example, in veterinary application), follow these guidelines:

Do not use Reveal 35C in any of these locations:

- In environments that are dusty or where water is used
- Where temperature or humidity fall outside of the defined parameters:

Environment	Operation
Ambient Temperature	+15°C to +35°C (60°F to 95°F)
Relative Humidity	15% to 90%
Atmospheric Pressure	70 to 106 kPa (20.7 in. to 30 in.)

- Where freezing or condensation occur

Flat Panel Detector Connection Constraints

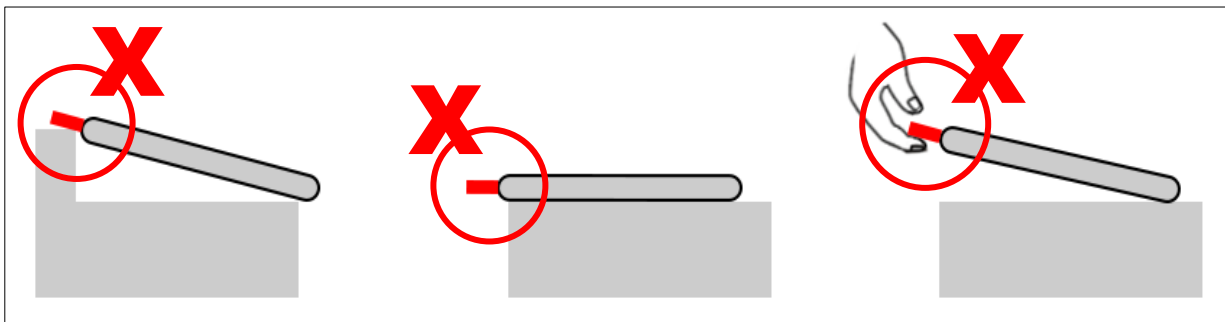


Do not place the FPD or its connector on the floor.



Ensure that the latches on either side of the connector are properly engaged.

Failure to comply with this warning could result in power loss during operation.

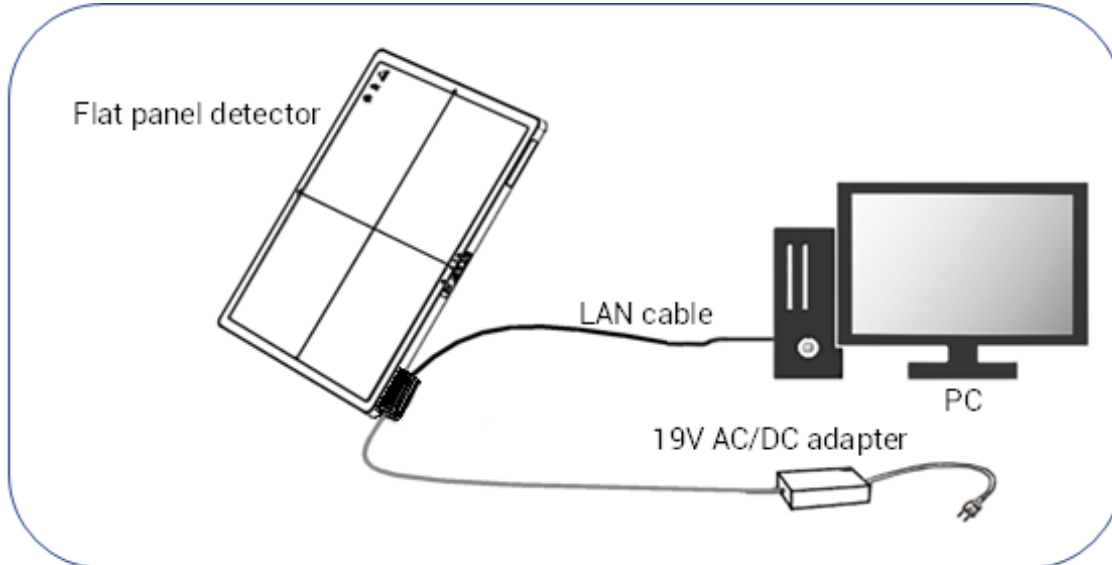


CONNECTOR
CANNOT
SUPPORT
DETECTOR AND
THE DETECTOR
MUST SIT FLAT

CONNECTOR
MUST NOT
PROTRUDE PAST
LIMITS OF
SUPPORTING
STRUCTURES

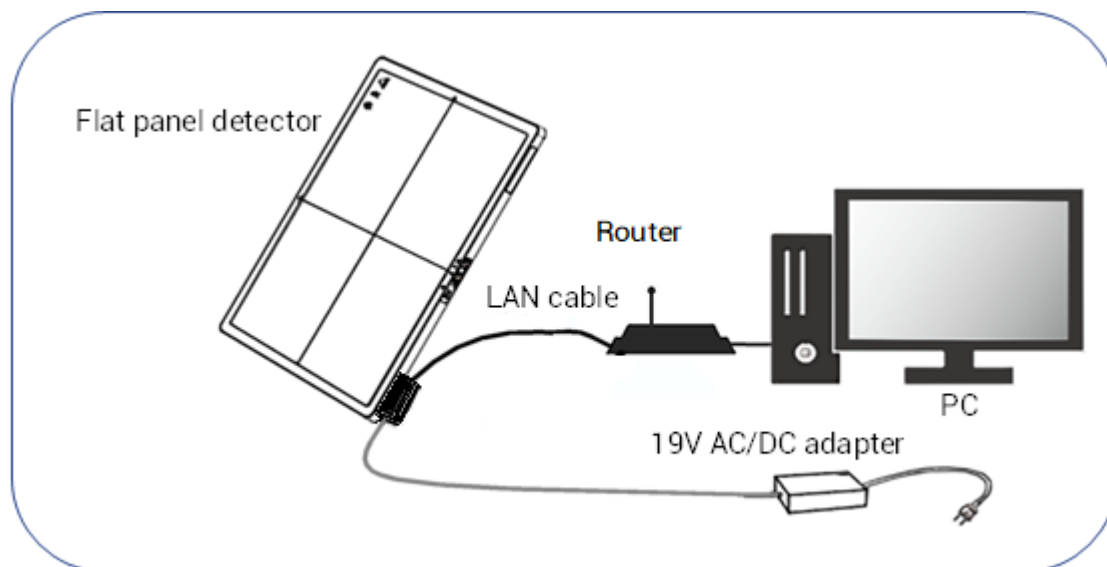
CONNECTOR
SHOULD NEVER
BE USED TO
MOVE OR LIFT
THE DETECTOR

Direct Ethernet Connection



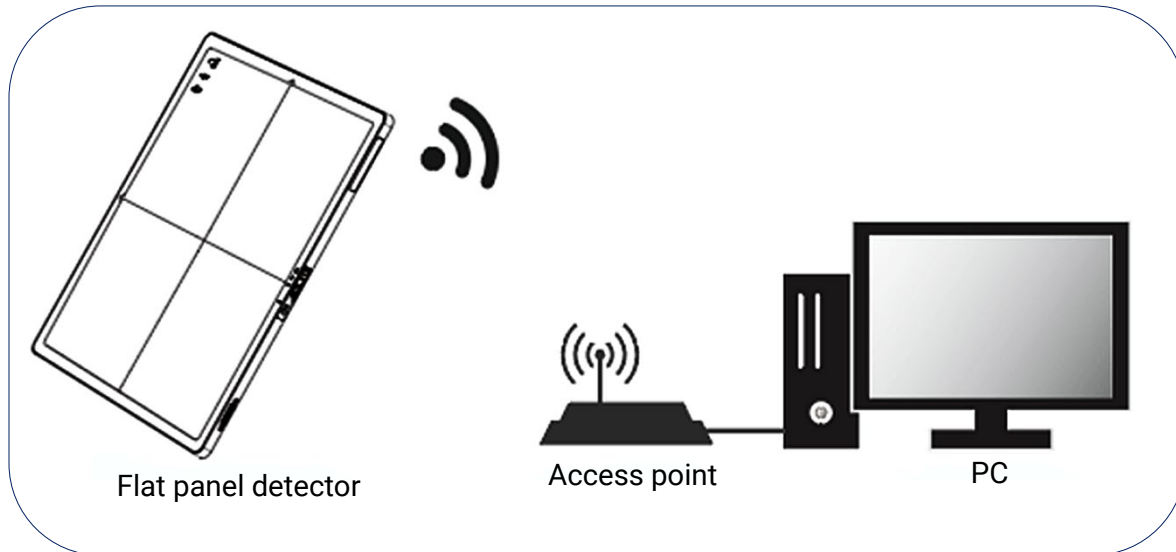
The illustration above demonstrates wired connection direct to PC, with no router.

Ethernet Through an Access Point



The illustration above demonstrates wired connection using a router, necessary only during connection using a dynamic IP.

Wireless Mode Connection



It is recommended that the access point be placed a minimum distance of 1.5 meters (5 feet) away from the FPD.



IMPORTANT NOTE

When the FPD battery is installed, no external connections are required.

Flat Panel Detector



To avoid the risk of electric shock, **CONNECT** this equipment to a supply main with protective earth **ONLY**.



The initial (first use) connection of the flat panel detector must be wired, as shown in the [Direct Wired Mode Connection](#) illustration on page 50.

To connect the Reveal 35C Flat Panel Detector:

1. Set up the FPD in a place that enables easy device disconnection.
2. Locate the I/O connector port on the front panel of the FPD, on the far-left side.
3. Plug the connector adapter into the connector port.
4. Plug the FPD cable into the connector adapter.
5. Plug the LAN (Ethernet) cable into the connector adapter.
6. Plug the AC/DC adapter on the FPD cable into the power supply cable, then into a wall socket that has a protective earth line.
7. Connect the LAN (Ethernet) cable to the PC as shown in the [Direct Wired Mode Connection](#) illustration on page 50.

Disconnecting the Flat Panel Detector

When finished with the Reveal 35C Flat Panel Detector, disconnect it:

- Disconnect the FPD cable and the LAN cable from the connector adapter located on the front lower left panel of the FPD.

REVEAL 35C SOFTWARE SETUP

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The initial (first use) connection of the Reveal 35C Flat Panel Detector (FPD) must be wired, an Ethernet connection must be made, and the Wi-Fi must then be configured to allow for future wireless connection and use.

Steps for Reveal 35C Software Setup: Process Overview

The steps for FPD setup in preparation for first use are as follows:

1. Connect the FPD to the Ethernet.
2. Power up the FPD.
3. Configure the FPD for Wi-Fi.
4. Power cycle the FPD.
5. Calibrate the FPD.
6. Configure examinations.

Process Overview: From Setup to First Use

FPD Configuration

The FPD (referred to as a sensor in the software that runs the device) must be configured before first use: firstly, to connect the sensor to Ethernet (and subsequently, Wi-Fi if desired), and secondly, to proceed to image acquisition.

Detector setup includes:

- Configuration of the sensor
- Configuration of the sensor to a generator
- Configuration of the sensor to a workstation

Ethernet Configuration and TCP Connection

To begin operating the Reveal 35C Flat Panel Detector, a TCP connection between the UI (user interface) on the PC and the FPD must be established. To establish this connection, the FPD should be ON and ready (indicated by solid green illumination of the power LED) and connected to the same network as the PC either by Ethernet. Because no default Wi-Fi configuration exists in the FPD's factory settings, the first connection must be made through Ethernet. TCP connection occurs automatically following FPD configuration, at restart of the application.

Calibration

Reveal 35C FPD must be calibrated after the initial installation and before the first use. If a successful calibration was carried out on the FPD at a previous point, repeat the offset and gain calibration.

It is possible to check for the presence of calibration data from the Configuration of the Console screen, in the Configuration of sensors section, where clicking the CALIBRATION button accesses the calibration landing page and displays this information.

Examination Configuration

Following successful calibration completion, or if an FPD has been previously calibrated, examination plans must be configured before image acquisition can begin.

Reveal 35C Flat Panel Detector Image Capture

The Reveal 35C Flat Panel Detector can simultaneously operate as a conventional digital radiography (DR) detector and a tissue-selective detector.

Image capture instructions are provided in [IMAGE ACQUISITION](#) on [page 77](#).

REVEAL 35C

USER MANUAL (EN)



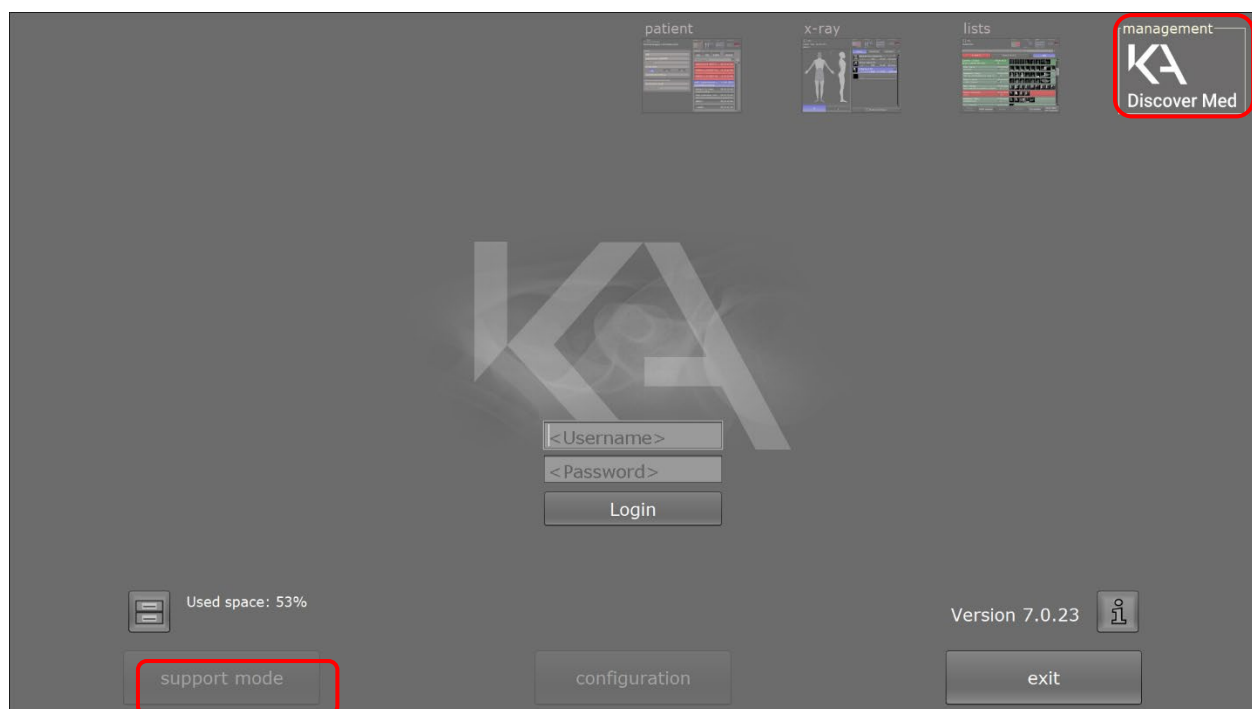
Detector Addition and Configuration

The detector to configure (referred to as a sensor in the DiscoverMed software) can be selected from a list of available sensors.

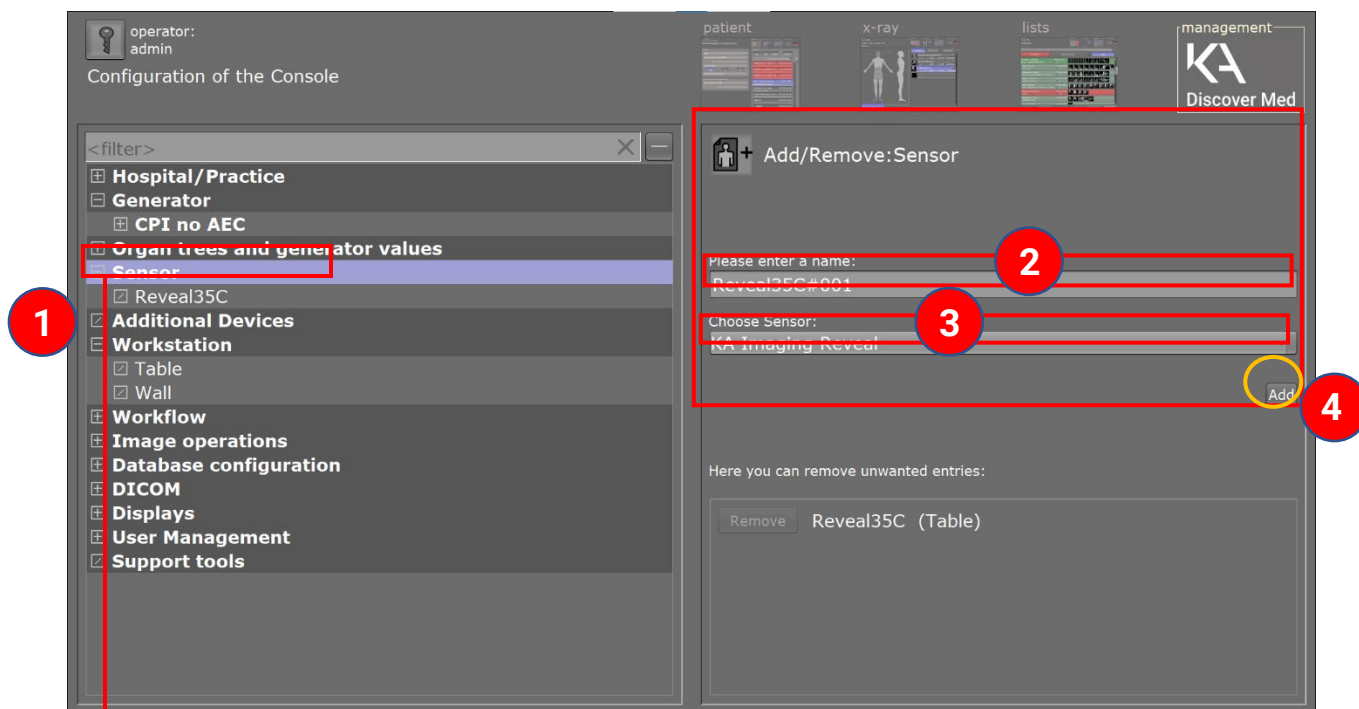
If the required sensor has not yet been added, it can be added to the list of configurable sensors.

To configure or add a detector (sensor), switch to the support mode by clicking on the 'management' view and then on the button SUPPORT MODE.

The user must have administrative rights to access SUPPORT MODE.



Add a New Sensor



Click on the 'parent' sensor heading

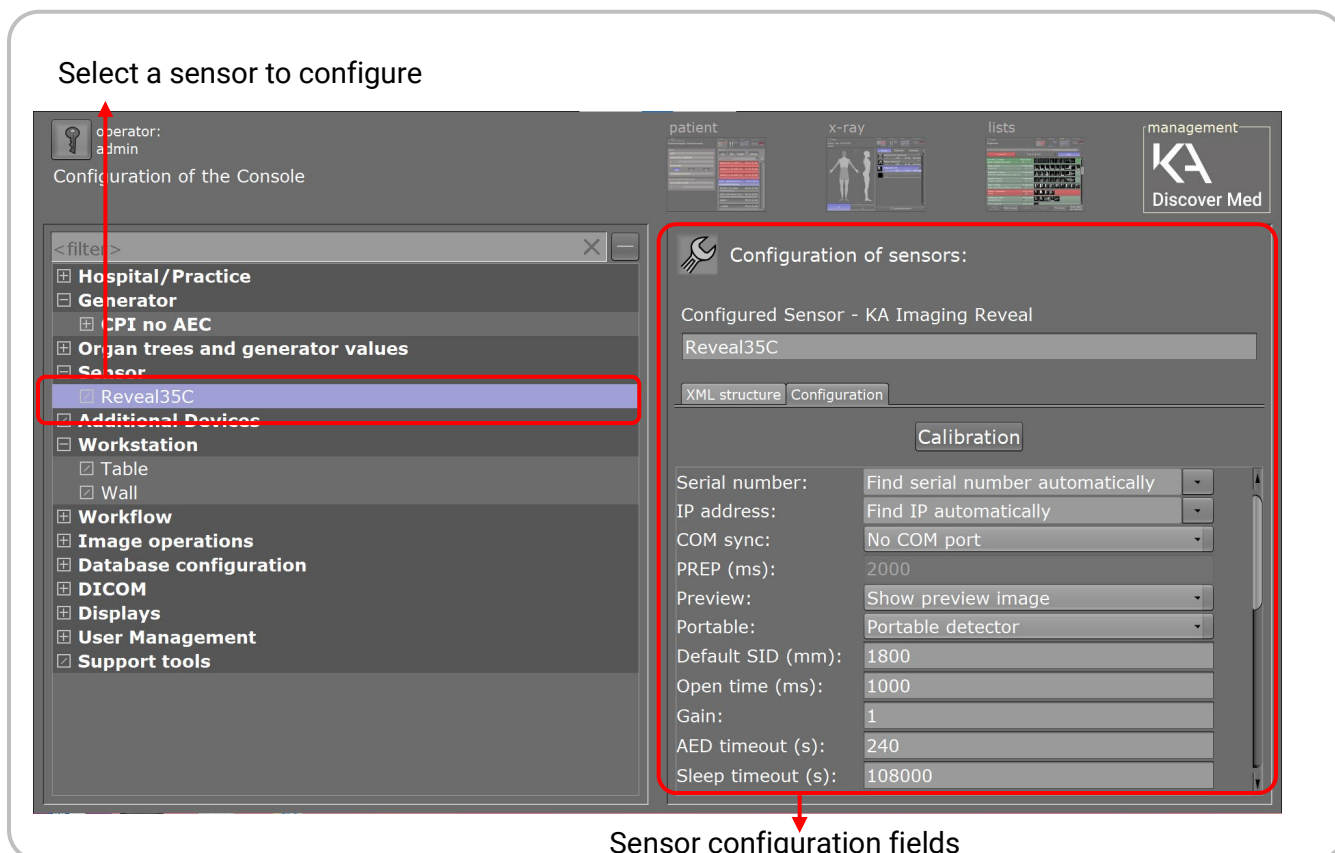
To add a new sensor:

1. Click on the parent 'Sensor' heading on the left side of the screen.
2. Enter the name of the sensor into the 'Please enter a name' field on the right side of the screen.
3. Select the sensor type (always KA Imaging Reveal for Reveal 35C detectors) from the dropdown list under 'Choose Sensor'.
4. Click ADD.



The bottom right area of the screen enables removal of preconfigured sensors. On the sample screen above, the Remove button is grayed out (unselectable) because a sensor cannot be deleted if it is associated with a workstation.

Configure a Previously-Added Sensor



When configuring a sensor, set all properties as desired for post-connection, and the software ensures all defined properties are adhered to when a connection is established.

The following configurations are recommended.

Serial number

Entry of the serial number is the most common (and the default) selection for panel look-up at time of connection.

While it is possible to enter both the serial number and the IP address, the software prioritizes the serial number connection when both fields contain values.

IP address

The IP address can be hardcoded for connection purposes, which may be useful in some scenarios on certain networks where the discovery protocol might be blocked by the IT network. *Only* configure IP if the FPD's IP address in the network is known and fixed. Setting this field to 'Find IP automatically' is recommended when using DHCP.

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Preview

This setting controls whether a preview image is shown immediately after image acquisition. Preview images provide a low-resolution version of the image available while the full-resolution image is being transferred through the network. Once transfer is complete, the preview image will be replaced. Set this field to 'Show preview image'.

Portable

Selecting 'portable detector' is recommended. While selecting 'Fixed detector' results in slightly faster processing times, the sensor must be alignment calibrated to the same geometry as is used for imaging.

Recovery

Enables or disables the CAPTURE HISTORY FEATURE. Leaving this enabled is recommended. Set this field to 'Image recovery enabled'.

Autorotation

Set this field to 'Use detectors rotation sensors' to automatically rotate images when FPD is used in a vertical orientation.

Wi-Fi SSID

Enter the name of your 802.11 wireless local area network (WLAN).

Wi-Fi Password

Enter the Wi-Fi network password.



By default, the preferred connection of the software is via Ethernet. If the sensor (detector) has access to the LAN through both Wi-Fi and ethernet, the ethernet connection is preferred by the UI.



Once the SSID and password are set, the FPD attempts to connect to Wi-Fi automatically when the FPD enters READY TO CONNECT mode.

Workstation Configuration

Once the sensor is fully configured, it must be attached to a workstation.

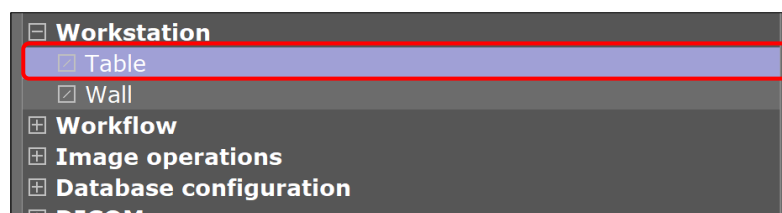
A workstation is a connection between a sensor and a generator. The generator is the X-ray source.



X-ray imaging cannot be performed with just a sensor; imaging must be undertaken in the context of a workstation.

Workstation Configuration: Selection

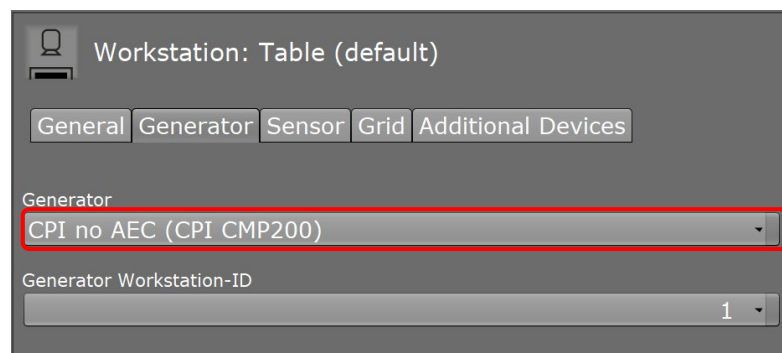
To select an existing (previously-configured) workstation for the purpose of attaching it to the Reveal 35C FPD, select the workstation from the dropdown list as shown.



Select the workstation from the dropdown list

Workstation Configuration: Generator

Click the GENERATOR tab and select the generator from the dropdown list.



Select the generator from the dropdown list.

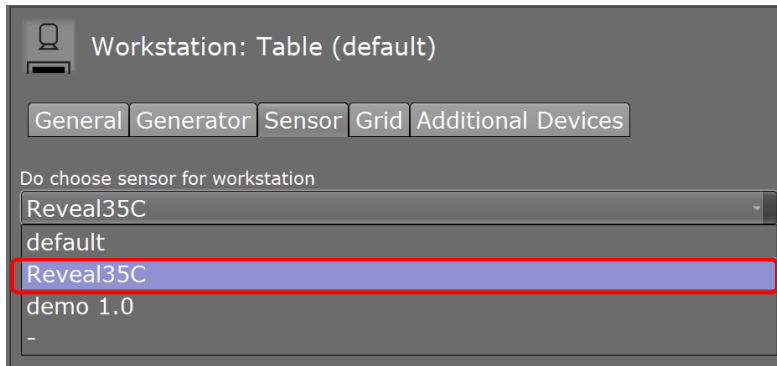
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Workstation Configuration: Sensor

Click the SENSOR tab and select the sensor to associate with the generator from the dropdown list.



Select the sensor from the dropdown list.



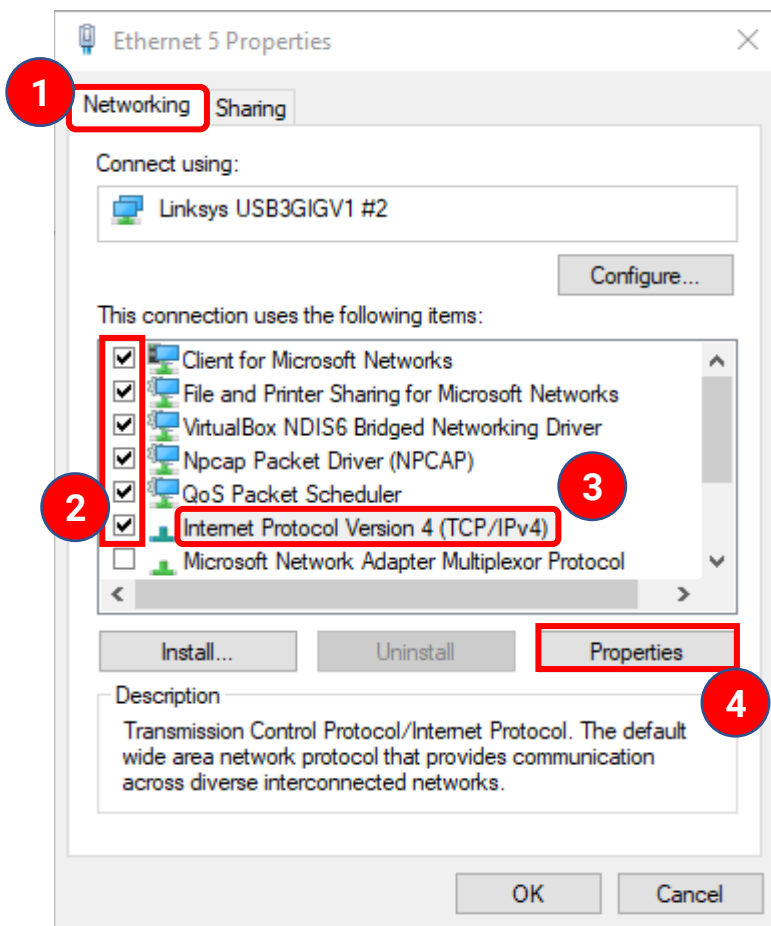
It is possible to have multiple workstation configurations available in a single X-ray room where there are multiple X-ray sources, workstations, and sensors.

Ethernet Connection Configuration and TCP Connection

Ethernet Connection Configuration

Direct ethernet connection (no router)

Note: These instructions are only for a direct connection. For an Ethernet connection through an access point, use **Obtain an IP address automatically**.



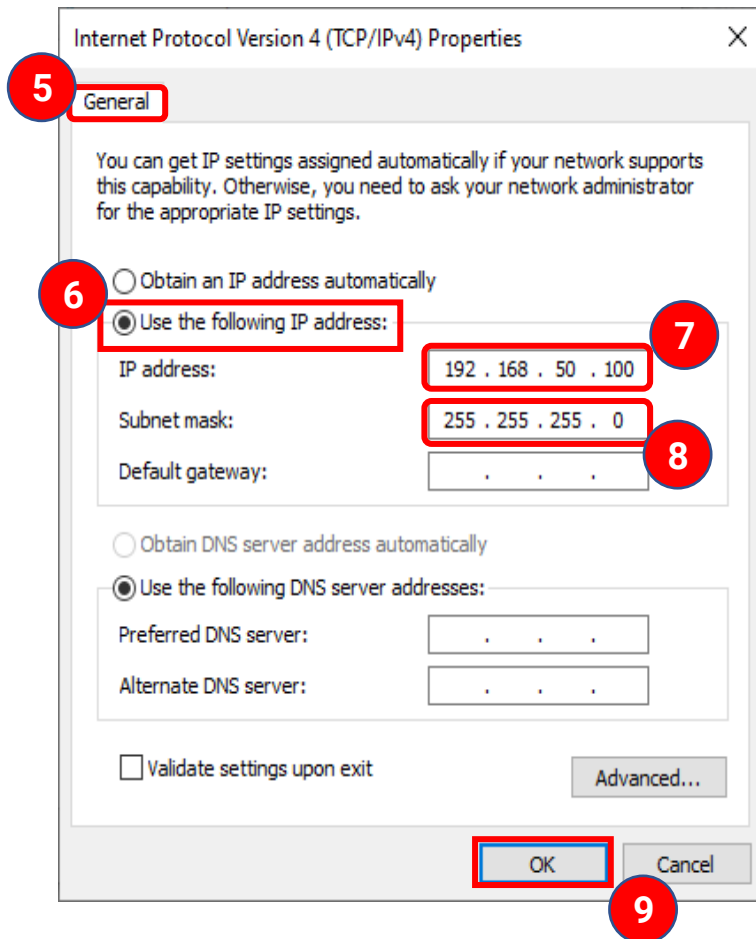
Configure the Ethernet connection to use a static IP:

1. Search for Ethernet Settings.
2. Click Ethernet settings, then Change adapter options, and finally, double-click the Ethernet tab.
3. Click the NETWORKING tab.
4. Checkmark-select the properties settings shown.

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5. Select INTERNET PROTOCOL VERSION 4 (TCP/IPV4).
6. Click the PROPERTIES button.



7. Click the GENERAL tab.
8. Click-select 'Use the following IP address' as shown.
9. Set the IP address to 192.168.50.100.
10. Set the Subnet mask to 255.255.255.0.
11. Click ok.

TCP Connection

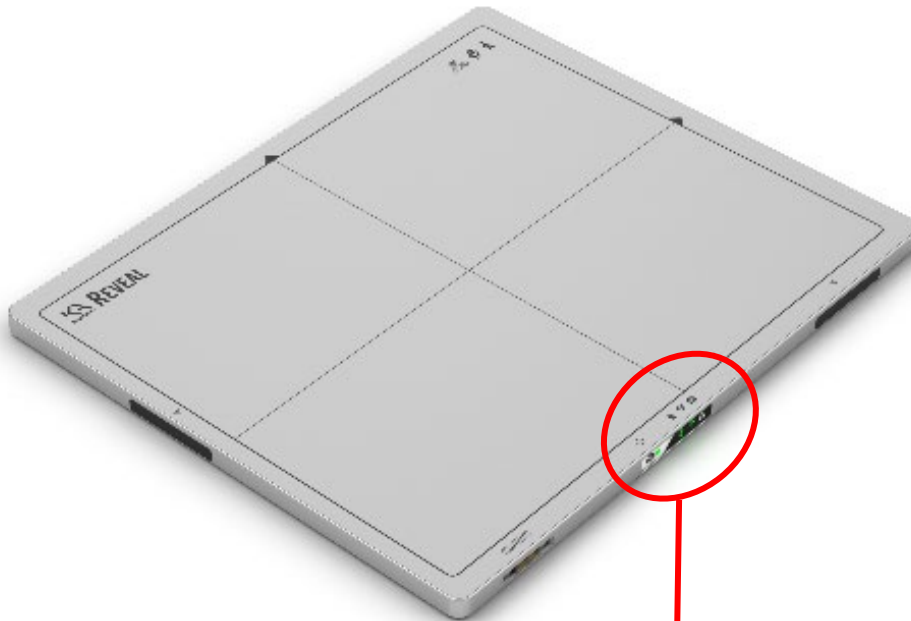
Once FPD configuration is complete, TCP connection occurs automatically.

1. Restart the application to launch the configured settings.
2. Verify the connection is made by confirming the Wi-Fi LED on the panel is illuminated (green) after the application opens.

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Power up the FPD



To power up the FPD:

- Press and hold the POWER button on the front panel of the flat panel detector for 3 to 4 seconds until the power button indicator flashes green.

Calibration

This section details the steps required to perform a full FPD calibration. Although an FPD can only be in two states—calibrated and not calibrated—calibration is divided into three separate procedures: Offset, Gain, and Alignment. All three must be successfully completed at least once before an image capture can be performed.

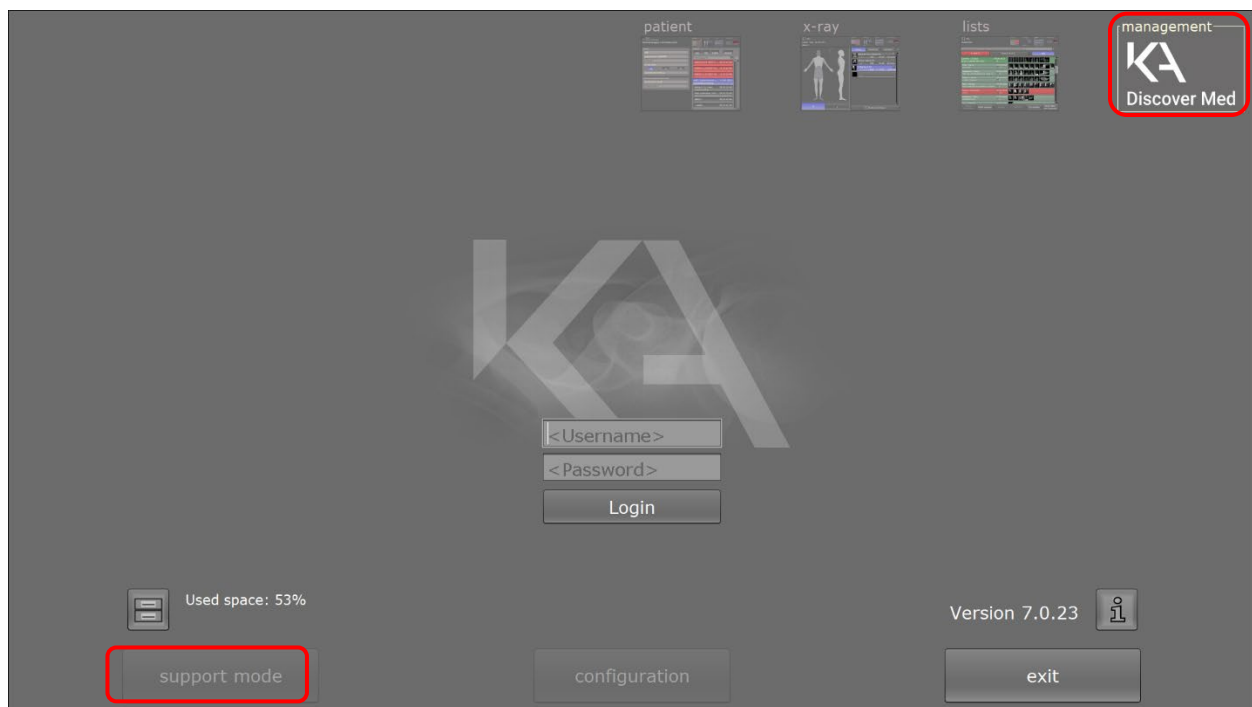


Follow the Calibration procedures as provided.

IMPROPER CALIBRATION CAN RESULT IN FUNCTION FAILURE.

To perform calibration:

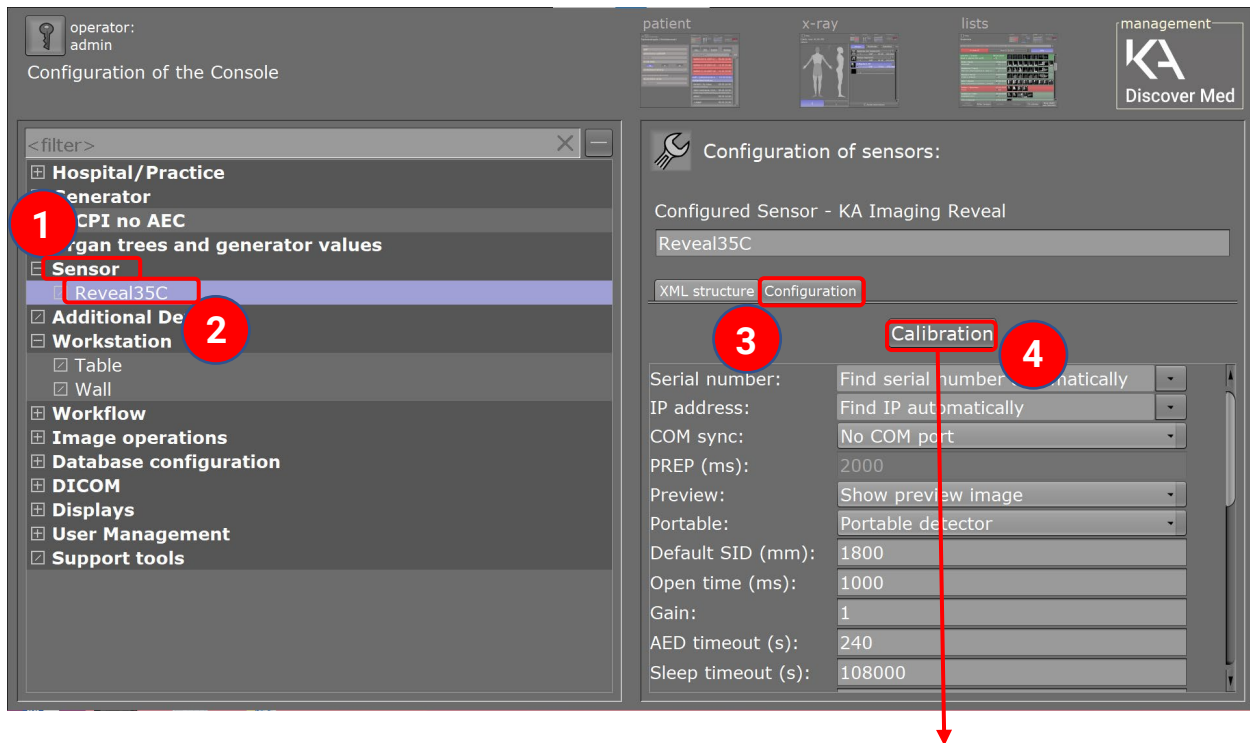
1. Log in using an administrative username and password.
You must have administrative rights to use SUPPORT MODE.
2. Switch to support mode by clicking on the 'management' view and then on SUPPORT MODE.



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Calibration Screen

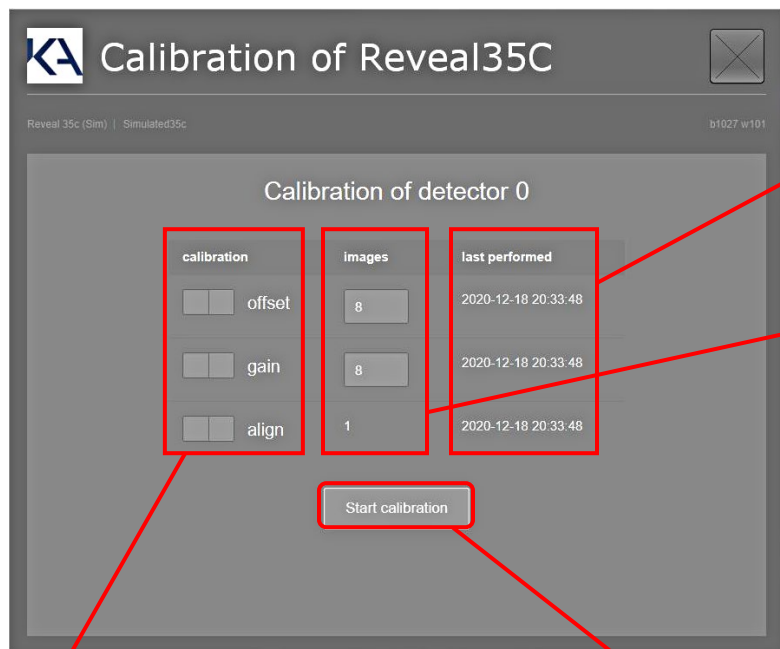


Click the CALIBRATION button to transfer to the calibration landing screen

1. Click the parent SENSOR tab on the left side of the screen.
2. Click-select REVEAL 35C to select it as the sensor to calibrate.
3. Click the CONFIGURATION tab.
4. Click the CALIBRATION button.

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Last date of performance of offset gain and alignment calibration.

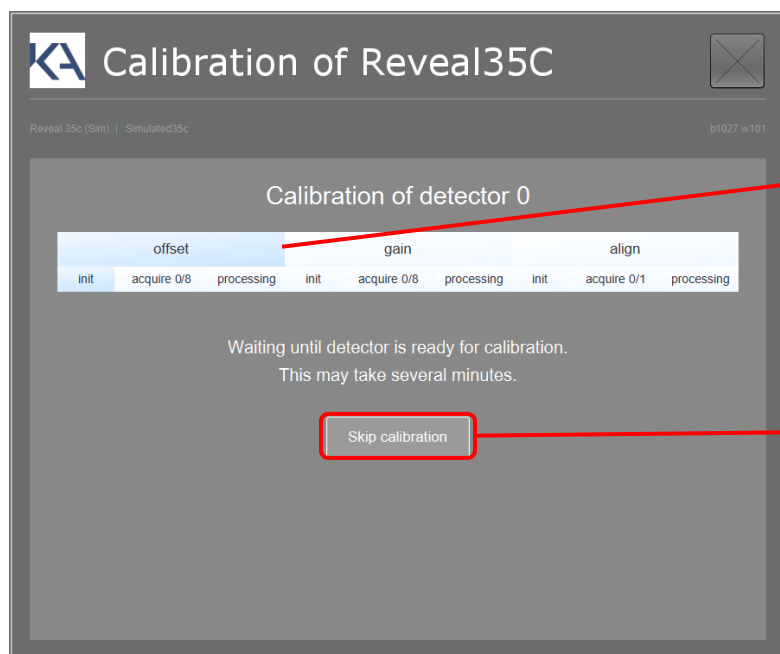
2 Define the number of images to be acquired per calibration type during calibration. Offset and gain values are editable.

1 Select, using the toggle switches, the desired calibration procedures to perform

3 Click START CALIBRATION.

Offset Calibration

In Auto Exposure Detection mode, offset calibration is required only before gain of alignment calibration. In standalone mode, perform offset calibration daily.



Offset calibration begins to initialize, as shown by the blue shading.

If the currently initializing calibration procedure was erroneously selected in Step 1, press SKIP CALIBRATION. Otherwise, wait for calibration to automatically complete.



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Offset Calibration does not require X-Ray exposure. The flat panel detector automatically performs the required steps for completion, and the system displays on-screen status of the calibration progress throughout. Once Offset Calibration completes, the system display indicates completion to the operator.

Gain Calibration

Perform gain calibration weekly, whenever the X-ray source or imaging geometry changes, or when image quality degrades.

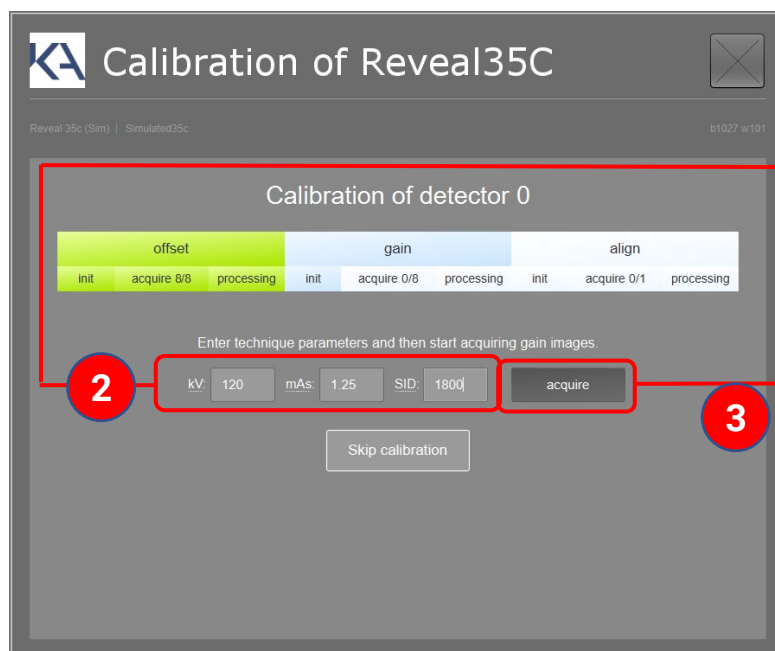
The operator must enter technique parameters before gain calibration can begin.

Gain Calibration requires X-Ray exposures to occur. The operator must at this time remove all obstructions as prompted and expose the FPD to X-rays; this exposure is automatically detected by the FPD.

The FPD sends the results of the exposure to the UI, and the UI cues the operator via an on-screen message to expose the FPD again. This process should repeat (in the sample shown) a total of 8 times (or the number of times specified between a minimum of 8 and a maximum of 32 as set). If any of the exposures fail, a window appears indicating the error that occurred.



Remove all objects and expose the detector to X-ray.



Enter technique parameters in accordance with the cautionary notes below the screen.

Click ACQUIRE button after parameter entries are complete.

NOTE

The SID on the Calibration screens is expressed in millimeters.





- The recommended generator setting for calibration is 120kVp.
- Adjust the mAs to obtain an estimated Air Kerma of $\sim 75\mu\text{Gy}$.



- The FPD must be positioned at the center of the beam path and located at a typical source-to-detector distance (SID) ($\sim 1800\text{mm}$ (6 ft.)). The collimator settings are such that the entirety of the FPD's active area is covered by the X-ray beam.
- The beam path must be clear. Ensure no objects are in the path of the beam.



After Gain Calibration completes, Alignment Calibration begins.

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Alignment Calibration

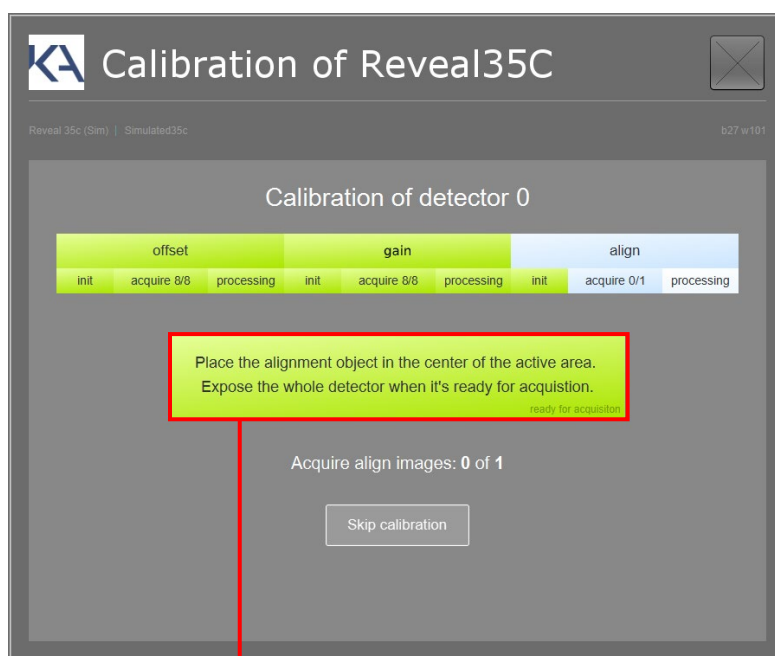
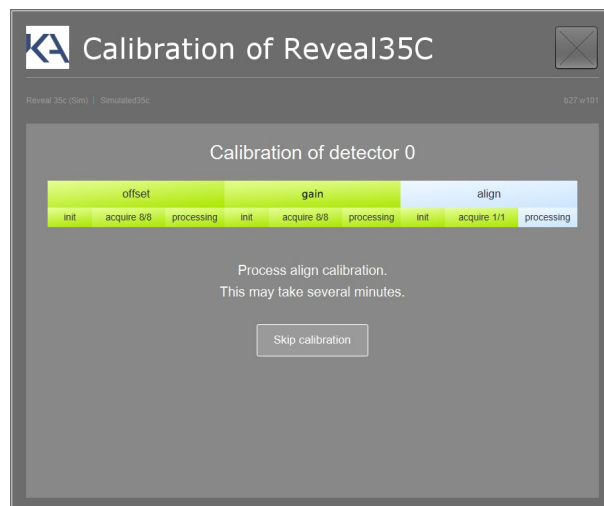
Perform alignment calibration when the imaging geometry changes substantially, the detector is bumped or dropped, or image quality degrades.

Alignment Calibration also requires intervention from the operator. Once Alignment Calibration initializes successfully, the FPD waits for a particular X-Ray exposure.

Now, the operator must place the alignment object immediately in front of the FPD and expose the FPD to X-rays.

The FPD detects the exposure and sends results to the UI.

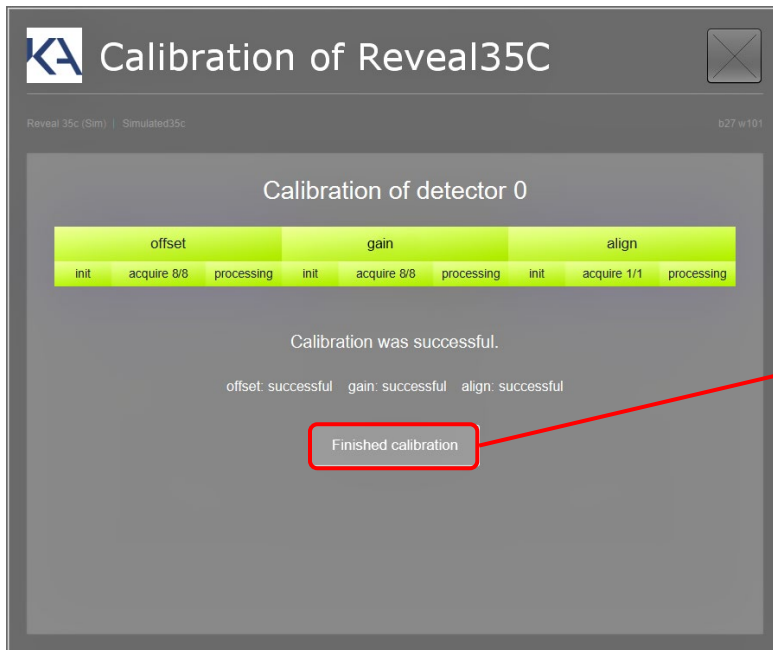
If calibration fails, a window appears to indicate the error that has occurred.



Place the alignment object and expose the detector to X-ray.

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Click FINISHED CALIBRATION at its appearance to confirm.

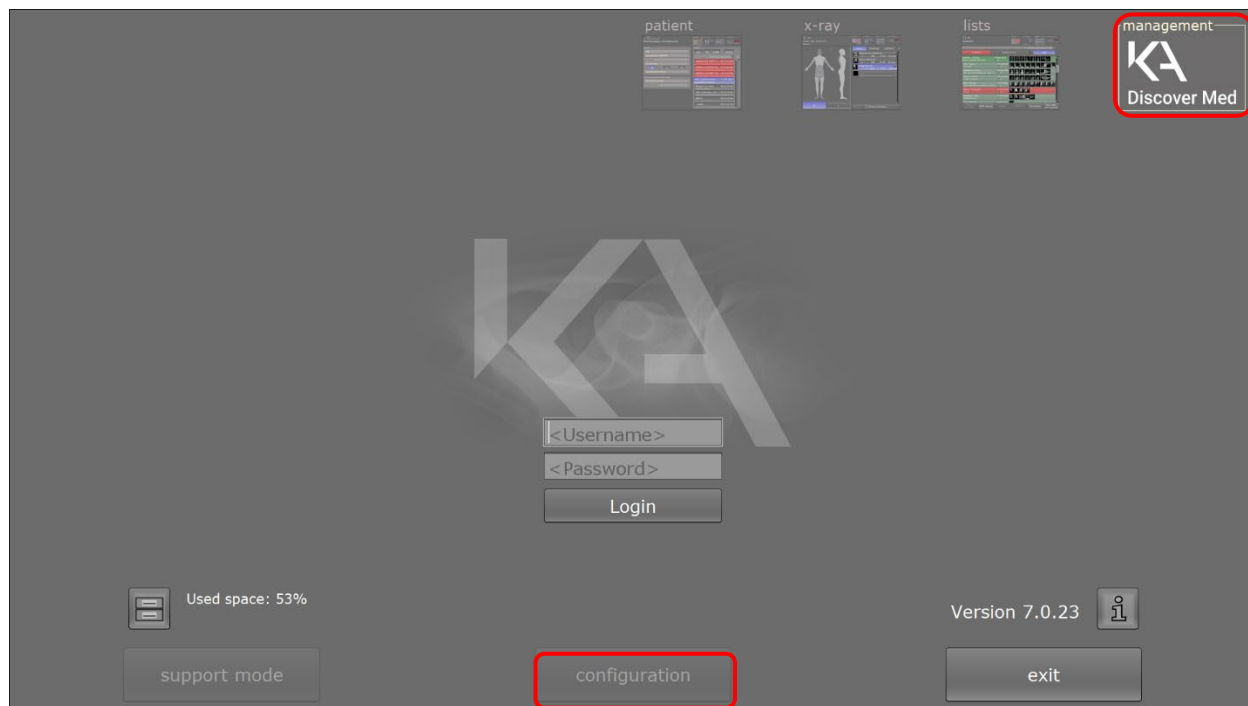


Once Alignment Calibration completes, the entire calibration process is also complete, as Alignment Calibration is the third and final step in the calibration process.

Examination Configuration

To configure examinations and macros, return to the Main screen and re-select configuration mode by clicking on the “management” view and then on CONFIGURATION.

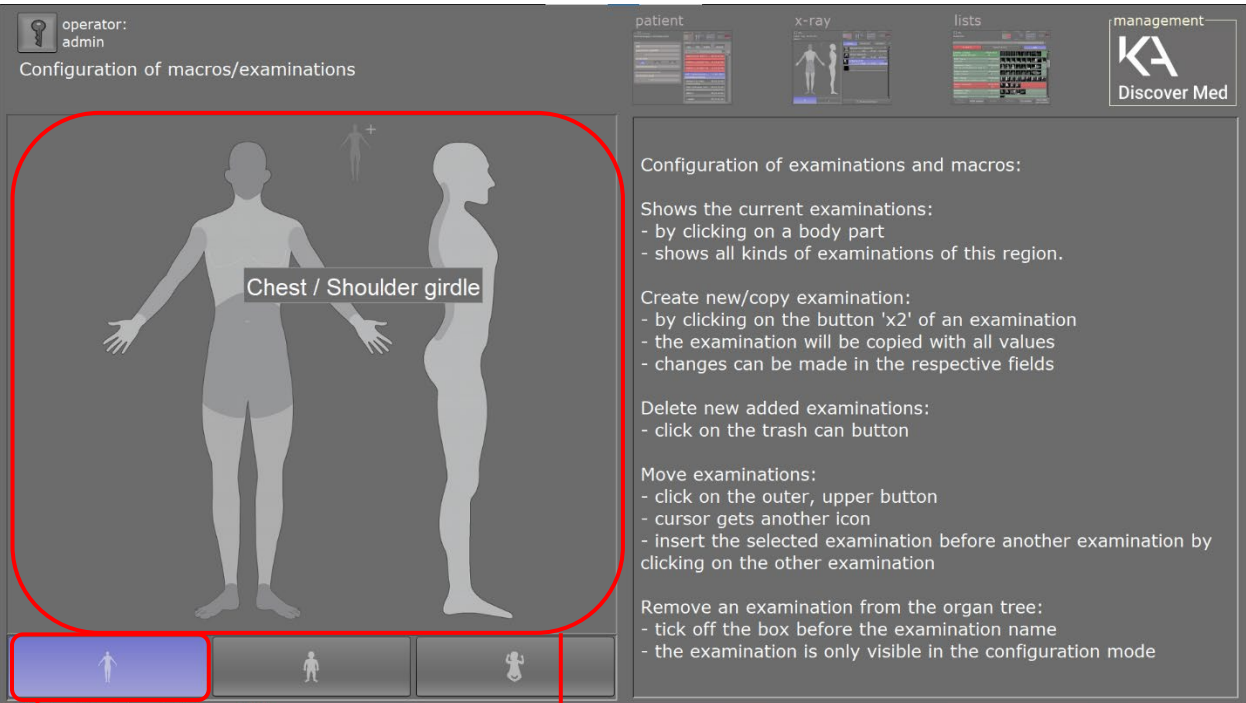
The user needs administrator rights to enter CONFIGURATION.



The configuration mode displays immediately and offers the possibility to customize and extend the supplied examinations in the organ trees for adults, pediatrics, and infants. It also facilitates the creation of macros (exam bundles), which include several individual X-ray examinations for recurring examination sequences.

The following list describes the configuration possibilities for macros and examinations:

- Create new examinations / macros
- Change examinations / macros
- Hide examinations / macros
- Change the color of examinations
- Change / insert procedure codes for examinations
- Change the image processing of examinations
- Change the order of examinations / macros



operator:
admin

Configuration of macros/examinations

patient x-ray lists management
KA
Discover Med

Chest / Shoulder girdle

Configuration of examinations and macros:

Shows the current examinations:
- by clicking on a body part
- shows all kinds of examinations of this region.

Create new/copy examination:
- by clicking on the button 'x2' of an examination
- the examination will be copied with all values
- changes can be made in the respective fields

Delete new added examinations:
- click on the trash can button

Move examinations:
- click on the outer, upper button
- cursor gets another icon
- insert the selected examination before another examination by clicking on the other examination

Remove an examination from the organ tree:
- tick off the box before the examination name
- the examination is only visible in the configuration mode

Selection of the age for which alterations are to be made

Interactive graphic allows mouse-selection of the body part to image

To configure an examination:

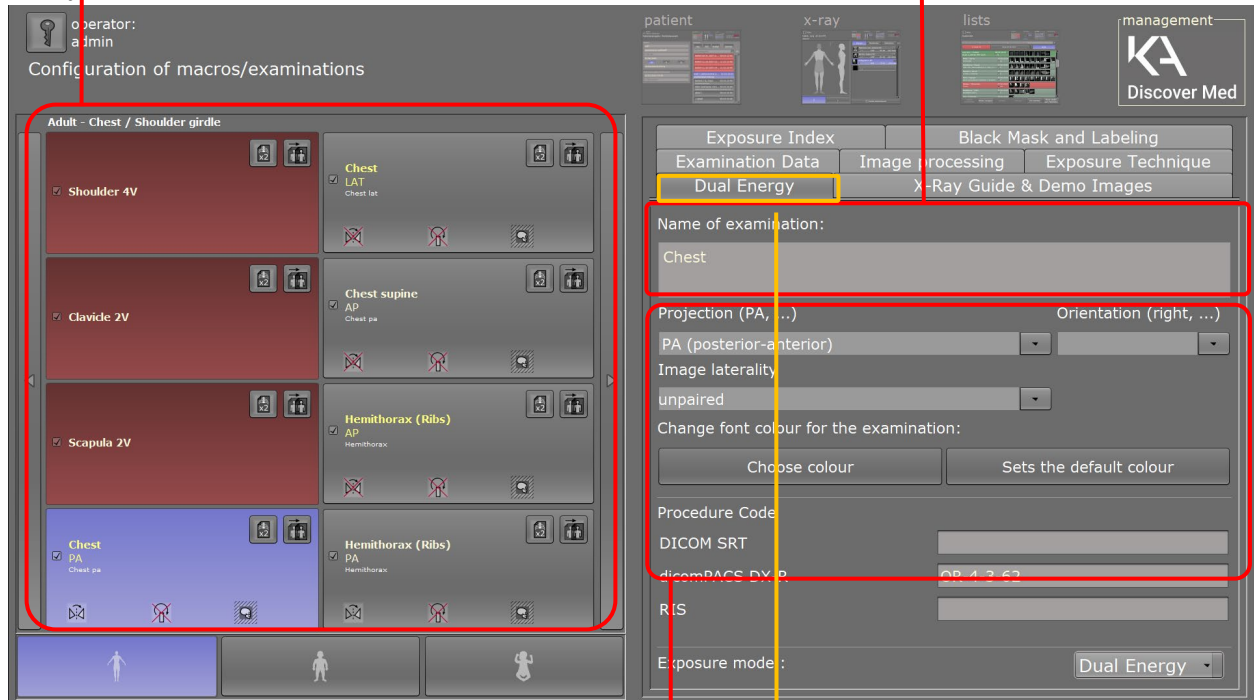
1. Selection of the age of the patient from the options at the lower-left of the window.
2. Click the body part to image on the interactive frontal anatomy graphic.

In the sample above, the user has selected the chest/shoulder girdle on the interactive frontal anatomy graphic to set up a Chest PA exam for an adult.

Clicking on an anatomical portion of the interactive model produces a configuration screen displaying a list of pre-installed examinations / macros within the body part of choice (chest / shoulder girdle in the example above).

Pre-installed examinations of the selected body part

Name of the examination can be changed



Choose projection, orientation, and image laterality

Dual Energy tab

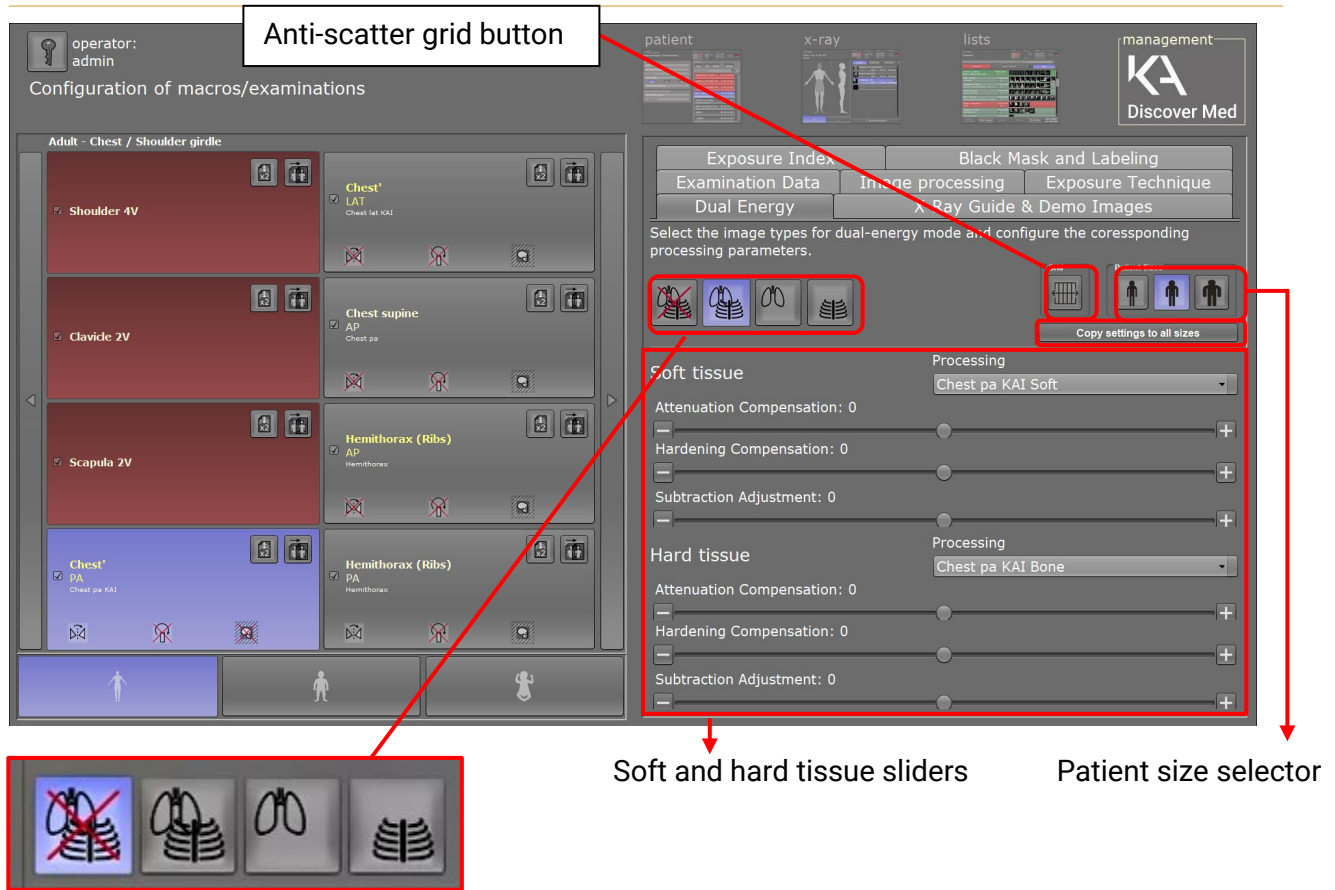
The user can select one of the pre-installed examinations from the list, or can scroll to the bottom of the list and click 'Create new examination'.

The 'Dual Energy' tab allows the user to select which dual-energy capabilities are needed for the specific exam.

Click the 'Dual Energy' tab to access a window that allows for selection of images in dual-energy mode, and configuration of the corresponding process parameters.

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The screenshot shows the 'Configuration of macros/examinations' window. A callout box labeled 'Anti-scatter grid button' points to a grid icon in the 'Chest' processing section. Another callout box labeled 'Soft and hard tissue sliders' points to the 'Soft tissue' and 'Hard tissue' processing sections, which contain sliders for 'Attenuation Compensation', 'Hardening Compensation', and 'Subtraction Adjustment'. A third callout box labeled 'Patient size selector' points to a row of four icons representing different patient sizes (Small, Medium, Large, Extra Large).

A series of four icons controls the selection of dual-energy capabilities.



The no dual-energy icon sets the image capture to the DR image (default).



The full dual-energy icon sets the image capture to both soft tissue and hard tissue.



The soft tissue icon sets the image capture to soft tissue only.

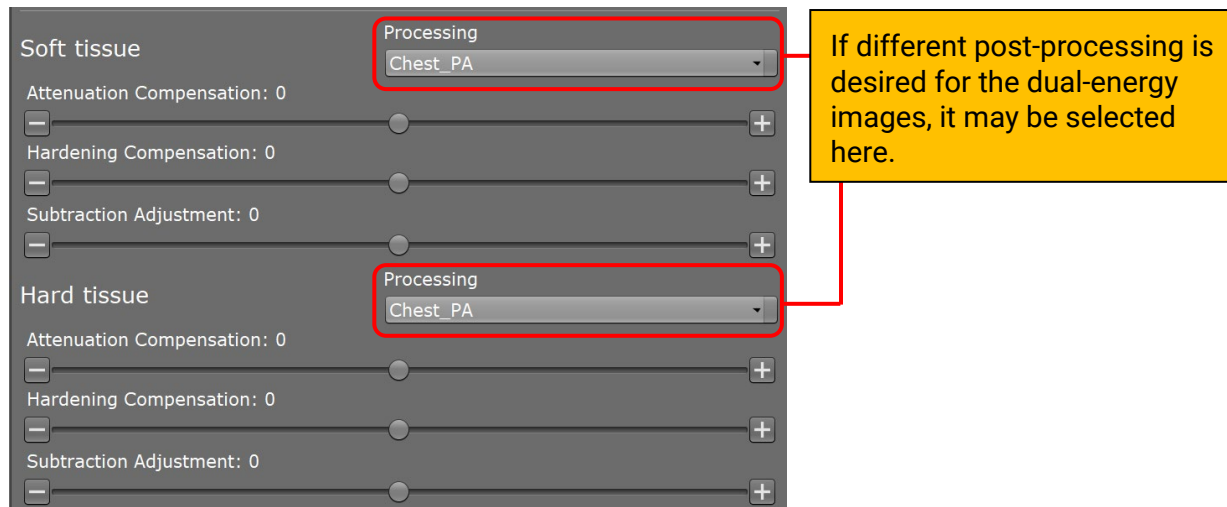


The hard tissue icon sets the image capture to hard tissue only.



If the default 'no dual-energy' setting is selected, the user has the ability, after the fact, to add the dual-energy image later and look at it.

The advantage of the Reveal 35C Flat Panel Detector is that every acquisition is technically a dual-energy acquisition.



The 'Soft tissue' and 'Hard tissue' slider tabs allow the user to set and adjust the dual-energy functions for each examination.

Attenuation Compensation (-100% → +100%)

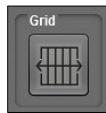
This setting increases or decreases the dual-energy subtraction algorithm's compensation for X-ray attenuation. Default value of 0% is tuned to the attenuation of a conventional thin human chest in PA orientation. Typically, a higher value is required for more attenuating objects and a lower value is required for less attenuating objects to maintain subtraction uniformity across the entire image.

Hardening Compensation (-100% → +100%)

This setting increases or decreases the dual-energy subtraction algorithm's compensation for X-ray beam hardening. Default value of 0% is tuned to the hardening of a conventional thin human chest in PA orientation. Typically, a higher value is required for more hardening objects and a lower value is required for less hardening objects to maintain subtraction uniformity across the entire image.

Subtraction Adjustment (-100% → +100%)

This setting finetunes the tissue subtraction in the dual-energy image. Default value of 0% is tuned for subtraction of typical human chest soft-tissue (in bone image) or typical human chest bone tissue (in soft-tissue image). Small changes to this value allow adaptation to different patient sizes. Large changes to this value allow adaptation to different tissue types. Small adjustments may be required if compensation factors are modified.









This tab selection allows the anti-scatter grid to be turned ON or OFF for the current examination configuration.



This tab selection allows the user to set specific dual-energy factors for particular patient sizes. The default factor applied if the user makes no alterations is medium.

The six possible combinations of factors resulting from selections above are as follows:

	Small patient	Medium patient	Large patient
Without Anti-Scatter Grid	 Small patient, no anti-scatter	 Medium patient, no anti-scatter	 Large patient, no anti-scatter
With Anti-Scatter Grid	 Small patient, use anti-scatter	 Medium patient, use anti-scatter	 Large patient, use anti-scatter

Using the COPY SETTINGS TO ALL SIZES button allows the user to set up one patient size/anti-scatter factor combination to an examination, then apply those same settings across all patient sizes if applicable (when the same factors apply to all patients regardless of size).

IMAGE ACQUISITION

6

This chapter provides direction regarding image acquisition and image view procedures.

Image Acquisition Types

Images can be acquired in one of two ways:

- Captured in CONNECTED AED mode
- Captured in STANDALONE mode



Do not start imaging with the Reveal 35C Flat Panel Detector (FPD) when the FPD battery charge is **less than 10%** (battery LED is solid yellow).



TO REDUCE THE EFFECTS OF BACK-SCATTERING IMAGE ARTIFACTS:

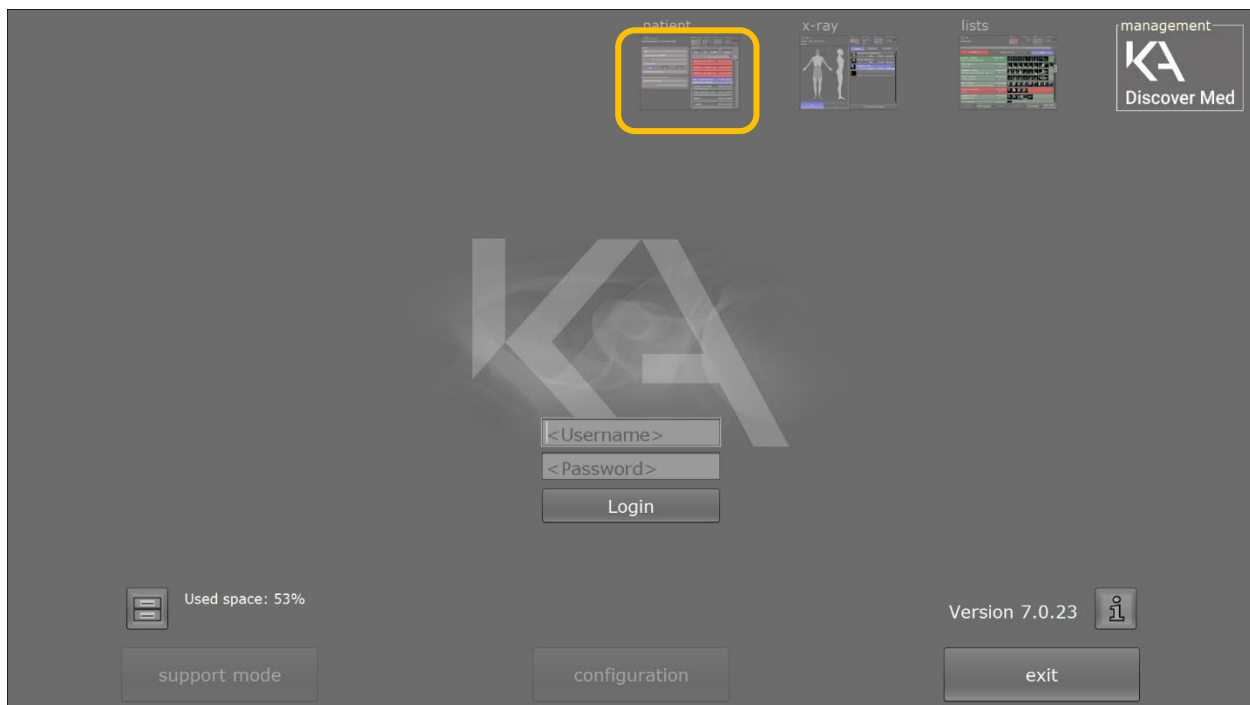
Always collimate the X-ray source beam as close as possible to the limits of the area of interest before imaging, and avoid leaving large regions of the FPD's active area fully exposed to the X-ray beam.

Image Acquisition: Adding a Patient

The Reveal 35C software allows not just imaging, but imaging inside the framework of patients and exams; i.e., *who* and *what* is being imaged.

The user must first log in and use the PATIENT and X-RAY tabs to set up the patient, the exam, and then perform image acquisition.

For image acquisition, the user needs a valid user login to access the PATIENT and X-RAY areas of the software.



Clicking the 'patient' tab leads to the Patient Input screen, where the user can:

- Enter/change patient data
- Enter/change work assignments
- Enter/change macros
- Search for X-ray assignments in the worklist
- Delete jobs

These instructions are relevant only if a Radiology Information System (RIS) from which to pull a worklist does not exist, or if connectivity to the worklist is interrupted and work must continue.

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Clicking the PATIENT tab leads to the patient input/worklist screen, as shown.

Logout and display of current user

Captures patients and work assignments

Search for X-ray assignments in the worklist

Delete jobs

operator: admin

patient input/worklist selection

patient

<title>

John

Doe

HOP001

01/01/1962

58 year(s)

M F N/A

<patient comments>

study

12/11/2020 17:44

<study description>

<accession number>

Worklist

new RIS emergency delete

name, description, accession number...

worklist orders

John Doe	17:44
----------	-------

Area for entering / changing patient data

Worklist

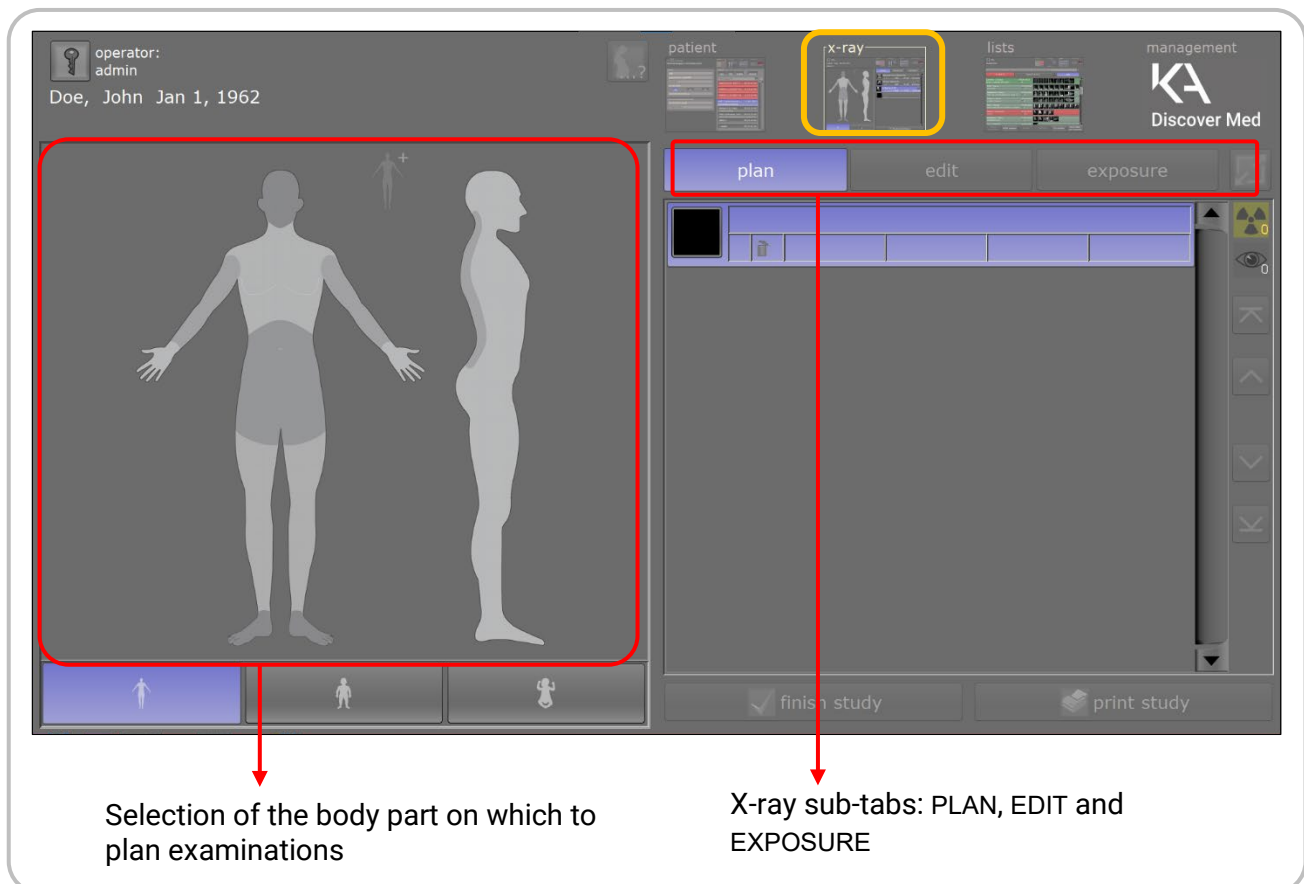
Input all the details of the patient, then click INSERT PATIENT.



Refer to the OR Technology User Manual, Chapter 3, Working with dicomPACS DXR, under subheading 3.2 *Patient view* for more information.

Image Acquisition: Creating an Exam Plan

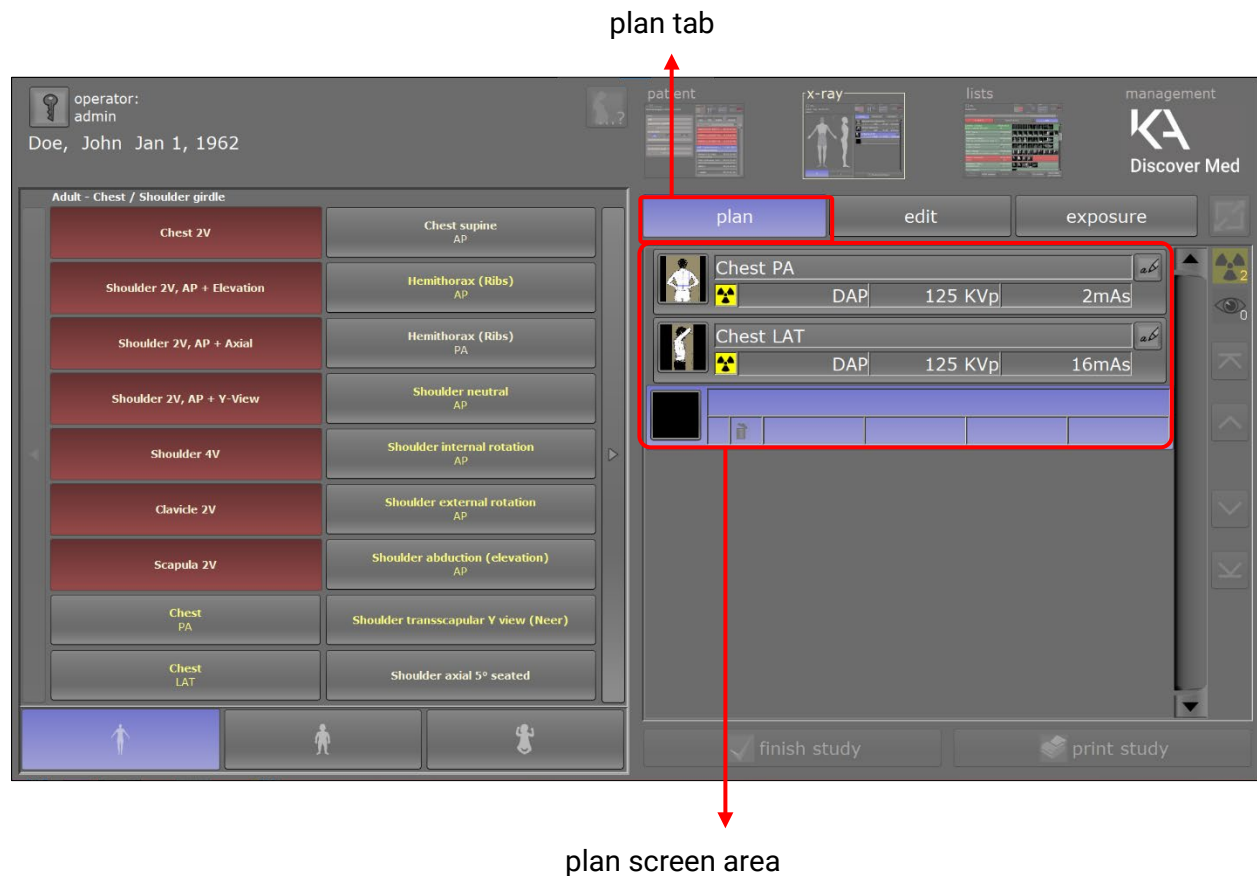
Once the patient has been created, click the upper X-RAY tab to transfer to the patient's exam plan screen. (Alternatively, you can double-click the patient's name to transfer to the patient exam plan screen.)



Acquisition begins with planning the X-rays to perform on the patient.

1. Select the PLAN sub-tab.
2. Click on the interactive image to select the body part to image.

A screen showing pre-installed examinations of the selected body part appears.

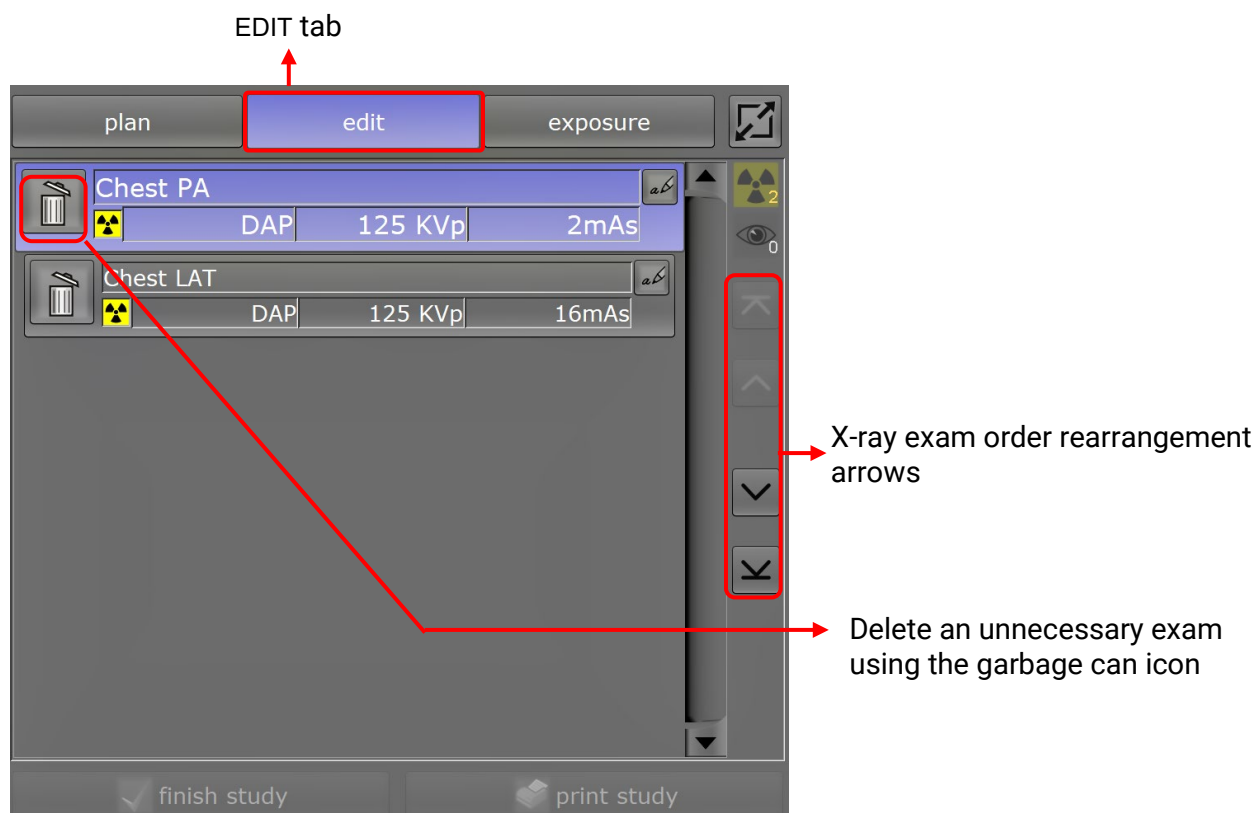


Scroll through the list and select the examinations to perform. In the sample above, one Chest PA and one Chest LAT X-ray are selected to the plan list.

The right side of the screen is the plan screen area.

Add as many examinations as are required by click-selecting from the list of pre-sets on the left side of the screen.

Image Acquisition: Editing an Exam Plan

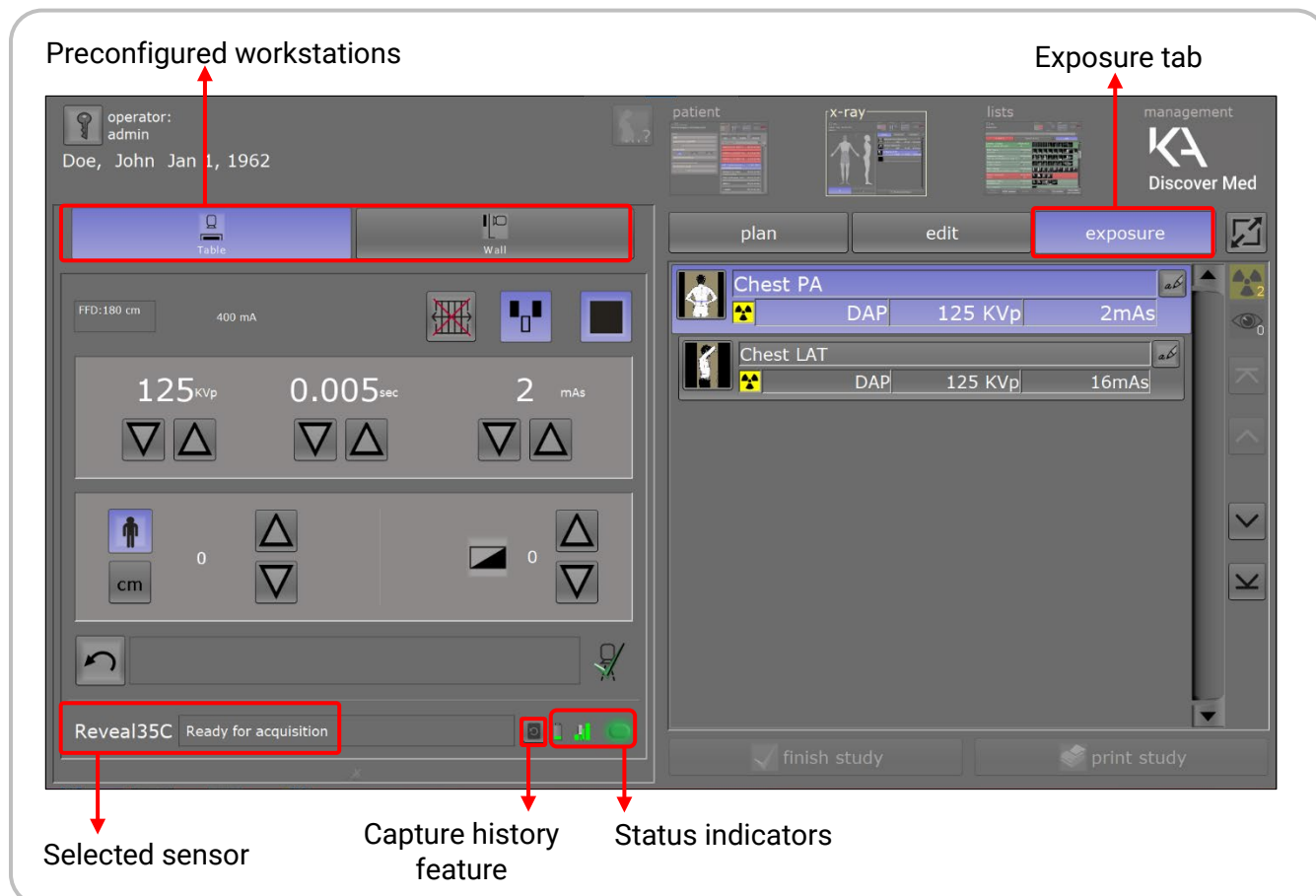


1. Select the EDIT tab.
2. Optionally, use the arrows on the right to rearrange the order of examinations.
3. Optionally, use the garbage can icon to delete any examinations that are not required.
4. When satisfied with the examination plan and ready to take the exposure, click the EXPOSURE tab.



CAUTION: To avoid a false trigger (a false image generated by the detector without receiving an X-ray), do not apply a strong mechanical force to the detector when the detector is in AED mode; instead, stay at the "plan" tab when the patient is lying down, then move to the "exposure" tab to put the detector in AED mode.

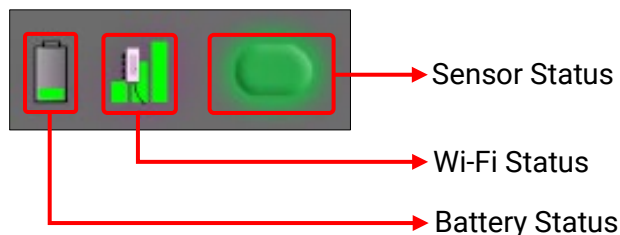
Image Acquisition: Configuring the Sensor to a Workstation



At screen display, following selection of the EXPOSURE tab, the preconfigured workstations become available for selection on the left-screen area.

The selected sensor (associated with the workstation) displays on the lower-left, with a status display indicator included in the display field. Click a workstation to select it.

Status Indicators



Battery Status

Indicates the level of charge on the sensor battery.

Wi-Fi Status

Indicates Wi-Fi signal strength of the sensor.

Sensor Status Indicator

The sensor status indicator color indicates different sensor states:

Indicator Color	Description
Green	Sensor is ready for acquisition
Yellow	Sensor is starting / image transfer is in progress
Red	Sensor is not connected

Image Recovery Feature



Click this icon to download the last image previously acquired by the panel. This function can be used to re-download an image that failed to transfer, or to download an image acquired in STANDALONE mode. The downloaded image is then associated with the selected examination.



Refer to the OR Technology User Manual, Chapter 3, Working with dicomPACS DXR, under subheading 3.3 X-ray view for more information.

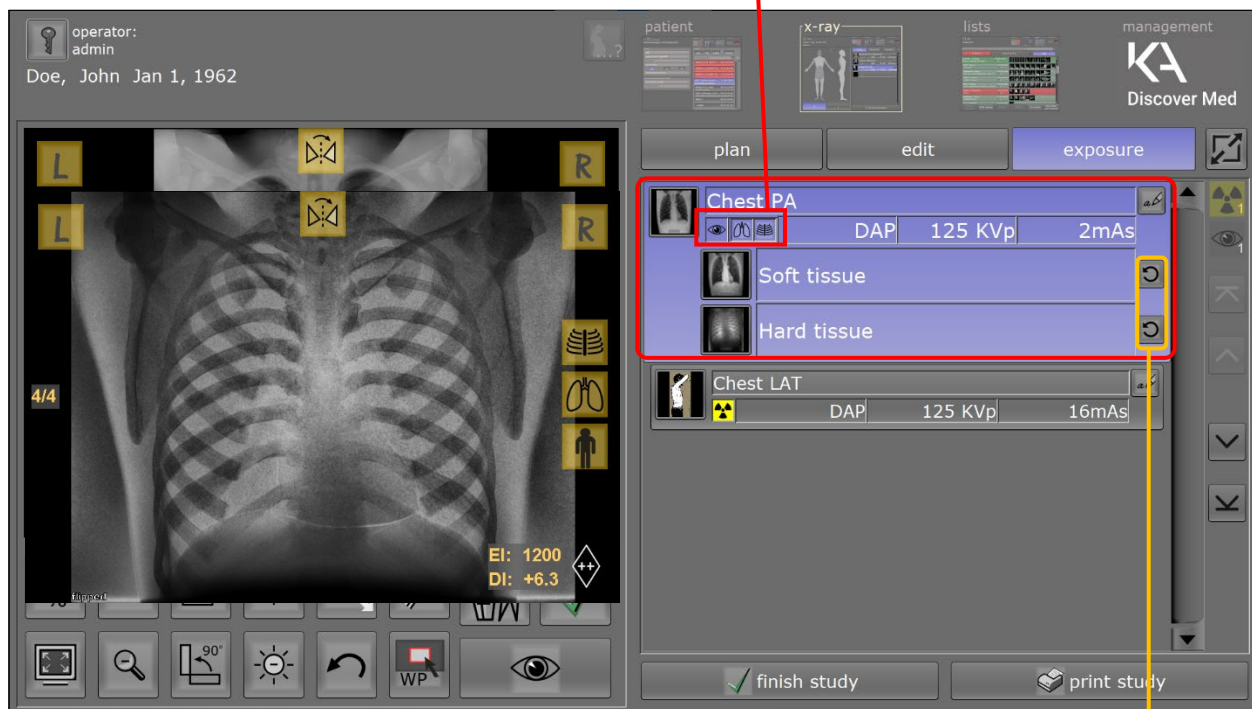
Image Acquisition: Dual Energy Capabilities

The following section explains Reveal 35C's dual energy capabilities.



The user exposes the panel to X-ray to start image acquisition.

Controls allowing changeover to dual-energy images



Reprocess buttons for the hard and soft images

The first image to display is the conventional DR image.

Hard and soft images are available for display from any X-ray capture. The user can select either or both dual-energy images for display in the image display window.

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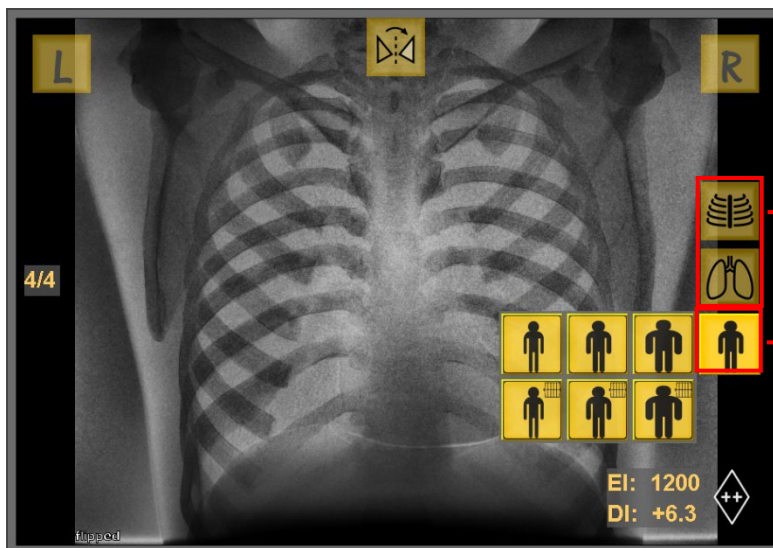


Reprocess buttons (shown on the screen capture on the previous page), allow the user to alter the dual-energy factors (Attenuation, Hardening Compensation, Subtraction Adjustment) via pop-up 'Soft tissue' and 'Hard tissue' slider tabs. These sliders allow for image fine-tuning.

If a user finds that a certain adjustment is repeatedly required, the adjustment can be set as the default for all future examinations of this type in the plan by clicking SET AS DEFAULT on the lower left of the pop-up window.



Set an adjustment to the default value for all subsequent acquisitions in the current plan



When the patient size factor selector is clicked, it expands to offer all six possible factor sets.



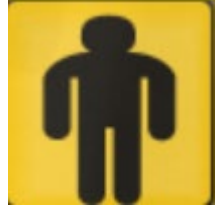



The hard tissue adjustment icon allows the user to increase the subtraction adjustment by 5% per click. The soft tissue adjustment icon allows the user to decrease the subtraction adjustment by 5% per click. The system applies anti-scatter grid automatically if the user previously selected that setting when setting up examinations; however, the user can change pre-sets using the patient size factor selector button shown in the graphic above.

Six factor sets are available per examination. These sets are described in the table below.



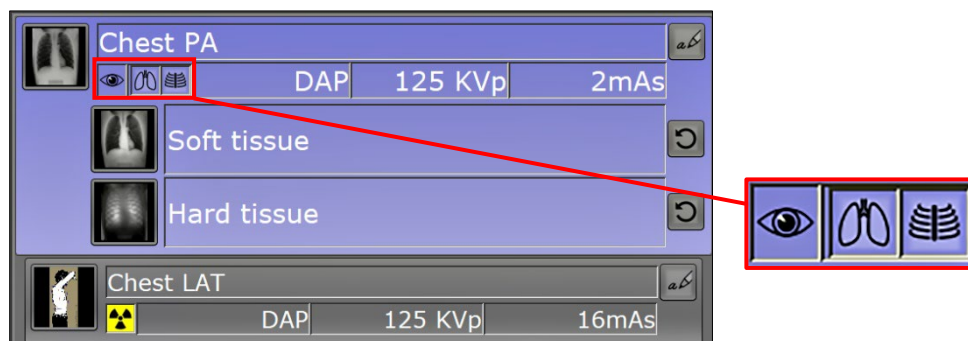
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	Small patient	Medium patient	Large patient
Without Anti-Scatter Grid	 Small patient, no anti-scatter	 Medium patient, no anti-scatter	 Large patient, no anti-scatter
With Anti-Scatter Grid	 Small patient, use anti-scatter	 Medium patient, use anti-scatter	 Large patient, use anti-scatter

At completion of adjustments, click the green checkmark icon under the image display window to save the changes. Pressing the 'accept' checkmark also locks the image.

If further adjustments are desired, click the unlock key under the image display window to unlock the image, allowing for more changes. Images can also be rejected, but then a new X-ray image must be acquired.



The soft tissue and hard tissue buttons here, beside the visibility eye icon, are used to either show or hide the hard and soft tissue images.

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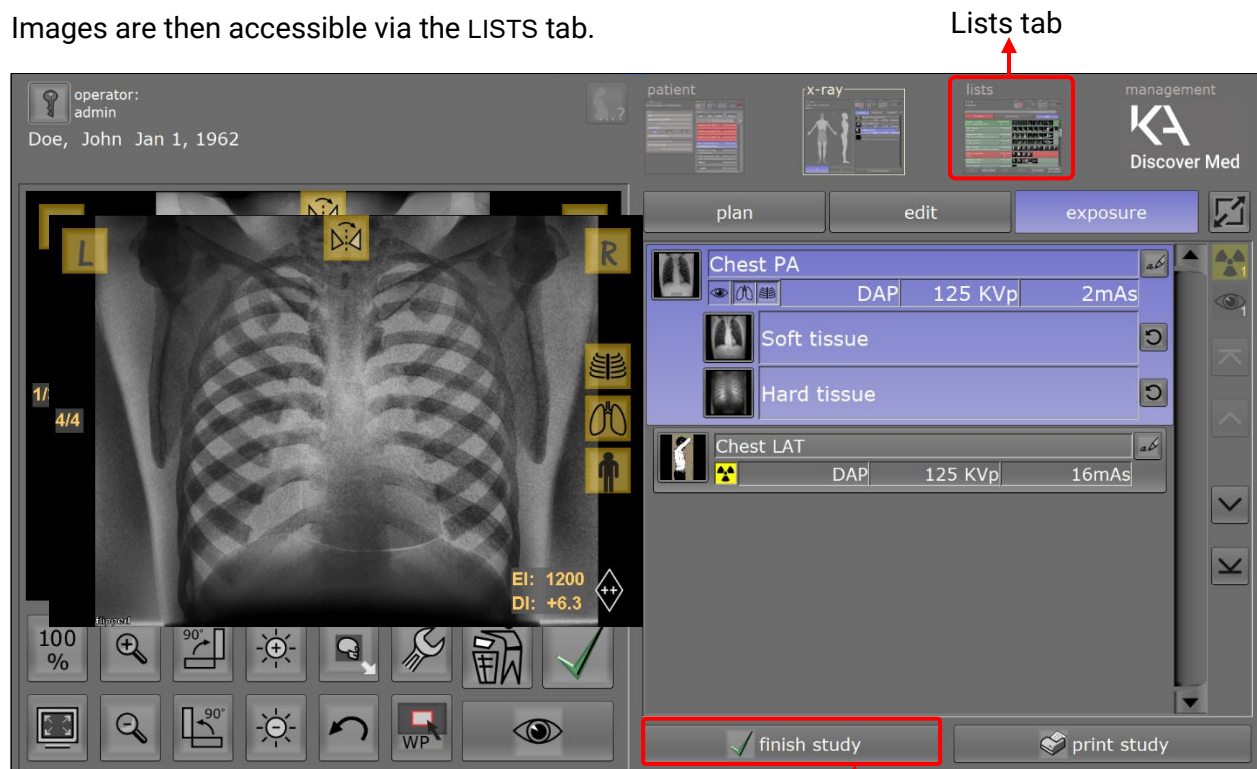
These soft / hard tissue visibility buttons work in both directions:

If the original selection in the examination configuration was set to dual-energy image capture, these buttons work as described on the previous page to show or hide the resulting images as desired.

If the original selection in the examination configuration was set to conventional image capture only, these buttons can be used to change that setting so that either or both the soft image and the hard image as well as the conventional DR image is captured.

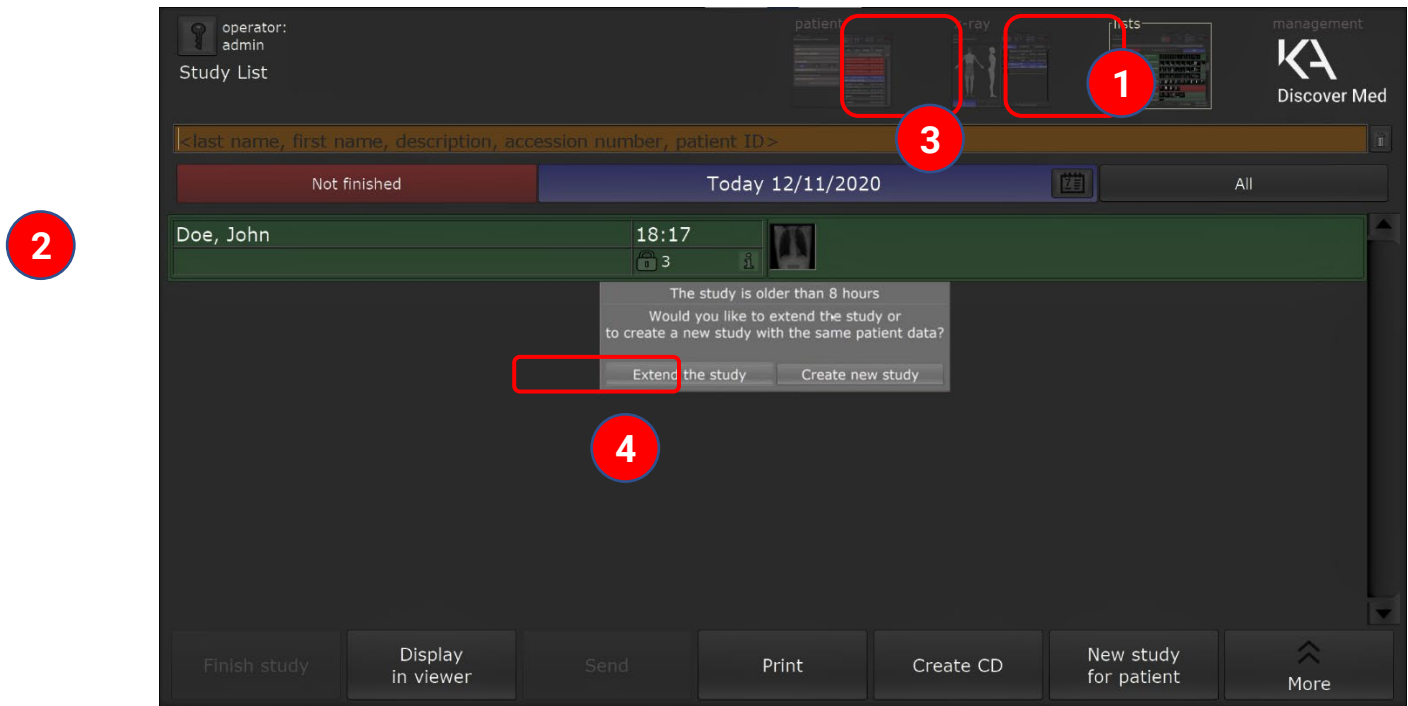
Once all changes and selections are complete, click FINISH STUDY.

Images are then accessible via the LISTS tab.



Extending a Study

It is possible to reprocess images from previous studies. This reprocessing of images from previously finished studies is called extending a study.



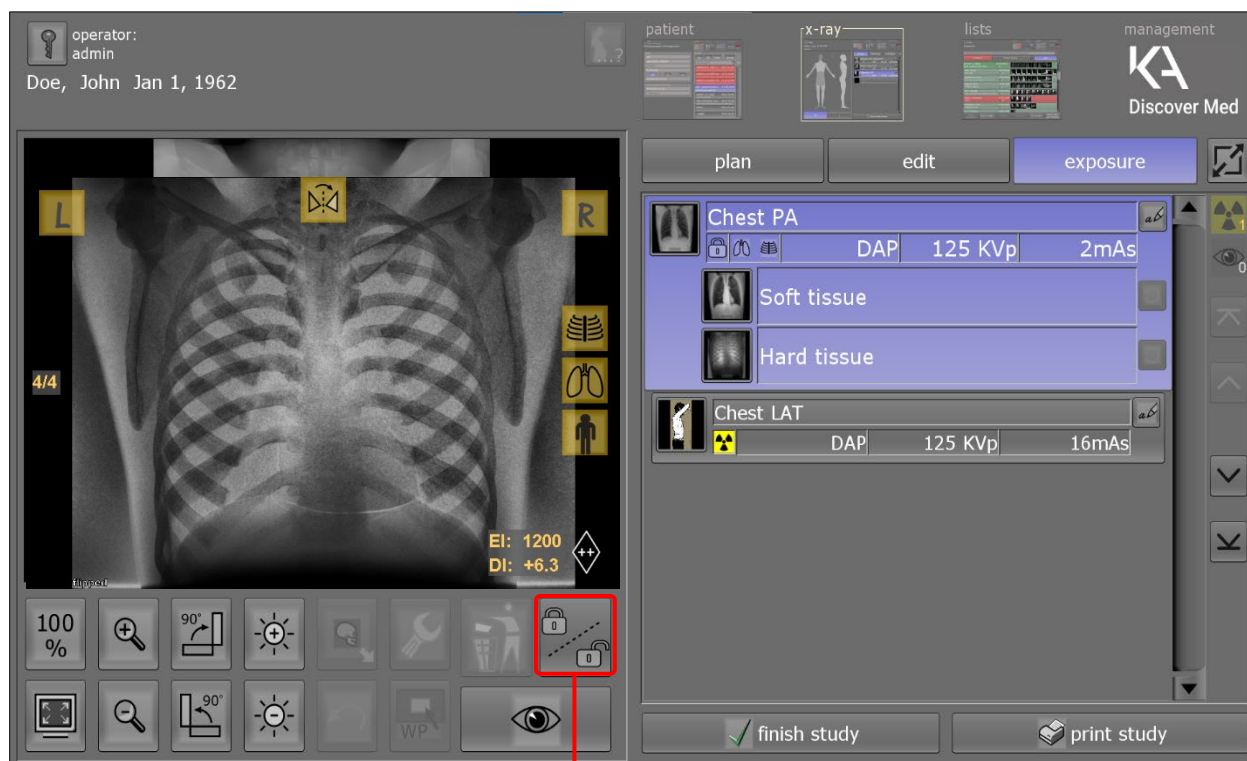
To reprocess a previously-finished image:

1. Click the LISTS tab.
2. Find and select a study from the list.
3. Click the X-RAY tab.
4. Click EXTEND THE STUDY.

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The screen that appears to enable reprocessing images is the same as the screen on page 85, and the changes that can be made are identical to those that can be made for the original study; that is, adjusting the X-ray factors, changing the image's orientation (rotation), and so on.



Unlock the image for further processing by clicking the unlock key

Changes cannot be made until the user unlocks the image using the lock/unlock key as shown above. This lock/unlock key, once unlocked, reverts to a green checkmark icon to allow changes made to be saved.

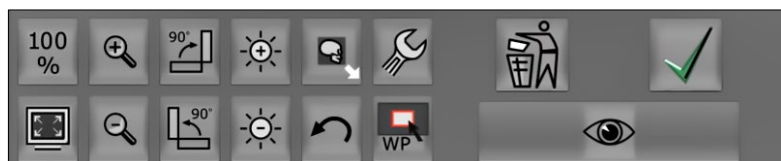
Once reprocessing is complete, click the green 'finish study' checkmark to save the changes and lock the image.

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The standard settings available for adjustment of the image, located under the left screen image display window (as shown on the previous page), have not changed for DiscoverMed from the original version of the OR Tech dicomPACS DX-R 6.0 software.



The following table, from the OR Tech User manual, Chapter 3, Working with dicomPACS DXR, (under subheading 3.3 X-ray view, specifically 3.3.4) is copied here to provide descriptions for the on-screen icons shown above.

	Displays the image pixel per pixel (full resolution)
	Shows the complete image
	Enlarges the image
	Shrinks the image
	Rotates the image to the right by 90°
	Rotates the image to the left by 90°
	Increases the perceived brightness (gamma curve)
	Reduces the perceived brightness (gamma curve)
	Draws or adapts the black mask around the image
	Restores the original condition of the image
	Rejects a failed exposure
	Accepts / reopens an exposure
	Opens the study using the included viewing application (diagnostic mode)
	Allows the quality assessment of new images
	Re-determines the Region Of Interest (ROI)

TROUBLESHOOTING

7

This chapter provides information and instructions regarding solutions to potential issues (Troubleshooting Table).



In the event of fire, or if any abnormal conditions are noted during operation—such as the presence of smoke, fumes, or strange sounds, unplug the power supply immediately from the AC outlet.



Inform your establishment's safety representative and ask for instructions.

Do NOT continue to use the X-ray detector during abnormal conditions.

Failure to comply with this warning may result in severe personnel injury, death, or substantial product damage.



Troubleshooting procedures must be performed by a trained service engineer. If an unqualified person attempts to troubleshoot an issue preventing Reveal 35C operation, damage to the FPD—its software and/or hardware—can result, and these damages void the system warranty.

Troubleshooting Table

Symptom	Potential Causes	Solution
FPD power fails to turn ON when operating under battery power only, without aid of a power cable.	Battery pack is installed incorrectly Battery pack is not charged Battery pack is dysfunctional	<ol style="list-style-type: none"> 1. Check the battery pack installation and re-install the battery pack if it is not installed correctly. 2. Charge the battery pack if the battery pack indicators show low power. 3. Change the battery pack. 4. Connect the FPD to external power using the adapter cable. 5. If the FPD still does not turn ON, contact KA Imaging.
Battery power drains too quickly.	Battery pack may be old Battery pack is operating in too cold an environment	<ol style="list-style-type: none"> 1. Batteries are consumable. If the current battery pack has been in service for a long period of time, change it. 2. Use the battery in a room- temperature environment only. If temperature is too low, the battery cannot maintain charge.
Battery pack and/or battery pack installation port is overheating.	The battery pack is failing. The FPD is failing.	<ol style="list-style-type: none"> 1. Exchange the battery pack for a new one. 2. If the problem of overheating persists, contact KA Imaging.
The flat panel detector fails to turn ON when connected to AC power.	Power cable is broken. An internal circuit is broken.	<ol style="list-style-type: none"> 1. Check the connection between the power cable and the inlet and outlet plugs. 2. Cycle the power. 3. Replace the power cable. 4. If the problem persists, contact KA Imaging.
The power LED indicator is flashing.	Green flashing, FPD may be powering up or down. Green flashing, the FPD may be busy with image capture, image transfer or image save. Yellow flashing, battery error, Wi-Fi connection error or capture error has occurred. Yellow flashing may also indicate a system error.	<ol style="list-style-type: none"> 1. Check the network cable connection. 2. Restart the system. 3. Check the temperature of the environment to ensure the FPD is not malfunctioning due to cold. 4. Check the surrounding wireless communication. 5. Check the cable connection with a tether interface cable.

<p>Communication test failure has occurred. A transmission error has occurred.</p>	<p>Network connection problem is indicated. Network settings problem is indicated. Wireless connection problems are occurring. Device errors appear on-screen.</p>	<ol style="list-style-type: none"> 1. Check the network connection cable to ensure a proper connection. 2. Check to ensure the correct cable is in use. 3. Reset the network information. 4. Check the software settings, including the firewall setting and release POWER SAVINGS mode if ON. 5. Check the surrounding wireless communication environment. 6. Reinitialize and reboot the Reveal 35C Flat Panel Detector. 7. Replace any faulty devices. 8. If problems persist, contact KA Imaging.
<p>Power LED stays ON solid yellow.</p>	<p>FPD does not power up.</p>	<ol style="list-style-type: none"> 1. Try to power up the FPD again by pressing and holding the power button for longer than 2 seconds. 2. Hard reset the FPD by pressing and holding the power button for longer than 12 seconds, then repeat Step 1. 3. If the problem persists, contact KA Imaging.
<p>Abnormal image captured by the system.</p>	<p>FPD calibration is off.</p>	<ol style="list-style-type: none"> 1. Calibrate the FPD per the calibration instructions. 2. If abnormal image capture persists, contact KA Imaging.
<p>Subtraction options greyed out</p>	<ul style="list-style-type: none"> • Items imported using import function • Images captured with blank generator settings 	<p>The Import function does not work as anticipated. Do not import or export via the DiscoverMed functions; import all images outside of the DiscoverMed program through use of the Simulator Tool, using the .kai3 files.</p> <p>If the source settings are blank after capturing an image, open the edit mask and input the Generator values (kV, mAs) used when capturing the image.</p> <p>If you import using the software tool, the Subtraction will be there but not active, the blank generator setting is correct and will be greyed out.</p>

Symptom	Potential Causes	Solution
Continuous False Trigger	Detector battery is low	<p>False triggers may happen if you use the detector with a low battery until the unit is dead.</p> <p>Change the battery if battery has less than 25% power remaining</p> <p>Option 1 Hard reset the FPD by pressing and holding the power button or longer than 12 seconds</p> <p>Option 2 Keep the unit ON overnight without a battery until the internal battery dies, then put a fully charged battery and start the FPD.</p>
Software Crash	Operating system and Software requirements	<p>Ensure that the DiscoverMed software is installed on a PC with the following requirements:</p> <ul style="list-style-type: none"> • Core i5 quad core or better processor, 16GB memory, • 80 GB free for Software and Operating System, • 420 GB for image archive, • 100Mbps Network connection, • Windows 10 64bit OS. • Windows 11 64bit OS
No response after exposure	Manual retrieval of image	<ol style="list-style-type: none"> 1. Ensure that the detector connected properly. 2. Ensure that the status is "detector is ready for acquisition" 3. Retrieve the last acquired capture using the recovery tool
Detector Connection Failed		Reconnect the detector to the user interface software to restore connectivity.
Error Initializing Detector	<ul style="list-style-type: none"> • Hardware License, • Connectivity, • Image retrieval 	<ol style="list-style-type: none"> 1. Ensure that the detector is licensed for use with the software. 2. Ensure connectivity between the detector and the software. 3. Ensure that images are being retrieved after the detector is connected to the software.

MAINTENANCE

8



Service and maintenance procedures should be performed by authorized service representatives ONLY.

For maintenance and service instructions, refer to the Reveal 35C Service Manual.



It is important to use the Reveal 35C Flat Panel Detector safely, and as intended for use.

If problems are found during inspection procedures, correct any problems before using Reveal 35C for diagnostic use on patients.

If a problem cannot be corrected using the measures provided in this guide, contact KA Imaging for direction.

KA Imaging recommends keeping records of inspections with or close to the FPD. The inspection charts provided in this chapter can be printed for use if required.

The service lifetime of the Reveal 35C Flat Panel Detector is 5 years from initial in-service date.

Daily Inspections

Before Turning ON Power

Inspect Cables

1. Check all cables to ensure they are not damaged and their cable jackets are not torn.
2. Check all connector plugs and locks to ensure they are securely fastened (not loose).
3. Ensure the power cord plug is securely connected to both the AC inlet and outlet.

Inspect the FPD

1. Check to ensure no visible panel damage is evident.
2. Check to ensure no damage is visible on the battery pack.

After Turning ON Power

Check Wi-Fi

- Check that the Wi-Fi connectivity LED indicator is illuminated solid green.

Battery

- Check the battery charge condition.

After Turning OFF Power

Check the FPD

- Check that Reveal 35C turned OFF normally and that all LEDs on the indicator display are OFF.

Clean

- Perform the cleaning procedures provided in this chapter.



The Daily Inspection Chart on the next page can be printed and used to maintain physical records of completion of your maintenance activities.

1. Click on the Daily Inspection Chart page.
2. Right-click and select Print.
3. In the Print window, select Pages to print and choose Current.
4. Click Print.

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Daily Inspection Chart

Date of Inspection Format: dd-mm-yyyy	Equipment/Test	Condition P – pass / F – fail	Remedial Action Taken
	Visually inspect cables for damage e.g., loose or torn cable jackets		
	Visually inspect cables/connector plugs		
	Check AC inlet and outlet power cord connections		
	Visually inspect flat panel detector		
	Check for damage on battery pack		
	Check Wi-Fi connectivity		
	Check battery charge		
	Visually inspect cables for damage e.g., loose or torn cable jackets		
	Visually Inspect cables/connector plugs		
	Check AC Inlet and outlet power cord connections		
	Visually inspect flat panel detector		
	Check for damage on battery pack		
	Check Wi-Fi connectivity		
	Check battery charge		

Annual Inspections

Image Quality Testing

Image Performance Test

1. Execute an Image Performance test.
2. If image degradation has occurred, calibrate the flat panel detector using the instructions provided under [Calibration](#) on [page 64](#).
3. If calibration fails to correct image degradation, contact KA Imaging for service.



The Annual Inspection Chart on the next page can be printed and used to maintain physical records of completion of your maintenance activities.

1. Click on the Annual Inspection Chart page.
2. Right-click and select Print.
3. In the Print window, select Pages to print and choose Current.
4. Click Print.

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Annual Inspection Chart

Date of Inspection Format: dd-mm-yyyy	Equipment/Test	Condition P – pass / F – fail	Remedial Action Taken
	Image Performance Test		
	Visual Inspection of cables/connection plugs		
	Visual Inspection of battery pack and charger		
	Visual Inspection of flat panel detector		
	Image Performance Test		
	Visual Inspection of cables/connection plugs		
	Visual Inspection of battery pack and charger		
	Visual Inspection of flat panel detector		
	Image Performance Test		
	Visual Inspection of cables/connection plugs		
	Visual Inspection of battery pack and charger		
	Visual Inspection of flat panel detector		

Cleaning and Disinfection Procedures



Following each diagnostic procedure, it is important to disinfect the FPD prior to next use.



Do NOT clean the FPD in an autoclave.

Recommended Disinfectant Wipes

- Wip'Anios Excel disinfecting wipes by Orfit Industries
- Sani-cloth Active Wipes by Ecolab

Recommended Disinfectant Product

- Surfa'Safe foaming spray by Anios Laboratories



Other disinfecting products compliant to Directive 98/8/EC may be used provided they are used as directed and according to MSDS.

Detergents must have a composition of Didecyldimethylammonium chloride and polyhexamethylene biguamide hydrochloride.

Turn OFF and unplug power before disinfecting Reveal 35C.

Do not allow cleaning solution to seep into the battery pack compartment.



Never use flammable cleaning agents such as thinner, benzene or acetone.

Failure to comply may result in electric shock, fire or other unknown dangers that could result in severe injury, death, or substantial product damage.

Do not re-use wipes.



Wear proper PPE—clothing, eye and face protection, and gloves—during cleaning procedures. Use disinfectants in well-ventilated areas.

Do not use abrasive brushes or scrapers to clean the product.

Disinfect the FPD

Disinfect the FPD After Each Use

To disinfect using the foaming spray:

1. Prepare the area (clear the table of all nearby objects) and find a clean, dry, non-woven cloth.
2. Spray the foaming detergent onto the cloth, not directly onto the surface of the FPD.
3. Gently wipe the surface of the FPD with the cleaner-dampened cloth.
4. Leave the FPD as is/where is for fifteen minutes to allow it to dry thoroughly.

Clean the FPD

Clean the FPD Every Three (3) Months

1. Remove any dirt or accumulated dust using a vacuum cleaner or air duster.
2. Unplug the power cord from the AC outlet, and remove dust or dirt from the plug, its periphery, and the AC outlet with a dry cloth.
3. Perform the disinfection procedure provided on the previous page.

SERVICE AND SERVICEABILITY

9

The following information is in this chapter.

- KA Standard Warranty information
- Serviceable Items
- Ordering Information



Service should be performed by authorized service representatives ONLY.

For maintenance and service instructions, refer to the Reveal 35C Service Manual.

KA Standard Warranty Information

Limited Warranty and Remedy

Limited Warranty

KA Imaging warrants that the equipment will be free from defects in materials and workmanship for twelve (12) months from date of delivery (except as excluded under 'Exclusions' below).

Sole Remedy

KA Imaging's obligation and liability under this warranty is limited solely, at KA Imaging's option, to repair or replacement of the products, or repayment or reduction of a reasonable portion of the purchase price for the products.

Exclusions

The Limited Warranty provided hereunder does not include the following: a) any work external to the equipment; b) maintenance, connection or removal of any device not furnished by KA Imaging; c) repair of damage resulting from accident, neglect, misuse, failure of environmental conditions, or repairs performed by persons other than KA Imaging employees, contractors or its authorized service representatives; d) relocating the equipment or damage caused by relocations; e) upgrading or otherwise modifying the equipment; f) any work for cosmetic purposes; g) modifications done to facilitate research usage; h) any custom work by KA Imaging.



Refer to your commercial agreement for specific Warranty details.

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Serviceable Items

Contact KA Imaging to order the following parts if required.

Item	FPD or Charger	Part Number
Battery charger	Charger	OTS-00008
24V AC/DC power adapter	Charger	OTS-00006
Power supply cord	Charger or FPD	OTS-00007
FPD cable	FPD	OTS-00057
Connector adapter	FPD	CON-00004
Battery pack	FPD	COS-00003
19V AC/DC power adapter	FPD	OTS-00005

Ordering Information

KA Imaging Inc.

560 Parkside Dr #3,

Waterloo, ON N2L 5Z4

Email: service@kaimaging.com

Telephone: [1-226-215-9897](tel:1-226-215-9897)



Note: Any serious incident that has occurred in relation to the device should be reported KA Imaging Inc. and the competent authority of the EU Member State or the regulatory authority of the country in which the user and/or patient is established.



KA Imaging Inc.

560 Parkside Dr #3, Waterloo, ON N2L 5Z4
info@kaimaging.com [1-226-215-9897](tel:1-226-215-9897)

FC Contains FCC ID: PD98265NG
Contains IC ID: 1000M-8265NG

CE 2862

EC REP

QualRep Services B.V. Utrechtseweg 310 -
Bldg B42, NL-6812 AR Arnhem,
The Netherlands

UKRP: Qserve Group UK, Ltd. 282
Farnborough Road, Farnborough
United Kingdom, GU14 7NA