

EXPD N-Series

User Manual

EXPD 4343N1 / EXPD 4343N / EXPD 3643N1 / EXPD 3643N
EXPD 4343U1 / EXPD 4343NU / EXPD 3643U1 / EXPD 3643NU
EXPD 4343NP / EXPD 3643NP



DRTECH

Digital Radiography Technologies

CE
0197



Manual Information

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

Please contact us if there are any problems while using the product

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Definition of Symbols

Symbols	Description
	Non-ionized radiation
	The Waste Electrical and Electronic Equipment Regulations indicate separate collection for electrical and electronic equipment.
	Protective Earth (Ground)
	Direct Current
	Alternating Current
	Power Off.
	Power On
	Read and understand all instructions and warning labels in the product documentation before using the equipment. Keep this manual for future reference.
	Product contains specific materials that are suitable for recycling.
	Should be treated with care because if mistreated it might explode.
	Keep away from fire and flames.
	Heavy loading is prohibited.
	Serial Number
	Date of manufacture
	Manufacturer
	For U.S.A standards Federal law restricts this device to sale by or on the order of a licensed practitioner

Symbols	Description
	Earth (ground) Terminal, directly connected to a circuit or to a screening part, that is intended to be earthed for functional purpose
	Medical device
	CE mark "0197" is the specific Notified Body number
	Unique device identifier
	General Warning
	This way up
	Stacking limit by number
	Keep away from rain
	This mark indicates that this is Type B Applied Part according to IEC 60601-1:2005 +AMD1:2012/COR1:2012
	Fragile; handle with care
	Hands with care

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1. Safety Information

1.1 General Safety Notice

1.1.1 Safety Notices

Follow the safety instructions in this User Manual along with the following warning and caution signs. Ignoring instructions, warnings, or cautions while handling the product may result in serious injury, accident, or product damage. To avoid any accident causing personal injury or product damage, be sure to read this manual carefully before using the product.

1.1.2 Safety Symbols

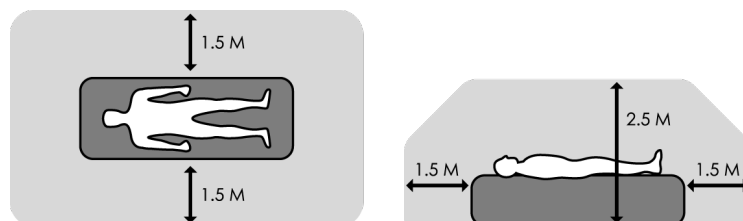
Symbols	Description
 WARNING	This indicates a potentially hazardous situation which may cause serious personal injury or death if misused.
 CAUTION	This indicates a potentially hazardous situation which may cause minor personal injury if misused
CAUTION	This indicates a potentially hazardous condition which may cause product damage.
 PROHIBITED	This indicates a prohibited operation.
	This indicates an action that must be performed.
 IMPORTANT	This indicates important operations and restrictions. Be sure to check this sign to prevent product damage or malfunction.
	This indicates the information about the basic operations of the detector for its user's reference. Users are recommended to read this notice.

1.1.3 Installation and Environment Use



- Do not operate or store the detector near flammable chemicals or substances such as alcohol, thinner, benzene, etc.
- If chemicals are spilled or evaporated, it may result in fire or electric shock, caused by their contacts with electric parts inside the detector. Some disinfectants are also flammable. Be cautious when using them.
- Do not connect the detector to any component, other than DRTECH's specified components. Doing so may result in fire or electric shock.
- Do not install the equipment in any of the locations listed below. It may result in fire, personal injury, or malfunction of the equipment.
- Close to fluid or places where fluids are used
- Where it may be exposed to direct sunlight
- Close to the air outlet of an air-conditioner or ventilation equipment
- Close to heat sources such as a heater
- Where the power supply is unstable
- In a saline or sulfurous environment
- Where temperature or humidity is high
- High condensation or extreme cold environment
- In area prone to vibration
- On an incline or in an unstable area
- Because the equipment cable is long, be careful cables do not become tangled during use. Also, be cautious not to get your feet caught in the cable. Otherwise, it may cause a malfunction of the equipment or the injury of the user due to tripping over the cable.
- Disposal of this product in an unlawful manner may have a negative impact on health and on the environment. When disposing of this product, therefore, be absolutely sure to follow the procedure which is in conformity with the laws and regulations applicable in your area.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

<Patient Vicinity>



1.1.4 Power Supply



WARNING



PROHIBITED



WARNING



- Do not operate the detector using any type of power supply other than the one indicated on the rating label. Otherwise, it may result in fire or electric shock.
- Do not handle the detector with wet hands. You may experience an electric shock that could result in serious physical injury or death.
- Do not place heavy objects such as medical equipment on cables or cords. Do not pull, bend, bundle, or step on them. These precautions are required to be followed to prevent cable and cord sheaths from being peeled. Do not alter the cables and cords. Otherwise, it may damage the cords which could result in fire or electric shock.
- Do not supply power to more than one device simultaneously by using the same AC outlet. Otherwise, it may result in fire or electric shock.
- Do not turn on the system power when condensation has formed on the detector. Otherwise, it may result in fire or electric shock.
- Do not connect multiple portable socket-outlets or extension cords to the system. Otherwise, it may result in fire or electric shock.
- Securely plug the power cord into the AC outlet.
- If contact failure occurs, or dust or metal objects come into contact with the exposed metal prong of the plug, fire or electric shock may result.
- Be sure to turn OFF the power before connecting or disconnecting the cords. Otherwise, you may get an electric shock which could result in death or serious injury.
- Be sure to hold the plug or connector when disconnecting the cord. If you pull the cord, the core wire may be damaged, resulting in fire or electric shock.
- To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.
- To make it easy to disconnect the plug at any time, avoid putting any obstacles near the outlet. Otherwise, it may not be possible to disconnect the plug in an emergency.
- Be sure to ground the equipment to an indoor grounded connector. Also, make sure to connect all the earth connections for the system to a common ground.
- Always connect the three-core power cord plug to a grounded AC power outlet.
- To avoid risk of electric shock, this equipment must be only connected to a power supply that maintains protective earth.
- The product has lower breaking capacity type. Do not install at the building power system prospective short-circuit current exceeding 35A.
- To reduce the risk of electric shock, the system must be connected to an electrical ground.
- A three-pin AC power cable is supplied with this system to provide the proper electrical grounding. The power cable must be plugged into an UL-approved/IEC-approved three-contact electrical outlet.
- Do not disassemble or modify the product as it may result in fire or an electric shock. There are no operator serviceable parts or adjustments inside the system. Only a trained and qualified person should be permitted access to the internal parts of the system.

1.1.5 Handling



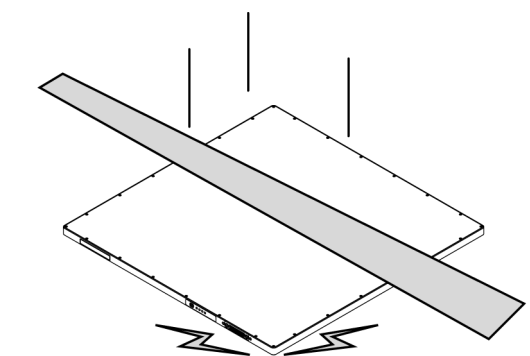
WARNING



PROHIBITED



- The system, partially or in whole, cannot be modified in any ways without any written approval from DRTECH.
- Never disassemble or modify the equipment. It may cause fire or electric shock, and result in severe personal injury or death by touching the components that cause electric shock.
- Do not place any object on top of the equipment. The object may fall and cause an injury. If metal objects such as needles or clips fall into the detector or if liquid spills, it may result in fire or electric shock.
- Do not hit or drop the equipment. The product may be damaged if it receives a strong jolt. Using a damaged detector without repair may result in fire or electric shock.
- Have the patient take a fixed posture and do not let patient touch the parts unnecessarily. If a patient touches connectors or switches, it may result in electric shock or malfunction of the detector.
- Do not spill liquid or chemicals onto the equipment. Especially in cases that the patient is injured, which requires the equipment to come in contact with blood or body fluids, protect the equipment with a disposable cover as necessary.
- Turn OFF the power to each piece of equipment for safety when not being used.
- Handle the equipment carefully.
- Do not submerge the equipment in water.
- The internal image sensor may be damaged if something hits against it, or if it is dropped, or receives a strong jolt.



- Be sure to use the detector on a flat surface to ensure that the detector is not bended. Otherwise, the internal image sensor may be damaged. Be sure to securely hold the detector while using it in upright position. Otherwise, the detector may fall over, resulting in personal injury, or may flip over, resulting in damage to the inner components.
- Do not place excessive weight on the detector. Otherwise, the internal image sensor may be damaged.
- In order to check the labeling on the product, please use it in an environment with illumination of 500 lux or higher.

1.1.6 When a Problem Occurs

 WARNING 	- If any of the following problems occur, immediately turn OFF the power, unplug the power cord from the AC outlet, and contact your sales representative or local DRTECH dealer: - When smoke, odd smell or abnormal sound occurs. - When liquid has been spilled into the detector or foreign metal object has entered inside the detector - When the equipment was dropped and damaged.
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1.1.7 Maintenance and Inspection

 WARNING  PROHIBITED 	- When cleaning the detector, be sure to turn OFF the power and unplug the power cord from the AC outlet. Otherwise, it may result in fire or electric shock. - Clean the plug of the power cord periodically by unplugging it from the AC outlet and removing dust or dirt from the plug. Clean the peripherals and AC outlet with a dry cloth. If the cord is kept plugged in for a long time in a dusty, humid or a sooty place, objects around the plug will attract moisture, and this could cause insulation failure that may result in a fire. - For safety reasons, be sure to turn OFF the power when performing the inspections indicated in this manual. Otherwise, electric shock may occur.
--	--

1.1.8 Pediatric Patients

**WARNING**



- Health care professionals and hospital administrators take special care in reducing radiation exposure to pediatric patients by following these steps:
- Discuss the rationale for the examination with the patient and/or parent to ensure a clear understanding of benefits and risks.
- Reduce the number of inappropriate referrals (i.e., justify X-ray imaging exams) by:
 - determining if the examination is needed to answer a clinical question,
 - considering alternate exams that use less or no radiation exposure, such as ultrasound or MRI, if appropriate, and
- checking the patient's medical imaging history to avoid duplicate exams.
- Use the pediatric protocols or technique charts included as following table:

Table 1. Age categories

NAME	DEFINITION	FDA CODE
NEONATES	NEWBORNS UP TO ONE MONTH	NEO
INFANTS	ONE MONTH TO TWO YEARS	INF
CHILDREN	TWO YEARS TO TWELVE YEARS	CHI
ADOLESCENTS	TWELVE YEARS TO SIXTEEN YEARS	ADO
OTHER	OTHER AGE GROUP STUDIED	OTH

Table 2. Pediatric protocols

Age categories	NEONATES		INFANTS		CHILDREN		ADOLESCENTS		OTHER		Collimation size	Protection
Body part	kVp	mAs	kVp	mAs	kVp	mAs	kVp	mAs	kVp	mAs		
Skull AP	60	10	70	10	75	12	70	16	70	20	8 x 10 or 10 x 12	chest, abdomen
Skull LAT	60	10	65	10	70	10	70	16	70	20	8 x 10 or 10 x 12	chest, abdomen
Chest PA	70	1	90	2	90	2	90	4	90	4	10 x 12 or 14 x 14	abdomen, gonadal
Chest LAT	80	2	90	2.5	95	2.5	100	4	100	4	10 x 12 or 14 x 14	abdomen, gonadal
Abdomen	50	4	60	6.3	70	6.3	75	20	75	25	10 x 12 or 14 x 14	thyroid, gonadal
Pelvis	50	4	60	6.3	70	6.3	75	20	75	25	10 x 12 or 14 x 14	gonadal

Please refer to the FDA website for details on pediatric information.

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

1.1.9 Cybersecurity



- In the event of a cyber security incident, contact the manufacturer or agency immediately and wait for instructions from the administrator for the further action.
- The software used on the device should be a product that does not engage in encrypted communication for data and should only be used within the hospital's closed network. Additionally, ensure the use of a PC with security systems such as a firewall and antivirus software.

1.2 Medical Device Safety Standards

1.2.1 Classification

Type of protection against electrical shock	Class I ME Equipment
Degree of protection against electrical shock	Type B Applied Parts (Applied Part: Detector panel)
Degree of protection against ingress of water	Ordinary equipment(IPX0)
Mode of operation	Continuous operation
Flammable anesthetics	Not suitable for use in the presence of a flammable anesthetic mixture containing air, oxygen, or nitrous oxide.

1.2.2 Safety Notice

EXPD-N Series is intended for use by qualified professional personnel who are trained and knowledgeable in the use of X-ray detectors, X-ray systems and electrical equipment.

The user is responsible for using and maintaining the X-ray detector according to prescribed installation, usage, maintenance, handling, and storage specification. To keep the X-ray detector and its accessories in safe and proper condition, only trained and qualified person(s) shall be in charge of maintenance.

In no event is the X-ray detector manufacturer liable for direct, indirect, or consequential injury, damage, or loss of equipment operation time or image data arising from the use of the X-ray detector, its components, and/or accessories.

1.2.3 Product Safety Standards

USA and Canada

ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA-C22.2 No. 60601-1:14	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2014+AMD1:2020 CSV	Medical electrical equipment-Part 1-2: Collateral standard: Electromagnetic compatibility-Requirements and tests

European Union

EN 60601-1:2006+A1:2013+A2:2021	Medical electrical equipment – Part1 : General requirements for Safety
EN 60601-1-2:2015+A1:2021	Medical electrical equipment–Part 1-2 : Collateral standard: Electromagnetic compatibility-Requirements and tests
EN 60601-1-6:2010+A1:2015+A2:2021	Medical electrical equipment –Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62304:2006+A1:2015	Medical device software–Software life cycle processes
EN 62366-1:2015+A1:2020	Medical device – Application of usability engineering to medical devices
EN ISO 14971:2019	Medical device – Application of risk management to medical devices

The EXPD 4343N1 / EXPD 4343N / EXPD 3643N1 / EXPD 3643N/ EXPD 4343U1 / EXPD 4343NU / EXPD 3643U1 / EXPD 3643NU/ EXPD 4343NP / EXPD 3643NP may be operated in:

	BE	BG	CZ	DK	DE	EE	IE	EL
	ES	FR	HR	IT	CY	LV	LT	LU
	HU	MT	NL	AT	PL	PT	RO	SI
	SK	FI	SE	UK				

Abbreviations

Belgium (BE), Bulgaria (BG), Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia(EE), Ireland(IE), Greece(EL), Spain(ES), France(FR), Croatia(HR), Italy(IT), Cyprus(CY), Latvia(LV), Lithuania(LT), Luxembourg(LU), Hungary(HU), Malta(MT), Netherland(NL), Austria(AT), Poland(PL), Portugal(PT), Romania(RO), Slovenia(SI), Slovakia(SK), Finland(FI), Sweden(SE) and United Kingdom(UK)

 WARNING	This device is restricted to indoor use in the 5150-5350MHz band.
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1.3 Declaration of Conformity

1.3.1 FCC Compliance Statement

***Contains FCC ID: RNH-TOP8812BU / FCC ID: RNH-EXPDWPCS (Wireless Charger)**

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment 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 reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

WARNING

Changes or modifications not expressly approved by the manufacturer (or party responsible) for compliance could void the user's authority to operate the equipment

BODY EFFECTS (X-Ray Detector)

This device was tested for typical body operation, keeping a distance of 1 cm (0.39 inch) between the user's body and the back of the phone. To comply with RF exposure requirements of the FCC standards, a minimum distance of 1 cm (0.39 inch) between the user's body and the back of the phone is required.

Belt-clips, holsters, and similar accessories containing metallic components from others manufacturers should not be used.

Accessories worn close to the body, without keeping a minimum distance of 1 cm (0.39 inch) between the user's body and the back of the phone, and that have not been tested for typical body operation, may not comply with FCC's RF exposure limits and should be avoided.

RF EXPOSURE

X-Ray Detector:

This equipment was tested in compliance with 0 cm between the external housing and user body.
(Limit 1.6 W/kg @1g SAR)

Wireless Charger:

This equipment should be installed and operated with minimum 5 cm between the radiator and your body.

1.3.2 IC Compliance Statement

* IC Number: 29808-TOP8812BU / IC : 29808-EXPDWPCS (Wireless Charger)

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- 1) This device may not cause interference.
- 2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- 1) L'appareil ne doit pas produire de brouillage;
- 2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

BODY EFFECTS (X-Ray Detector)

This device was tested for typical body operation, keeping a distance of 1 cm (0.39 inch) between the user's body and the back of the phone. To comply with RF exposure requirements of the FCC standards, a minimum distance of 1 cm (0.39 inch) between the user's body and the back of the phone is required.

Belt-clips, holsters, and similar accessories containing metallic components from others manufacturers should not be used.

Accessories worn close to the body, without keeping a minimum distance of 1 cm (0.39 inch) between the user's body and the back of the phone, and that have not been tested for typical body operation, may not comply with FCC's RF exposure limits and should be avoided.

EFFETS SUR LE CORPS (Détecteur de rayons X)

Cet appareil a été testé pour un fonctionnement corporel typique, en gardant une distance de 1 cm (0,39 pouce) entre le corps de l'utilisateur et l'arrière du téléphone. Pour se conformer aux exigences d'exposition aux RF des normes FCC, une distance minimale de 1 cm (0,39 pouce) entre le corps de l'utilisateur et l'arrière du téléphone est requise.

Les clips de ceinture, les étuis et les accessoires similaires contenant des composants métalliques provenant d'autres fabricants ne doivent pas être utilisés.

Les accessoires portés près du corps, sans garder une distance minimale de 1 cm (0,39 pouce) entre le corps de l'utilisateur et l'arrière du téléphone, et qui n'ont pas été testés pour un fonctionnement corporel typique, peuvent ne pas être conformes aux limites d'exposition RF de la FCC et devrait être évité.

RF EXPOSURE

X-Ray Detector: This equipment was tested in compliance with 0 cm between the external housing and user body. (Limit 1.6 W/kg @1g SAR)

Wireless Charger: This equipment should be installed and operated with minimum 5 cm between the radiator and your body.

EXPOSITION AUX RF

Détecteur de rayons X :

Cet équipement a été testé dans le respect du 0 cm entre le boîtier externe et le corps de l'utilisateur. (Limite de 1,6 W/kg à 1 g SAR)

Chargeur sans fil :

Cet équipement doit être installé et utilisé à au moins 5 cm entre le radiateur et votre corps.

1.4 Labels and Markings on the Equipment

The EXPD-N Series detector has its label and markings. Their contents and locations are indicated in this chapter.

 IMPORTANT	Any label removal or evidence of attempting to remove the label will void the warranty of the product.
 PROHIBITED	Do not jolt or apply excessive load.

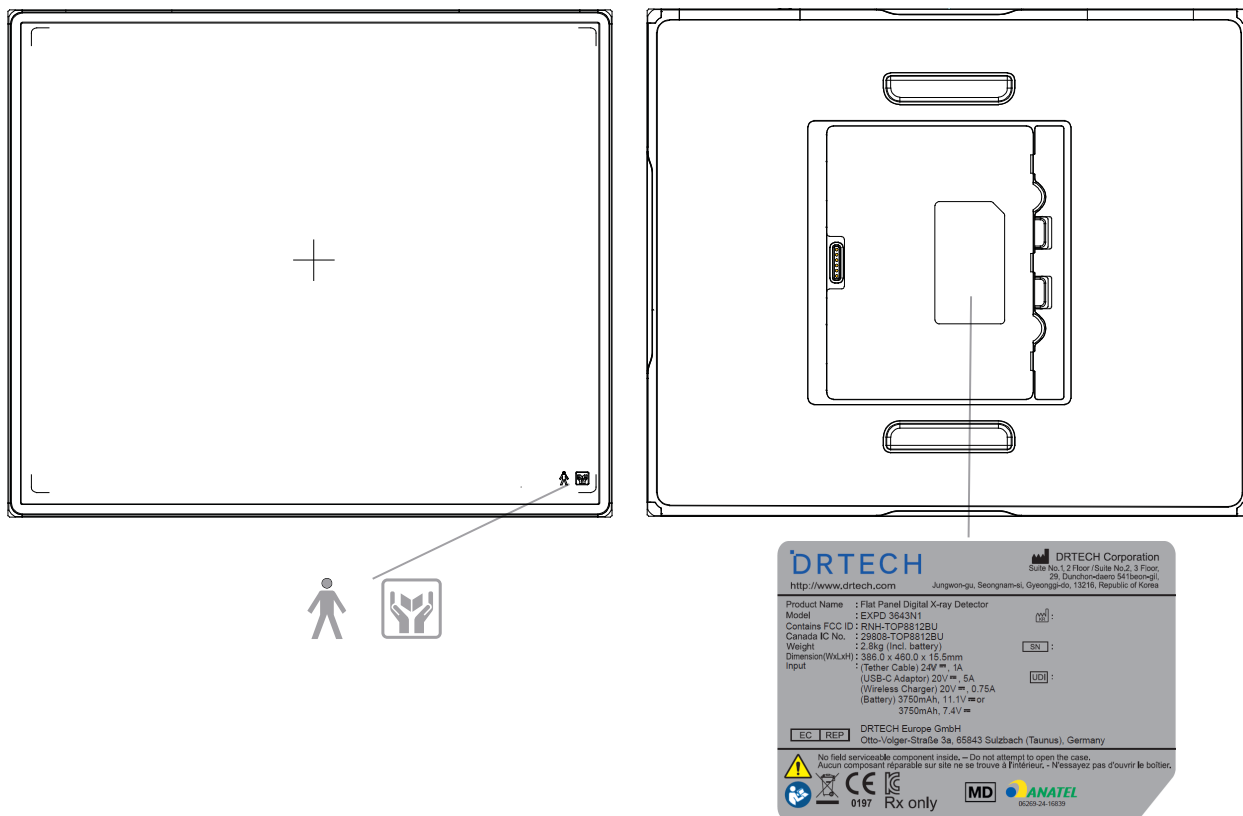


Figure 1. Product Label and Marking position of the EXPD-N Series (3643 size)

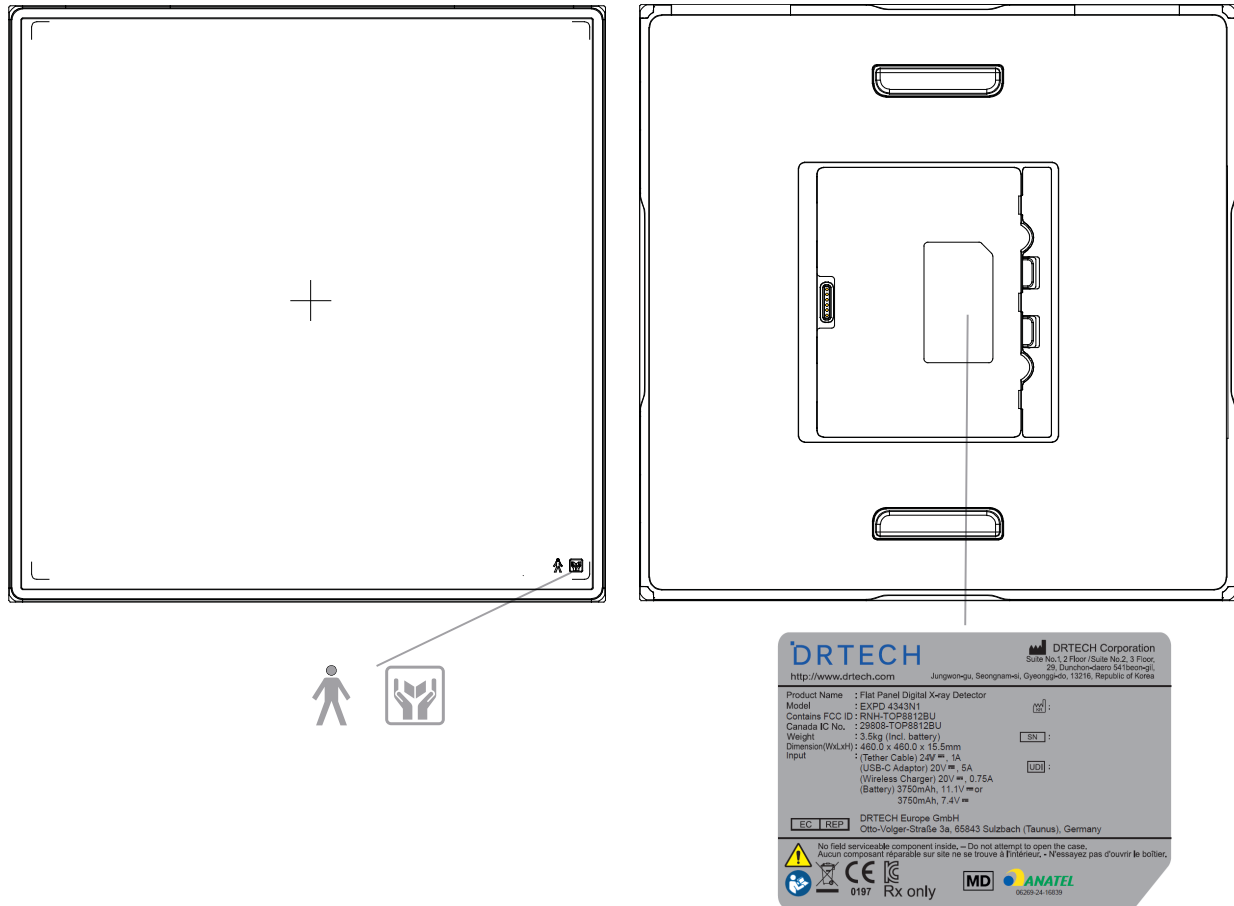


Figure 2. Product Label and Marking position of the EXPD-N Series (4343 size)



Figure 3. Product Label and Marking position of the Battery pack

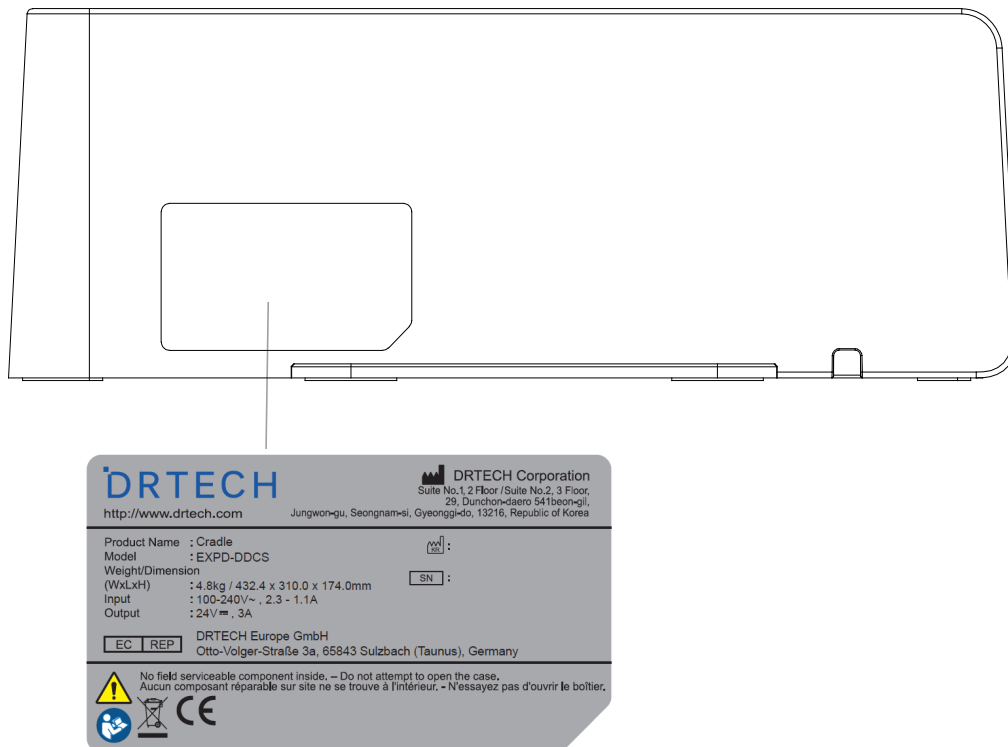


Figure 4. Product Label and Marking position of the Cradle(EXPD-DDCS)

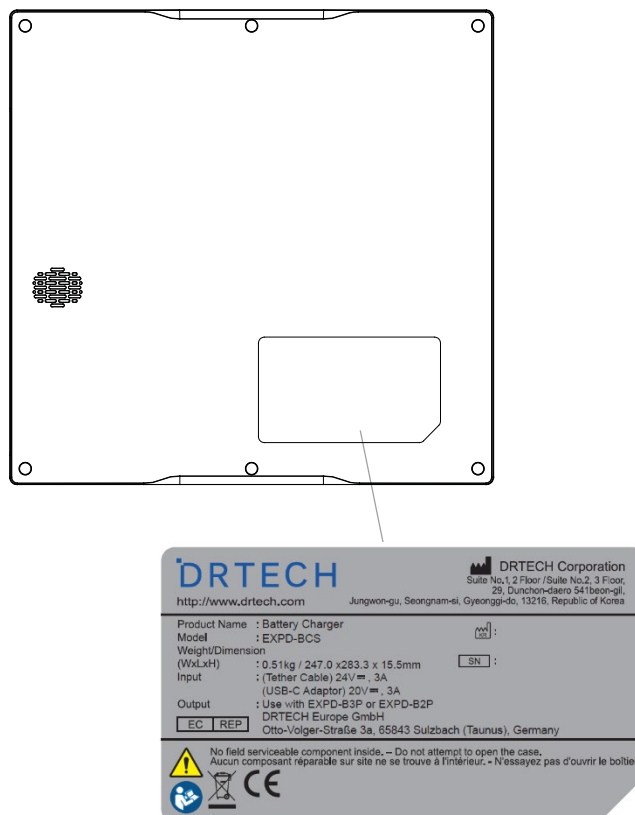


Figure 5. Product Label and Marking position of the Battery Charger(EXPD-BCS)

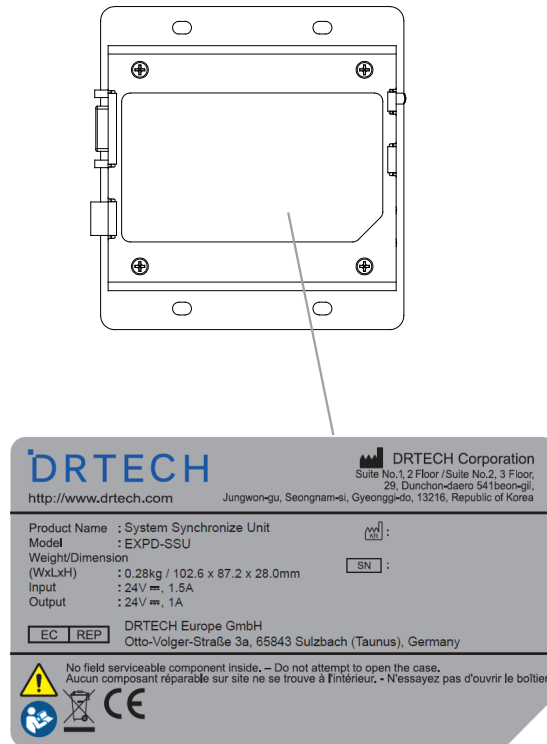


Figure 6. Product Label and Marking position of the System Synchronize Unit(EXPD-SSU)

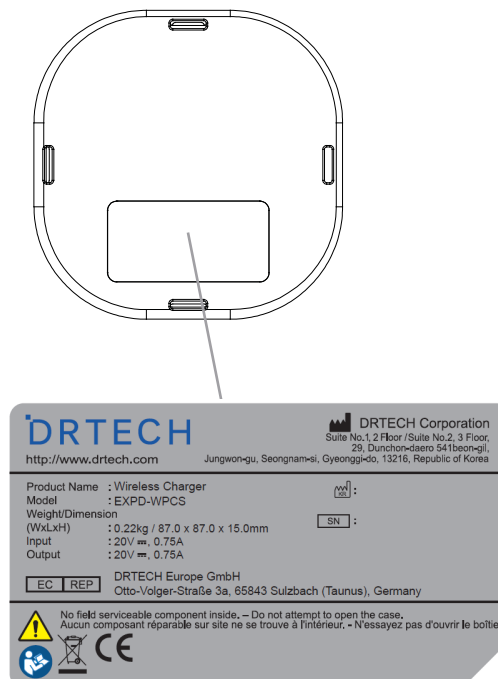


Figure 7. Product Label and Marking position of the Wireless Charger(EXPD-WPCS)

1.5 Precautions regarding electromagnetic waves

1.5.1 Guidelines from manufacturer: Electromagnetic Emission

The EXPD-N Series is used in the following electromagnetic settings. Users of the EXPD-N Series should check whether their systems are used in these settings.

Emission Test	Compliance	Electromagnetic setting: Guidelines
RF emissions CISPR11	Group 1	Since the EXPD-N Series only uses RF energy for internal functions, it has very low RF emissions and normally cause no interference to neighboring electronic devices.
RF emissions CISPR11	Class B	The EXPD-N Series is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This EXPD-N Series is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the EXPD-N Series or shielding the location.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC61000-3-3	Compliance	

1.5.2 Electromagnetic Immunity

The EXPD-N Series System is used in the following electromagnetic settings. Users of the EXPD-N Series System should check whether their systems are used in these settings.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge(ESD) IEC 61000-4-2	$\pm(2, 4, 8)$ kV contact $\pm(2, 4, 8, 15)$ kV air	$\pm(2, 4, 8)$ kV contact $\pm(2, 4, 8, 15)$ 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 (100kHz PRF) ± 1 kV for input/output lines(100kHz PRF)	± 2 kV for power supply lines (100kHz PRF) ± 1 kV for input/output lines(100kHz PRF)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to ground	± 1 kV line to line ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T for 1 cycles 40 % U_T for 5 cycles 70% U_T for 25/30 cycles 0% U_T for 250/300 cycles	0% U_T for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U_T for 1 cycles 40 % U_T for 5 cycles 70% U_T for 25/30 cycles 0% U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EXPD-N series requires continued operation during power mains interruptions, it is recommended that the EXPD-N series to be powered from an uninterruptible power supply

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.
Proximity magnetic fields in the frequency range 9 kHz to 13.56MHz immunity IEC 61000-4-39	65 A/m 134.2 kHz PM 2.1 kHz 7.5 A/m 13.56 MHz PM 50kHz	65 A/m 134.2 kHz PM 2.1 kHz 7.5 A/m 13.56 MHz PM 50kHz	Resistance to magnetic fields was tested and applied only to surfaces of enclosures or accessories accessible during intended use

Caution: U_T is the AC main voltage prior to application of the test level.

Do not use cables and parts other than those used for the current system.

If cables and parts other than those used for the current system are used, the immunity may be affected.

	WARNING AVERTISSEMENT	Use of Product adjacent to or stacked with other device should be avoided as it could result in improper operation. If such use is necessary, this product and the other device shall be observed to verify that they are operating normally. Il convient d'éviter l'utilisation des série EXPD-N à proximité d'un autre appareil ni posés sur ou sous un autre appareil, au risque de provoquer un dysfonctionnement. Si une telle utilisation est nécessaire, ce produit et l'autre appareil doivent être observés pour vérifier qu'ils fonctionnent normalement. Use of accessories, transducers and/or cables that are not specified or provided by the DRTECH of Product could result in increased electromagnetic emissions or decreased electromagnetic immunity of product and result in improper operation. L'utilisation d'accessoires, de transducteurs et/ou de câbles non spécifiés ou non fournis par le DRTECH de l' série EXPD-N peut entraîner une augmentation des émissions électromagnétiques ou une diminution de l'immunité électromagnétique du produit et un dysfonctionnement. Portable RF communications equipment(including peripherals such as antenna cables and external antennas) shall be used no closer than 30 cm(12 inches) to any part of the Product including cables specified by DRTECH.
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		Les périphériques de communication RF portables (y compris les périphériques tels que les câbles d'antenne et les antennes externes) ne doivent pas être utilisés à moins de 30 cm (12 pouces) de toute partie de l' série EXPD-N, y compris les câbles fournis par DRTECH.
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The EXPD-N series is intended for use in the electromagnetic environment specified below.

The customer or the user of the EXPD-N series should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz – 80 MHz	3 Vrms	Mobile and mobile RF communications equipment should not be used closer to any part of the Ultrasound System, including cables, than the recommended separation distance. This is calculated using the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\sqrt{P}$
	6 Vrms 150 kHz – 80 MHz In ISM bands	6 Vrms	
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d = 2.0\sqrt{P}$ 80 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). 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 equipment marked with 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 strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EXPD-N series is used exceeds the applicable RF compliance level above, the EXPD-N series should be observed to verify normal operation. If abnormal

performance is observed, additional measures may be necessary, such as reorienting or relocating the EXPD-N series.

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

c. The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz

The EXPD-N series is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Mobile RF communications equipment should be used no closer than 30cm (12 inches) to any part of the EXPD-N series. Otherwise, degradation of the performance of this equipment could result.

Immunity test	Band a	Service a	Modulation	IEC60601 test level	Compliance level
Proximity fields from RF wireless Communications IEC61000-4-3	380 - 390 MHz	TETRA 400	Pulse modulation 18Hz	27 V/m	27 V/m
	430 – 470 MHz	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704 – 787 MHz	LTE Band13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800 – 960 MHz	GSM800:900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	28 V/m	28V/m
	1700 – 1990 MHz	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse modulation 217 Hz	28 V/m	28V/m
	2400 – 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28V/m	28V/m
	5100 – 5800 MHz	WLAN 802.11a/n	Pulse modulation 217 Hz	9 V/m	9 V/m

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.

a. For some services, only the uplink frequencies are included.

b. The carrier shall be modulated using a 50% duty cycle square wave signal.

c. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

 IMPORTANT	When the EXPD-N Series is disturbed by EM, the obtained images could have an abnormal condition such as artifacts or noise.
 IMPORTANT	- Other cables and accessories may negatively affect EMC performance. - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) shall be used no closer than 30 cm (12 inches) to any part of the Product including cables specified by DRTECH.

1.5.3 Recommended separation distances between portal and mobile communication equipment and the EXPD-N series

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

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]	
	IEC 60601-1-2: 2020	
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 2.7 GHz $d = 2.0\sqrt{P}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20

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.

2. General Description

2.1 EXPD-N Series Detector

2.1.1 Overview



Figure 8. EXPD-N Series Detector

EXPD-N Series is an indirect type (CsI) digital X-ray detector designed to be integration into products by X-ray system manufacturers. The device is recommended for use for general radiography imaging applications.

EXPD-N Series provides high performance even at low dose, which brings itself to be optimum solution for surgical imaging. DRTECH's QX-Platform contributes to ultimate performance even at low dose. Pre-processing technology is embedded within detector to deliver high quality image and lessen the burden on PC.

2.1.2 Intended Use

- Indications for Use**

The Digital X-ray detector, EXPD-N Series, is designed for use in digital imaging solutions for general radiographic diagnosis of human anatomy. This device is intended for use in all general diagnostic procedures, replacing film or screen-based radiographic systems for both adult and paediatric patients.

It is not intended for use in mammography.

- Intended Patient Population**

Considerations	Requirement Description
Age	Paediatric to Geriatric
Gender	No special requirements
Weight	>20 kg
Height	Not relevant
Nationality	No special requirements
Health	Not relevant
*Patient is not the user	

- Intended Part of the body or type of tissue applied to or interacted with**

- Measuring site: overall part of the body except breast (the device is not intended for mammography.)

- Target diagnosis group**

- The group of patients is all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications)

- Target disease**

- ICD-11 Code: XY9R Diagnosis confirmed by imaging
- All general-purpose diagnostic procedures

- Clinical benefits**

- Non-invasive and painless diagnosis of diseases and monitoring of therapy
- Support of medical and surgical treatment planning
- Improvement of psychological
- Improvement of discomfort

- **Contraindications**

Patients with the following conditions are prohibited to use the device or asked to consult their physician or doctor before using it.

1. Patients having pacemaker implants.
2. Patients with metal device implants.
3. Patients who are unable to holding a position during imaging.
4. Patients who are allergic reactions to X-Ray radiation.
5. Patients with additional symptoms which may at higher risk for X-ray side effects.
6. Patients who are pregnant or assumed to be pregnant.

- **Intended User Profile**

Considerations		Requirement Description
Education	Minimum	• A professional with specialist knowledge/ qualifications who has fully understood the product and the contents of this document. (Such as a radiologist or radiological technologist)
Knowledge	Minimum	• Read and understand Western "Arabic numerals" written in Arial font • Can distinguish human body • Understands hygiene
Language understanding	Minimum	• Understand the manual in English
Experience	Minimum	• Licensed physician or equivalent
Permissible impairments	Minimum	• Mild reading vision impairment or corrected vision to log MAR 0.2 • Average degree of age-related short-term memory impairment • Impaired by 40 % resulting in 60 % of normal hearing at 500 Hz to 2 kHz



CAUTION
MISEENGARDE

U.S. Federal Law restricts this device to the sale by or on the order of a licensed physician or other qualified medical professional

2.1.3 Technical Specifications

- Digital Flat Panel X-ray Detector

ITEM	Details
Purpose	General Radiography
Panel / Scintillator	- Panel: a-Si / IGZO / Flexible a-Si - Scintillator: CsI
Panel Area	- EXPD 4343N / EXPD 4343NP / EXPD 4343NU : 430.2mm × 430.2mm - EXPD 3643N / EXPD 3643NP / EXPD 3643NU : 353.4mm × 430.2mm - EXPD 4343N1 / EXPD 4343U1 : 430.08mm × 430.08mm - EXPD 3643N1 / EXPD 3643U1 : 358.4mm × 430.08mm
Resolution	- EXPD 4343N / EXPD 4343NP / EXPD 4343NU : 3,072 × 3,072 pixels - EXPD 3643N / EXPD 3643NP / EXPD 3643NU : 2,560 × 3,072 pixels - EXPD 4343N1 / EXPD 4343U1 : 4,302 × 4,302 pixels - EXPD 3643N1 / EXPD 3643U1 : 3,534 × 4,302 pixels
Pixel Pitch	- EXPD 4343N / EXPD 4343NP / EXPD 4343NU / EXPD 3643N / EXPD 3643NP / EXPD 3643NU : 140μm - EXPD 4343N1 / EXPD 4343U1 / EXPD 3643N1 / EXPD 3643U1 : 100μm
Limiting Resolution	- EXPD 4343N / EXPD 4343NP / EXPD 4343NU / EXPD 3643N / EXPD 3643NP / EXPD 3643NU : 3.57 lp/mm - EXPD 4343N1 / EXPD 4343U1 / EXPD 3643N1 / EXPD 3643U1 : 5 lp/mm
MTF (Typical)	- EXPD 4343N / EXPD 4343NP / EXPD 4343NU / EXPD 3643N / EXPD 3643NP / EXPD 3643NU : 35% *2.0lp/mm (RQA5, 2μGy according to IEC 62220) - EXPD 4343N1 / EXPD 4343U1 / EXPD 3643N1 / EXPD 3643U1 : 40% *2.0lp/mm (RQA5, 2μGy according to IEC 62220)
DQE (Typical)	- EXPD 4343N / EXPD 4343NP / EXPD 4343NU / EXPD 3643N / EXPD 3643NP / EXPD 3643NU : 60% *0.5lp/mm (RQA5, 2μGy according to IEC 62220) - EXPD 4343N1 / EXPD 4343U1 / EXPD 3643N1 / EXPD 3643U1 : 60% *0.5lp/mm (RQA5, 2μGy according to IEC 62220)
Cycle Time.	≤8.5 sec.
X-ray Window	Max. 60 sec.(typ.0.5sec.)
A/D Conversion	16bit
Energy Range	40 – 160kVp
Power	(Tether Cable) 1 A, 24 Vdc (USB-C Adaptor) 5 A, 20 Vdc (Wireless Charger) 0.75 A, 20 Vdc (Battery) 3750 mAh, 11.1 Vdc or 3750 mAh, 7.4 Vdc

ITEM	Details
On-board Memory	• 2GB (expandable up to 8GB)
SD Memory	• 32GB SDHC card
Image Acquisition Time	• Wired : Less than 5 seconds, Wireless : Less than 10 seconds
Data Interface	• Gigabit Ethernet / IEEE 802.11n/ac
Overall Dimension	4343N / 4343NP / 4343NU / 4343N1 / 4343U1 : 460mm (W) × 460mm (L) × 15.5mm (H) [±0.5mm] 3643N / 3643NP / 3643NU / 3643N1 / 3643U1 : 386mm (W) × 460mm (L) × 15.5mm (H) [±0.5mm]
Weight	4343N / 4343NP / 4343N1 : 3.5 kg ± 5% 4343NU / 4343U1 : 3.2 kg ± 5% 3643N / 3643NP / 3643N1 : 2.8 kg ± 5% 3643NU / 3643U1 : 2.6 kg ± 5%
Waterproof	• Ordinary equipment(IPX0)

- Battery Pack**

Item	Description
Model	- EXPD-B3P - EXPD-B2P
Cell Type	Lithium Polymer
Number of Cells	- EXPD-B3P: 3S1P (3series 1 Parallel) - EXPD-B2P: 2S1P (2series 1 Parallel)
Rated Power Supply	- EXPD-B3P - Output : 3750 mAh, 11.1 Vdc (41.6W) - EXPD-B2P - Output : 3750 mAh, 7.4 Vdc (27.7W)
Lifetime	Approx. 500 cycles of use (complete charge/discharges 1 cycle)
Dimensions (W x H x D)	208mm (W) × 157.2mm (L) × 7mm (H) [±0.5mm]
Weight	- EXPD-B3P: Approx. 350g - EXPD-B2P: Approx. 270g

- Cradle**

Item	Description
Model	EXPD-DDCS
Rated Power Supply	- Input: 2.3 – 1.1 A, 100 – 240 V~, 50/60 Hz - Output: 3 A, 24 Vdc
Dimensions (W x H x D)	432.4mm (W) × 310mm (L) × 174mm (H) [±0.5mm]
Weight	4.8Kg ± 5%

- Battery Charger

Item	Description
Model	EXPD-BCS
Charging Time	Less than 1 hour
Rated Power Supply	Input: (Tether Cable) 3 A, 24 Vdc (USB-C Adaptor) 3 A, 20 Vdc Use with EXPD-B3P or EXPD-B2P batteries.
Dimensions (W x H x D)	247mm (W) × 238.3mm (L) × 15.5mm (H) [±0.5mm]
Weight	510g ± 5%

- System Synchronize Unit

Item	Description
Model	EXPD-SSU
Rated Power Supply	- Input: 1.5 A, 24 Vdc - Output : 1 A, 24 Vdc
Dimensions (W x H x D)	102.6mm (W) × 287.2mm (L) × 28.0mm (H) [±0.5mm]
Weight	280g

- Wireless charger

Item		Description	Note
Model		EXPD-WPCS	
Dimensions (W x H x D)		87mm (W) × 87mm (L) × 15mm (H) [±0.5mm]	
Weight		220g ± 5%	
Charging Transceiver IC		MCU: M4825SIDAE Transmitter Power IC: NU1028	Medium Power
Charging Receiver IC		MCU: M4825SIDAE Receiver Rectifier IC: NCP4306DADZZ Transmitter Power IC: MTB11N03BVB	Medium Power
WPC Qi Specification		V1.2.4	
Rx, Tx Distance	Coil to Coil	Typ. 4mm(±1mm)	Max. 8mm
	Center to Center	Typ. 4mm	Max. 8mm
Input Voltage		20Vdc, 0.75A	Tx Module Input
Output Power		20Vdc, 0.75A	Rx Module Output
Standby Current/Power		Typ. 27.22mA / 326.6mW	
Max Power Efficiency		83%	
Ambient Temperature	Storage Temperature	-15 – +55°C	
	Operating Temperature	+10 – +35°C	

- X-ray System Requirements**

Contents		Requirements	
Generator	Power frequency	30~ 240kHz	
	KV	40 ~ 150kVp	
	mA Range	10 ~ 1000mA	
	Exposure Time	0.001~10sec	
	mAs Range	0.1~1000mAs	
	Accuracy	± 5%	
Bucky	Operating Type	Moving	Stepping Motor
			Spring
			CAM Motor type
		Static(Fixed)	
Grid	Trey size (mm)	460 mm × 460 mm × 15.5 mm or higher	
	Ratio	5:1, 6:1, 8:1, 10:1, 12:1, 15:1	
	Line	85 ~ 215 Line	
	SID	100 ~ 180 cm	

- RF General Information**

Frequency	IEEE Std. 802.11 Protocol	Channel Number	EIRP power	EIRP Limit
2412 MHz ~ 2472 MHz	802.11b	1-13 [13]	10.45 dBm	≤ 20 dBm
	802.11g	1-13 [13]	10.62 dBm	≤ 20 dBm
	802.11n (HT20)	1-13 [13]	10.51 dBm	≤ 20 dBm
2422 MHz ~ 2462 MHz	802.11n (HT40)	3-11 [9]	10.60 dBm	≤ 20 dBm
5180 MHz ~ 5240 MHz	802.11a	36-48 [4]	18.23 dBm	≤ 23 dBm
	802.11n (HT20)	36-48 [4]	18.34 dBm	≤ 23 dBm
5190 MHz ~ 5230 MHz	802.11n (HT40)	38-46 [2]	18.47 dBm	≤ 23 dBm
5260 MHz ~ 5320 MHz	802.11a	52-64 [4]	16.22 dBm	≤ 23 dBm
	802.11n (HT20)	52-64 [4]	16.52 dBm	≤ 23 dBm
5270 MHz ~ 5310 MHz	802.11n (HT40)	54-62 [2]	16.47 dBm	≤ 23 dBm
5500 MHz ~ 5700 MHz	802.11a	100-140 [11]	16.68 dBm	≤ 23 dBm
	802.11n (HT20)	100-140 [11]	17.00 dBm	≤ 23 dBm
5510 MHz ~ 5670 MHz	802.11n (HT40)	102-134 [5]	16.94 dBm	≤ 23 dBm

- Antenna Gain (Peak)**

2.4 GHz : -5.50 dBi / 5 GHz : 2.10 dBi

- Reliability (Lifetime Dose)**

- Expected service life: 5 years

The device's lifetime is estimated based on a lifetime test conducted under the condition of 1 day
(30 patients × 5 shots) = 150 shots.

2.1.4 Detector Functions

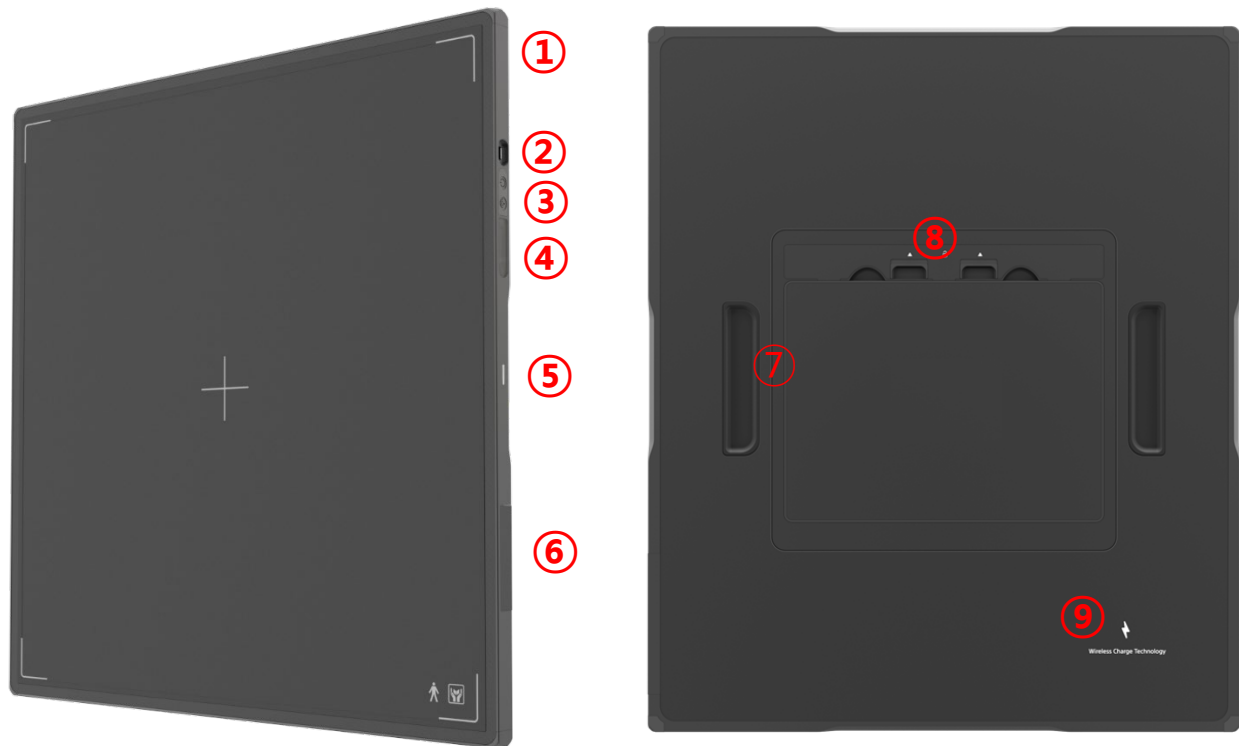


Figure 9. Connectors and LED of the EXPD-N Series

No.	ITEM	Details
1	Magnetic Tether Connector	• Connectors for power and wired communications
2	USB-C Connector	• Connector for charging the battery with a USB-PD adapter
3	Power & AP Button	• Power on/off and wireless settings change switches
4	OLED Display	• Display that shows product status
5	LED Indicator	• LED indicating product status
6	Antenna	• Antennas for wireless communications
7	Dual Handle	
8	Battery Removal Hook	
9	EXPD-WPCS	• EXPD-WPCS RX for wireless charging

2.1.5 Detector Cradle(EXPD-DDCS)

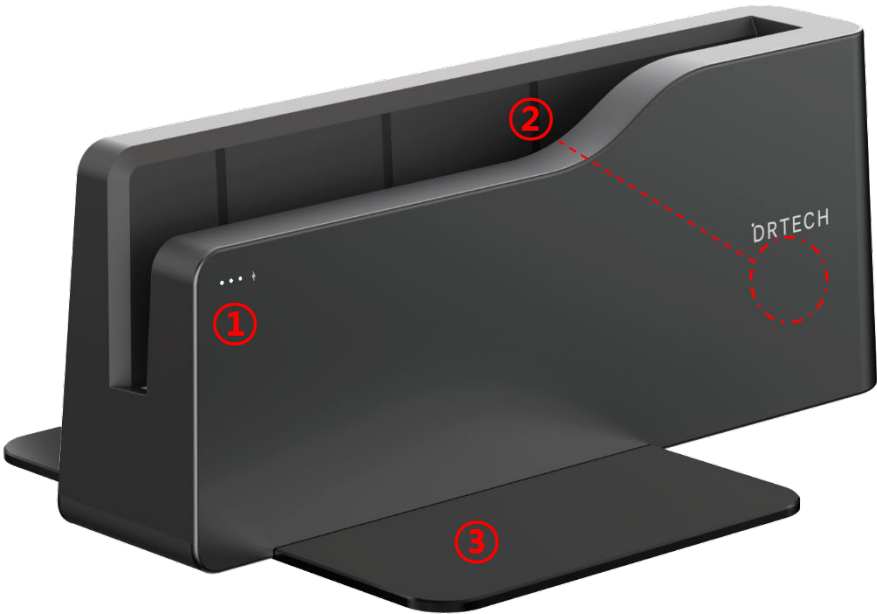


Figure 10. Detector Cradle

No.	ITEM	Details
1	Charging Indicator	Power and Charge Status LED Indicator
2	Magnetic Tether Connector	Magnetic pogo connector for detector attachment
3	Cradle Support Plate	

2.1.6 Battery Charger(EXPD-BCS)

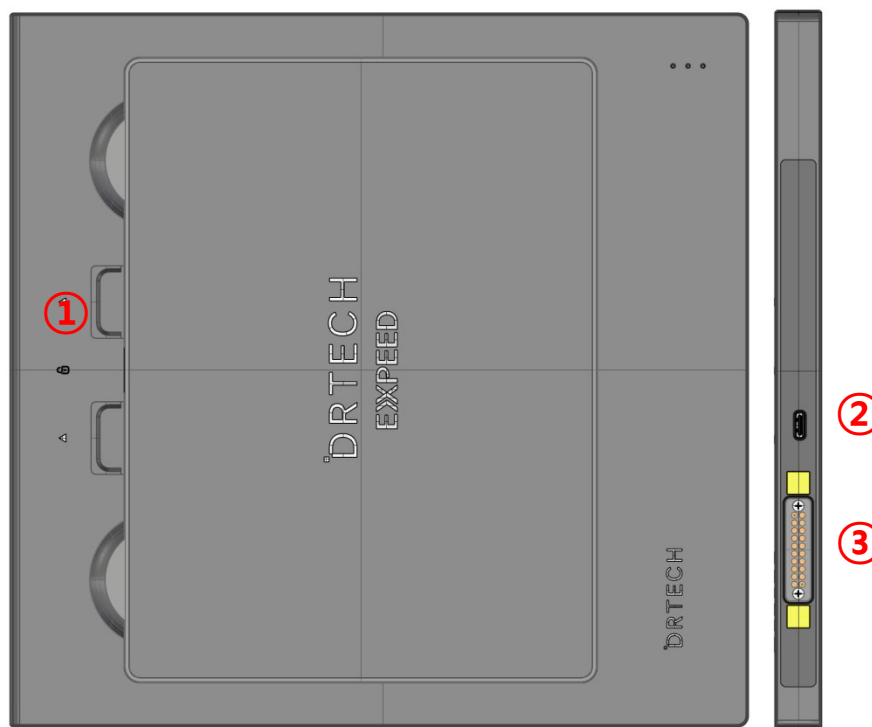


Figure 11. Battery Charger

No.	ITEM	Details
1	Battery Removal Hook	Remove the battery by pushing the hook
2	USB-C Connector	USB-C connector for PD adapter charging, Connected to UES140A3-SPC by USB-C Cable.
3	Magnetic Pogo Connector	Magnetic pogo connector for detector cradle docking

2.1.7 Battery Pack

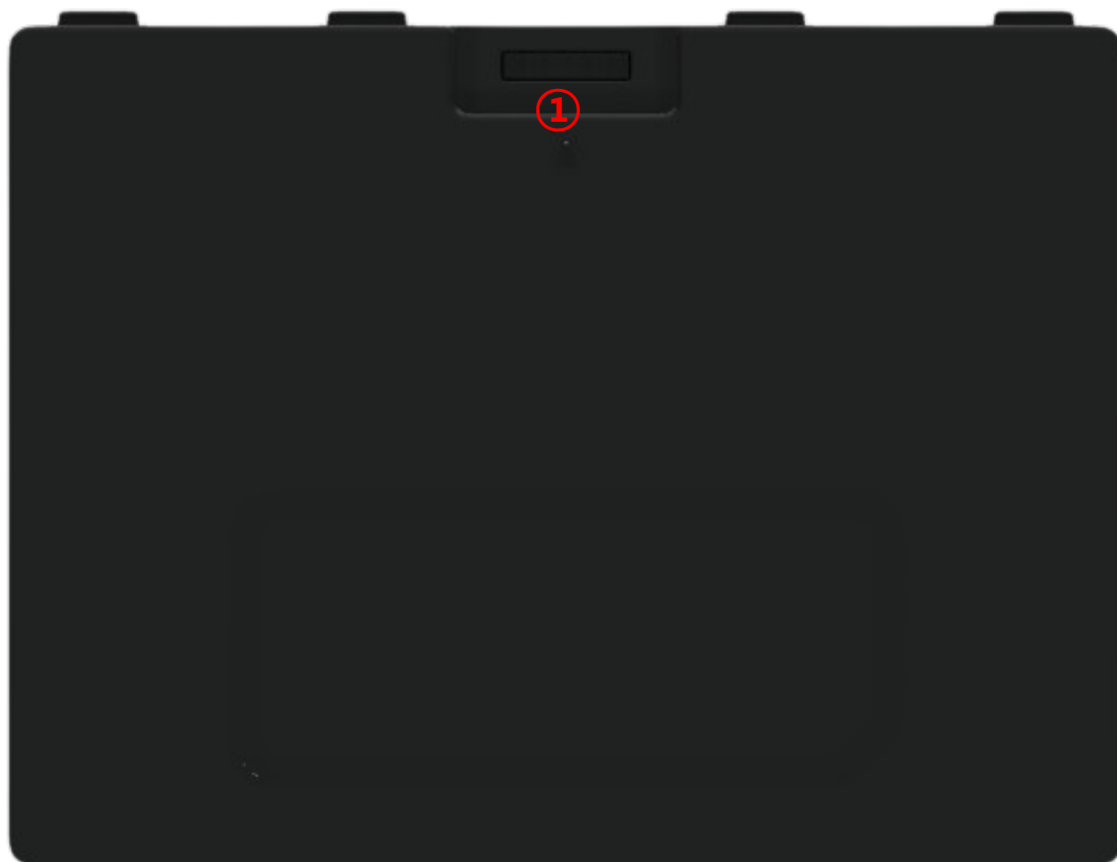


Figure 12. Battery Pack

No.	ITEM	Details
1	Battery Connector	Connector for charging/discharging and monitoring

NOTE. Battery packs are available in two types: high-capacity and lightweight.

2.1.8 System Synchronize Unit (EXPD-SSU)



Figure 13. Power & External Sync Interface Port PIN assignment

No.	Part name	Specification
1	RJ45 Connector	Connector for communication with PC
2	DC Jack	Input Power, DC 24V / Max 1.5A, Connected to UES48-240150SPA3.
3	Power Switch	Power On/Off Switch
4	D-SUB Connector	X-Ray Generator interface
5	Tether Connector	Detector power input and communication connector
* 4, 5 Connector, and Cable can be customized according to customer request.		

2.1.9 EXPD-WPCS TX Module

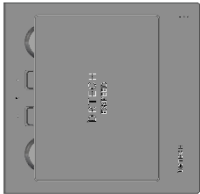


Figure 14. Power & External Sync Interface Port PIN assignment

No.	Part name	Specification
1	EXPD-WPCS TX Coil	EXPD-WPCS RX Coil for Wireless Charging
2	USB-C Connector	Wireless charging input power connector, connect to UES140A3-SPC by USB-C Cable

This EXPD-WPCS wireless charging system is primarily designed for integration within the bucky or patient table of an X-ray system, where it is placed alongside the X-ray detector. As such, the EXPD-WPCS is not intended to come into direct contact with the user, particularly at the back of the device.

2.2 Components List

Name	Image	Description
EXPD-BCS Battery Charger		- Input: (Tether Cable) 3 A, 24 Vdc (USB-PD Adaptor) 3 A, 20 Vdc - Use with EXPD-B3P or EXPD-B2P batteries
EXPD-B3P Battery Pack (3S1P)		3S1P Battery Pack - Output: 3750 mAh, 11.1 Vdc (41.6W)
EXPD-B2P Battery Pack (2S1P)		2S1P Battery Pack - Output: 3750 mAh, 7.4 Vdc (27.7W)
EXPD-DDCS Detector Cradle		- Input: 2.3 – 1.1 A, 100 – 240 V~, 50/60 Hz - Output: 24Vdc, 3A
EXPD-WPCS TX Module		- Input: 20Vdc, 0.75A - Output: 20Vdc, 0.75A
EXPD-SSU		- Input: 24Vdc, 1.5A - Output: 24Vdc, 1A
Wireless AP		
Bi-Direction Tether Cable (Optional)		6m POE Cable - Power input from EXPD-SSU - Gigabit Ethernet - X-ray Trigger
Uni-Direction Tether Cable (Optional)		6m POE Cable - Power input from EXPD-SSU - Gigabit Ethernet

Name	Image	Description
Gigabit Ethernet Cable		- Gigabit Ethernet I/F [LAN]: Category 7 - Length: 15m
USB PD Adaptor & USB Cable		- Adaptor (UES140A3-SPC, UE) - Input: 80-264VAC, 2.5A, 47-63Hz - Output: 28V, 5A
AD/DC Adaptor		- Adaptor (UES48-240150SPA3, UE) - Input: 90~264VAC, 1.1A, 47-63Hz - Output: 24V, 1.5A
Power Cord (Optional)		- Max. 250V Power Cord - Cross sectional area: 3X 0.75mm² - Rating: 10A - Length: 1.8m
Power Cord (Optional)		- Max. 125V Power Cord - Cross sectional area: 3X 18AWG - Rating: 10A - Length: 2m
USB-C to Lan		Used for product installation and debugging



- If you find any items missing from the list above upon unpacking, please contact DRTECH Corporation.

3. System Configuration

3.1 System Specifications

ITEM	Details
Operating System	Windows 10 64bit
CPU	Intel Desktop i5 CPU or higher
Memory	8GB or more
Storage	SSD 120GB or more
LAN Card	Gigabit Ethernet

3.2 System Configuration

3.2.1 Configuration Diagram

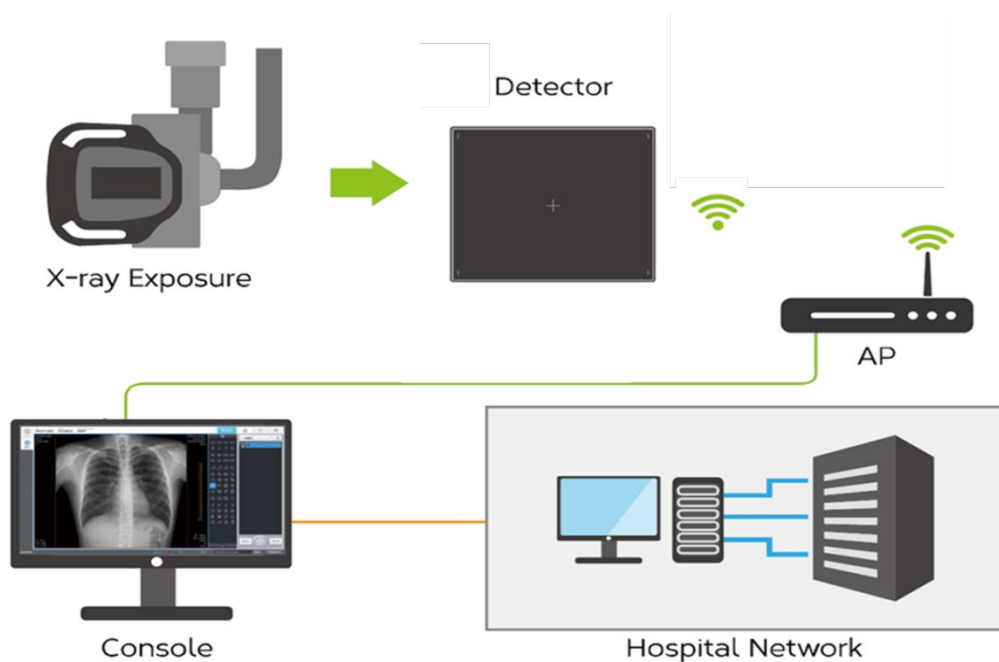


Figure 15. Schematic of the Wireless configuration

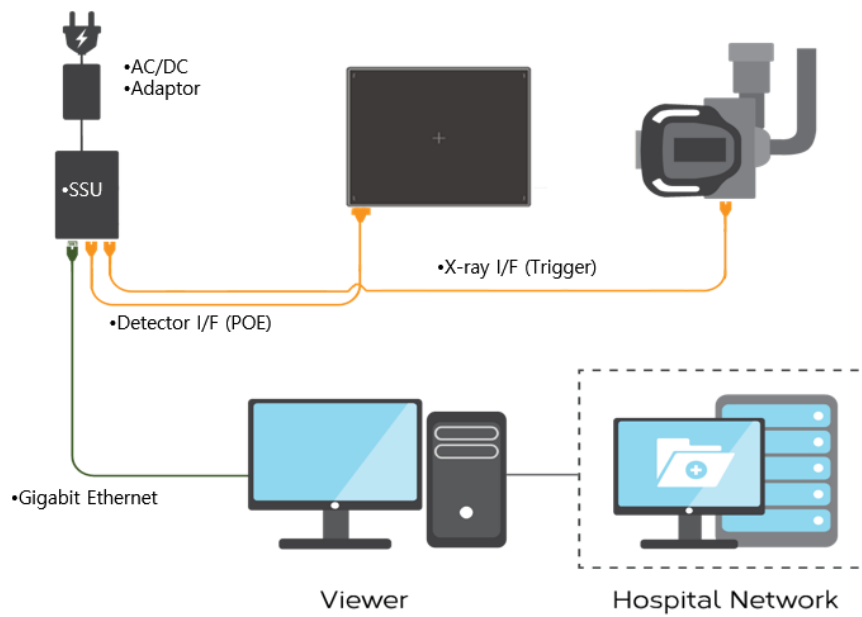


Figure 16. Schematic of the Wired configuration

3.2.2 Detector Dimension

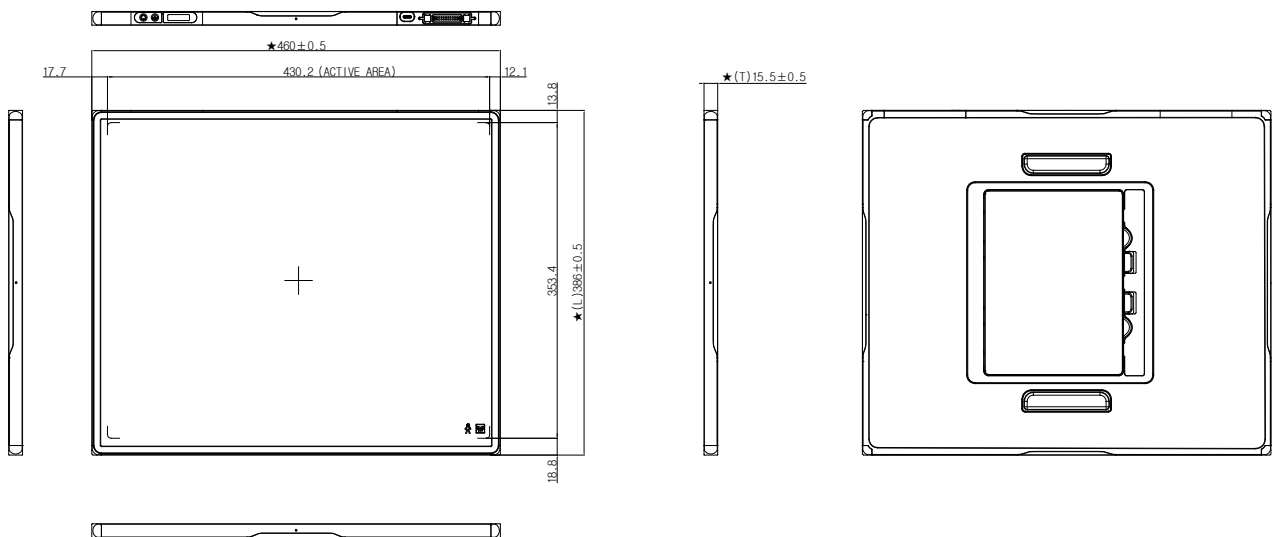


Figure 17. Drawing of the EXPD-N Series (3643 size)

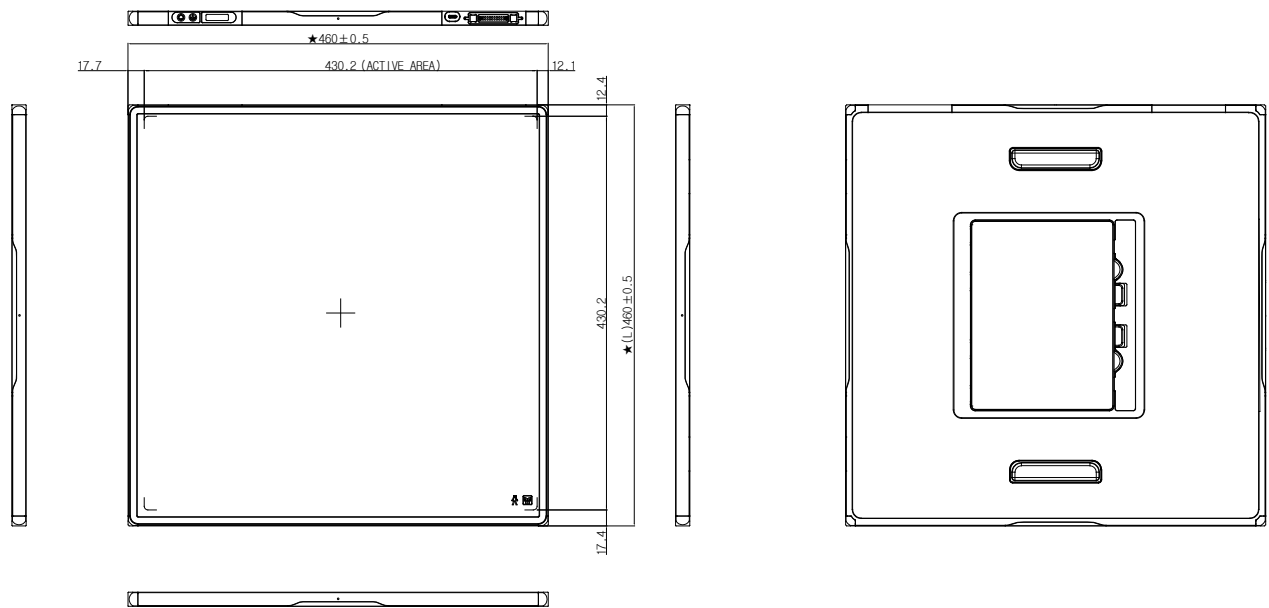


Figure 18. Drawing of the EXPD-N Series (4343 size)



IMPORTANT

- When installing the detector to the system, the Torque value should be less than 10N·m.

3.2.3 Power & External Sync Interface Cable Diagram

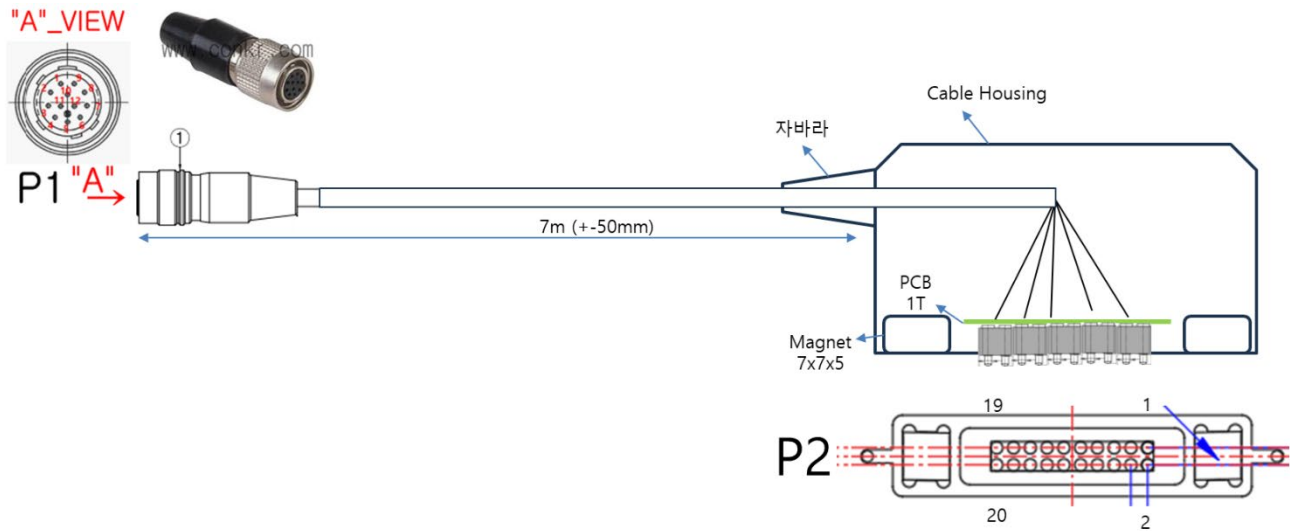


Figure 19. Drawing of the Power & External Sync Interface Cable

No.	Part name	Specification
P1	EXPD-SSU Connector	Circular 12-pin connector that connects to the EXPD-SSU
P3	Detector Pogo Connector	Magnetic pogo connector connected to the detector
* P1, P2 Connector, and Cable can be customized based on customer request.		

3.3 System Interface

3.3.1 Interface pin map of EXPD-SSU equipment



Figure 20. Power & External Sync Interface Port PIN assignment

No.	Part name	Specification
1	RJ45 Connector	• Connector for communication with PC
2	DC Jack	• Input Power, DC 24V / Max 1.5A
3	Power Switch	• Power On/Off Switch
4	D-SUB Connector	• X-Ray Generator interface
5	Tether Connector	• Detector power input and communication connector
* 4, 5 Connector, and Cable can be customized based on customer request.		

No.	Signal Name	I/O	Description
1	EXP_REQ_+	Input	Exposure Request Signal (5~12V)
2	EXP_REQ_-	Input	Detector Power Ground
3	EXP_REQ_TTL	Input	Exposure Request Signal (5~12V)
4	EXP_REQ_GND	Input	Detector Power Ground
5	EXP_OK_PWR	Input	Power of Signal (Bi-directional) (5~12V)
6	EXP_OK+	Output	Request Ok Signal (5~12V)
7	EXP_OK-	Output	Ground of Signal
8-15	N.C.	-	Open



- Do not connect unused PIN to the ground. Leave unused I/O PIN unconnected.

3.3.2 Interface Signal Circuit

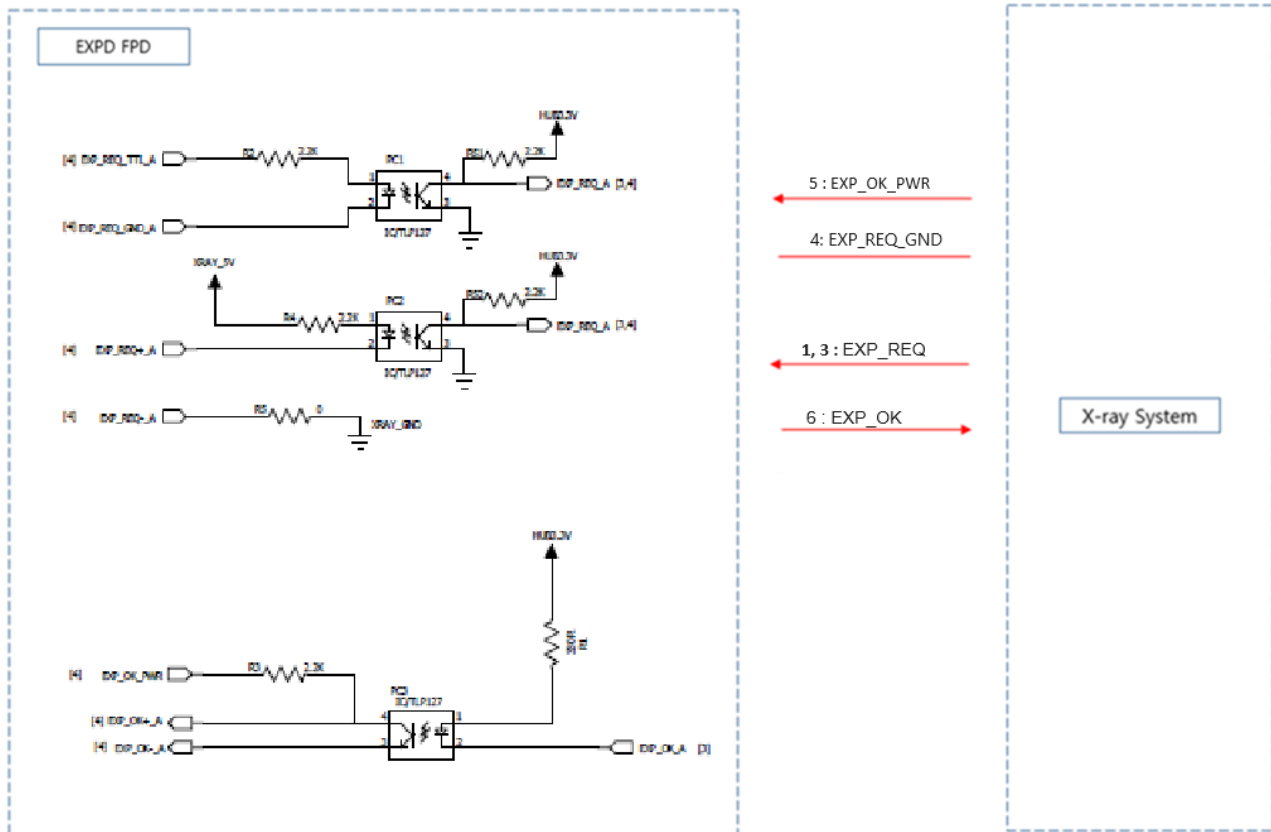


Figure 21. Schematic of the Interface Signal Circuit

The synchronization interface circuit of EXPD-N Series is as above. It is composed of 2 input signals and 1 output signals, and is electrically isolated between the X-ray system and the EXPD-N Series by using a photocoupler for each signal. The input signals EXP_REQ and EXP_OK signals operate “Low-active”.

3.3.3 Interface Type

Type	Description
Internal Trigger	- The detector acquires images by the S/W trigger that detector generated with a predetermined frame rate by a user. - The detector generates “EXPOSURE_OK” Trigger output signals, so the X-ray generator can use the signal for X-ray exposure.
External Trigger	- The detector acquires images by the H/W trigger that the User's system generated. Each image is acquired by each H/W trigger signal. - The detector generates “EXPOSURE_OK” Trigger output signals, so the X-ray generator can use the signal for X-ray exposure.

3.3.4 Timing Diagram

3.3.4.1 Internal Trigger

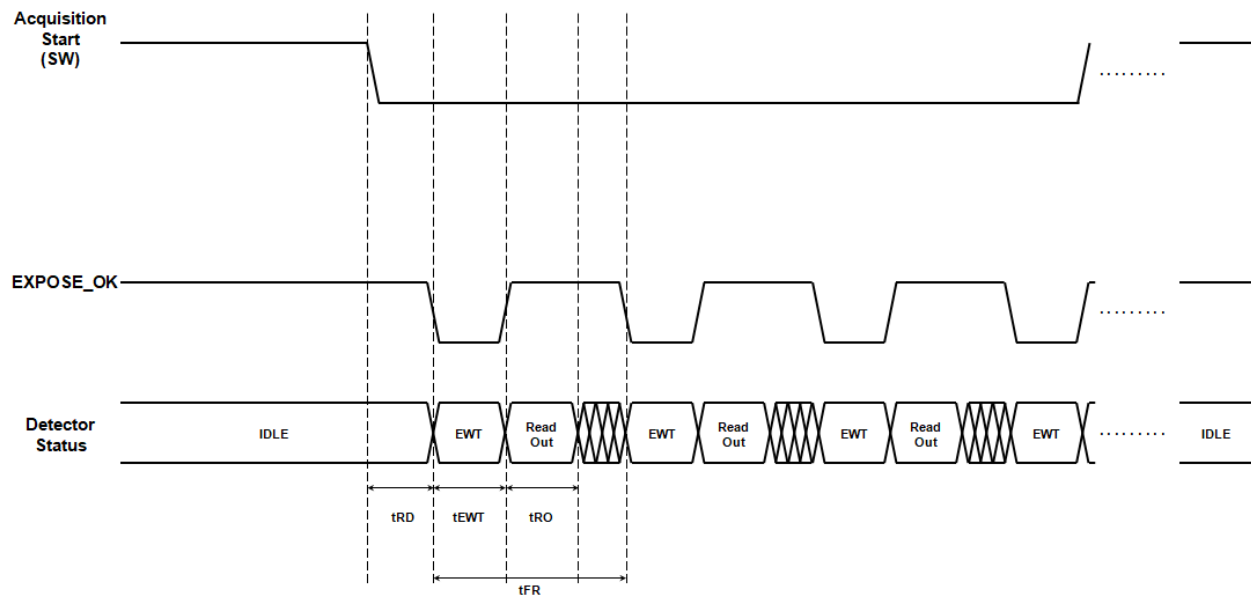


Figure 22. Timing Diagram for the Multi-frame Internal type

Symbol	Definition	Limitation
tEWT	Expose Window Time	Min. 0ms (for Continuous X-ray Exposure)
tRO	Readout Time	Min. 50ms (@ Non-binning, Full resolution)
tFR	Frame Time	Min. 50ms (@ Non-binning, Full resolution)

3.3.4.2 External Trigger

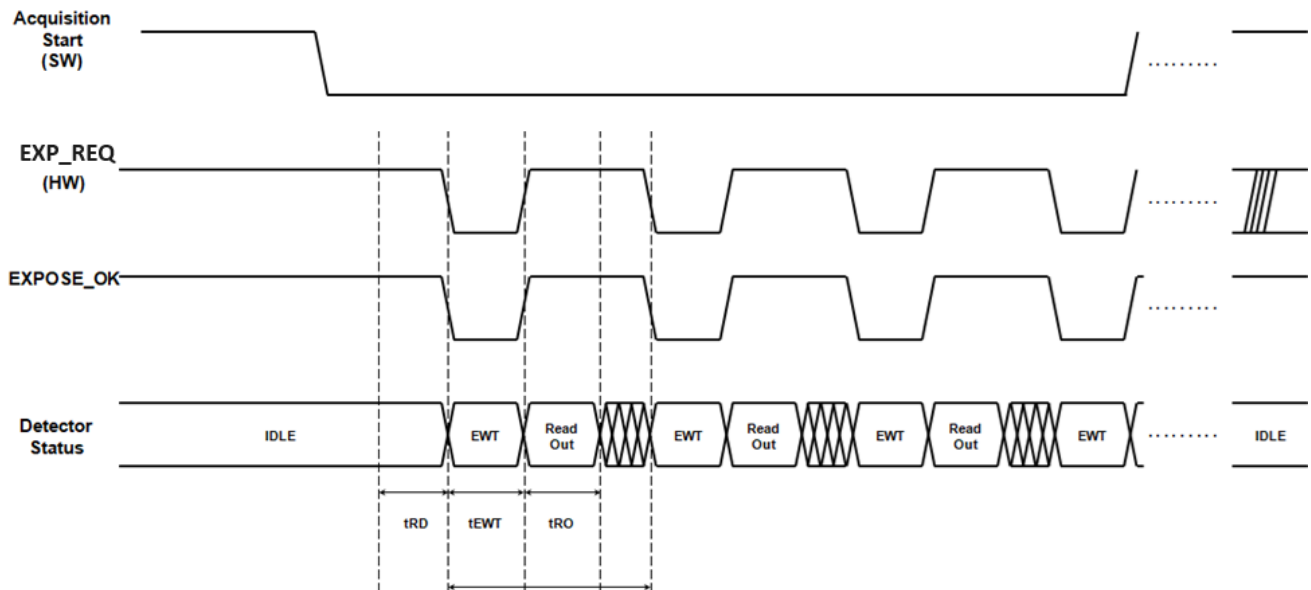


Figure 23. Timing Diagram for the Multi-frame External type

Symbol	Definition	Limitation
tEWT	Expose Window Time	Min. 0ms (for Continuous X-ray Exposure)
tRO	Readout Time	Min. 50ms (@ Non-binning, Full resolution)
tFR	Frame Time	Min. 50ms (@ Non-binning, Full resolution)



- Minimum Readout Time and Minimum Frame Time depend on the Binning and ROI setting.

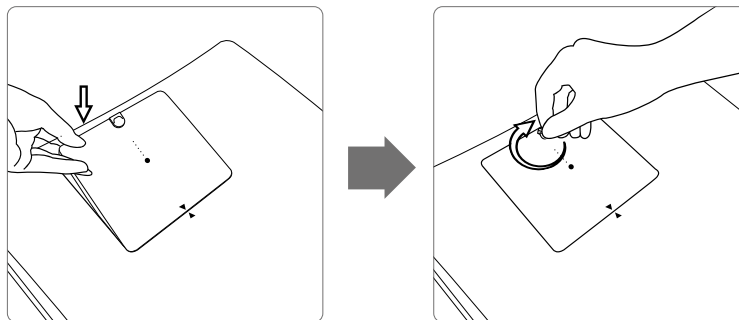
4. Operation Setting

4.1 H/W Preparation

4.1.1 Insert the battery

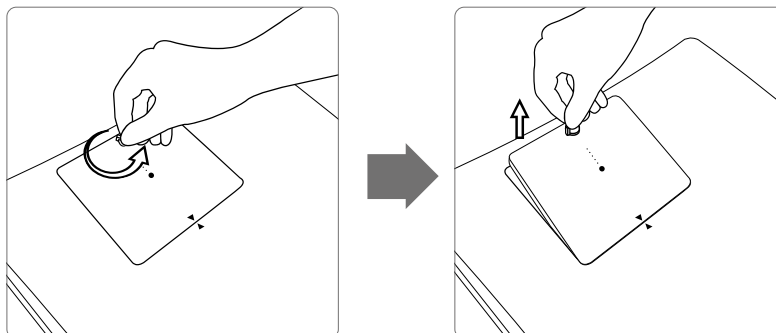
- Insert the charged battery into the detector battery slot.

How to Attach a Battery Pack



- 1) Align the arrows on the detector and battery pack.
- 2) Push down the battery pack.
- 3) Turn the battery lock knob 90 degrees clockwise.

How to Detach a Battery Pack



- 1) Turn the battery lock knob 90 degrees counter-clockwise.
- 2) Pull up the battery pack grabbing the knob.



WARNING
AVERTISSEMENT

Make sure to turn off the detector before detaching a battery pack. Press and hold the power button for about 2 seconds. All status LED lamps will be turned off when the detector is turned off.

Securely attach the battery into the detector or charger. If contact failure occurs, or if dust or metal objects come into contact with the exposed connector pins of the detector or charger, fire or electrical shock may occur.

4.1.2 Power-On the Detector

- Press the power switch for more than 3 seconds to turn on the power.

	EXPD-N Series requires at least 5 minutes(10 minutes are recommended) to warm up after the main power has been turned on.
 CAUTION	Be sure to use the power supply dedicated to the EXPD-N Series detector.

4.1.3 Check LED Status

Lamp	Status
PWR ON	- Power Status LED ■ Blue ON – Power Supplied, Network not connected
Acquisiton On	■ Green ON – Powered, Network connected, Acquisition mode on state
Acquisiton Off	■ Orange ON – Powered, Network connected, Acquisition mode off state
PWR OFF	- Power Status LED ■ LED OFF – Power offed

4.1.4 Power-Off the Detector

- Turn off the detector by switching off the system power or adaptor.

 IMPORTANT	Do not turn off the detector during image acquisition
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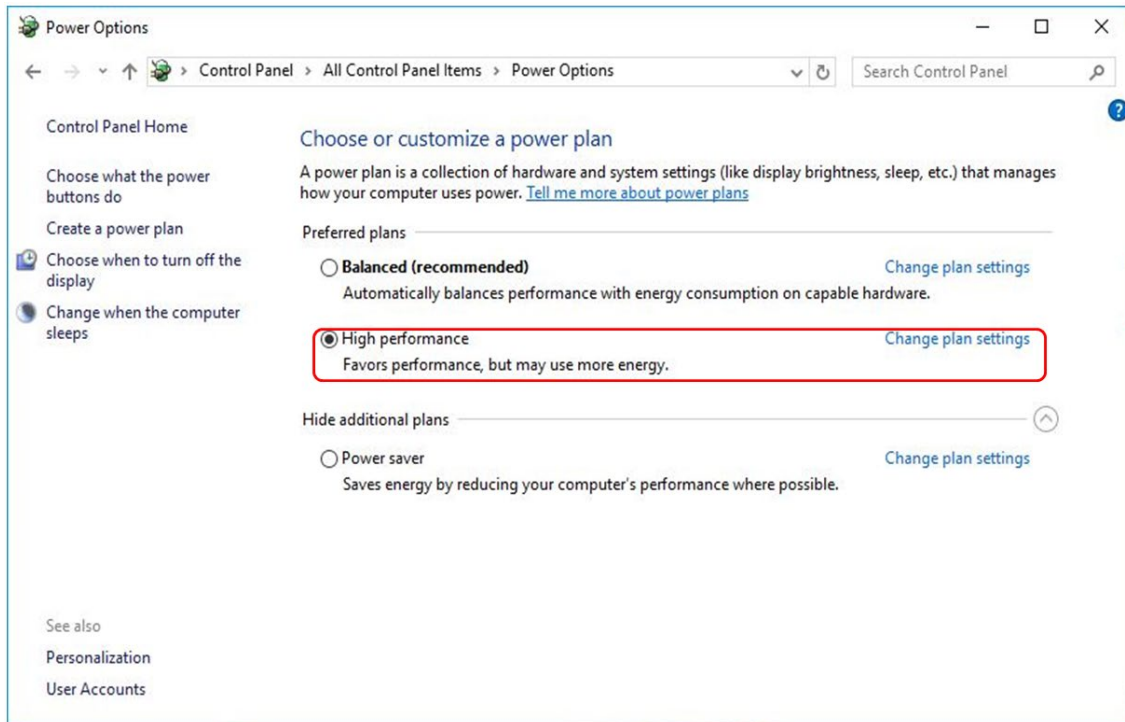
4.1.5 Cooling Requirement

- There are no particular cooling requirements during detector operation in ambient temperature with natural airflow cooling. If there is no natural airflow cooling and ambient temperature is high, an additional air cooling system (e.g. air cooling fan) is recommended for stable operation of the detector. Before using a cooling system, the user has to verify whether the cooling system affects the quality of images.
- During the operation, a caution message can be programmed to be sent by the detector to the system if internal temperature exceeds a pre-determined threshold.

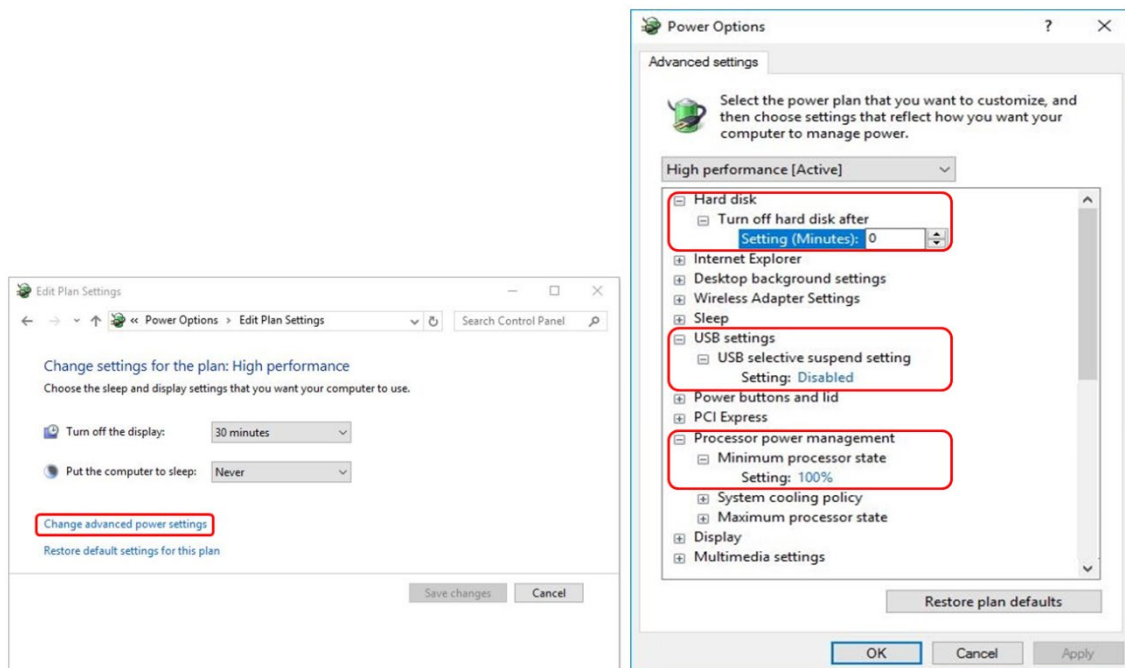
WARNING PROHIBITED	• Do not operate the detector using any type of power supply other than the one indicated on the rating label. Otherwise, it may result in fire or electric shock. • Do not handle the detector with wet hands. You may experience an electric shock that could result in serious physical injury or death. • Do not place heavy objects such as medical equipment on cables or cords. Do not pull, bend, bundle, or step on them. These precautions are required to be followed to prevent cable and cord sheaths from being peeled. Do not alter the cables and cords. Otherwise, it may damage the cords which could result in fire or electric shock. • Do not supply power to more than one device simultaneously by using the same AC outlet. Otherwise, it may result in fire or electric shock. • Do not turn on the system power when condensation has formed on the detector. Otherwise, it may result in fire or electric shock. • Do not connect multiple portable socket-outlets or extension cords to the system. Otherwise, it may result in fire or electric shock.
WARNING	• Securely plug the power cord into the AC outlet. • If contact failure occurs, or dust or metal objects come into contact with the exposed metal prong of the plug, fire or electric shock may result. • Be sure to turn OFF the power before connecting or disconnecting the cords. Otherwise, you may get an electric shock which could result in death or serious injury. • Be sure to hold the plug or connector when disconnecting the cord. If you pull the cord, the core wire may be damaged, resulting in fire or electric shock. • To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth. • To make it easy to disconnect the plug at any time, avoid putting any obstacles near the outlet. Otherwise, it may not be possible to disconnect the plug in an emergency. • Be sure to ground the equipment to an indoor grounded connector. Also, make sure to connect all the earth connections for the system to a common ground. • Always connect the three-core power cord plug to a grounded AC power outlet. • To avoid risk of electric shock, this equipment must be only connected to a power supply that maintains protective earth. • The product has lower breaking capacity type. So do not install at the building power system prospective short-circuit current exceeding 35A. • To reduce the risk of electric shock, the system must be connected to an electrical ground. • A three-pin AC power cable is supplied with this system to provide the proper electrical grounding. The power cable must be plugged into an UL-approved/IEC-approved three-contact electrical outlet. • Do not disassemble or modify the product as it may result in fire or an electric shock. There are no operator serviceable parts or adjustments inside the system. Only a trained and qualified person should be permitted access to the internal parts of the system.

4.1.5.1 Power Management Setting (PC)

- Click "High performance" at the "Power Option" in the control panel, and click "Change plan settings" of High performance.

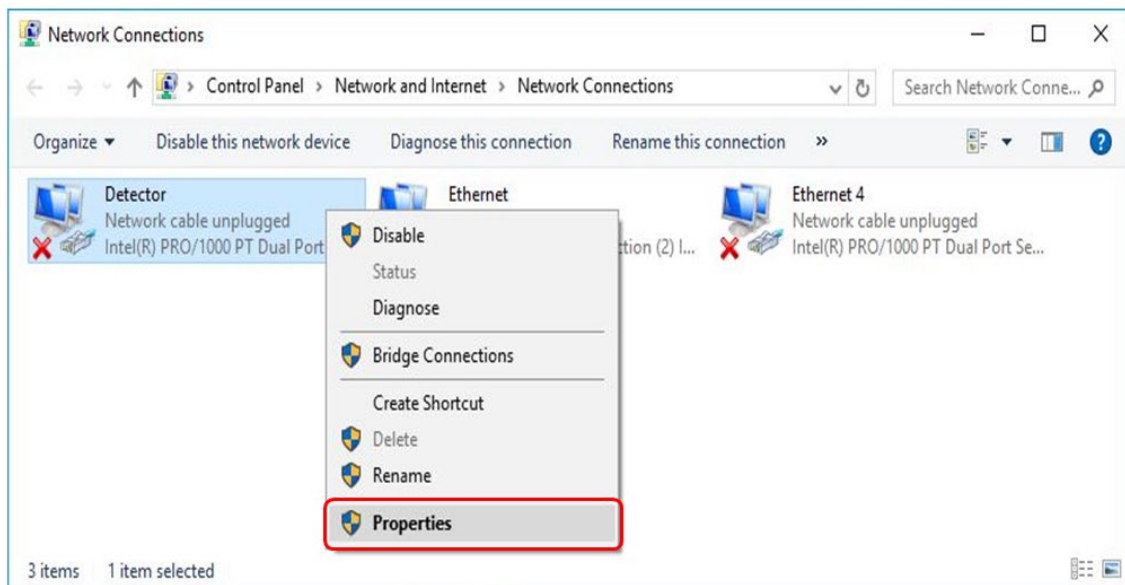


- Click "Change advanced power settings" and set "Hard disk", "USB settings" and "Processor power management" as shown in the right image.

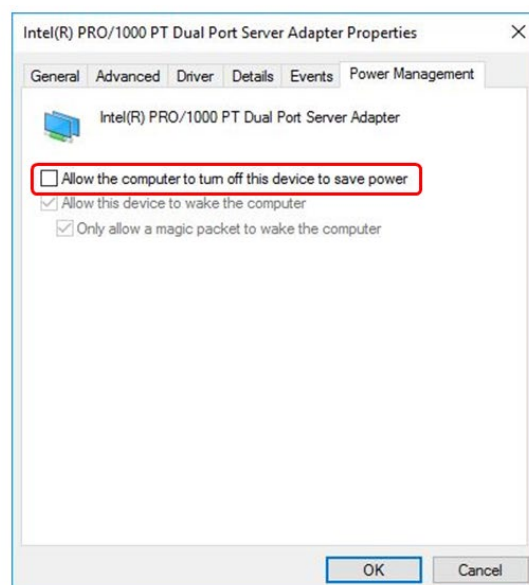
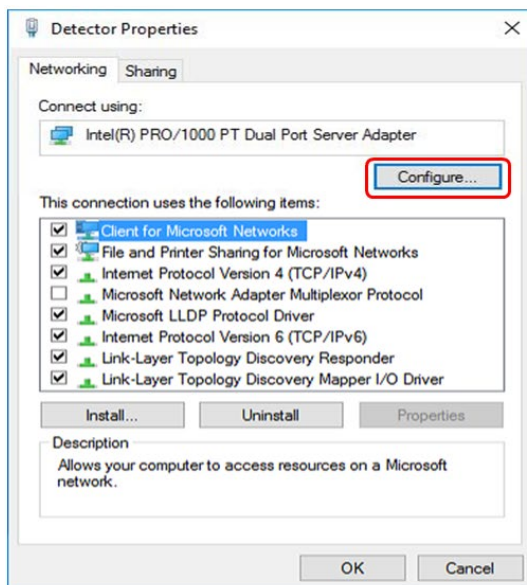


4.1.5.2 Power Management Setting (LAN Card)

- Select the network connected to the detector in the "Network Connections" and click the "Properties"

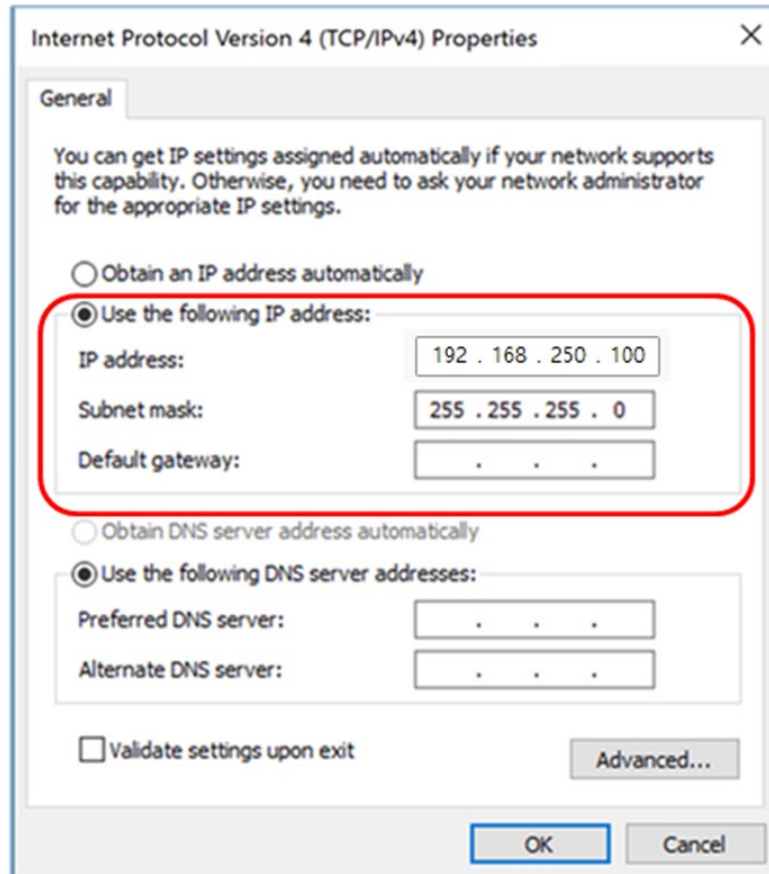


- Click the "Configuration" button and RELEASE the check box of "Allow the computer to turn off this device to save power".



4.1.5.3 Network Adaptor Setting

- Select the "Internet Protocol Version 4 (TCP/IPv4)" and click the "Properties" button it the Network Properties.
- Change the IP address setting as the below image.



5. Maintenance

5.1 Operating / Storage Environment

Be sure to use and store the equipment under the conditions described below.

	Operation	Storage	In Transit
Temperature	• +10 – +35°C (50 – 95°F)	• -15 – +55°C (5 – 131°F)	• -15 – +55°C (5 – 131°F)
Humidity	• 20 – 85% RH (Non-condensing)	• 10 – 90% RH (Non-condensing)	• 10 – 90% RH (Non-condensing)
Rate of change	• < 10°C (50°F)/hour	• < 15°C (59°F)/hour	-
Atmospheric pressure	• 700 – 1060 hPa	• 500 – 1060 hPa	• 500 – 1060 hPa
Warm-up time from power-on	• 5mins (Minimum) – 10mins (Recommended) • 30mins for Calibration		

 CAUTION	Do not expose the equipment to high temperatures and/or high humidity. This may cause the product to malfunction.
 CAUTION	When not in use, keep the detector, handle unit, and grid in a designated location or in a location where they are safe and cannot fall down.

5.2 Image Quality Maintenance Recommendation

To ensure optimal performance of the detector is maintained, it is important that all calibrations are regularly performed and used for image processing. To maintain high image quality, regular checking and update of pixel and gain map is recommended.

5.3 Disinfection and Cleaning

- Wipe it with a dry cloth slightly damped with a neutral detergent.
- Do not use solvents such as alcohol, thinner, or benzene. It may damage the surface of the equipment.
- The power should be switched OFF and equipment should be unplugged before cleaning.
- The exterior of the array can be cleaned with common hospital decontamination solutions including 5% of ButylCellosolve. A 0.55% Benzalkonium Chloride, 0.63% Sodium Hypochlorite, or 70% alcohol solution can also be used. To apply the cleaning solution, power down the system and disconnect from the power source, moisten a cloth with the solution and wipe the panel.

6. Trouble shooting

In order to ensure that the equipment is used safely, be sure to inspect the equipment before use. If any problem is detected during the inspection and cannot be corrected, please contact your sales representative or local DRTECH dealer.

6.1 Before Turning On

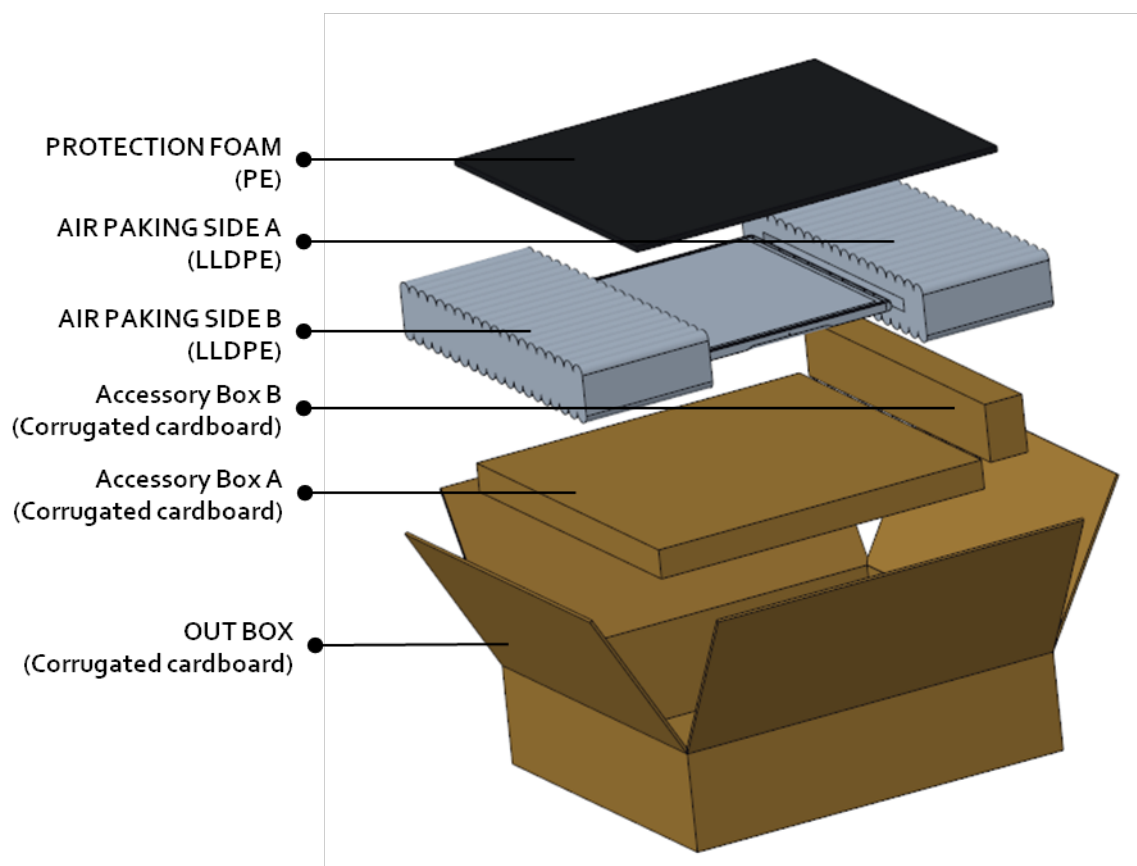
	Inspection	Pass/Fail	Remedy
Environment Check	Check if temperature and humidity are within normal operational range.	☐	Adjust environment to recommended range.
Cables	Check if the cables are not damaged or torn.	☐	Contact DRTECH or your local distributor if there is any problem.
	Check if the plugs, locks and connectors are not loose.	☐	Full insert the cables and lock them.
	Check if the cover of parts is not damaged or loose.	☐	Contact DRTECH or your local distributor if there is any problem.
System Check	Check if all components are not damaged and are properly connected.	☐	Contact DRTECH or your local distributor if there is any problem.
Detector Exterior Inspection	Check that the detector exterior is not contaminated with liquid or other contaminants.	☐	Clean the detector exterior following the recommended disinfectant and cleaning instructions
	Check for signs of physical shock or fire/burn traces	☐	Contact DRTECH or your local distributor if there is any problem.

6.2 After Turning On

	Inspection	Pass/Fail	Remedy
Power	Check that the PWR LED (Green) when the PWR/SYNC cable is connected.	☐	Insert the connector of PWR/SYNC cable all the way. Contact DRTECH or your local distributor if there is any problem.
Self-Test	When the power is turned on, the detector will automatically run a series of self-test.	☐	Contact DRTECH or your local distributor if there is any problem.
	Check the status of CAT7 Legacy connector LED & Power LED.	☐	

	Inspection	Pass/Fail	Remedy
	If 2 LED indicators light, it means the self-test has been passed.	□	
When detector is not connected	Check network configuration and firewall settings. Do ping test to 192.169.250.125	□	Contact DRTECH or your local distributor if there is any problem.
When detector is not READY		□	
When detector can't acquire images		□	
Detector Exterior Inspection	Check the displayed image for - Abnormal image - Indications of data loss - Image defects	□	Retry from the beginning or after 10 minutes system aging. Contact DRTECH or your local distributor if there is any problem.

7. Packaging



8. Revision History

Revision	Date	Descriptions
00	2024-07-30	Initially prepared.
01	2024-11-22	- Reliability(Lifetime dose) of the device is corrected. - The Indications for Use and Intended Use have been clearly distinguished, and the Indications for Use statement has been added to Annex 1.

Annex 1. Indications for Use Statement

The Indications for Use of the device submitted for the FDA 510(k) clearance are as follows.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: 07/31/2026 See PRA Statement below.
Submission Number (if known)	
Device Name EXPD 4343N1; EXPD 4343N; EXPD 4343U1; EXPD 4343NU; EXPD 4343NP; EXPD 3643N1; EXPD 3643N; EXPD 3643U1; EXPD 3643NU; EXPD 3643NP	
Indications for Use (Describe) The Digital X-ray detector, EXPD-N Series, is designed for use in digital imaging solutions for general radiographic diagnosis of human anatomy. This device is intended for use in all general diagnostic procedures, replacing film or screen-based radiographic systems for both adult and paediatric patients. It is not intended for use in mammography.	
Type of Use (Select one or both, as applicable) ☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	
CONTINUE ON A SEPARATE PAGE IF NEEDED.	
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