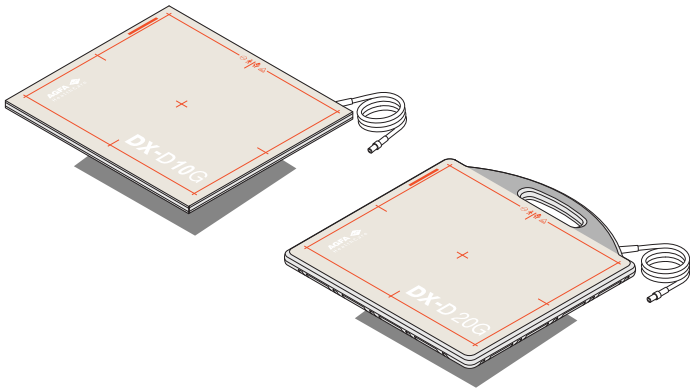
DX-D 10C, DX-D 10G, DX-D 20C, DX-D 20G

User Manual



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Contents

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Varex Imaging Corporation, 1678 So. Pioneer Rd, Salt Lake City, UT 84104, USA

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Introduction to this Manual

Topics:

Scope of this Manual

This manual contains information for safe and effective operation of the DX-D 10G, DX-D 10C, DX-D 20G and DX-D 20C portable DR Detector, further referred to as the DR Detector.

About the safety notices in this document

The following samples show how warnings, cautions, instructions and notes appear in this document. The text explains their intended use.

DANGER:
A danger safety notice indicates a hazardous situation of direct, immediate danger for a potential serious injury to a user, engineer, patient or any other person.

WARNING:
A warning safety notice indicates a hazardous situation which can lead to a potential serious injury to a user, engineer, patient or any other person.

CAUTION:
A caution safety notice indicates a hazardous situation which can lead to a potential minor injury to a user, engineer, patient or any other person.

An instruction is a direction which, if it is not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.

A prohibition is a direction which, if it is not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.

Note: *Notes provide advice and highlight unusual points. A note is not intended as an instruction.*

Disclaimer

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Every care has been taken to ensure the accuracy of the information in this document. However, Agfa assumes no responsibility or liability for errors, inaccuracies or omissions that may appear in this document. To improve reliability, function or design Agfa reserves the right to change the product without further notice. This manual is provided without warranty of any kind, implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

Note: *In the United States, Federal law restricts this device to sale by or on the order of a physician.*

Introduction

Topics:

Intended Use

The DR Detector is a wired radiographic digital X-ray imaging device commonly referred to as flat panel detector. It is designed for general radiography applications. The DR Detector will be used in a radiological environment by qualified staff to capture and route static X-ray images.

The DR Detector is not intended for mammography applications.

Intended User

This manual has been written for trained users of Agfa products and trained diagnostic X–Ray clinical personnel who have received proper training.

Users are those persons who actually handle the equipment and those who have authority over the equipment.

Before attempting to work with this equipment, the user must read, understand, note and strictly observe all warnings, cautions and safety markings on the equipment.

Configuration

The DR Detector is a component that can be integrated in an X-ray system, connected to an NX workstation and to the X-ray generator through the X-Ray Device Integration (XRDI) software.

Operation Controls

The DR Detector is controlled via the NX workstation and via the DR Detector control unit.

The DR Detector control unit has a switch to power the DR Detector on and off.

The DR Detector control unit has indicator lights that reflect the status of the DR Detector.

Note: Depending on the integration, the DR Detector control unit may not be available to the user.

System Documentation

The documentation consists of a User manual (this document) and related documentation:

- NX User Manual (4420).
- NX Key User Manual (4421).
- NX Getting Started Sheets (4424).
- NX Problem Solving Sheets (4425).
- DX-D DR Detector Calibration Key User Manual (0134).
- DX-D System User Documentation (if applicable).

The documentation shall be kept with the system for easy reference.

The most extensive configuration is described within this manual, including the maximum number of options and accessories. Not every function, option or accessory described may have been purchased or licensed on a particular piece of equipment.

Technical documentation is available in the product service documentation which is available from your local support organization.

The most recent version of this document is available on *http://www.agfahealthcare.com/global/en/library/index.jsp*

Product Complaints

Any health care professional (for example a customer or a user) who has any complaints or has experienced any dissatisfaction with the quality, durability, reliability, safety, effectiveness, or performance of this product must notify Agfa.

If the device malfunctions and may have caused or contributed to a serious injury, Agfa must be notified immediately by telephone, fax or written correspondence to the following address:

Agfa Service Support - local support addresses and phone numbers are listed on www.agfa.com

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Compliance

- The product has been designed in accordance with the MEDDEV Guidelines relating to the application of Medical Devices and have been tested as part of the conformity assessment procedures required by 93/42/EEC Medical Device Directive (European Council Directive 93/42/EEC on Medical Devices).
- IEC 60601-1 2nd edition
- IEC 60601-1-2 2nd edition

Connectivity

The DR Detector is connected to the control unit. The DR Detector's control unit is connected to the mains power, to the NX workstation and to the X-ray generator.

Messages

Under certain conditions the system shows a dialog box in the middle of the screen containing a message, or a message is displayed in a fixed message area in the user interface. This message informs the user that either a problem has occurred or that a requested action cannot be performed. The user must read these messages carefully. It will provide information on what to do from then on. This will be either performing an action to resolve the problem or to contact the service organization. Details on the contents of messages can be found in the service documentation which is available to service personnel.

Labels

Symbol	Explanation
I	On (power: connection to the mains)
O	Off (power: disconnection from the mains)
	Tube side
	Direct current
	Alternating current
	Protective earth (ground)
	This mark indicates that this is a Type B Equipment
	Handle with care
	Maximum patient weight
	Patient orientation mark

Cleaning and Disinfecting

All appropriate policies and procedures should be followed to avoid contamination of the staff, patients and equipment. All existing universal precautions should be extended to avoid potential contaminations and to avoid patients coming into (close) contact with the device. The user is responsible for selecting a disinfection procedure.

Topics:

Cleaning

To clean the exterior of the equipment:

1. Stop the system

WARNING:
When the equipment is going to be cleaned, be sure to turn OFF the power of each device, and to unplug the power cord from the AC outlet. Never use anhydrous or high solvency alcohols, benzine, thinner or any other flammable cleaning agent. Otherwise, it may result in fire or electric shock.

2. Wipe the exterior of the system with a cloth slightly moistened with a neutral detergent. Some approved disinfectants can be used for cleaning as well.

CAUTION:
Make sure no liquid gets in the device.

CAUTION:
Clean the equipment with only a little moisture. Do not spray disinfectants or detergents directly on the equipment. Do not pour liquid directly on the equipment.

CAUTION:

Do not use solvents such as anhydrous or high solvency alcohols, thinner or benzine. Do not use any corrosive, dissolving or abrasive cleaning or polishing detergents.

Doing so may damage the surface of the equipment. Using unsuitable cleaning agents or methods can damage the property when surface becomes dull and brittle (e.g. by using alcohol-containing agents).

Note: Do not open the equipment for cleaning. No components inside the device require cleaning by the user.

3. Start up the system.

Use of protective plastic bag

WARNING:
Liquids ingressing the DR Detector may cause malfunction and contamination.

If there is a chance that the detector comes in contact with liquids (bodily fluids, disinfectants,...), the DR Detector must be wrapped in a protective plastic bag while performing the examination.

It is considered good clinical practice to use a single-use protective bag in all cases where contact of the device or contaminants is expected, to avoid contamination of others.

Make sure that the plastic bag is not wrinkled to avoid the creases showing in the image.

Disinfecting

To disinfect the device, use only disinfectants and disinfection methods that are approved by Agfa and that correspond to the national regulation and guidelines as well as explosion protection. If you plan to use other disinfectants, approval of Agfa is needed before use, as most disinfectants can damage the device. UV disinfection is also not allowed.

Perform the procedure following the instructions for use, the disposal instructions and the safety instructions of the selected disinfectants and tools and of the hospital.

Approved disinfectants

Refer to the Agfa website for specifications on the disinfectants that have been found compatible with the cover material of the device and can be used on the outer surface of the device.

http://www.agfahealthcare.com/global/en/library/overview.jsp?ID=41651138

Maintenance

Always consult the Agfa Service documentation and an Agfa trained and authorized Service engineer for complete maintenance schedules.

Maintenance of the DR Detector

The DR Detector requires regular calibration. Calibration instructions are described in the DR Detector Calibration Key User Manual (doc 0134).

Environmental protection

Figure 1: WEEE symbol

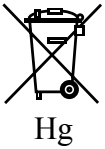


Figure 2: Battery symbol

WEEE end user notice

The directive on Waste Electrical and Electronic Equipment (WEEE) aims to prevent the generation of electric and electronic waste and to promote the reuse, recycling and other forms of recovery. It therefore requires the collection of WEEE, recovery and reuse or recycling.

Due to the implementation into national law, specific requirements can be different within the European Member States. The WEEE symbol on the products, and/or accompanying documents means that used electrical and electronic products should not be treated as, or mixed with general household waste. For more detailed information about take-back and recycling of this product please contact your local service organization and/or dealer. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources.

Battery notice

The battery symbol on the products, and/or accompanying documents means that the used batteries should not be treated as, or mixed with general household waste. The battery symbol on batteries or its packaging may be used in combination with a chemical symbol. In cases where a chemical symbol is available it indicates the presence of respective chemical substances. If your equipment or replaced spare parts contain batteries or accumulators please dispose of them separately according to local regulations.

For battery replacements please contact your local sales organization.

Safety Directions

WARNING:
Safety is only guaranteed when an Agfa certified field service engineer has installed the product.

WARNING:
Improper changes, additions, maintenance or repair of the equipment or the software can lead to personal injury, electrical shock and damage to the equipment. Safety is only guaranteed when changes, additions, maintenance or repairs are carried out by an Agfa certified field service engineer. A non certified engineer performing a modification or service intervention on a medical device, acts on his own responsibility and makes the warranty void.

WARNING:
Ionizing radiation can lead to radiation injuries if handled incorrectly. When radiation is applied, the required protective measures must be complied with.

WARNING:
System unavailability due to hardware or software failure. If the product is used in critical clinical workflows, a backup system has to be foreseen.

WARNING:
For children and for patients with sensitive skin, direct contact between the skin and the surface of the detector should be avoided.

WARNING:
The operator and end-user must take precautions to protect themselves against dangerous X-ray exposure when using the DR Detector in the X-ray beam path of an X-ray source.

WARNING:
The DR Detector is not intended to be used as a primary barrier to X-rays. The user is responsible for ensuring the safety of the operator, bystanders, and the subjects being radiographed.

CAUTION:
All Agfa medical products must be used by trained and qualified personnel.

CAUTION:
Strictly observe all warnings, cautions, notes and safety markings within this document and on the product.

CAUTION:
Position the DR Detector control unit so that it is possible to disconnect the mains power connection if required.

CAUTION:
When rolling or pulling the cable of the DR Detector, take care not to wind the cable too tightly. The bending radius of the cable should not be smaller than 10 cm

CAUTION:
Observe great care when handling the DR Detector. The detector is shock sensitive and drops should be avoided. Warranty will be void if it is obvious that operating conditions are not met.

If the DR Detector has been dropped:

1. *Visually check the DR Detector for deformations.*
2. *Perform a calibration of the DR Detector. For instructions, refer to the DX-D DR Detector Calibration Key User Manual (document 0134).*
3. *Perform a flat field exposure and check the image for visible artifacts. Typical flat field exposure settings are 75 kV, 10 µGy, large focus and using 1.5 mm Cu filter without grid.*

CAUTION:
Damaged grid. Reduced image quality. Please handle the grids with special care.

CAUTION:
If weight is put on the DR Detector, it must lie on a flat surface.

CAUTION:
The load on the DR Detector must not exceed 100 kg.

CAUTION:
Excessive ambient temperature may impact the performance and cause permanent damage to the device. If ambient temperature and humidity is outside the range of 10 - 35 °C and 30 - 75% RH, do not operate the system or use air conditioning.

Warranty will be void if it is obvious that operating conditions are not met.

Limitations for patient contact

This device is not intended to supply heat to a patient. However, during normal use, surfaces will become heated due to power dissipation.

Figure 3: Caution heated surface

The temperature increases based on the frequency of image acquisitions taken. Patient contact surfaces will not exceed 8 degrees C above ambient temperature under normal use conditions, i.e. no more than 150 image acquisitions per hour. If the temperature of the detector exceeds 41 degrees C, it is shut down automatically.

The operator should monitor and evaluate how much of the patient's body area is in contact with these surfaces and for how long. Exposure beyond limitations may result in, but not limited to, the surface layer of the skin to become reddened, welted, and swollen with pain.

Limitations for patient contact are:

- Patient contact time between 1 and 10 minutes.
- No more than 10% of a patient's body area should be in direct contact with the surfaces.
- No more than 10% of patient's head area should be in direct contact with the surfaces.
- For children and for patients with sensitive skin, direct contact between the skin and the surface of the detector should be avoided.
- No additional pressure should be applied when the patient is in contact with surfaces.
- Number of image acquisitions should not exceed 150 per hour.

Basic Workflow

Topics:

Starting the DR Detector

Note: Depending on the integration, the DR Detector may be started automatically together with the X-ray system.

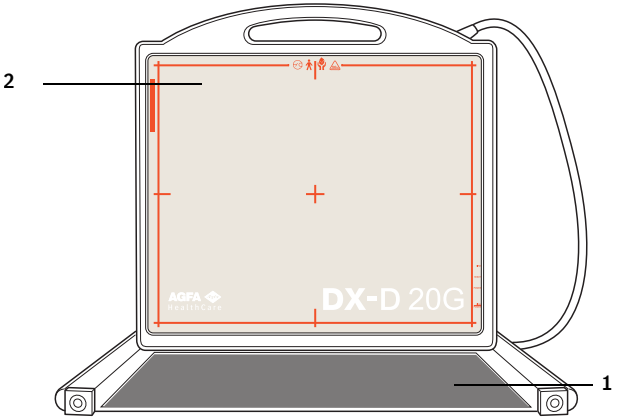
To start the DR Detector:

1. Check if the DR Detector cable is connected to the control unit.
2. Check if the power cable of the DR Detector control unit is connected to the mains power.
3. Power on the DR Detector using the power switch at the back of the control unit.

Attaching the Grid

To attach the grid to the DR Detector

1. Lay down the grid on a flat surface.
2. Lay the DR Detector in the grid, bottom edge first, with the tube side facing down.
3. Attach the grid to the DR Detector.



1. Grid
2. DR Detector

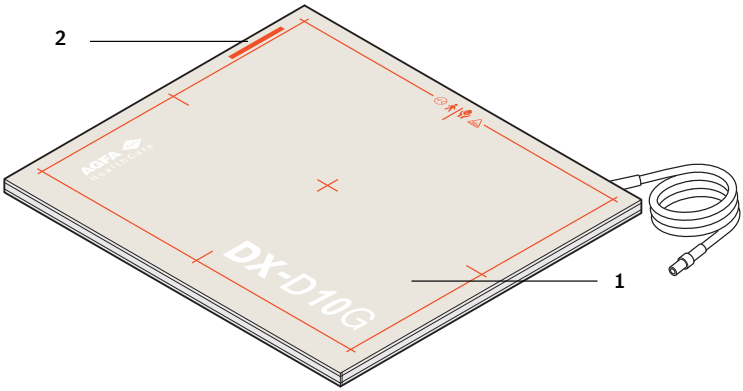
Figure 4: Example: attaching the grid to the DX-D 20G or DX-D 20C

WARNING:
Use only the grid that is supplied as option to the DR Detector.

Positioning the DR Detector

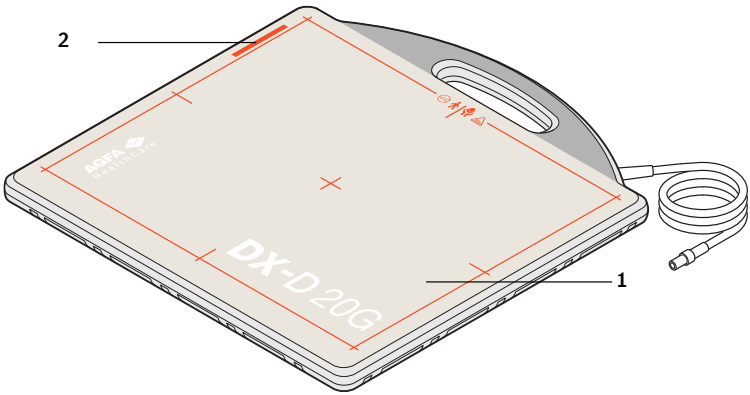
When performing an exposure, keep in mind the following detector orientation aids:

- tube side
- patient orientation marker



1. Tube side of the detector
2. Location red patient orientation marker

Figure 5: Detector orientation aids - DX-D 10G

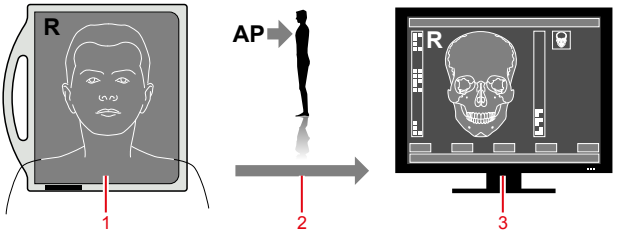


1. Tube side of the detector
2. Location red patient orientation marker

Figure 6: Detector orientation aids - DX-D 20G

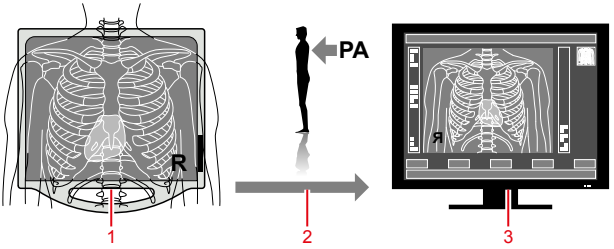
The detector orientation and the patient orientation are exposure settings on the NX workstation. The detector orientation is displayed on the NX workstation as cassette orientation.

Below some examples to illustrate the importance of the detector orientation marker.



1. Detector orientation (Portrait)
2. Patient orientation (AP)
3. Result on monitor

Figure 7: Skull AP portrait



1. Detector orientation (Landscape)
2. Patient orientation (PA)
3. Result on monitor

Figure 8: Chest PA landscape

Table 1: Table with bucky

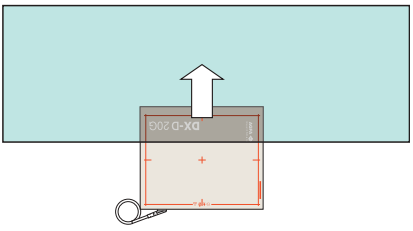
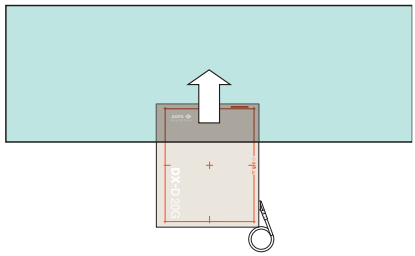
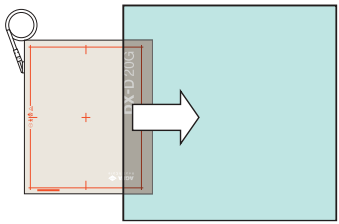
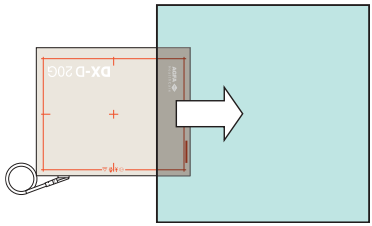
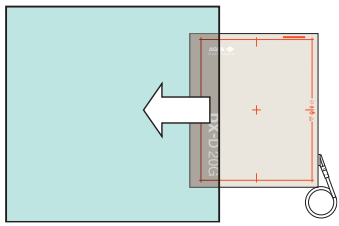
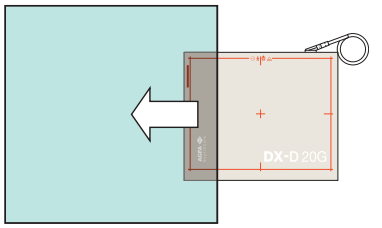
Table with bucky, portrait	

Table with bucky, landscape	

Note: NX is configured for a specific patient orientation, either head left (default) or head right.

Table 2: Wallstand bucky

Wallstand with left loading bucky, portrait	
Wallstand with left loading bucky, landscape	
Wallstand with right loading bucky, portrait	

Wallstand with right loading bucky, landscape	

Executing the Exposure

Note: The DR Detector is activated only when an exposure is executed. The preparation cycle of the exposure is limited by a time-out. If an exposure is not initiated within seven seconds after the “Prep” command., the exposure is disabled, to avoid overheating of the DR Detector.

To execute the exposure after a time-out has occured, release the exposure button and after at least one second, initiate the exposure again.

Stopping the DR Detector

Note: Depending on the integration, the DR Detector may be stopped automatically together with the X-ray system.

To stop the DR Detector:

Power off the DR Detector using the power switch at the back of the control unit.

Problem solving

Topics:

DR Detector must be recalibrated

Details	A message is displayed on NX indicating that the DR panel must be recalibrated.
Cause	DR Detector must be recalibrated at regular intervals.
Brief Solution	Perform calibration of the DR Detector. For details, refer to the DX-D DR Detector Calibration Key User Manual (0134).

DR Detector Problem

Details	An error message is displayed on NX indicating a problem related to the DR detector.
Cause	-
Brief Solution	**1.** Power off the DR detector. **2.** Stop the NX workstation. **3.** Power on the DR detector. **4.** Start the NX workstation.

Technical Data

DR Detector Technical Data

Manufacturer	
Manufacturer DR Detector	Varex Imaging Corporation, 1678 So. Pioneer Rd, Salt Lake City, UT 84104, USA
Original manufacturer model name	
DX-D 10G / DX-D 20G	4336R (part number 7358)
DX-D 10C / DX-D 20C	4336R (part number 20665)
Electrical connection	
Operating voltage	100-240 V(AC)
Mains fuse protection	6A
Mains frequency	50/60 Hz
Power consumption	
Maximum power consumption during operation	65 W
Environmental conditions (during storage and transport)	
Temperature (ambient)	between -20 °C and +70 °C
Humidity (non condensing)	between 10 % and 90 %
Atmospheric pressure	between 500 hPa and 1100 hPa
Environmental conditions (during normal operation)	
Room temperature	between +10 °C and +35 °C
Humidity (non condensing)	between 30 % and 75 %

Atmospheric pressure	between 700 hPa and 1100 hPa
Warming-up time	
30 minutes	
Throughput	
Maximum number of image acquisitions	150 acquisitions per hour
End of Life	
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	100000 RAD
Pixel Matrix	
Pixel size	139 μm (H,V)
Pixel matrix	2560 (H) x 3072 (V)
Active pixel matrix	2540 (H) x 3072(V)
Fill factor	> 90%
Detector type	Amorphous Silicon
Active area size	35,6 cm (H) x 42,7 cm (V)
Dimensions	(approx. values in cm) - width x length x height
DX-D 10G, DX-D 10C	46.0 cm x 38.4 cm x 1.5 cm
DX-D 20G, DX-D 20C	49.2 cm x 47.5 cm x 2.3 cm
Weight	
DX-D 10G, DX-D 10C	approximately 3.9 kg (8.6 lb)
DX-D 20G, DX-D 20C	approximately 4.9 kg (11 lb)
Shock tolerance	
Shock tolerance	20 G
Drop tolerance	60 cm

Maximum load	
Maximum total load	100 kg

	DX-D 10G DX-D 20G	DX-D 10C DX-D 20C
Maximum Linear Dose using RQA5	75 μGy	50 μGy
Minimum Modulation Transfer Function (MTF) using RQA5		
1 lp/mm	0.45	0.50
2 lp/mm	0.15	0.25
3 lp/mm	0.05	0.12
Minimum Detective Quantum Efficiency (DQE) using RQA5 at 2.1 μGy dose level with reduced cycle time		
0.5 lp/mm	0.23	0.45
1 lp/mm	0.18	0.35
2 lp/mm	0.08	0.20
3 lp/mm	0.02	0.10
Minimum Signal Noise Ratio for 1mR		
SNR	115:1	120:1
Conversion screen	GOS	CsI