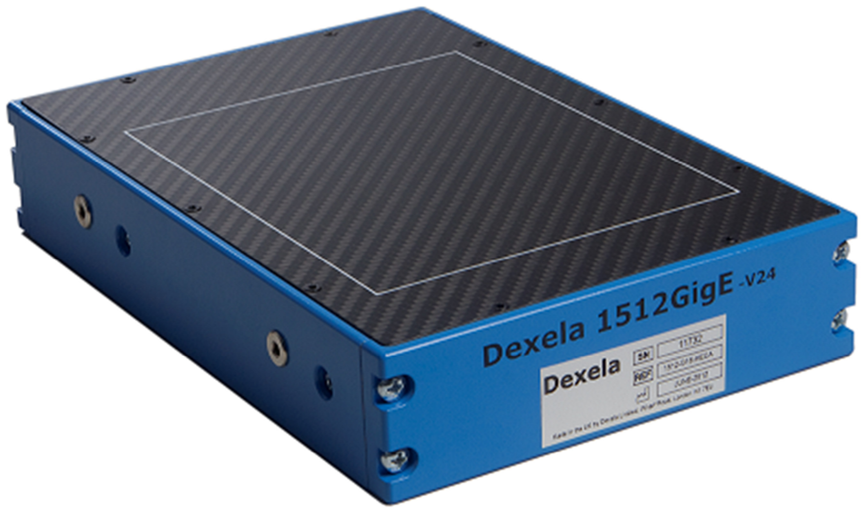
Instruction for Use - Dexela CMOS X-ray detectors 24V



1512 CL/GigE
1207 CL/GigE

Before using the Dexela flat panel X-ray detector please be sure to read these instructions thoroughly, along with any other documentation provided for software and/or other system components.

Keep these instructions easily accessible for future reference.

Dexela CMOS detector series – 24V

Instruction for Use

PerkinElmer®
For the Better

Table of Contents

List of Figures

List of Tables

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1 Indications for use

1.1 Disclaimer

Unless otherwise specified, Dexela flat panel X-ray detectors are components intended to be integrated into products by X-ray system manufacturers.

System manufacturers are responsible for qualifying and validating their products for their intended uses, and for meeting all applicable regulatory requirements.

***WARNING**: THE DETECTOR AND ASSOCIATED COMPONENTS SHOULD ONLY BE INSTALLED AND USED BY PERSONS WITH APPROPRIATE TRAINING AND EXPERIENCE AND IN ACCORDANCE WITH THE INSTRUCTIONS GIVEN IN THIS MANUAL.*

*DEXELA LIMITED **MUST BE** CONSULTED FOR GUIDANCE WHEN INSTALLING DETECTORS IN A MEDICAL APPLICATION.*

1.2 Contraindications:

THE DETECTOR AND ASSOCIATED PARTS SHOULD NOT BE USED FOR:

- obtaining images which are used as direct input to radiation treatment planning systems.
- imaging as part of a feedback system for servo-based surgical interventions
- imaging as part of a feedback system for image-guided radiotherapy
- direct control of x-ray beam duration or intensity, without other appropriate controls and interlocks.
- the detector is not intended for use as a dosimeter for measuring or controlling patient dose.

***WARNING**: INTERPRETATION OF DIAGNOSTIC IMAGES IS A SKILLED PROCEDURE AND SHOULD TAKE INTO ACCOUNT THE PERFORMANCE LIMITATIONS AND IMAGE ARTIFACTS ASSOCIATED WITH DIGITAL X-RAY DETECTOR PANELS.*

1.3 Limitations on use

Limitations on installation and usage are specified below, which are in accordance with the identified hazards and device classification:

- When installed in a host system, the detector **must be** installed within a housing or cover which prevents direct contact with the patient or operator

- The detector **must not** be used as part of a control or feedback system where the X-ray image can directly control surgical processes, therapeutic radiation or other processes which could potentially harm the patient as a consequence of a fault in the detector.

- The detector is able to signal to another part of the system (*e.g.* X-ray generator or computer) that an image is ready to be exposed via a BNC port on the back panel of the detector. The signal from the port **must not** be the sole activation means for X-ray delivery, and **must be** used in association with other control inputs: for example, a hand switch, safety interlocks, and a means of controlling the beam duration.

The detector **must not** be used in a situation where it controls the X-ray dose delivered to the patient.

1.3.1 Interference with other devices

***WARNING**: ANY TESTING ON DEXELA FLAT PANEL X-RAY DETECTORS DEMONSTRATES COMPLIANCE OF THE DETECTORS WHEN USED IN ISOLATION. THE TESTING UNDERTAKEN DOES NOT PROVE COMPLIANCE ONCE THE DETECTOR IS INTEGRATED INTO A SYSTEM.*

WHERE SYSTEM COMPLIANCE IS REQUIRED (IE: TO IEC 60601-1-2:2007) TESTING WITH THE DETECTOR INTEGRATED IN THE SYSTEM MUST BE COMPLETED AND IS THE RESPONSIBILITY OF THE SYSTEM MANUFACTURER

2 Storage and use

Dexela flat panel X-ray detectors may be used or stored within the following conditions:

Operation and storage (without packaging)	
Operating temperature	+10C to +40C
Storage temperature	-10C to +50C
Humidity	10% to 90% non condensing
Atmospheric pressure	690 hPa – 1080 hPa
Transportation (packaged)	
Temperature range	-10C to +50C
Humidity	0 to 98% non condensing
Atmospheric pressure	690 hPa – 1080 hPa

Table 1: Storage and use conditions.

WARNING: *WHEN DEXELA FLAT PANEL X-RAY DETECTORS ARE TRANSFERRED FROM EXTREME TEMPERATURE OR HUMIDITY CONDITIONS, ALLOW AT LEAST ONE HOUR OF STABILISATION TO NORMAL OPERATING TEMPERATURE OR HUMIDITY PRIOR TO USE.*

2.1 List of symbols and abbreviations

2.1.1 Symbols

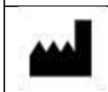
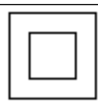
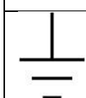
Symbol	Description
	Equipment should not be disposed of in the normal waste stream
	Manufacturer
REF	Catalogue number
SN	Serial Number
	Class II double insulation
	Ground

Table 2: List of symbols.

2.1.2 Abbreviations

GigE	GigE vision interface
CL	Camera Link
PSU	Power supply unit
Fps	Frames per second
ADC	Analog-to-digital
DAQ	Data acquisition
T_R	Readout time
T_{EXP}	Exposure time

Table 3: List of abbreviations.

2.1.3 Other sources of information

Software instructions

The SCAP application is fully described in **SCAP User Instructions**

Software developers' resources

The **Native API (**Application Programing Interface) provides hardware interfacing functions as well as image processing utilities for developers integrating the Dexela detectors into custom applications.

3 Note on model variants

These instructions for use describe the complete range of Dexela flat-panel X-ray detectors. Where the information is specific to one model, the following symbols are used:

Applies to Dexela 1512

Applies to Dexela 1207

When GigE or CL connectors have to be specified, the 'CL' or 'GigE' indication will be added to the above symbols.

NOTE: the Mammography version of detectors are discussed in document DX-001554

4 Description

An X-ray detector panel converts an incident X-ray signal into a digitised image. It is used in association with other components, including: an X-ray tube and generator, a support structure and housing, a DC power supply and a host computer, which together form a complete medical imaging system.

Dexela flat panel X-ray detectors are supplied to X-ray equipment manufacturing companies as a component of a larger system (see Figure 1) They may be supplied with optional power supply units and cables on request.

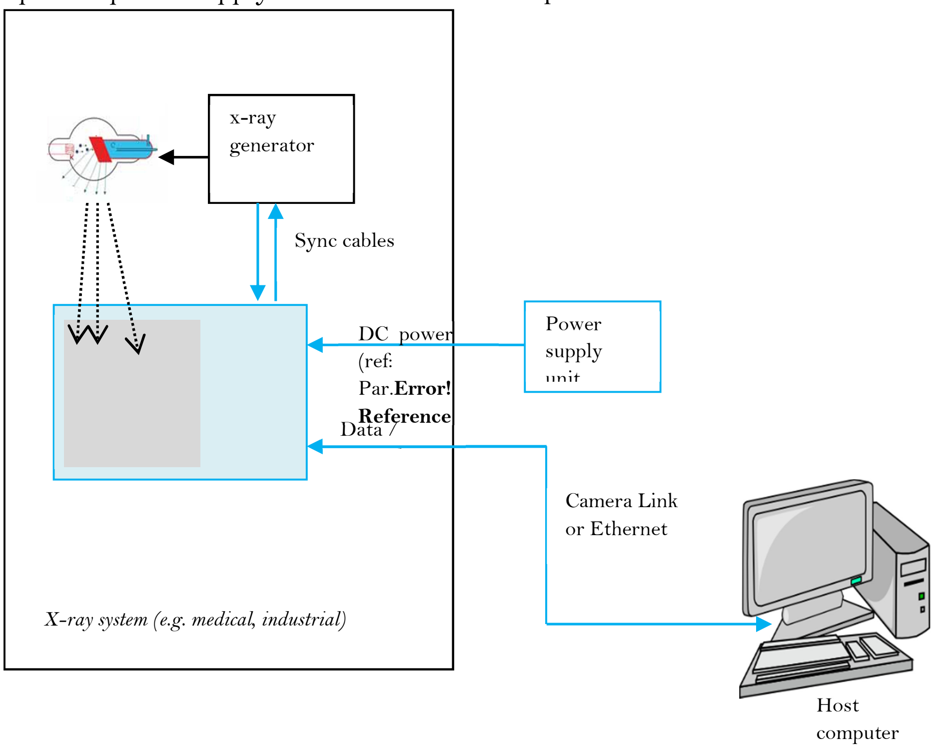


Figure 1: The detector used in a typical X-ray imaging system

The detector does not function as a stand-alone system and requires an X-ray generator to produce images. BNC ports on the detector allow direct connection to an X-ray generator for synchronising the X-ray exposure with the image read-out.

The detector is designed to be used with a PC which can process, display and store images.

Dexela is able to supply a range of development software, including drivers and source code, which will enable developers to interface the detector with a range of third-party or proprietary imaging software.

SCAP, a Windows Demo application (also supplied by Dexela), allows the user to acquire, process, store and display images. It may be used as a stand-alone application for test or research purposes only, or as a utility for the testing and evaluation of the detector before designing into an end system.

***WARNING**: SOFTWARE PROVIDED BY DEXELA IS INTENDED TO BE USED FOR INTEGRATION, TEST OR RESEARCH PURPOSES ONLY. IT **MUST NOT** BE USED IN A MEDICAL APPLICATION.*

4.1 Functions

The detector performs the following functions within a typical X-ray system:

- conversion of incident X-rays into a digitised image
- transmission of a raw image to a remote host computer as a serial data stream
- control of basic image adjustments: offset and linearity

4.2 Embedded features

Dexela flat panel X-ray detectors are designed with several functions (detailed below) built in to provide the user with flexibility when undertaking X-ray imaging tasks. The detector is designed so that the balance between image resolution, sensitivity and readout speed can be adjusted continuously by the PC software.

- selectable binning: 1x1, 2x2, 4x4
- two pixel sensitivity settings, optimized for high sensitivity (real time imaging) and high dynamic range (static imaging)
- continuous dosimetry mode (signal integration with non-destructive readout)
- non-linear pixel response correction

4.3 Detector design

The Dexela detectors 24V are based on the same basic CMOS sensor design and use a 75µm square pixel pitch, with 5 different sizing and tiling configurations.

Model	Sensor unit	Tiling
1512	1536 columns x 1944 rows	Single
1207	1536 columns x 864 rows	Single

The CMOS sensor operates with variable binning and switchable pixel capacitance (‘well size’) and is optically coupled to a scintillator plate, which converts X-ray photons in the energy range 30 – 225keV into light photons depending on the selected detector version. The coupling is via a Fibre Optic Faceplate (FOP) which is used to shield a significant amount of X-rays from the sensor, that could otherwise generate image noise and cause gradual damage.

The scintillator plate, composed either of Caesium Iodide or Gadolinium OxySulphide, is pressed in contact with the FOP but not glued. The unit is housed in an aluminium enclosure, with a carbon fibre composite panel providing an X-ray 'window' in the image field of view.

A circuit board (ADC) connected to each CMOS sensor digitises the analogue signals, and provides the timing signals needed to drive them. A communications board (DAQ) converts the data stream from the ADC(s) to the required format, either Camera Link or Gigabit Ethernet.

4.4 Power supply

All Dexela flat panel X-ray detectors require a DC power supply, details of the power requirements can be found in section **Error! Reference source not found.**.

When a detector is to be used in a medical application, it is recommended that an IEC 60601-1 compliant PSU is used.

Integration of the power supply into a final system is the responsibility of the system manufacturer along with any associated qualification and validation.

WARNING: *POWER SUPPLY MUST IN ALL CASES PROVIDE CLASS II DOUBLE ISOLATION.*
FOR MEDICAL APPLICATIONS IT IS RECOMMENDED THAT AN IEC 60601-1 COMPLIANT PSU IS USED.SEE SECTION 8 FOR INDIVIDUAL DETECTOR POWER REQUIREMENTS.

4.5 Data interface

Communication between the Dexela flat panel X-ray detectors and the host computer is via Camera Link or Gigabit Ethernet (according to the product variant).

In the case of **Camera Link**; Dexela software drivers are written for the EPIX range of frame grabbers, but other software may be used if the appropriate Dexela drivers are integrated.

In the case of **Ethernet**; the interface is using GigE Vision standard, and requires a 1000BaseT network interface card (NIC).

WARNING*: IT EQUIPMENT ATTACHED TO DEXELA FLAT PANEL X-RAY DETECTORS WITHIN THE MANUFACTURERS SYSTEM SHOULD BE IEC60950 APPROVED AS A MINIMUM.*

4.6 Servicing

The service and repair of the detector unit should only be carried out by a qualified Dexela service agent. Under no circumstances should you attempt to disassemble the detector(s). **There are no user-serviceable parts inside**.

Opening or removing parts from the detector(s) may result in exposure to dangerous voltages or other risks. Incorrect reassembly of the detector(s) may result in electric shock to the user when subsequently operated.

In case of fault please immediately contact Dexela using details below to arrange for the detectors return

Dexela Limited, a PerkinElmer company
Wenlock Business Centre
50 – 52 Wharf Rd
London N1 7EU

+44 20 7148 3107
www.dexela.com

***WARNING**: ABSOLUTLEY NO MODIFICATION OF DEXELA X-RAY PANEL DETECTORS IS PERMITTED*

5 Installation

WARNING: DEXELA FLAT PANEL X- RAY DETECTORS ARE DESIGNED TO BE USED AS COMPONENTS OF A MEDICAL SYSTEM AND ARE SUPPLIED FOR INTEGRATION ONLY

This installation procedure applies to the development kit supplied by Dexela, which includes the following items:

- Detector unit
- Software installation disk (CD-ROM)
- User documentation

OPTIONAL – PROVIDED ON REQUEST

- Mains power supply unit (PSU)
- DC cable
- Camera Link cable
- Mains cable
- EPIX frame grabber board

In addition, a PC is required to control the detector and receive images. The minimum requirements are shown in Table 4.

Processor:	Intel i5
Memory:	2GB
Disk space:	10GB
Spare slot:	PCIe x1
NIC	Intel PRO 1000/PT board
Operating system:	Win7 (32 Bit / 64 Bit), Win XP Pro (32 Bit / 64 Bit)

Table 4: PC requirement.

Using the following steps, a Dexela flat panel X-ray detector CL may be installed and connected, and a first raw X-ray image captured.

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*DEXELA LIMITED **MUST BE** CONSULTED FOR GUIDANCE WHEN INSTALLING DETECTORS IN A MEDICAL APPLICATION.*

WARNING: DEXELA FLAT PANEL X-RAY DETECTOR'S CONTAINS FRAGILE OPTICAL AND ELECTRONIC PARTS. EXCESSIVE SHOCK AND VIBRATION DURING HANDLING AND INSTALLATION MAY CAUSE DAMAGE

Error! Reference source not found. below shows the connections found on Dexela flat panel X-ray detector units.

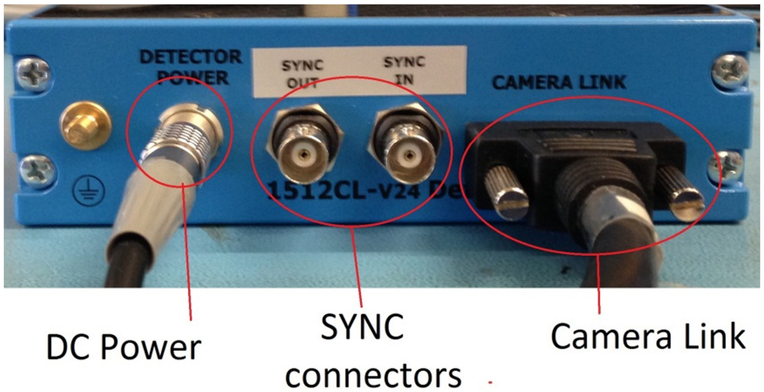


Figure 2: Panel connections.

1512
1207

The 1207 and 1512 have one Camera Link Base 80MHz/GigE connection and two SYNC connections (one SYNC IN and one SYNC OUT) on the back panel.

The instructions below at all times assume that the PSU and accessories supplied are those available as an option from Dexela.

If you are using alternative accessories/PSU please follow the manufacturers instructions for your specific make and model at each stage below.

1. (This point 1 is for CL detectors only) Install the EPIX EB1 framegrabber board in a spare PCI Express slot in the host PC. Insert the EPIX CD-ROM and follow the on-screen instructions to install the device drivers.

5.1 Power Up Sequence

2. Install the detector unit and PSU in a suitable place (below) in the X-ray device. Install in positions where there is adequate air circulation and the fan aperture is not covered. Warm air is expelled to the room and does not circulate back into the unit. The detector unit will become warm during continuous operation - this is normal.

3. Connect the DC power cable between the PSU and the detector. Connect the PSU mains cord to a suitable outlet (110 – 250V AC, 50 – 60Hz), but do not switch it on yet.

WARNING, IF USING DEXELA SUPPLIED PSU *:DO NOT REMOVE THE COVER OF THE PSU, THE PSU CONTAINS PARTS WITH EXPOSED HIGH VOLTAGE TERMINALS. DO NOT COVER THE PSU, OR OBSTRUCT THE AIR VENTS ON THE BACK OR THE UNDERSIDE OF THE UNIT, THIS MAY LEAD TO OVERHEATING. THE PSU MUST NOT BE MODIFIED.*

THIS WARNING IS RELEVANT TO MOST PSU, HOWEVER PLEASE REFER TO MANUFACTURERS INSTRUCTIONS FOR YOUR SPECIFIC MAKE AND MODEL

4. Complete the Dexela software installation (see **SCAP User Instructions**).

5. **Camera Link:** Connect the Camera Link cable between the detector and the EPIX board in the PC. **GigE:** Connect the GigE cable between the detector and the Intel PRO 1000/PT board in the PC.

6. Switch on the PC. Then switch on the PSU, and check that it is operational as per manufacturers instructions.).

SCAP should be launched after the detector has been powered-up. This ensures that configuration and calibration data is downloaded to the detector's internal memory when SCAP starts.

(For the next stages, refer also to SCAP User Instructions.)

7. Start Windows and then launch SCAP.

8. Click on **Test Mode** then click **Snap**. A quad grey-scale pattern should appear, as in Figure 3. This indicates that the detector unit is communicating correctly with the PC.

1512 The 1512 displays a single grey scale:

1207 The 1207 displays a single grey scale:

Figure 3: Test patterns for each Dexela CMOS detector.

9. Ensure that the **Auto-contrast** check box is ticked. Click on **Normal** then click **Snap** again. A blank image similar to Figure 4 should be visible. This is a high-

contrast image which shows different sections of the panel as grey vertical rectangles.

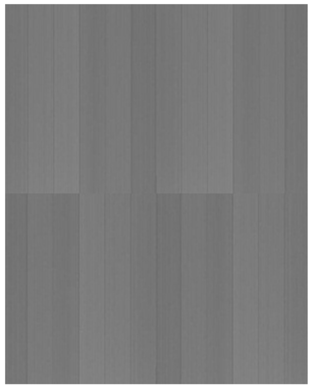


Figure 4: Dark image.

10. Position the detector unit under the X-ray source with a small metal object (*e.g.* pen) placed diagonally on the detector surface, within the white square, near the centre.

    Set the generator to 30kV, 5mA with an SID of 60cm.

11. Set the detector exposure time to 100ms using the **Configuration** menu. With the X-ray beam on, capture a single image by clicking **Snap**.

    An uncorrected image should be visible, similar to Figure 5. Some vertical lines may be visible on the image - this is normal.

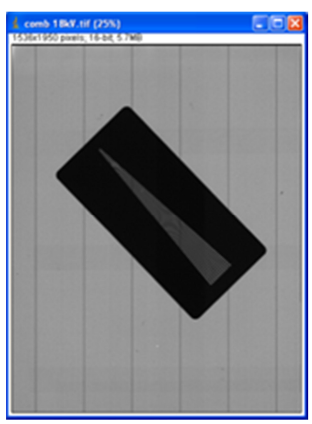


Figure 5: Raw X-ray image.

12. The image may appear too dark or too bright. Move the cursor over the displayed image, and note the pixel **Value** (displayed to the right of the image).

    - If it is above 16,000, the image is overexposed, and the X-ray mA should be reduced.

- If it is below 2,000, the image is underexposed, and the tube mA should be increased. If the mA cannot be increased the exposure time can be increased instead.

13. When the right combination of mA and exposure time has been determined, which gives an open-field pixel value of around 12,000 – 14,000, **note this combination**. It will be used for the next stage.

6 Producing a correct X-ray image

In the following steps, the detector is calibrated so that fully corrected images can be displayed, this allows SCAP to provide automatic correction of X-ray images immediately after they are captured.

Two calibration images must be obtained first.

<u>**Dark current calibration image:**</u>

14. Under the **Configuration menu**, select **Darks**. Enter the **Exposure time** noted in step 13 above, and set **Quantity** to 10.
15. With the X-ray beam off, under the **Tools** menu, select **Collect Dark**. A set of 10 dark images will now be captured, averaged and stored for background subtraction.

<u>**Flood field calibration image:**</u>

16. Under the **Configuration** menu, select **Floods**. Enter the **Exposure time** noted in step 13 above, and set **Quantity** to 10.
17. Remove any object from the field of view.
18. Turn the X-ray beam on, with the same mA setting as in step 13 above.
19. Under the **Tools** menu, select **Collect Flood**.
    An average of 10 images will now be calculated and stored as a flood image for flat-field gain correction.

Ensure that the X-rays do not terminate before the images have been captured.

<u>**Producing a corrected X-ray image**</u>

20. Tick all 7 check boxes to the right of the image display: **Auto-contrast, Auto-descramble, Linearisation, Dark correction, Gain correction, Defect correction** and **Suppress zingers**.
21. Place a phantom or test object on the detector surface or anywhere within the field of view.
22. Using the mA and exposure time as in step 13 above, start X-rays and click **Snap**.

The result should be a clean-looking image with no obvious background shading, striping, artefacts or lines, as shown below (Figure 6):

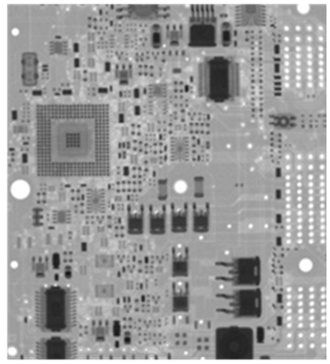
 

Figure 6: Sample images.

6.1 Power-down sequence

- Close Scap following the manufaturer instruction.
- If the PSU has an independant on/off switch ensure this is in the off position
- Unplug th PSU from the detector.
- Switch off the PSU at the wall

7 Calibration and image quality guidelines

SCAP provides image processing stages which compensate for imperfections of the X-ray system and detector:

- Beam flatness and heel effect
- Scintillator grain
- Visible structures in the protective cover and fibre optic plate
- Pixel voltage offset and gain variation
- Pixel non-linear response
- Defective lines and pixels

The automatic image processing functions provided in SCAP are:

Dark correction: The dark image is an average of several dark frames. Dark correction removes static offsets between pixels, so that a dark image is presented as an approximately uniform grey value. The dark correction is sensitive to changes in integration time and temperature. The averaged dark image should be acquired shortly before or after the acquisition of the image to be corrected and with the same integration time.

Linearity correction: Detector pixels have a slightly non-linear response to light, which corresponds to about 2% deviation from the linear response at mid-scale. To ensure that the flood calibration works accurately over the dynamic range of the detector, both the raw image and the flood image are corrected for non-linearity.

Gain correction: The flood calibration image can be inspected under the **View** menu, and is a floating-point multiplication matrix normalised to 1. The calibration image is created from the average of several flood images, which are also dark corrected. Multiplying by the flood calibration image has the effect of reversing the variation in X-ray conversion gain between pixels or regions, so that a corrected open field X-ray image will have near-constant grey levels across the field of view.

Defect correction: Some defective lines and pixels may be present on the sensor. These are defined as having a response which deviates by a specified amount from the ideal. A defect map is created during factory testing of the detector and is installed in the SCAP program folder. On the final processed image, pixels tagged on this defect map are replaced by interpolated values in order to improve the image presentation.

Guidelines for achieving optimum image quality:

- When creating flood and dark calibration images, and when doing frame-averaging operations, set **Quantity** to as large a value as possible, within practical time constraints. When **Quantity** is large, the images will take longer to acquire, but the noise is reduced. As a general rule, the noise reduces by a factor of $\sqrt{2}$ (≈ 1.4) when **Quantity** is doubled.

- When changing the exposure time significantly, create a new dark calibration image with the same exposure time as the image that is to be acquired. A frequently renewing of the dark images is recommended to improve the image quality.

- Update the flood calibration image if changing the technique (kV-mA), source-imager distance (SID), or beam incident angle significantly. For clinical or industrial applications, several sets of dark and flood images may be stored and called up according to the X-ray generator settings.

- Aim for an open-field signal level of around 11,000 – 12,000 for flood calibration images, this will give good dynamic range without saturation.

- The Dexela falt panel X-ray detector is designed for maximum sensitivity to X-rays, enabling optimal image quality for a low dose exposure. In some situations, a higher dose is used to improve the image quality, but this may cause the pixels to saturate. The solution is to use a shorter detector exposure time, and to capture more than one frame by using the **Collect Average** function (in the **Tools** menu) instead of **Single Exp**. This will generate an average of several frames, rather than a single saturated frame. The averaging process reduces the image noise. The number of averaged frames can be set in the **Configuration** menu.

- Two settings of pixel gain can be programmed via the **Configuration** menu:
  - **High Full Well** mode should be used where high saturation dose is important, and this would apply to most static X-ray imaging applications.
  - **Low Full Well** mode increases the pixel gain by a factor of approximately 3.5 in comparison to High Full Well mode, and this mode

should be used where high sensitivity (low dose per frame) is required. This mode is suitable for fluoroscopy and tomosynthesis.

8 External DC power supply requirements

WARNING: POWER SUPPLY MUST IN ALL CASES PROVIDE CLASS II DOUBLE ISOLATION. FOR MEDICAL APPLICATIONS IT IS RECOMMENDED THAT AN IEC 60601-1 COMPLIANT PSU IS USED.

THE DETECTOR MUST BE CONNECTED TO A POWER SUPPLY UNIT WHICH HAS BEEN SUPPLIED BY DEXELA, OR A POWER SUPPLY UNIT WHICH IS CONSTRUCTED IN ACCORDANCE WITH THE REQUIREMENTS IN THIS SECTION. FAILURE TO USE THE CORRECT POWER SUPPLY MAY CAUSE THE DETECTOR TO OVERHEAT.

A means of isolating the Power Supply must be provided (by the system manufacturer) which enables the disconnection of both Live and Neutral poles simultaneously.

As low DC voltages are used to supply the detector, the voltage drop in the DC cable is a significant factor.

POWER SUPPLY VOLTAGES MUST BE HIGH ENOUGH TO OVERCOME A VOLTAGE DROP CAUSED BY CONDUCTOR RESISTANCE IN THE CABLES - ESPECIALLY WHERE THINNER CONDUCTORS ARE USED IN FLEXIBLE CABLES FOR ROTATING OR MOVING PLATFORMS.

The power supply must be designed together with the cable, to ensure that the correct voltages are delivered at the connector taking into account voltage drops. During normal operation of the detector the current is constant and does not vary significantly.

The detector can be powered using a DC power supply and cables, in accordance with the requirements in **Error! Reference source not found.**. The supply voltage requirements for the detector, as measured at the detector power input connector.

Note: When installed within a medical system, it is recommended that the external DC supply is compliant with safety and EMC standards appropriate to Medical Devices: IEC 60601-1 and IEC 60601-1-2.Use mating connector type FGG.1B.303.CLAD52Z.

8.1 24V detectors voltage requirements

The supply voltage requirements for the 24V detectors, as measured at the detector power input connector, are shown in Table 5 and Table 6.

Pin	***Voltage (relative to pin 3)***		***1512 CL***		***1512 GigE***	
	Min	***Max***	***Current (active)***	***Current (standby)***	***Current (active)***	***Current (standby)***
1	*+23V*	*+25V*	*0.39A*	*0.03A*	*0.50A*	*0.10A*
2	*Earth*		*0A*	*0A*	*0A*	*0A*
3	*0V*		*0.39A return*	*0.03A return*	*0.50A return*	*0.10A return*
Ripple and noise, all outputs			*1% peak-peak measured over 0-20 MHz.*			

Table 5: Power supply requirement for 1512 CL/GigE 24V detectors.

Pin	***Voltage (relative to pin 3)***		***1207 CL***		***1207 GigE***	
	Min	***Max***	***Current (active)***	***Current (standby)***	***Current (active)***	***Current (standby)***
1	*+23V*	*+25V*	*0.46A*	*0.03A*	*0.58A*	*0.10A*
2	*Earth*		*0A*	*0A*	*0A*	*0A*
3	*0V*		*0.46A return*	*0.03A return*	*0.58A return*	*0.10A return*
Ripple and noise, all outputs			*1% peak-peak measured over 0-20 MHz.*			

Table 6: Power supply requirement for 1207 CL/GigE 24V detectors.

Note: Use mating connector: FGG.1B.303.CLAD52Z or equivalent

9 Permanent mounting in an X-ray installation

Mounting

The detector unit should be mounted in a frame or chassis using the mounting points. When used in medical systems, the unit must be mounted under a cover which prevents direct contact with a patient or operator.

WARNING*: THE TOP PLATE OF THE DETECTOR IS CONSTRUCTED FROM A FLAMMABLE MATERIAL. ENSURE THAT THE COVER IS MADE OF A MATERIAL WHICH HAS THE APPROPRIATE FLAMMABILITY RATINGS FOR MEDICAL EQUIPMENT. .*

Protective earthing

A protective earth terminal is located on the back panel, this is used for grounding the unit to minimise any mains leakage current which may be generated if the primary earth connection on the PSU or PC is disconnected.

It should be connected to the nearest available grounding point on the earthed equipment chassis or frame.

The earthing connection should be able to withstand a continuous current of 40A - this can be achieved by installing an earth cable of **at least** 18AWG conductor thickness which should be terminated with crimped ring terminals and secured with screws of 4mm diameter or larger.

Cooling

The detector units generate heat during continuous use. This heat must dissipate to the surrounding air, or the equipment in which the detector is installed.

10 Connection to a X-ray generator

Dexela flat panel X-ray detectors can be used in a stand-alone mode, where the detector image acquisition is triggered by software (via the data interface) while X-rays are controlled separately.

In an integrated X-ray machine, the image acquisition is controlled automatically by the X-ray generator in response to the operator starting the beam. This requires communication between the generator and the detector.

The detector is supplied with BNC connectors which provide a direct connection to an X-ray generator to allow for timing synchronisation.

The following synchronisation modes are supported:

1. Software Trigger Mode - the trigger is sent by the software (SCap or API function) using Camera Link
2. Edge Trigger Mode – the detector can trigger the X-ray generator when the sensor is ready to be exposed
3. Duration Trigger Mode - the detector image capture is timed by a hardware signal from the generator.

***WARNING**: THE DETECTOR IS NOT DESIGNED TO CONTROL THE DURATION OF AN X-RAY EXPOSURE. OUTPUT SIGNALS FROM THE DETECTOR SHOULD BE USED TO INDICATE THAT THE DETECTOR IS READY TO ACQUIRE AN IMAGE, OR WHEN THE X-RAY EXPOSURE SHOULD START, OR OTHER EVENTS WHICH DO NOT INFLUENCE OR EXTEND THE X-RAY EXPOSURE TIME.*

11 Mode of operation

11.1 Trigger Modes

Triggering the detector is the attempt to synchronise the detector to other devices e.g. X-ray sources having their specific schemes of radiating X-ray pulses.

11.1.1 Software Trigger Mode

In Software Trigger Mode, the trigger is sent by the software (SCap or API function). In SCap, this mode is selected using **Configuration – External Trigger Mode – Software Trigger** and following the sequence below (see **Error! Reference source not found.**).

1. Before an exposure, the detector is continuously reading dark frames from the sensor to avoid the accumulation of dark current in the pixel.
2. The user sends the trigger signal from the software to the detector (T_{WSI}).
3. When the detector receives the trigger, it finishes the current readout (T_R).
4. After T_R the detector enters the exposure period (T_{EXP}) and the **Sync Out 2** level changes**.**
5. At the same time, the detector starts accumulating the image on the sensor.
6. After the detector's programmed exposure time T_{EXP}, the frame is read out and transmitted to the PC.
7. The detector resumes the dark frame readout cycles until the next software trigger.

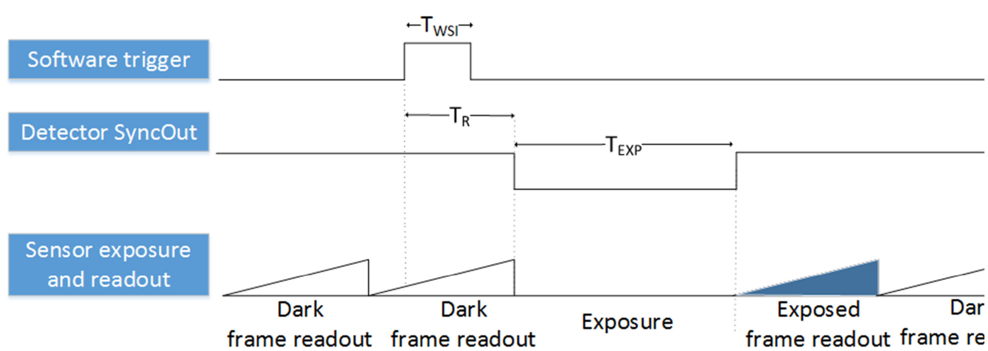


Figure 7: Software trigger schematic. Values are shown in Table 7.

<table>
<tr><th>Symbol</th><th>Description</th><th>Value</th><th>Notes</th></tr>
<tr><td>T_{WSI}</td><td>Sync In pulse duration</td><td>Minimum = 200 µs</td><td>Shorter pulses (e.g. 1.5 µs) will work in software trigger, but cannot be guaranteed for an external trigger.</td></tr>
<tr><td>T_{R}</td><td>Detector reset time</td><td>Minimum = 200 µs Maximum = See Frame readout times Table 4 to check the maximum reset time for each detector.</td><td>T_{R} is measured from the rising edge of the trigger to the falling edge of Sync Out 2.</td></tr>
<tr><td>T_{EXP}</td><td>Sync Out 2 pulse width</td><td>Minimum: 200 µs</td><td>T_{EXP} is the frame exposure time (not including the readout- see
<table>
<tr><th></th><th></th><th colspan="2">1207[ms]</th><th colspan="2">1512[ms]</th></tr>
<tr><th></th><th></th><th>CL</th><th>GigE</th><th>CL</th><th>GigE</th></tr>
<tr><td rowspan="3">Binning</td><td>1x1</td><td>16.9</td><td>16.9</td><td>37.7</td><td>37.7</td></tr>
<tr><td>2x2</td><td>6.4</td><td>6.4</td><td>14.2</td><td>14.2</td></tr>
<tr><td>4x4</td><td>5.2</td><td>5.2</td><td>11.5</td><td>11.6</td></tr>
</table>
Table 8). Due to latency in the optocoupler, a pulse sent to the output has an additional 100 µs duration.</td></tr>
</table>

Table 7: Trigger timing specification.

In some generators, there may be a delay between asserting **Sync Out 2** and the actual start of X-ray emissions. This must be compensated by increasing the programmed exposure time T_{EXP}, so that frame readout does not start before the X-ray emission has finished.

Sync Out 1 indicates when the detector is ready to accept a **Sync In** pulse. It is low (inactive) during a system reset cycle, during power-down (sleep) mode, and during a frame exposure cycle.

		1207[ms]		**1512[ms]**	
		CL	**GigE**	**CL**	**GigE**
Binning	**1x1**	16.9	16.9	37.7	37.7
	2x2	6.4	6.4	14.2	14.2
	4x4	5.2	5.2	11.5	11.6

Table 8: Minimum frame readout times.

		1207		1512	
		CL	GigE	CL	GigE
Binning	1x1	59.1	31.6	26	14
	2x2	155.7	126.6	70	56
	4x4	190.7	191	86	86

Table 9: Minimum frame per second.

Note: the GigE frame per second is slower than the one expected from the readout time (1000ms/readout time), this is due to a longer time needed for the data to be delivered.

Example – Common case:

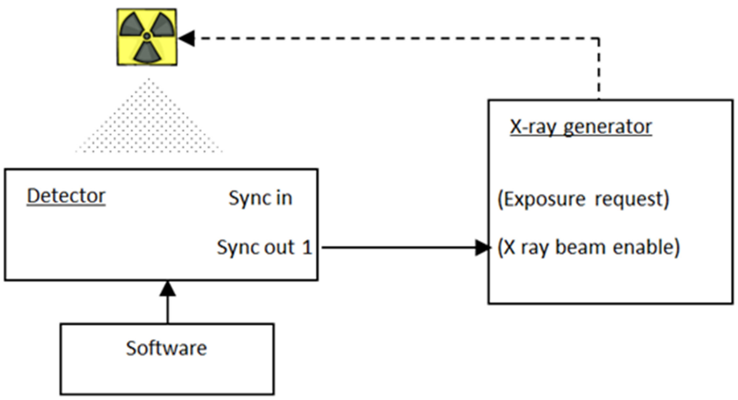


Figure 8: Sync connection for software trigger mode.

In this case, the generator is informed that the detector is ready to receive the X-ray emission when the Sync Out 2 level changes (step 4 of the Sequence explanation).

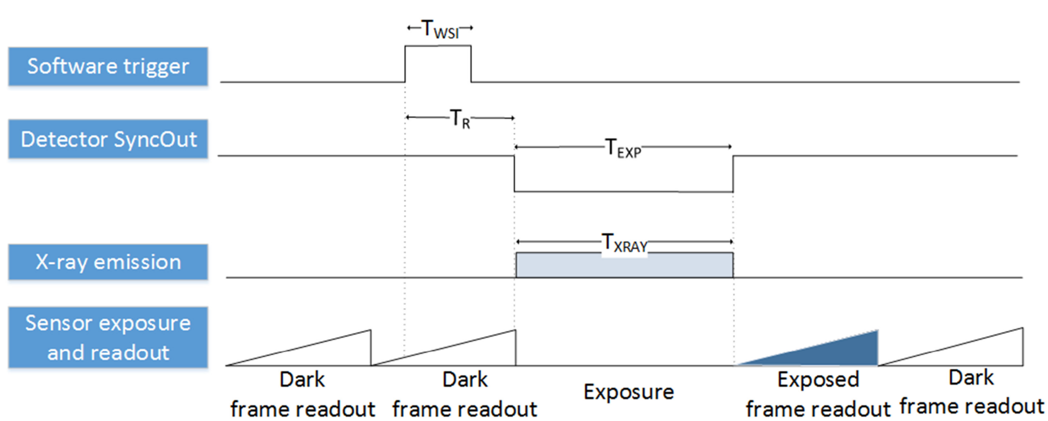


Figure 9: Software trigger mode timing.

11.1.2 External Edge Trigger Mode

In External Edge Trigger Mode, the detector is triggered by an external signal, i.e. Generator. The detector exposure time is pre-defined by the software (SCap or API). In SCap, this mode is selected using **Configuration – External Trigger Mode – External Edge Trigger** and the following steps below:

1. Before an exposure, the detector is continuously reading dark frames from the sensor.
2. The user activates an external signal that drives **Sync In** high and the Sync Out 1 level changes.
3. When the detector receives the trigger, it finishes the current readout (T_R).
4. After T_R the detector enters the exposure period (T_{EXP}) and the **Sync Out 2** level changes**.**
5. At the same time, the detector starts accumulating the image on the sensor.
6. After the detector's programmed exposure time T_{EXP}, the frame is read out and transmitted to the PC.
7. The detector resumes the dark frame readout cycles until the next **Sync In** pulse.

It behaves essentially like the Software Trigger Mode but the trigger signal comes from an external source and it's directed into the SyncIn port. The timing specifications are shown in Table 7.

Sync Out 1 indicates when the detector is ready to accept a **Sync In** pulse. It is low (inactive) during a system reset cycle, during power-down (sleep) mode, and during a frame exposure cycle.

Example – Common Case:

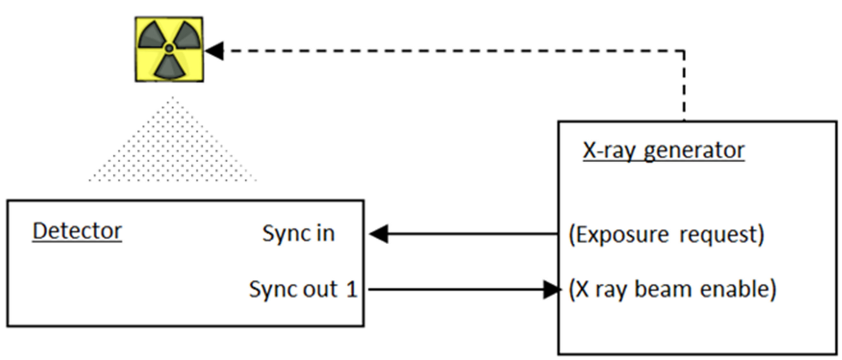


Figure 10: Sync connection for edge trigger mode.

In this case, the **Sync In** pulse is driven high when the user activates the 'Expose' button for the X-ray equipment. With the change of the **Sync Out 2** level the generator is informed that the detector is ready to receive the X-ray emission and starts to irradiate (**Error! Reference source not found.**).

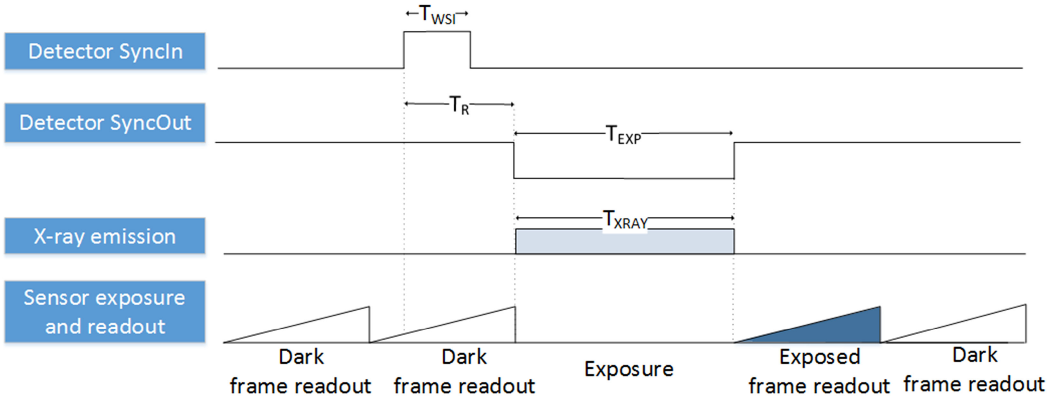


Figure 11: Edge trigger mode timing.

11.1.3 External duration trigger mode

In Duration Trigger Mode, the detector is triggered by an external signal, i.e. Generator. The detector exposure time is defined by the width of the pulse. In SCap, this mode is selected using **Configuration – External Trigger Mode – External Duration Trigger** and the following step:

1. Before exposure, the detector is continuously reading dark frames from the sensor.
2. The external trigger signal drives Sync In high when ready to begin image acquisition.
3. The current dark frame-read out finishes (Tr) and then the exposure period begins.
4. The detector continues exposing until the external trigger signal drives Sync In low.
5. The detector reads out the image and transmits it to the PC.
6. While Sync In is low, Sync Out continues to pulse at interval T_I.

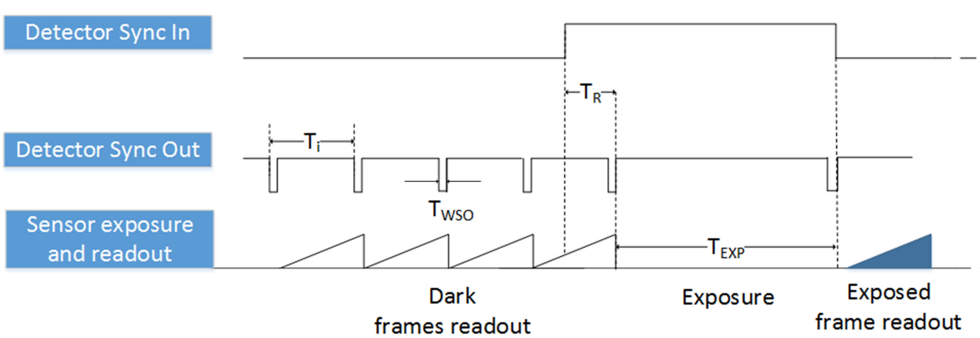


Figure 12: Duration trigger mode timing.

Symbol	Decription	Value	Notes
T_I	**Sync Out 1** idle pulse interval	1 frame readout time	
T_{WSO}	**Sync Out 1** pulse width	2ms	
T_D	X-ray emission delay after **Sync Out 1**		Depends on the start-up characteristics of generator and tube
T_{RD}	frame start delay after **Sync Out 1**	Minimum = 3ms Maximum : See Frame readout times Table 4 to check the maximum reset time for each detector.	Programmed setting in detector. Ensure that $T_{RD} < T_D$
T_{FD}	Frame readout delay after **Sync Out 1** inactive	Minimum = 0ms Maximum = 1.6s	Programmed setting in detector. Ensures that frame readout starts after the end of X-ray emission.

Table 10: Duration trigger mode specification.

Example - Trigger signal driven by the generator:

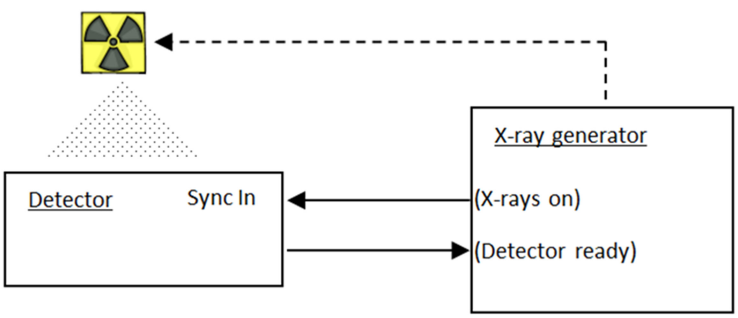


Figure 13: Sync connection for duration trigger mode.

The sequence is as follows:

1. Before exposure, the detector is continuously reading dark frames from the sensor.
2. The user activates the 'Expose' button for the X-ray equipment.
3. When the generator is ready to produce X-rays, it waits for the next **Sync Out** pulse from the detector.
4. At the active (falling) edge of **Sync Out**, the generator drives **Sync In** high, while starting the X-ray emission.

5. Immediately after the X-ray emission, the generator drives **Sync In** low. The detector reads out the image and transmits it to the PC.

6. While **Sync In** is low, **Sync Out** continues to pulse at interval T_I.

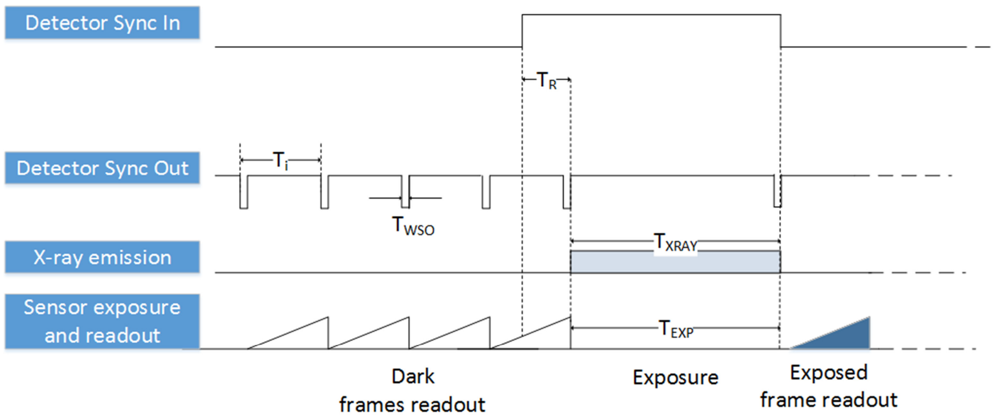


Figure 14: Duration trigger mode timing.

11.1.4 Signal levels

The signal levels on the trigger connectors are as follows. The core is the *positive* terminal, and the shell is the *negative* terminal.

Condition	Min	Max	Notes
Sync In = high	3 V	15 V	Input is opto-isolated from detector ground
Sync In = low	0 V	1.5 V	
Sync Out 1 & 2 = high	3.0	3.3 V	output impedance = 1.2kΩ
Sync Out 1 & 2 = low	0V	0.4 V	

Table 11: Signal levels.

11.2 Exposure modes

11.2.1 Expose and read

In Expose and Read Mode, the detector receives a trigger and grabs an image. This mode is compatible with the three trigger modes. In SCap, this mode is selected using **Configuration – Exposure Mode – Normal**.

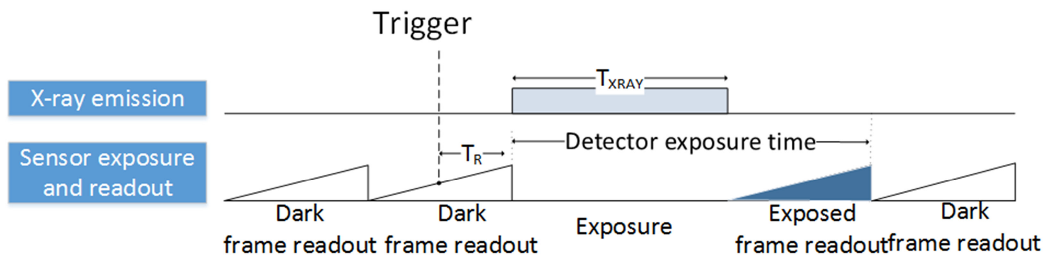


Figure 15: Expose and read mode.

11.2.2 Sequence exposure

In Sequence Exposure Mode, the detector receives a trigger and grabs certain number of images. The numbers of images and the detector exposure time (Exposure + Exposed frame readout in the image) have to be previously set by software (SCap or API). In SCap, this mode is selected using **Configuration – Exposure Mode – Sequence Exposure**.

Example: set of 3 images.

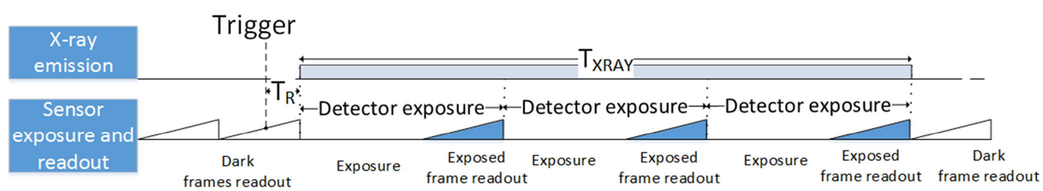


Figure 16: Sequence exposure mode.

11.2.3 Frame-rate exposure

In Frame-rate Exposure Mode, the detector receives a trigger and grabs certain number of images leaving a gap between exposures. The numbers of images, the detector exposure time and the gap between exposures have to be previously set by software (SCap or API). This mode only works with Software Trigger Mode and External Edge Trigger Mode. In SCap, this mode is selected using **Configuration – Exposure Mode – Frame rate mode**.

Example: set of 2 images.

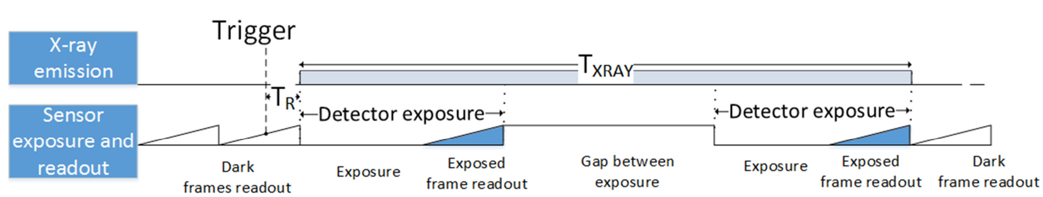


Figure 17: Frame rate mode timing.

11.2.4 Pre-programmed exposure

In Pre-programmed Exposure Mode, the detector receives a trigger and grabs certain number of images that can have different detector exposure times. The number of images (with a maximum of 4) and the detector exposure time of each image have to be previously set by software (SCap or API). This mode only works with Software Trigger Mode and External Edge Trigger Mode. In SCap, this mode is selected using **Configuration – Exposure Mode – Pre-programmed Exposure**.

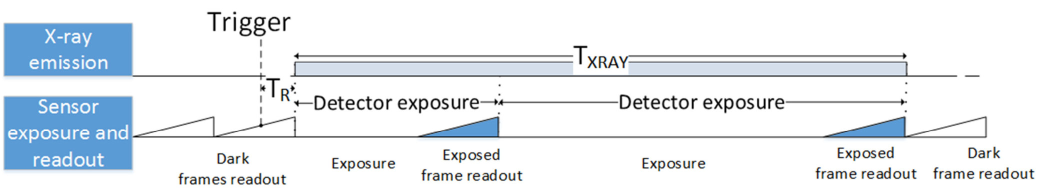


Figure 18: Pre-programmed exposure mode, 2 images example.

11.2.5 Pre-shot mode

This mode is like the Pre-programmed one, but just 2 images can be programmed. This is used mostly for High Dynamic Range imaging.

12 Installation in a medical system: data connection to the PC

X-ray systems which comply with international safety standards for medical devices (IEC 60601-1) are designed with high levels of protection against mains failure. This includes low leakage current from the enclosure under normal and single-fault (e.g. mains earth disconnection) conditions.
Some types of PC, for example medical panel PCs which have an insulating touch keypad, are rated to medical standards (IEC 60601-1), and a direct connection can be made without modification of the mains supply or data connection. However, when the detector is connected directly to a PC which is not designed to medical equipment standards, the data connection (*e.g.* Camera Link) could cause excessive leakage current to flow into the detector. This would compromise the electrical safety of the medical system, to a point where it no longer complies with medical equipment safety standards.
Some guidelines are as follows.

1. In a medical system incorporating the detector as a component:
    a. The leakage current from the detector enclosure to other parts of the medical system should be less than 0.1mA rms, when power is applied.
    b. When the PC mains earth terminal is disconnected, and the PC and detector are powered on, the leakage current from the detector enclosure to other parts of the medical system should be less than 0.5mA rms.

A combination of protection techniques can be used to reduce the leakage current to below these levels:

- Additional protective earthing of the detector to the medical system (for both CL and GigE, Figure 19).
- Common protective earth between the detector and the PC, in additional to protective earthing to the medical system (for both CL and GigE, Figure 20).
- Electrical isolation of the Camera Link signals (Figure 21).
- Isolation of the PC from its electrical environment (for both CL and GigE, Figure 22).

2. Where the PC is located outside the X-ray room, an additional protective earth cable must connect the PC and the detector, if they do not share a common mains earth. Alternatively, an isolator should be used in the Camera Link connection. A Camera Link to fibre converter would provide isolation.
3. Where the PC is located within the patient environment, within 1.5m of the patient, a common earth wire should be used to provide additional protection. Alternatively, or in addition, mains isolation can be used.

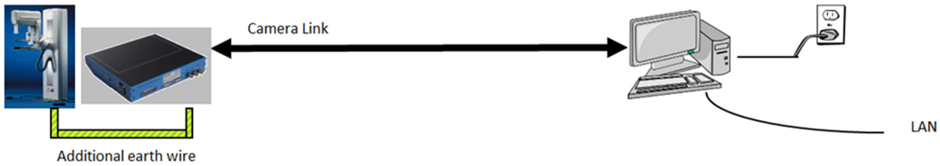


Figure 19: Detector earthed to medical equipment. The same applied to GigE.

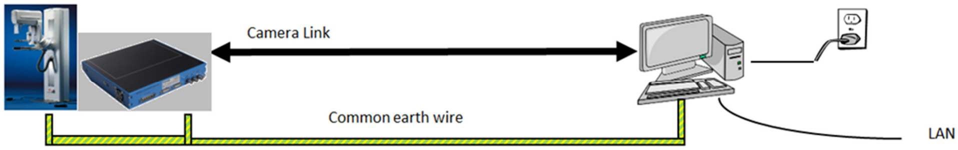


Figure 20: Protective earth between detector and PC. The same applied to GigE.

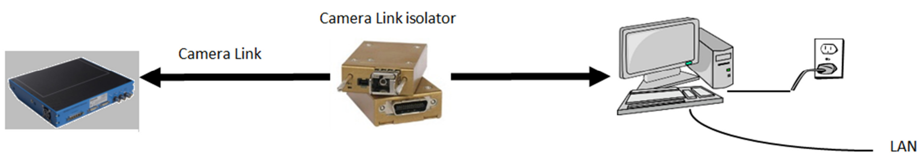


Figure 21: Camera Link isolation.

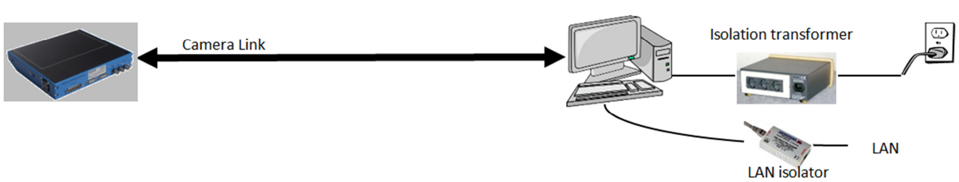


Figure 22: Mains and LAN isolation. The same applied to GigE.

13 Disposal – Waste Electrical and Electronic Equipment (WEEE)

If the detector is activated by high energy x-rays, gamma rays, or neutrons follow the local radiation protection regulation.

Contact your supplier or distributor, and check the terms of conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

A label with a crossed-out wheeled bin symbol and a rectangular bar indicates that the product is covered by the Waste Electrical and Electronic Equipment (WEEE) Directive and is not to be disposed of as unsorted municipal waste. Any products marked with this symbol must be collected separately, according to the regulatory guidelines in your area.

The objectives of this program are to preserve, protect, and improve the quality of the environment, protect human health, and utilize natural resources prudently and rationally. Specific treatment of WEEE is indispensable in order to avoid the dispersion of pollutants into the recycled material or waste stream. Such treatment is the most effective means of protecting the customer's environment.

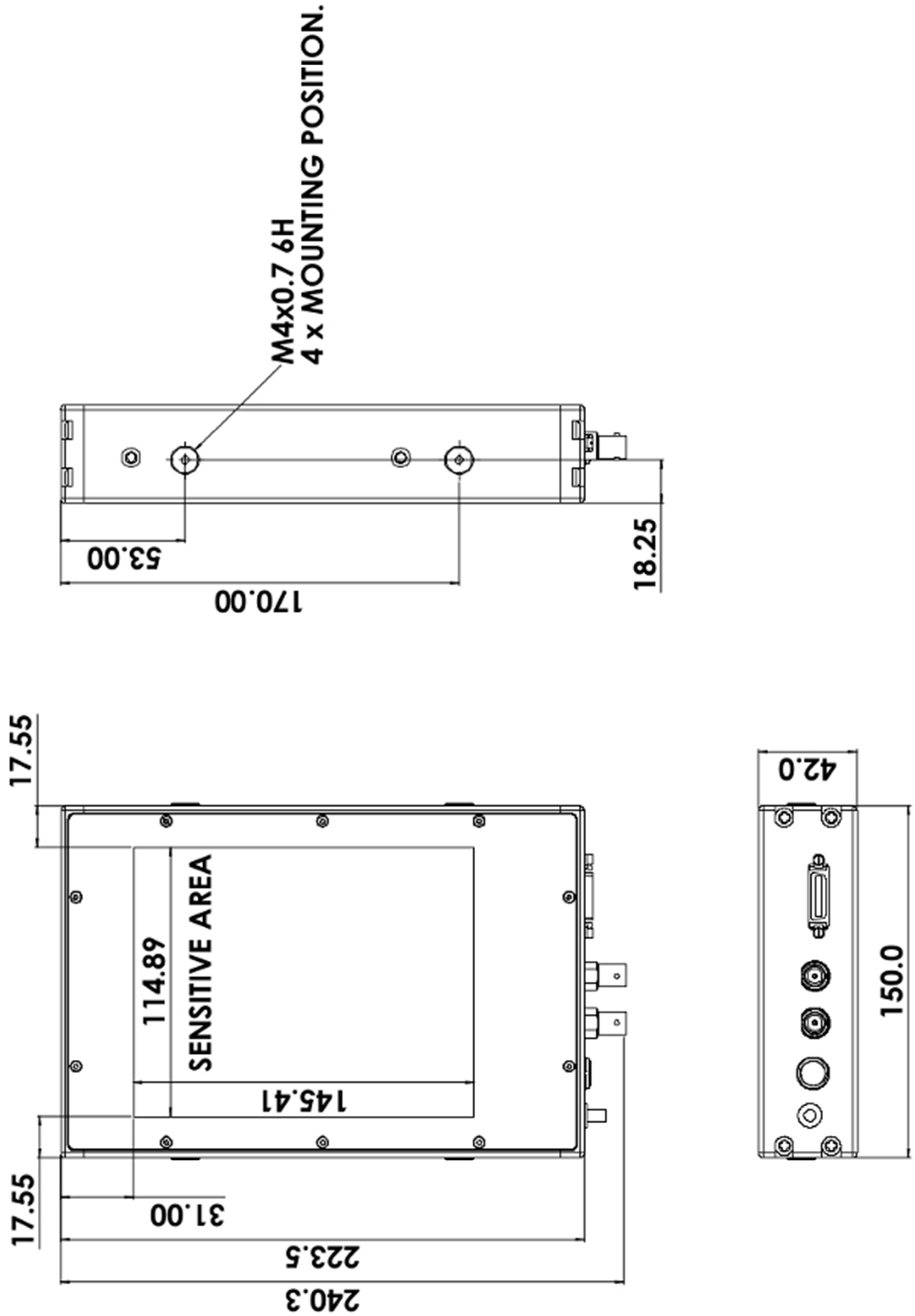
Requirements for waste collection, reuse, recycling, and recovery programs vary by regulatory authority at your location. Contact your local responsible body (for example, your hospital, clinic, establishment, or site manager) or authorized representative for information regarding applicable disposal regulations. Contact PerkinElmer at the Web site listed below for information specific to PerkinElmer products.

Web Address:
http://www.perkinelmer.com/pages/010/onesource/environmental-health-and-safety/environmental-directives-compliance.xhtml

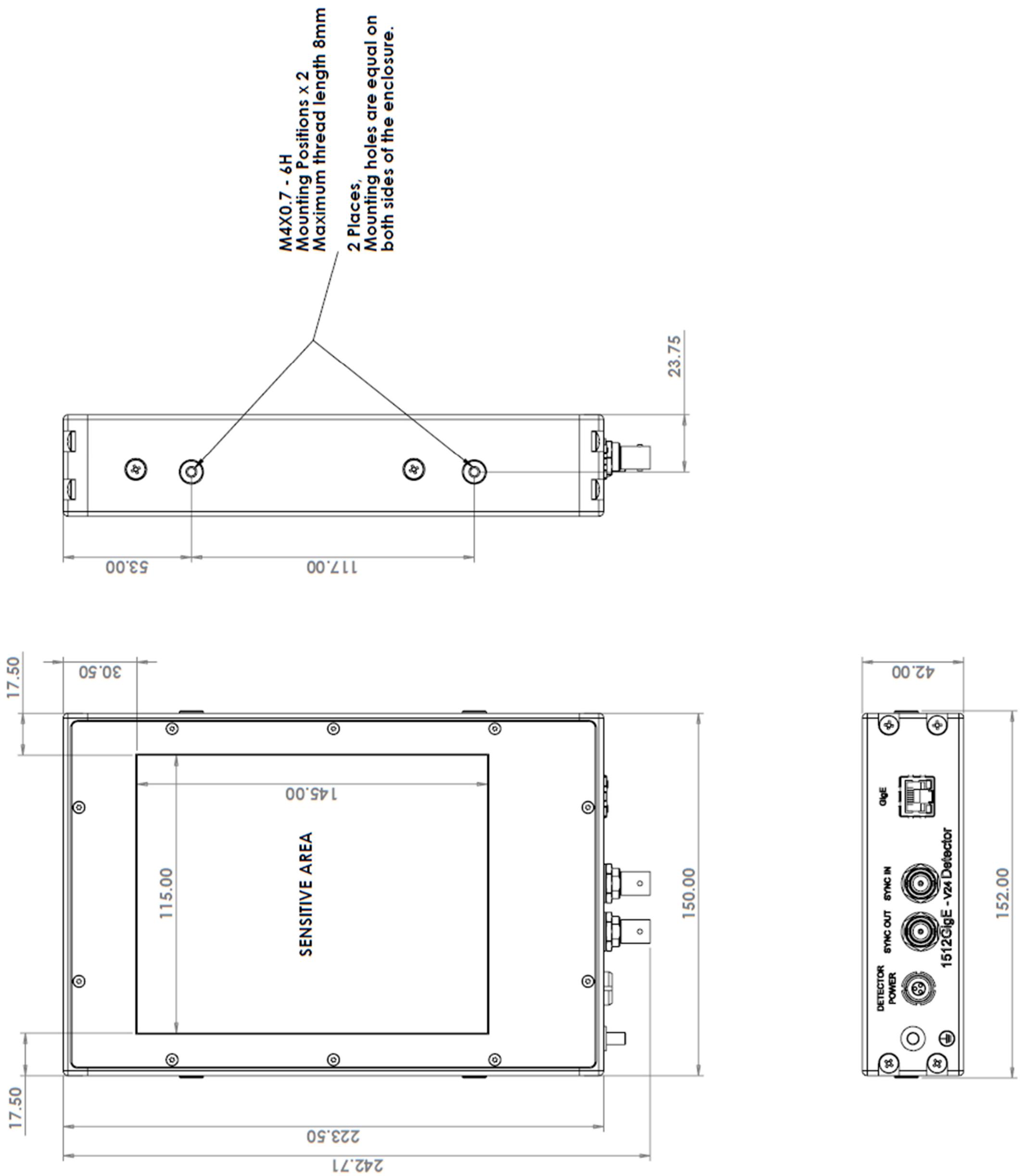
The PerkinElmer product may be attached as part of a component to other manufacturers' systems. These other manufacturers are directly responsible for the collection and processing of their own waste products under the terms of the WEEE Directive. Contact these producers directly before discarding any of their products. Consult the PerkinElmer Web site (above) for producer names and Web addresses.

14 Appendix 1 – Technical drawings

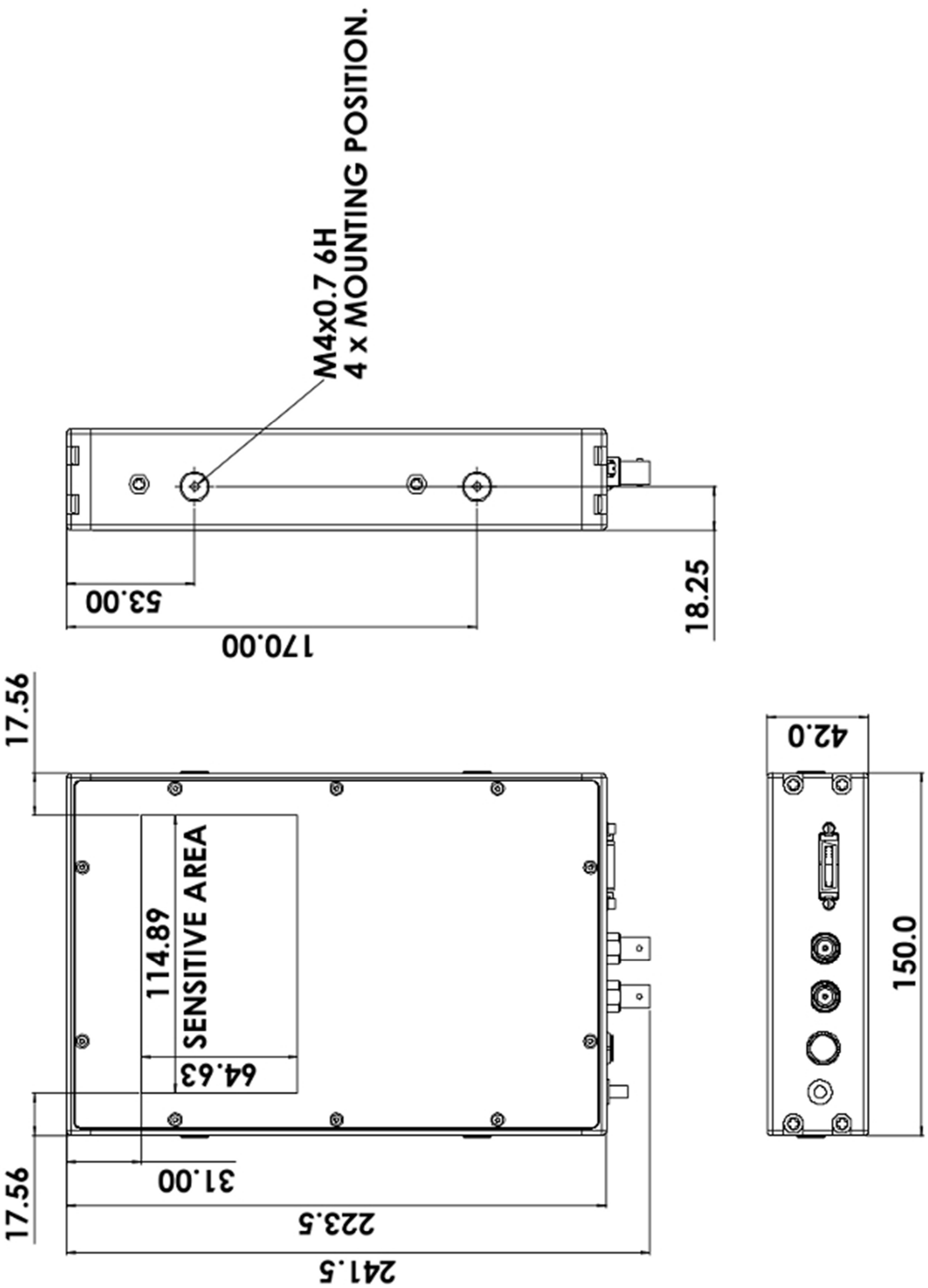
1512 CL



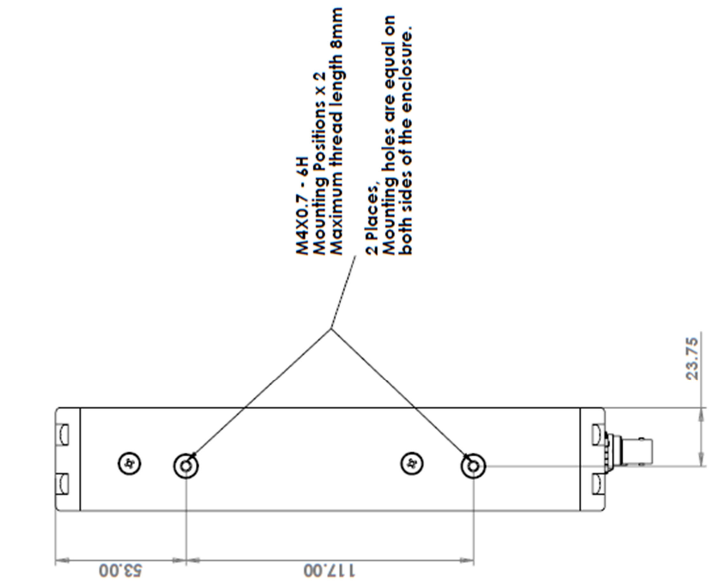
1512 GigE

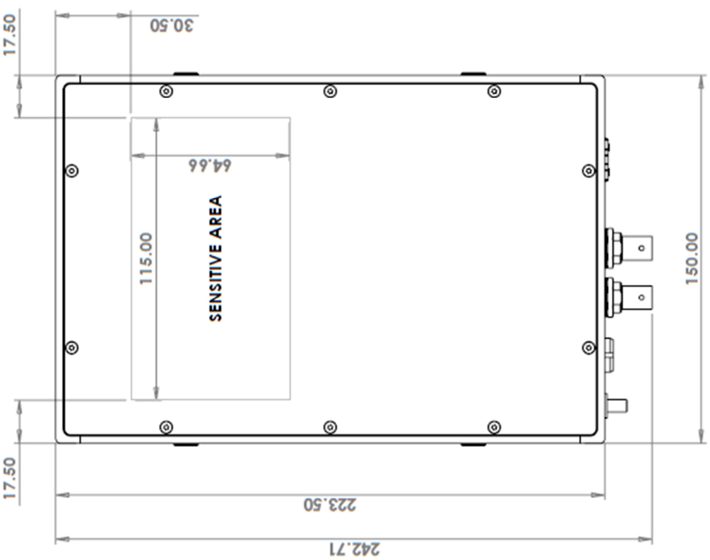

M4X0.7 - 6H
Mounting Positions x 2
Maximum thread length 8mm
2 Places,
Mounting holes are equal on
both sides of the enclosure.
23.75
53.00
117.00
17.50
30.50
145.00
115.00
SENSITIVE AREA
150.00
17.50
223.50
242.71
42.00
GigE
SYNC IN
SYNC OUT
DETECTOR POWER
1512GigE - V24 Detector
152.00

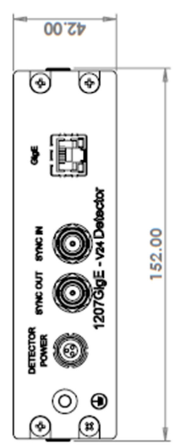
1207 CL


M4x0.7 6H
4 x MOUNTING POSITION.
53.00
170.00
18.25
17.56
114.89
SENSITIVE AREA
64.63
17.56
31.00
223.5
241.5
42.0
150.0

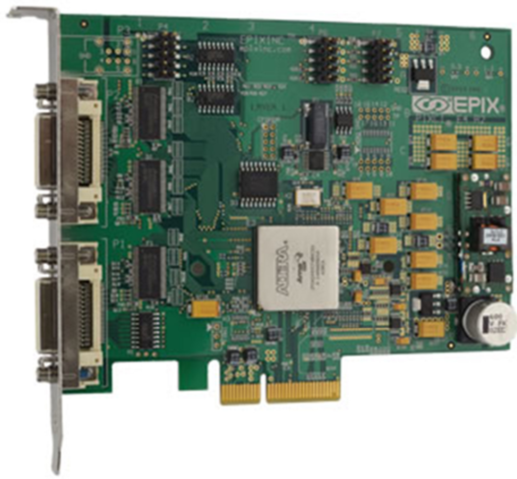
1207 GigE


M4X0.7 - 6H
Mounting Positions x 2
Maximum thread length 8mm
2 Places,
Mounting holes are equal on
both sides of the enclosure.
23.75
53.00
117.00


17.50
30.50
64.66
115.00
SENSITIVE AREA
150.00
17.50
223.50
242.71


42.00
GigE
SYNC IN
SYNC OUT
DETECTOR POWER
1207GigE - V24 Detector
152.00

15 Installing and configuring Epix Camera Link cards



15.1 Overview

Dexela optionally supplies the Epix E4 (dual cable) or EB1 (single cable) Camera Link card with its detectors.
This Annex describes how to

- install the card and its supporting software
- configure memory for storing multiple images
- create a Camera Link configuration file (.FMT) for third-party applications if using the Dexela or Epix libraries.

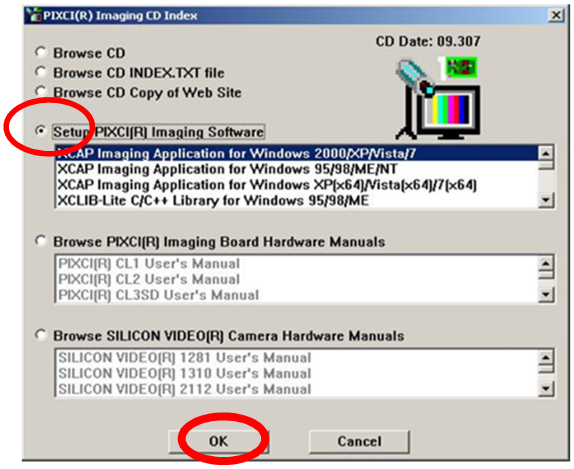
15.2 Installing the card

Plug the card into a spare PCIe x1, PCIe x4 or PCIex16 slot. The PCIe slot with higher bandwith is preferred. On many PCs, at least one PCIe x16 slot is wired directly into DMA memory, which provides maximum speed.

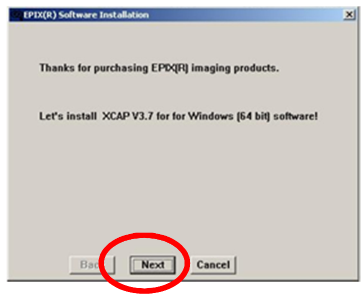
15.3 Installing the Software and Driver

Insert the Epix CD provided with the board. The **PIXCI(R) Imaging CD Index** dialog box should be displayed; if not, browse to the CD drive and run **setup.exe**.

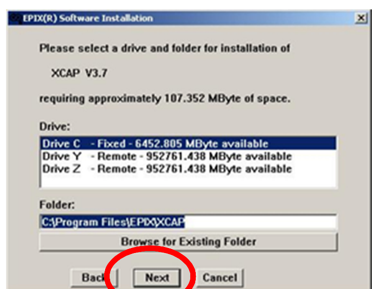
Select **Setup PIXCI(R) Imaging Software** and then click on **XCAP Imaging Application** with the appropriate OS platform. Then click **OK**.

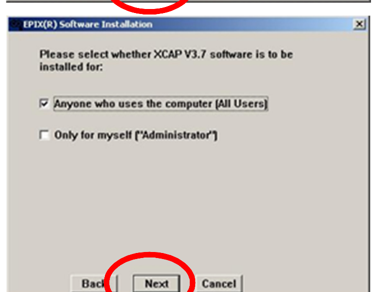


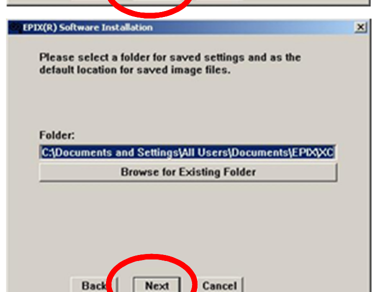
On the following screen, click **Next**

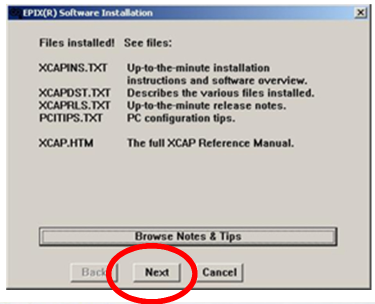


On the following series of dialog boxes, select the default options, unless other options (*e.g.* another disk drive) are required

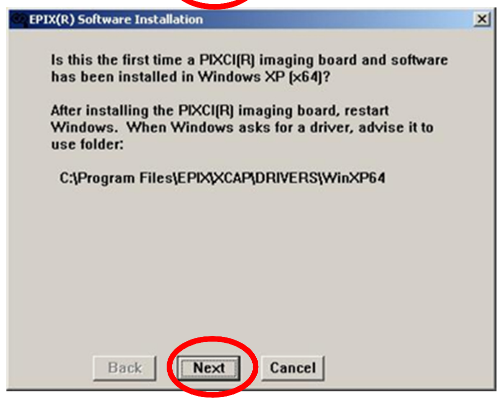


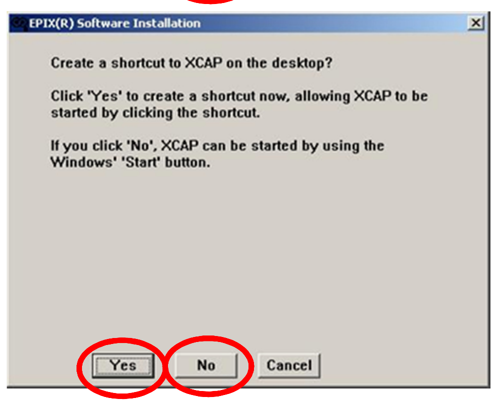




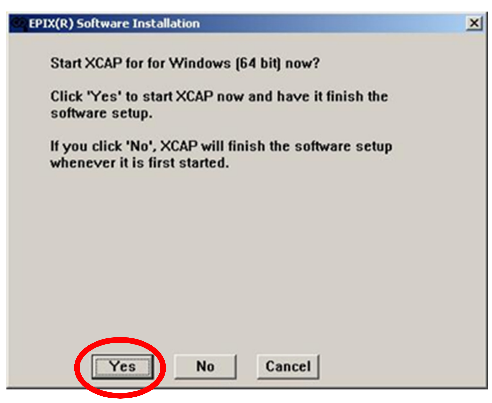


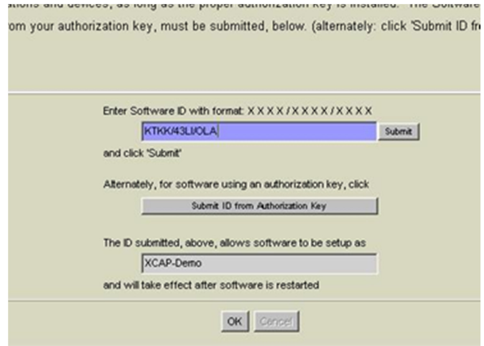
The Camera Link driver can now be installed. In the next dialog box, note that the path for a 32-bit Windows installation be different to the 64-bit folder shown:





Select **Yes** to start XCAP. Click **Agree** after reading the licence terms, enter the Software ID on the dialog box which follows. The Software ID is printed on the envelope which contains the driver CD. Keep this in a safe place, as the code will be needed if the drivers need to be re-installed.





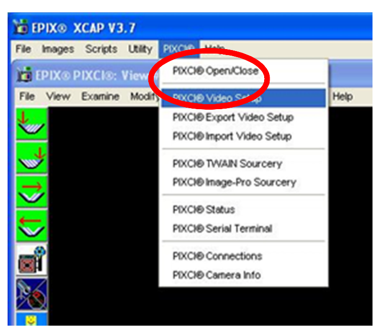
Now restart the computer. It will recognise the new card and start the New Hardware Wizard.

When Windows has found the driver, the following dialog box is displayed. Click **Continue Anyway**.

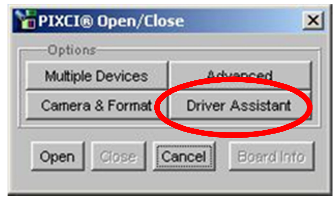
15.4 If the driver is not detected by Windows

If the New Hardware Wizard does not appear, the driver can be installed using the XCAP software. Launch XCAP, and the following dialog will appear. Click **Cancel.**

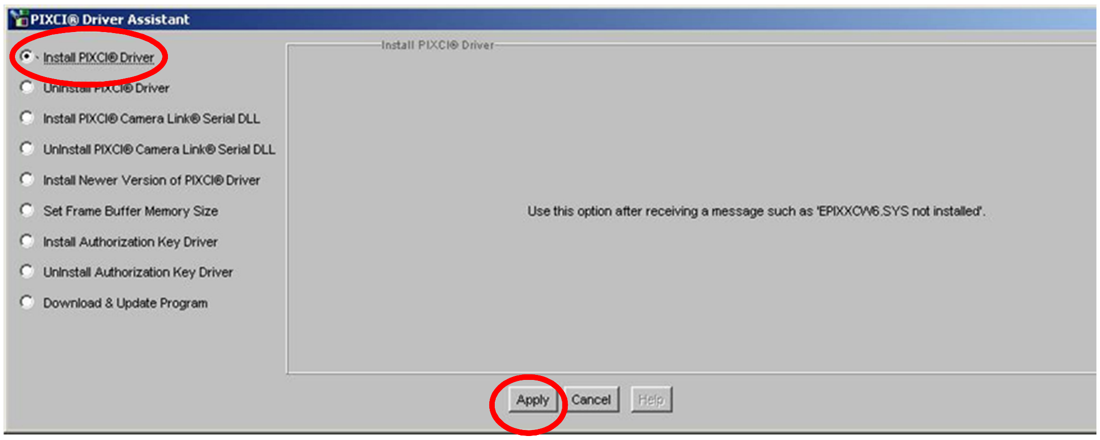
Then choose the menu item **PIXCI® Open /Close** from the **PIXCI** menu:



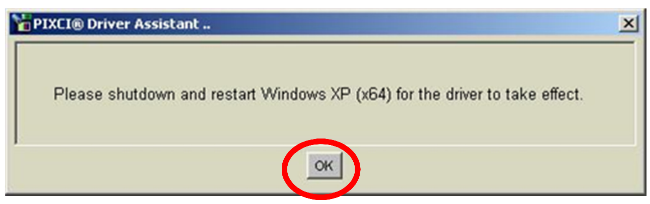
Select **Driver Assistant** from the dialog box.



On the next dialog box, select **Install PIXCI Driver** and then click **Apply**. The driver will then be installed.



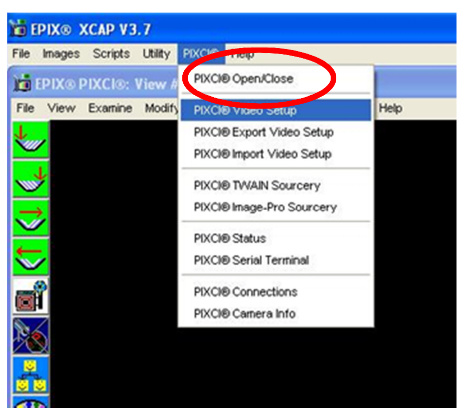
After installation is finished, click OK to reboot the PC:



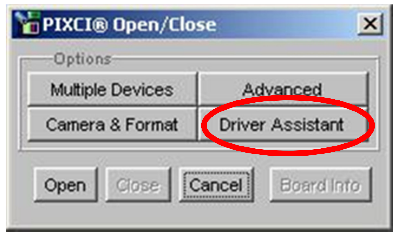
15.5 Configuring memory for the frame buffer

To store multiple frames from the card, sufficient system memory must be allocated. The minimum should be about 5 frames, but more may be needed according to the application. The frame partition size should be at least as big as one frame. In this example the partition size is set to 24MBytes as the frame size is 22.8MBytes.

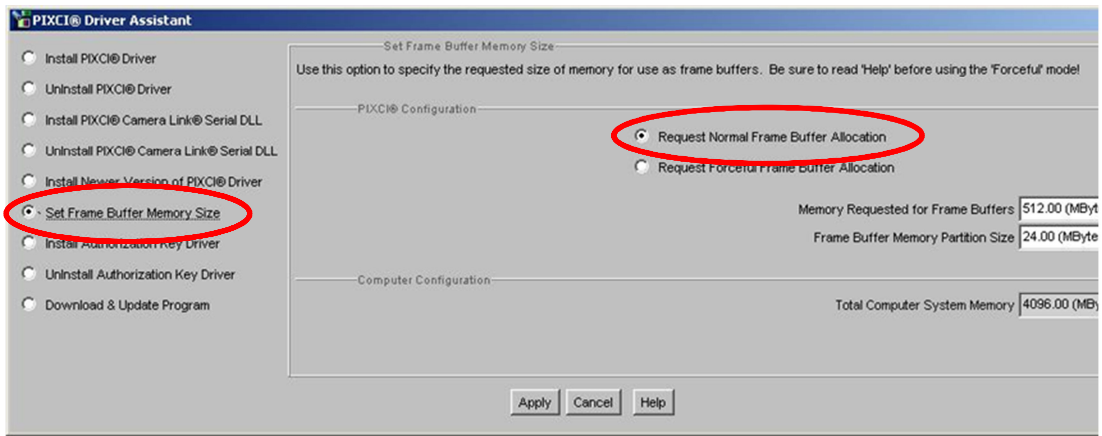
First select **PIXCI® Open /Close** from the **PIXCI** menu:



Select **Driver Assistant**:



Then select **Set Frame Buffer Memory Size**.



Request Normal Frame Buffer Allocation should normally be chosen, but refer to the Epix documentation for other options. In the example shown, the **Use Default** checkbox has been cleared, the reserved memory (**Memory Requested for Frame Buffers**) has been set to 512MBytes and the **Frame Buffer Memory Partition Size** to 24MB.

Note the **Total Computer System Memory** figure which is displayed. This will give an indication of how much frame buffer memory can be used. The frame buffer memory should be at least 1GByte less than the total system memory.

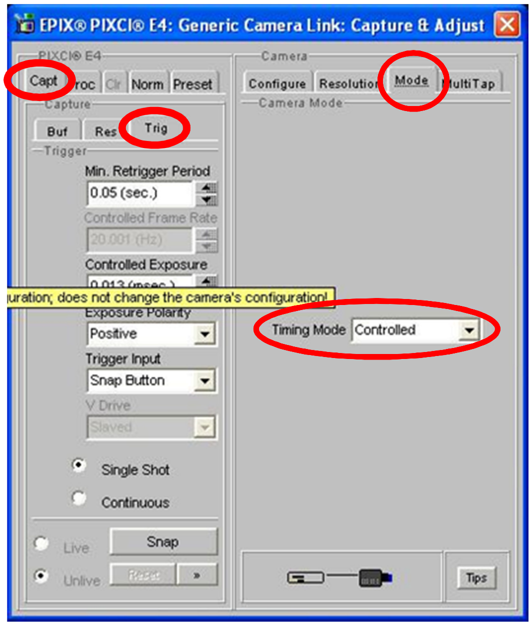
15.6 Creating FMT files for use of third party applications

SCap, the Dexela SDK and other third-party software that uses the XCLIBWNT.dll (XClib library) all require a camera setup or format file called an FMT file. This file can be created using the XCAP software. This section describes how to configure XCAP for different types of camera, and to export the FMT file for use by other programs.

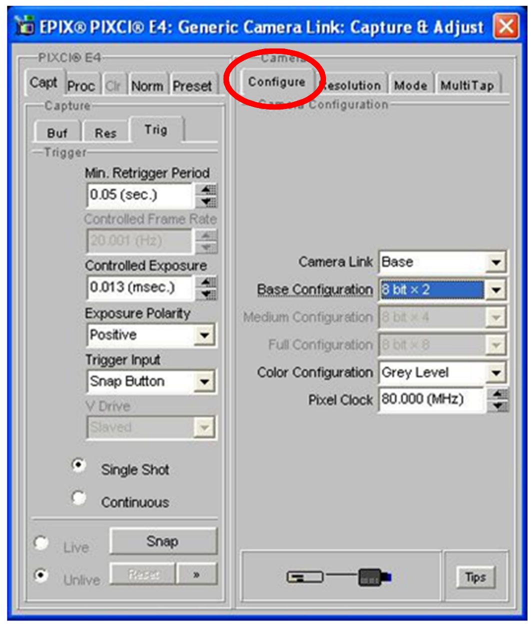
When XCAP opens, it will display a dialog box with the title **Generic Camera Link: Capture & Adjust**. This controls most of the camera configuration.

First click on the **Mode** tab. The **Timing Mode** should be set to **Controlled**.

Then select the **Capt** tab, and the **Trig** tab below. Set the **Min Retrigger Period**, the **Controlled Exposure** pulse time, the **Exposure Polarity** and the **Trigger Input** to the desired values as shown in the example below:



Next select the **Configure** Tab. Under this tab, the type of Camera Link interface is defined. The choices are **Base**, **Medium** or **Full**. Select **Grey Level** for **Color Configuration**, and **80MHz** for **Pixel Clock**. For Base configuration (e.g. 1512) select **8 bit x 2**.

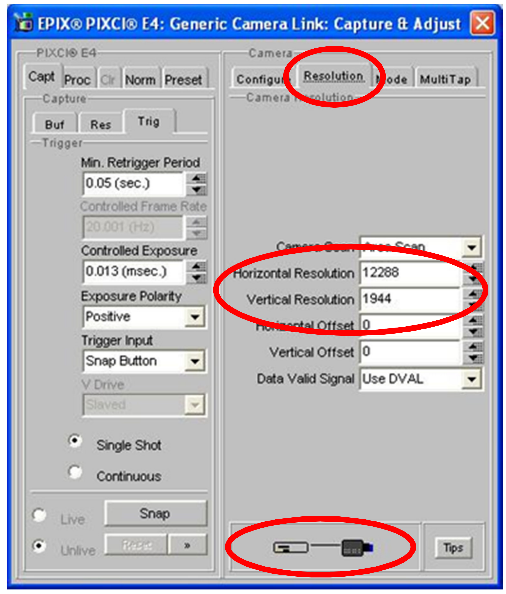


Next, the dimensions and scope of the data are defined.

Pixels are specified in units of bytes. The pixels from tiled sensors are read off as interlaced, and the picture displayed by XCAP is therefore scrambled.

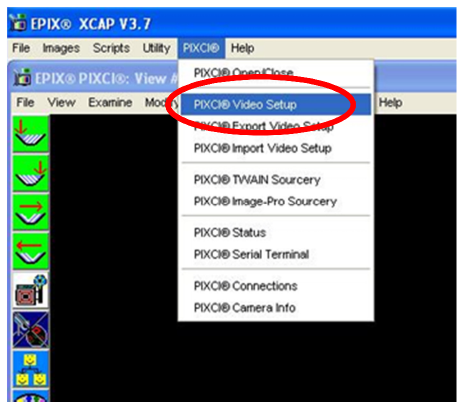
	1512	***1207***
Horizontal resolution	3072	3072
Vertical resolution	1944	864

At the foot of he dialog box, a camera icon is joined to a card icon. If there is Camera Link communication with the camera, the icon will display activity. If no activity is shown when the **Snap** button is clicked, refer to ‘Communicating with the Detector’ in the Troubleshooting section.

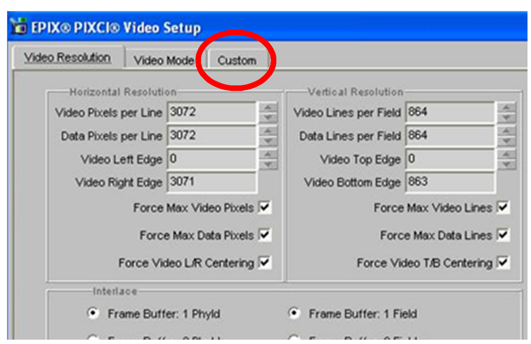


The software trigger mechanism which drives the Camera Link CC1 signal must be configured to provide third-party access. This will affect XCAP’s ability to function using the Snap button, so it should be reset once the FMT file has been exported.

First choose **PIXCI Video Setup** from the **PIXCI** menu.

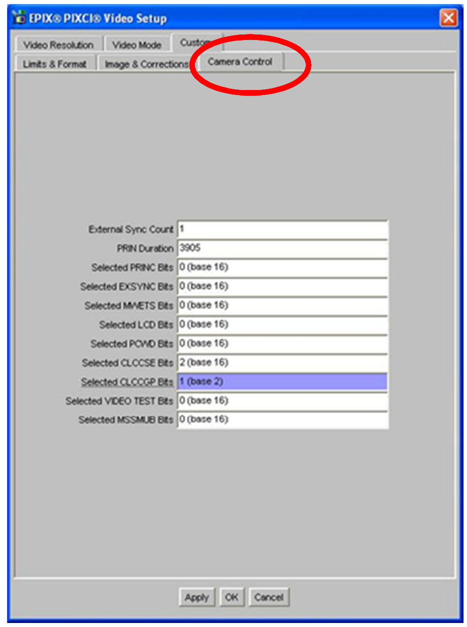


In the next dialog box select the **Custom** Tab.

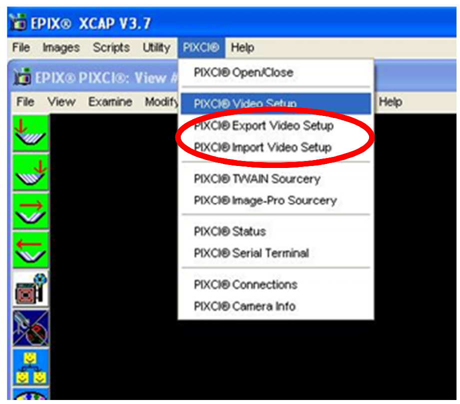


Select the **Camera Control** tab. Set **Selected CLCCGP Bits** to 1 (the default is 0).

Click on **Apply** and then **OK**.



The Video setup can now be exported. Choose **Export Video Setup** from the **PIXCI** menu. In the dialog choose a path and file name, then click **Apply** and **OK**. The FMT file is now ready for use by other programs.



15.7 Troubleshooting

PCI overflows are caused by the PC architecture not being able to handle the data throughput. Try using a PCIe x16 slot that is recommended for the main graphics card as this may have better throughput compared with the other slots. Epix Inc (see www.epixinc.com) may be able to help in finding approved motherboards.

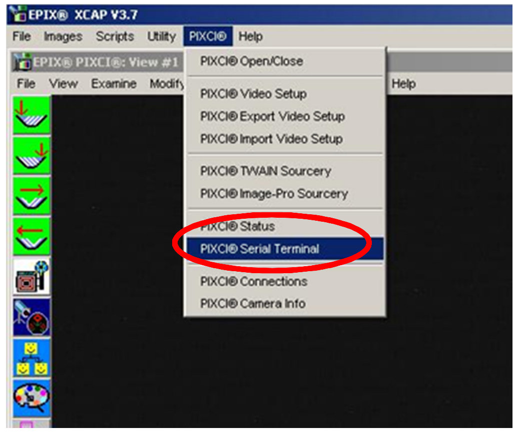
Communicating with the detector.

If the detector does not respond to Camera Link communication, first check that:

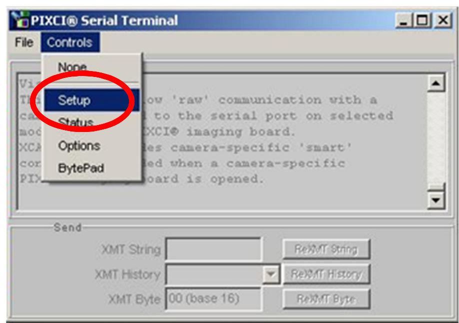
- the power supply is on
- the power cable is connected
- The Camera Link cables are connected the right way round. Connector 1 should be connected to the lower (nearest the motherboard) port of the Epix frame grabber.

If the detector appears to be powered on and connected correctly, it may required an initialization command to be sent to start the Camera link Interface.

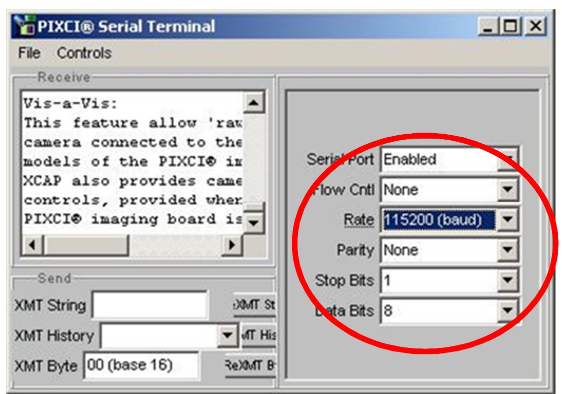
First choose **PIXCI Serial Terminal** from the **PIXCI** menu.



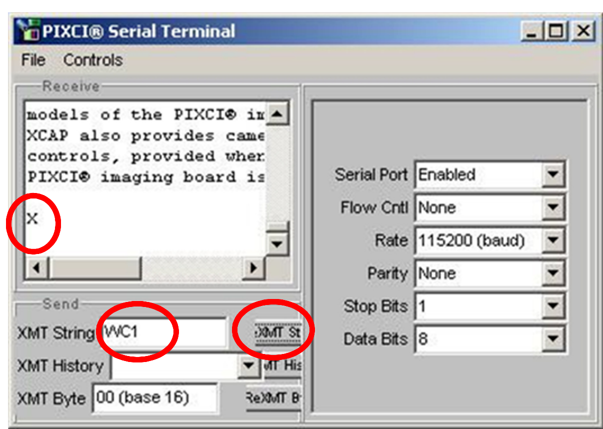
Then in the resulting dialog box choose **Setup** from the **Controls** drop down menu.



Configure the terminal settings as shown. The only change from the default is to set **Rate** to 115200.



Now issue the Camera Link wake-up command to the detector by typing **WC1** in the **XMT String** text box and clicking the button to the right. In the Receive window, you should see the detector return **X** as confirmation of a successful command.



The detector is now ready to accept capture requests. Having established communication, it is recommended to close XCAP and use SCap instead for further work, since this will set up camera offsets and descramble the interleaved pixels to display a coherent image.

15.8 Installing and configuring of GigE devices

The instruction to install drivers and software fo GigE devices can be found in the document DX-001308 (revision A), that can be found in the SDK cd sent together with a GigE detector.