SHIMADZU

VIVIX-S 4343FW Specifications

(FXRD-4343FAW)

CE 2460

Contents

1. Instruction

1.1 Document Guide

1.1.1 Target

This document is intended for customers who use the **VIVIX-S 4343FW** detector.

1.1.2 Symbols

This product should be operated under the safety instructions with the warning or caution symbol in this manual. It is important for you to read and understand the contents to operate the products safely.

Caution and Warning

- This symbol is used to indicate a potentially hazardous situation that may cause death, personal injury, or substantial property damage if the instructions are ignored. Users should be well acquainted with this symbol and the related contents.

Information

- This symbol is used for indicating product related references and supplementary information. Users are recommended to read the sentences with this notice carefully.

1.1.3 Notations

Bold Types

Words in bold indicate products terms, or the sentences which are needed to transmit clear meaning to the customers.

1.2 Revision History

Ver.	Date	Descriptions
1.0	2023-05-28	Initial Release

1.3 Contact Us

- This manual is provided in print format upon request by the customer.
- For comments or inquiries regarding this document and relevant products, contact via email below:

Item	Contents
Department	Customer Support Team at Vieworks
E-mail	CustomerSupport@vieworks.com

- You can download this manual from VDS (Vieworks Download System) website: https://clouds.vieworks.com:5001/.
- To obtain an ID and password for manual download, please contact the customer support team in Vieworks.

2. Products

2.1 Detector

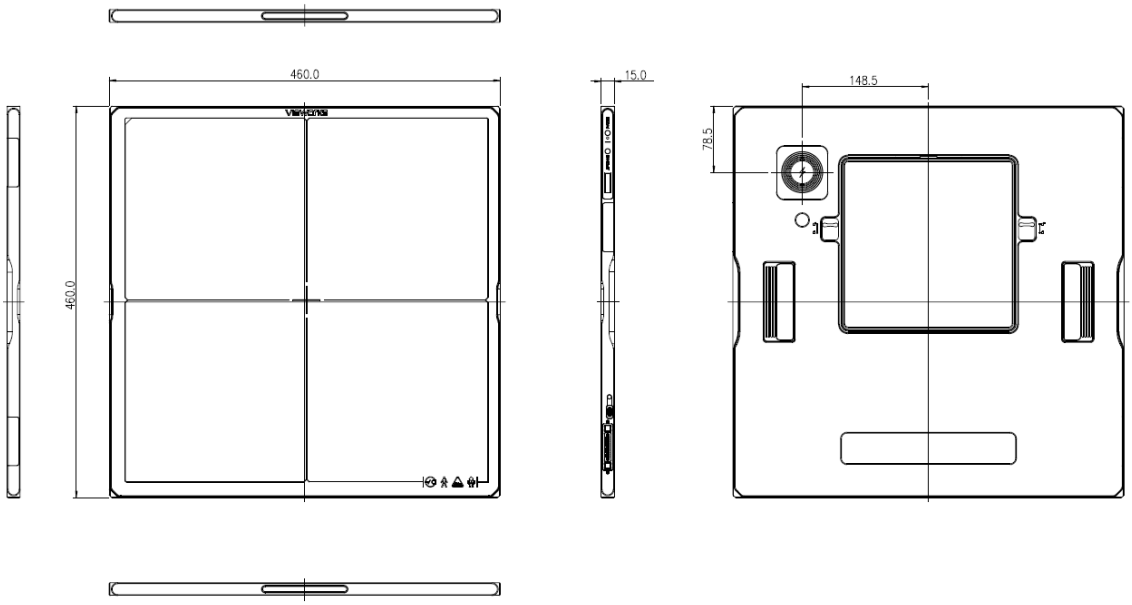
2.1.1 Specifications

Item	Specifications
Model	• FXRD-4343FAW
Image Sensor	• Flexible a-Si(Amorphous Silicon) TFT with PIN diode
X-ray Scintillator type	• CsI
Pixel Pitch	• 0.099㎜ (99㎛)
Field of View	• 43cm x 43cm (17" x 17")
Active Area (H x V)	• 427.284㎜ × 427.284㎜
Active Array	• 4316 x 4316 pixels
Effective Area	• 423.324㎜ x 423.324㎜
Effective Array	• 4276 x 4276 pixels
Grayscale	• 16 bit
Spatial Resolution	• Min. 5 lp/㎜
Image Acquisition Time (Wired)	• Max. 4.5 sec. (Exposure time is set to 100ms, Excluding exposure time)
Image Acquisition Time (Wireless)	• Max. 4.5 sec. (IEEE802.11ac, MiMO 3x3, 5GHz, 80MHz) (Exposure time is set to 100ms, Excluding exposure time)
Capacity for Image Backup	• Max. 200 images
Cycle Time	• Min. 7 sec. (Optimal wired/wireless environment, Exposure time is set to 100ms, Image processing time of software is not included)
Multi Frame Mode	• SG2 (Speed Grade 2) ▫ 6 fps(1x1, PF, Exposure time 45ms, Frame count 48) • SG1 (Speed Grade 1) ▫ 3.5 fps(1x1, PF, Exposure time 45ms, Frame count 48) • Supported Binning 2x2 • Max. frame rate depends on the exposure time or binning or AOI. • Max. exsposure time depends on the frame rate or binning or AOI. • Max. frame count depends on the binning or AOI.
X-ray Synchronization Control	• AED (Auto Exposure Detection) • DR Trigger (External line trigger) • Passive Trigger (External line trigger) • Software Trigger
Detector sharing	• NFC / Preset Switching Function
Power Supply	• Powered by SCU via tether interface cable: DC 24V, Max. 1.0A • Powered by AC-DC adapter: DC 18V, Max. 4.44A

	• Powered by cradle: DC 24V, Max. 3.33A • Powered by wireless power transmitter: DC 12V, Max. 1.25A • Powered by 2 battery packs: DC 9 ~13.2V, Max. 78.54Wh
Power Consumption	• Max. 24W(No Charging), Max. 80W(Charging)
Operating Time (Early life of battery)	• One battery pack ▫ 7.5 hours (SCU AP, image acquired every 100 seconds) ▫ 8 hours (SCU AP, standby) • Two battery packs ▫ 15 hours (SCU AP, image acquired every 100 seconds) ▫ 16 hours (SCU AP, standby)
Weight (Including battery packs)	• One battery pack : 2.95kg • Two battery packs : 3.15kg
Dimensions (H × W × D)	• 460㎜ × 460㎜ × 15.0㎜
Image Transfer	• Wired: Gigabit Ethernet(1000BASE-T) via PoE(Power over Ethernet) • Wireless: IEEE802.11n/ac(2.4GHz/5GHz), Antenna 3ea
Data Transmission Rate (Wired)	• Max. 1Gbps
Data Transmission Rate (Wireless)	• Max. 300Mbps (IEEE802.11n, MIMO 2x2, 5GHz, 40MHz) • Max. 1300Mbps (IEEE802.11ac, MIMO 3x3, 5GHz, 80MHz)

2.1.2 Drawing Sheet

FXRD-4343FAW



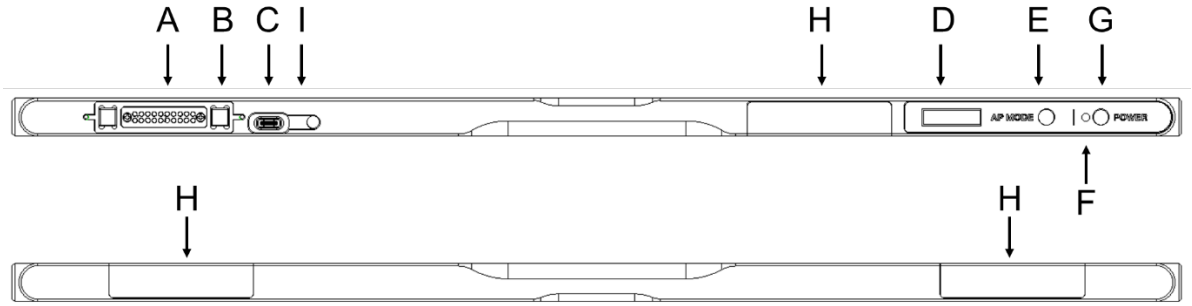
Item	Description
Dimensions (H × W × D)	460.0㎜ × 460.0㎜ × 15.0㎜
Curvature of Edges	C3.5

- The allowed tolerance of a thickness of detector is from **-2.0㎜ ~ +1.0㎜**. (Under the **ISO4090** regulation).

2.1.3 Functions

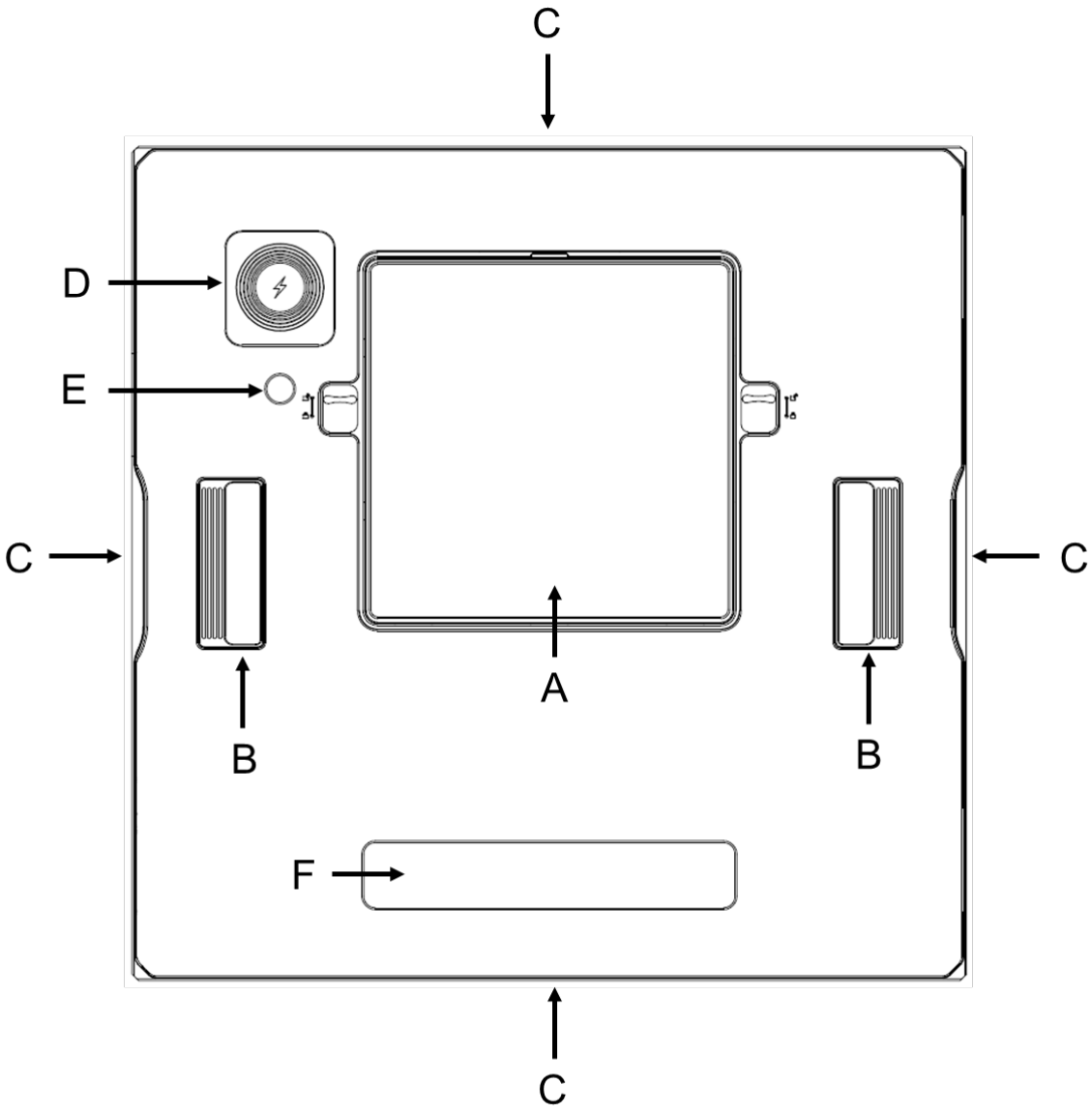
FXRD-4343FAW

Side



	Name	Description
A	**Tether Interface Connector**	• Tether interface cable connector ▫ Used for wired connection between a detector and SCU • Connector for a cradle ▫ Used for battery charging through a cradle
B	**Fixing magnet for tethered interface**	Used for fixing a tether interface cable
C	**AC-DC Adapter Connector**	• Connector for fastening the AC-DC adapter • Used for fast battery charging
D	**OLED Display**	• Displays battery status • Displays wired / wireless connection status • Displays sleep mode status
E	**AP Button**	• Changes AP settings button in wireless communication (Change detector AP / STAION or change preset in STATION mode) • Changes OLED screen
F	**Power Indicator LED**	• Displays system power status • Displays system boot status
G	**Power Button**	• System power on/off • Changes OLED screen
H	**Antenna for Wireless LAN**	Antennas for wireless communication (3ea)
I	**Charge Status LED**	Displays the charge status of the battery

Rear



	Name	Description
A	**Battery Pack Cover**	The cover needs to be opened and closed when replacing the battery pack.
B	**Handle**	A handle for carrying a detector
C	**Lift Structure**	Used when the detector is placed on flat surface
D	**Wireless Power Receiver and NFC antenna**	The part exposed to wireless power transmitter or NFC card
E	**Infrared LED**	Infrared transmitter that controls wireless power ON/OFF from detector
F	**Label Attachment**	Label attaching part

2.1.4 Use Environment

Item	Operation	Storage & Transportation
Temperature	0 ~ +40℃	-15 ~ +55℃
Humidity	5 ~ 90% (Non-condensing)	5 ~ 90% (Non-condensing)
Atmospheric pressure	700 ~ 1060hPa	500 ~ 1060hPa
Shock	20G	30G
Vibration	2G	5G

2.2 Battery Pack

2.2.1 Specifications

Item	Specifications
Model	FXRB-04A
Type	Lithium Ion Polymer
Norminal voltage	DC +11.55V
Norminal Capacity	3,400mAh
Number of Cell	3S1P (3 Series 1 Parallel)
Life	Approx. 800 times (Fully charged/Discharged completely, 1 cycle)
Dimension (H × W × D)	Max. 189.0㎜ × 89.0㎜ × 6.65㎜
Weight	Max. 185g

- The battery operation time increases under the sleep mode depending on the operational condition and environment.

3. Performance

3.1 FXRD-4343FAW

- Test Condition: RQA5, 2.5uGy, IEC 62220-1 Standard, Gain type = 1
- The typical values are for reference only.

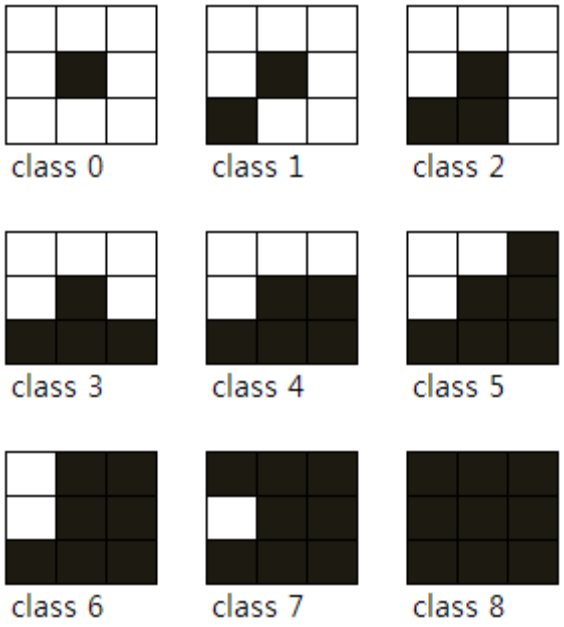
Parameters	Unit	Minimum	Typical	Maximum
Dark Noise	cts	-	5	6
Offset (Black Image)	cts	500	-	3500
Sensitivity at G=1	cts/uGy	540	600	660
Quantum Limited Dose	uGy	-	-	0.3
Signal to Noise Ratio	dB	18	-	-
Max. Exposure Level	uGy	90	-	-
Dynamic Range	a.u	303	-	-
MTF	0.5 lp/㎜	81	83	-
	1 lp/㎜	58	60	-
	2 lp/㎜	27	30	-
	3 lp/㎜	12	15	-
	4 lp/㎜	6	8	-
	5 lp/㎜	3	5	-
DQE	0.5 lp/㎜	61	67	-
	1 lp/㎜	52	58	-
	2 lp/㎜	40	48	-
	3 lp/㎜	29	40	-
	4 lp/㎜	16	27	-
	5 lp/㎜	6	13	-

- The formula of dynamic range is as follows;
  - $Dynamic\ Range = \frac{Max.Exposure\ Level}{Quantum\ Limited\ Dose}$

4. Defect

4.1 Defect Type

Type	Description
Single Defect	Isolated defects, adjacent pixels are normal. (Class 0)
Cluster Defect	More than consecutive 2 pixels are defected. (Class 1~Class 7)
Line Defect	Defect occur horizontal direction from left ro right, or vertical direction from top to bottom.



- No cluster defects are allowed over 3x3 pixels.

4.2 Defect Allowance

Item	Unit	Value
Total number of pixel defects	cts	Max. 40,000 pixels
Number of line defects	cts	Max. 5 lines
Number of normal lines between two bad lines	cts	Min. 3 lines

5. Regulatory Information

5.1 Medical Equipment Classification

Item	
Type of protection against electrical shock	Class Ⅰ or Internally Powered
Degree of protection against electrical shock	Type B applied parts
Degree of protection against ingress of water and dust	IP67 (Degrees of protection againt ingress of water and dust provided by enclosure.)
Operation mode	Continuous operation
Flammable anesthetics	NOT suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.

5.2 Product Safety Standard

South Korea

Electrical and mechanical safety tests shall be in accordance with IEC 60601-1.
Test for electromagnetic interference prevention shall be in accordance with IEC 60601-1-2.

U.S.A / Canada

Item	
IEC 60601-1:2012 (ed.3.1)	Medical electrical equipment – Part1: General requirements for basic safety and essential performance
ANSI/AAMI ES60601-1(2005) + AMD1(2012)	Medical electrical equipment – Part1: General requirements for basic safety and essential performance
CAN/CSA-C22.2 No. 60601-1:14	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (adopted IEC 60601-1:2005, including Amendment 1:2012, with Canadian deviations)
IEC 60601-1-2: 2014(ed.4)	Medical electrical equipment-Part 1-2: Collateral Standard: Electromagnetic compatibility
IEC 62304:2006	Medical device software-software life cycle processes
ISO 14971:2012	Medical Device- Application of risk management to medical devices

European Union

Item	
MDD (Medical Device Directive)	(93/42/EEC as amended by 2007/47/EC) Medical Device Directive
EN ISO 13485:2016	Medical devices – Quality Management systems – Requirements for regulatory purposes
IEC 60601-1:2012 (ed.3.1)	Medical electrical equipment- Part1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2014(ed.4)	Medical electrical equipment-Part 1-2: Collateral Standard: Electromagnetic compatibility - Requirements and tests
IEC 62304:2006	Medical device software-Software life cycle processes
ISO 14971: 2012	Medical device – Application of risk management to medical devices.

SHIMADZU

Vieworks Co., Ltd.

Headquarter

41-3, Burim-ro 170beon-gil, Dongan-gu, Anyang-si,

Gyeonggi-do, 14055 Republic of Korea

Telephone: +82-70-7011-6161

Fax: +82-31-386-8631h

Homepage: http://www.vieworks.com

Hwaseong Site

25-7, Jeongnamsandan 2-gil, Jeongnam-myeon, Hwaseong-si,

Gyeonggi-do, 18514 Republic of Korea

Telephone: +82-70-7011-6161

Homepage: http://www.vieworks.com

European representative: Obelis s.a

Bd. Général Wahis 53

1030 Brussels, BELGIUM

Tel: +(32) 2.732.59.54

Fax: +(32) 2.732.60.03

E-mail: mail@obelis.net