

DIRECT DIGITIZER





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Operation Manual



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Introduction

Introduction

Digital radiography AeroDR SYSTEM (hereafter referred to as this device) performs X-ray imaging of the human body using an X-ray planar detector that outputs a digital signal, which is then input into an image processing device, and the image acquired with a digital image acquisition device is then transmitted to a filing system, printer, and image display device as diagnostic image data.

- Diagnostic X-ray image data of this device does not provide mammographic images.
- This device is also used for carrying out exposures on children.

There are 5 types of X-ray planar detectors for this device: AeroDR 1417HQ (AeroDR P-11), AeroDR 1417S (AeroDR P-12), AeroDR 1717HQ (AeroDR P-21), AeroDR 1012HQ (AeroDR P-31) and AeroDR II 1417HQ (AeroDR P-51), and connection is made by either wireless or wired connection.

The DIRECT DIGITIZER CS-7 or ImagePilot (hereafter referred to as the image processing controller), which controls the receiving, processing, and output of image data of this device, is required for operation. For the operation of the image processing controller, refer to the "Operation Manual" of the image processing controller.

This operation manual provides instructions on the basic functions for operation of this device. Those operating this device for the first time should read this manual beforehand.

Also, store this manual close to this device after reading it through, so it can be used as a guide to allow optimum operating conditions.

- * If the pages of the operation manual are smudged and illegible, replace it with a new one. (There is a fee for this service.)
- * The illustrations in this manual use the AeroDR II 1417HQ (AeroDR P-51) and AeroDR Battery Charger as the example.

Indications for Use

The AeroDR SYSTEM is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures.

<Only for USA>

The AeroDR SYSTEM with P31 is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.



Federal law restricts this device to sale by or on the order of a phisitian.

Summary of usability specifications (for IEC/EN 60601-1-6, IEC/EN 62366)

- 1) Medical purposes
 - Provision and reading of disease and injury diagnostic images.
- 2) Patient groups
 - No patient population exists who uses or is in contact with the device.
 - Patient population for the X-ray images read is not specified.
- 3) Parts of body or organizations to which the device is mounted or that interact with the device.
 - AeroDR Detector contacts the body surface of a patient.
 - AeroDR Interface Unit/AeroDR Interface Unit2 contacts the body surface of an operator.
- 4) Operating principle
 - AeroDR Detector forms the still images according to the X-ray energy passing through the human and animal body; after digitizing the exposed image, it is transmitted to the console (the image processing controller) with wired or wireless communication by way of AeroDR Interface Unit/AeroDR Interface Unit2.
 - AeroDR Interface Unit/AeroDR Interface Unit2 supplies the power to any of AeroDR Detector, AeroDR Generator Interface Unit, and Access Point (radio communication device).
 - AeroDR Generator Interface Unit or AeroDR Interface Unit2 interfaces with an X-ray device.
 - Access Point (radio communication device) performs a wireless communication with AeroDR Detector.
 - The console (the image processing controller) processes the image data into the diagnostic image, and then stores and outputs the images added with the patient information.
 - The AeroDR Battery Charger/AeroDR Battery Charger2 charges the AeroDR Detector. It registers the using cassette with the exposure room.
- 5) Significant physical characteristics
 - Refer to "7.1 Specifications".
- 6) Significant performance characteristics
- Refer to "2.1 Overview of this device".
- 7) User of this device
 - No special training is required to use this device. The intended users of this device are as follows.
 A professional in good health with specialist knowledge/qualifications who has fully understood the content of this document. (Such as a doctor or radiological technologist)

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AeroDR SYSTEM name correspondence table

Product name (Operation Manual name)	Model name (nameplate name)
AeroDR Detector	AeroDR P-11 AeroDR P-12 AeroDR P-21 AeroDR P-31 AeroDR P-51
AeroDR Interface Unit	AeroDR B-1
AeroDR Interface Unit2	AeroDR Interface Unit2
AeroDR Generator Interface Unit	AeroDR X-1
AeroDR Battery Charger	AeroDR D-1
AeroDR Battery Charger2	AeroDR Battery Charger2

Term description

The meanings of terms used in this operation manual are as follows:

Terms	Explanation		
AeroDR Detector	Collective term indicating AeroDR 1417HQ, AeroDR 1417S, AeroDR 1717HQ, AeroDR 1012HQ and AeroDR II 1417HQ.		
Image processing controller	The image processing workstation (CS-7 or ImagePilot) is referred to as the image processing controller.		
Calibration	Processing for calibrating the characteristics of the AeroDR Detector for each pixel.		
PoE	An abbreviation for Power over Ethernet. Provides power using an Ethernet cable.		
Wired cable	Collective term indicating AeroDR I/F Cable and AeroDR UF Cable.		
Aero Sync	This is a mode in which exposure is performed without being synchronized with the X-ray device.		

Structure of pages 3.1 • Startup and shutdown (1) -Normally, this device is used with the power on. When not used for more than 1 day, operate the start-up/shutdown as follows. 3.1.2 Startup of this device The startup methods of this device are as follows. Reference Refer to the "Operation Manual" of the image processing controller regarding on/off for the image processing controller. (4) AcroDR Interface Unit, AcroDR Generator Interface Unit and Access Point • The startup methods of the AcroDR Interface Unit, AcroDR Generator Interface Unit and Ac-cess Point are as follows. 3.1.1 Startup sequence of this device 1 Turn the power switch of the AeroDR In-terface Unit on, and confirm that the LED (2) The startup sequence of this device is as follows. (green) lights. When using AeroDR Interface Unit 1 AeroDR Interface Unit ₽ AeroDR Generator Interface Unit í Access Point e 2 Image processing controller LED (green) Power witch AeroDR Detector AeroDR Battery Charger/ AeroDR Battery Charger2 2 When the power switch of the AeroDR Interface Unit is turned on, power is also supplied to the AeroDR Generator Interface Unit, and the LED (green) will flash. Confirm that the AeroDR Detector is ready for use on the image processing controller. When using AeroDR Interface Unit2 Π 1 AeroDR Interface Unit2 ₽ Access Point LED (gr 2 Image process een) ing controller 🞉 HINT AeroDR Detector AeroDR Battery Charger/ AeroDR Battery Charger2 - (3) In Aero Sync mode, the AeroDR Generator Interface Unit is not used. ₽ Confirm that the AeroDR Detector is ready for use on the image processing controller. 46

Number	Item	Description	lcon
(1)	Item heading	Describes the titles of described content.	-
(2)	Operation procedure	The operating procedure is described in sequential numerical steps.	-
(3)	Hint	Describes important information.	HINT
(4)	Reference	Describes reference items. Refer to these as necessary.	Reference
-	Important items	Describes the important items for operation. Be sure to read them.	



Safety Precautions & Warnings

This chapter describes precautions and warnings

to ensure safe use of this device.

1.1 • Symbols relating to safety

1.1.1 Safety alert symbol



1.1.2 Warning notice (signal words)

Signal words indicate the degree of potential hazards in the use of the product.

Signal words include the following three types, which are used according to risk of damage caused by danger and the severity of damage.

/!\ DANGER

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

/!\ WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

/!\ CAUTION

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury. It may also be used to indicate hazardous situation where only physical damage is likely to occur.

1.1.3 **Description of graphic** symbols



Indicates the on position for the main power switch of this device.

Indicates the position where the ground is attached.



Indicates a B-type Applied Parts medical device.



Indicates that full caution is required when handling this device.



Indicates that it is necessary to read the User's Manual before use or operation of this device.



Indicates devices including radio frequency transmitters.

It means conformity with the Medical De-**C € 0197** vices Directive 93/42/EEC.

0197 is Notified Body number. It means conformity with the Radio

Equipment and Telecommunications **(()** Terminal Equipment Directive 1999/5/ EC. And the alert sign (!) means that is categorized Class 2 radio equipment.

1.2 • Warning labels

Various warning labels are attached to this device on the locations shown below. Do not remove these labels from this device. Warning labels are there to make sure that the user recognizes potential hazards when operating this device.

* If a warning label is too dirty or damaged to read, contact Konica Minolta technical representatives to have a new warning label attached, and redisplay by parts replacement. (There is a fee for this service.)

1.2.1 AeroDR Detector



1.2.2 AeroDR Battery Charger



1.2.3 AeroDR Battery Charger2



1.3 • Safety precautions

Read all safety precautions thoroughly before using this device.

Be sure to observe the safety precautions described in this section.

1.3.1 Precautions before usage

- The operators (hospitals and clinics) hold responsibility for the usage and maintenance of this device.
 Do not use this device unless you are a physician or certified person under law.
- This device excluding the image processing controller is suitable for use in the patient environment. (PC used for the image processing controller is not suitable for use in the patient environment.)
- Confirm that this device is operating normally before using.
- When a problem occurs with this device, turn the power off, attach an appropriate sign, such as "malfunction", on this device, and contact Konica Minolta technical representatives.
- This device is not explosion-proof, so do not use any flammable or explosive gas near this device.
- For the basic operation of the computer, display monitor, and optional parts for this device, refer to their operation manuals.
- Please follow the rules and regulations of your relevant authorities in the disposal of this product, accessories, options, consumables, media and their packing materials.



For EU member states only

This symbol means: Do not dispose of this product together with your household waste!

Please refer to the information of your local community or contact our dealers regarding the proper handling of end-of-life electric and electronic equipments.

Recycling of this product will help to conserve natural resources and prevent potential negative consequences for the environment and human health caused by inappropriate waste handling.

1.3.2 Precautions for usage

- The AeroDR Detector is a precision instrument. If it is dropped or hit against any object, a failure may occur due to strong impact or excessive load.
- Take note of the following when using this device:
 Do not subject the AeroDR Detector to strong shocks or excessive loads by dropping it, etc.



- Do not exceed the specified overall load range when applying a load to an AeroDR Detector.
- Do not disassemble or modify this device.
- Do not connect any devices that were not purchased from Konica Minolta.
- Do not turn the power switch off or pull out the power cable while the system is operating.
- Be careful not to drop the AeroDR Detector on any part of a person's body by catching the AeroDR I/F Cable or AeroDR UF Cable on your feet.
- Do not lean on or put pressure on the AeroDR Battery Charger installed on a wall.
- The AeroDR I/F Cable and AeroDR UF Cable are connected to the AeroDR Detector using magnetic force. When moving the AeroDR Detector, do not hold onto the cable, and always hold on the AeroDR Detector. Also, do not grasp and pull the AeroDR Detector forcefully.



- If there is any smoke, odor, or abnormal sound, it may cause a fire if use is continued, so immediately turn the power switch off, unplug the power plug from the wall outlet, and contact Konica Minolta technical representatives.
- Take note of the following to reduce the risk of fire, electric shock, or electrical leakage:
 - Use specified cables for the power cable, etc.
 - Use a wall outlet with the correct rating as a power source.
 - Connect the power plug to the wall outlet properly without any slack.
 - Use a grounded power source.
 - If you do not plan to use this device for an extended period of time, unplug the power plug.
 - The supplied power cable is dedicated for this device, so do not use it elsewhere.
 - Avoid exposure to liquid such as water.
 - Make sure that foreign material, such as pieces of metal or wire, does not get inside.
 - Do not allow any metal or conductive objects to come into contact with the spring connector of the AeroDR I/F Cable, AeroDR UF Cable or AeroDR Battery Charger2.
 - Do not handle the power plug with wet hands.
 - Do not let soil or dust accumulate on the power plug, AeroDR I/F Cable, AeroDR UF Cable or AeroDR Battery Charger2.
 - Do not use extension cords.
 - Do not connect many plugs to a single electrical outlet.
 - Do not damage the power cable, AeroDR I/F Cable, or AeroDR UF Cable. Also, do not use damaged cables.
 - Do not block the ventilation openings.
- If there is any abnormality in appearance such as deformation of the housing or a crack, stop using the device immediately and contact Konica Minolta technical representatives.

- Take note of the following when using this device:
 - Do not use devices that emit electromagnetic waves such as high-frequency therapy equipment, mobile phones, or pocket pagers, close to this device.
 - Take note of the reception status for radios and TVs near this device, since interference may occur in them when this device is in use.
 - Use under the specified environmental conditions. Failure to do so may result in degradation of performance or malfunction.
 - Limit continuous use in a hot and humid environment (35 to 37°C/95% or lower) of an incubator to within 25 minutes.
 - Do not insert the AeroDR 1012HQ into the Aero-DR Battery Charger because the charger cannot be used for registration or charging the battery.

- Take the following notes when using the AeroDR Detector:
 - Use the AeroDR Detector on a flat base. If the AeroDR Detector is placed on a sloping surface and subjected to a load, its internal sensor may be damaged.







- When laying the patient onto the AeroDR Detector during positioning, do so very slowly.
- When placing the AeroDR Detector under the patient as part of the exposure process, insert and pull out the detector slowly.
- Use the recommended adapter when you need to perform exposure on a stretcher or a place where load is to be applied locally.

The AeroDR Detector is not waterproof. If it is exposed to or immersed in patients' body fluids, chemicals, water, or other liquids, such liquids may enter the instrument through exterior gaps, causing a failure. Be sure to use a vinyl sheet or other material to cover or wrap the AeroDR Detector when it is possible that the AeroDR Detector may be exposed to patients' body fluids, chemicals, water, or other liquids.



- Never leave AeroDR Detectors in hot and humid environments for long periods of time.
- The AeroDR Detector has wireless antennae positioned at 2 places. Do not block them with the body or metal because that will interfere with, disconnect or slow down wireless communication.
- Pressing the power switch causes each LED (green, orange, blue) to light temporarily or flash. After this, only green begins to flash in a slow cycle. Please check the lighting or flashing of each color once.
- The battery capacity is designed to allow the life period calculated based on the standard usage of the AeroDR Detector. It can be replaced with a new battery for a fee if replacement is necessary after the warranty period due to battery breakdown or decrease in capacity.
- Check that the buzzer sounds when the AeroDR Detector is inserted into the AeroDR Battery Charger/AeroDR Battery Charger2. Also, check that the LED is in the charge status.
- Be careful not to get your hand caught when setting the AeroDR Detector into the AeroDR Battery Charger/AeroDR Battery Charger2.

 If the AeroDR Detector is inserted into the Aero-DR Battery Charger/AeroDR Battery Charger2, make sure that the AeroDR Battery Charger/ AeroDR Battery Charger2 will not tip over due to any shock applied to the AeroDR Detector.



- The AeroDR Detector is precision equipment, and therefore impact or vibration during radiography or image transfer may affect the image quality. Be careful when handling the AeroDR Detector during and just after radiography.
- Never leave AeroDR Detectors around heat generators such as electric carpet.
- Do not damage or deform the AeroDR Detector; doing so may have an effect on exposed images, or lead to injury.
- When using the AeroDR I/F Cable or AeroDR UF Cable, observe the following:
 - Remove the cable by holding the connector housing.
 - Do not let the cable get pinched by doors and do not place heavy objects on it.
 - Do not bend or pull the cable excessively.
 - Make sure that the cable is properly connected to the AeroDR Detector without wobbling.
 - Do not connect the connector housing backwards.
- Do not sit on or put your feet on the AeroDR Battery Charger/AeroDR Battery Charger2.

- Take note of the following if the AeroDR Detector is damaged and fluorescent medium or lead is exposed:
 - Immediately stop using the device, and contact Konica Minolta technical representatives.
 - If the fluorescent medium gets in your eyes, do not rub and instead wash with running water immediately.
 - If you have swallowed any of the fluorescent medium or if the fluorescent medium has gotten into your eyes, administer first-aid treatment immediately, and consult a doctor.
 - If the medium comes into contact with your skin directly, wash the affected area thoroughly with water.
 - Use and store in a location inaccessible to children.
- When the AeroDR Detector is used for exposure, pay attention to the following items.
 - Start exposure after confirming on the display of the image processing controller that the machine is ready for exposure.
 - Perform exposure under the X-ray imaging conditions that has been confirmed by us.
 - Use the specified grid to perform exposure.
 - Apply the specified operation methods to use the grid.
 - Do not let the AeroDR Detector vibrate or receive shock until the preview image is displayed.
- · Precautions when performing exposure in
- Aero Sync mode.
- Confirm that the image processing controller is ready for exposure through its display before performing exposure.
- Confirm that a confirmation is sounded from the image processing controller after the start of exposure.
- Do not let the AeroDR Detector vibrate or receive shock until the preview image is displayed.
- Confirm that the AeroDR Detector's battery level is full before performing exposure.
- Use the system under the exposure condition confirmed prior to exposure.
- When setting the maximum exposure time to 4.0, 6.7, 10.3, be sure to contact Konica Minolta technical representatives.

1.3.3 Precautions regarding electromagnetic waves

EMC Statement

This device has been tested and found to comply with the limits for medical devices in IEC 60601-1-2: 2007.

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in its vicinity. However, there is no guarantee that interference will not occur in a particular installation.

Whether this device does cause harmful interference to other devices can be determined by turning this device off and on. If it causes harmful interference, the user is encouraged to try to correct the interference by 1 or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the devices.
- Connect this device into a wall outlet on a circuit different from that to which the other devices are connected.
- Contact Konica Minolta technical representatives.

- Supplementary information regarding IEC 60601-1-2: 2007
- Take precautions against this device especially regarding EMC. Install and put into service according to the electromagnetic compatibility (EMC) information provided in the manual (Table 1 - Table 4).
- (2) Do not use mobile phones or pocket pagers in the vicinity of this device. Use of mobile phones or pocket pagers near this device can cause errors in operation due to electromagnetic wave interference, so such devices should be turned off in the vicinity of this device.
- (3) Cable list
 - Power cable (3.048m/3-Wire/No Shielding)
 - Ethernet cable (max 100m/100 BASE-TX)
 - Ethernet cable (PoE) (30m/No Shielding)
 - Various AeroDR I/F Cables
 - Various AeroDR UF Cables
 - AeroDR Collimator Cable Set
 - Various AeroDR XG Cable Sets
- (4) The use of accessories, transducers and cables other than those sold by Konica Minolta, Inc. as internal components, may result in increased emissions or decreased electromagnetic immunity of this device.
- (5) Do not use this device adjacent to or stacked with other devices. If adjacent or stacked use is necessary, confirm normal operation in the configuration in which this device will be used.
- (6) Specifications regarding RF transmitters frequency:
 - Frequency: 2412 to 2472 MHz
 - 5180 to 5320 MHz, 5500 to 5825 MHz
 - Modulation: 2412 to 2472 MHz: DSSS/CCK/OFDM 5180 to 5320 MHz, 5500 to 5825 MHz: OFDM
 - Maximum effective radiation power: +10 dBm
 - This device may be interfered with by other devices that conform to CISPR emission requirements.

1.3 Safety precautions

Table 1

Guidelines and manufacture's declaration - electromagnetic emissions				
This device is intended for use in the electromagnetic environment specified below.				
The customer or the user	of this device sh	ould assure that it is used in such an environment.		
Emissions test	Electromagnetic environment - guidelines			
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.		
RF emissions CISPR 11	Class B			
Harmonic emissions IEC 61000-3-2	Class A	This device is suitable for use in all establishments including the following: Domestic establishments and those directly connected to the public low-		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	voltage power supply network that supplies buildings for domestic purposes.		

Table 2

Guidelines and manufacturer's declaration - electromagnetic immunity				
This device is intended for use in the electromagnetic environment specified below.				
The customer or the user	of this device should assur	re that it is used in such an	environment.	
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines	
Electrostatic discharge (ESD)	± 6 kV contact	± 6 kV contact	Floors should be wood, concrete or	
IEC 61000-4-2	± 8 kV air	± 8 kV air	ceramic tile. If floors are covered with	
Electrical fast transient/	± 2 kV for power supply lines	± 2 kV for power supply lines	should be at least 30%. Mains power guality should be that of a typical com-	
IEC 61000-4-4	± 1 kV for input/output lines	± 1 kV for input/output lines	mercial or hospital environment.	
Surge	± 1 kV differential mode	± 1 kV differential mode	Mains power quality should be that of a	
IEC 61000-4-5	± 2 kV common mode	± 2 kV common mode	typical commercial or hospital environ- ment.	
Voltare dire chart	<5% U $_{\rm T}$ (>95% dip in U $_{\rm T}$) for 0.5 cycle	<5% U _T (>95% dip in U _T) for 0.5 cycle	Mains power quality should be that of a	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	40% U _T (60% dip in U _T) for 5 cycles	40% U _T (60% dip in U _T) for 5 cycles	typical commercial or hospital environ- ment. If the user of the device requires	
	70% U _T (30% dip in U _T) for 25 cycles	70% U _T (30% dip in U _T) for 25 cycles	interruptions, it is recommended that the	
	<5% U $_{\rm T}$ (<95% dip in U $_{\rm T})$ for 5 sec	<5% U $_{\rm T}$ (<95% dip in U $_{\rm T})$ for 5 sec	power supply or a battery.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical lo- cation in a typical commercial or hospital environment.	
[NOTE] U_T is the AC mains voltage prior to application of the test level.				

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Table 3

Guidelines and manufacturer's declaration - electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below.			
The customer or the us	er of this device should	assure that it is	used in such an environment.
Immunity test	IEC 60601	Compliance	Electromagnetic environment - guidelines
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz [3] V 3 Vrms 150 kHz [3] V 3 Vrms 150 kHz [3] V 13 Vrms 150 kHz [3] V 150 kHz [3] V/m 160 kHz [3] V/m 170 kHz [3] V/m 170 kHz [3] V/m 170 kHz [3] V/m 160 kHz [3] V/m 170 kHz [3] V/m 170 kHz [3] V/m 170 kHz [3] V/m 170 kH		
			with the following symbol:
 [NOTE] At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. [NOTE] These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. 			
 a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this device. b Over the frequency range 150 kHz to 80 MHz, field strength should be less than [3] V/m. 			

1.3 Safety precautions

Table 4

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

Patod maximum output	Separation distance according to frequency of transmitter			
nower of the transmitter	m			
W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
	d=[1.2] √P	d=[1.2] √P	d=[2.3] √P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	8	
100	12	12	23	

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

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

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

1.3.4 Precautions regarding wireless communication

- This device is equipped with a communication function that operates via wireless LAN. Conformance is required with the relevant regulations defined by the countries in which this device is to be used.
- Inappropriate usage may cause interference in radio communication. Also, if this device is modified, approval and warranty according to the radio law of the applicable government will be voided.
- It may affect aeronautical systems, so do not use on-board airplanes.
- This device may be affected by other wireless devices. Make sure that the environment is free of wireless communications.
- AeroDR Detector has been confirmed to comply with the relevant regulations of the following countries:

United States & Canada

Federal Communications Commission Statement / Canadian Department of Communications

- AeroDR Detector complies with Part 15 of FCC Rules and Industry Canada licenseexempt RSS standard(s). Operation is subject to the following 2 conditions:(1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of this device.
- This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.
- 5.15-5.35 GHz band is restricted to indoor operations only.
- The available scientific evidence does not show that any health problems are associated with using low power wireless devices. There is no proof, however, that these low power wireless devices are absolutely safe. Low power Wireless devices emit low levels of radio frequency energy (RF) in the micro-wave range while being used. Whereas high levels of RF can produce health effects (by heating tissue), exposure of low-level RF that does not produce heating effects causes no known adverse health effects. Many studies of low-level RF exposures have not found any biological effects. Some studies have suggested that some biological effects might occur, but such findings have not been con-firmed by additional research. AeroDR Detec-tor has been tested and found to comply with FCC/IC radiation exposure limits set forth for a controlled equipment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the IC radio frequency (RF) Exposure rules.
- High-power radars are allocated as primary users (i.e. priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices.

 Compliance with FCC requirement 15.407(c): Data transmission is always initiated by software, which is the passed down through the MAC, through the digital and analog baseband, and finally to the RF chip.

Several special packets are initiated by the MAC. These are the only ways the digital baseband portion will turn on the RF transmitter, which it then turns off at the end of the packet. Therefore, the transmitter will be on only while one of the aforementioned packets is being transmitted. In other words, this device automatically discontinue transmission in case of either absence of information to transmit or operational failure.

• Compliance with FCC requirement 15.407(g): Frequency Tolerance: 20ppm

FCC WARNING

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

European Union

European Union Directives Conformance Statement

AeroDR Detector conforms with the Declaration of Conformity (DoC) to Directive 1999/5/ EC (to R&TTE Directive). This device purposely connects to an access point of a 5 GHz network.

AeroDR Detector is used for the following countries indicated by country code (ISO3166 2-letter code).

AT	BE	BG	CY	CZ	DK
EE	FI	FR	DE	GR	HU
IE	IT	LV	LT	LU	MT
NL	PL	PT	RO	SK	SI
ES	SE	GB	IS	LI	NO
СН					

Taiwan

Observe the following based on the regulations stated in Article 10 of Administration Measures for Low-power Radiation Electric Machines.

Article 12

As for type-approval qualified low-power radiofrequency generator, no company, firm, or user may arbitrarily change the frequency, increase the power or alter the function or characteristics of the original design without prior permission.

Article 14

The use of low-power radio-frequency electric machines shall not affect air flight safety or disturb lawful communication. If disturbance is found, the use of such electric machines shall be suspended immediately and such use shall not be resumed until the disturbance is eliminated.

Lawful communication mentioned in the preceding paragraph refers to wireless communication operation in accordance with the provisions of the Telecommunication Law.

Low-power radio-frequency electric machines shall tolerate disturbance from lawful communication or from radio-wave radiation electric machine for industrial, scientific or medical use.

China

- Clearly indicate the technical indicators and the scope of usage in the accompanying document, and explain the usage of all controls, adjustments, and switches, etc.
 - Operating frequency range: 5725-5850 MHz
 - Transmit power: ≤500 mW and ≤27 dBm
 - Equivalent isotropic radiated power (EIRP): ≤2 W and ≤33 dBm
 - Maximum radiation power density: ≤13 dBm/MHz and ≤19 dBm/MHz (EIRP)
 - Frequency Tolerance limit: 20 ppm
 - Transmit power at the band edge (EIRP): ≤80 dBm/Hz (≤5725 MHz or ≥5850 MHz)
 - Spurious emissions:
 ≤-36 dBm/100 kHz (30-1000 MHz)
 ≤-40 dBm/1 MHz (2400-2483.5 MHz)
 ≤-40 dBm/1 MHz (3400-3530 MHz)
 ≤-33 dBm/100 kHz (5725-5850 MHz)
 (Note: Other than ±2.5-times supported channel bandwidth)
 ≤-30 dBm/1 MHz (Other 1-40 GHz)
- 2. Do not arbitrarily change frequency or increase transmit power (including the added radio frequency amplifier). In addition, do not mount an antenna without permission, or change to another transmission antenna.
- When in use, do not cause harmful interference in other legal wireless communication services. If you find interference to be occurring, discontinue use immediately. After taking measures to eliminate interference, you may continue using the device.
- 4. If you use low power radio equipment, you must accept interference from various wireless services or radiation interference from industrial, scientific and medical application equipment.
- 5. Do not use near a plane or an airport.

South Korea

Because this wireless equipment may be affected by radio interference, it cannot provide services related with life safety.

Thailand

AeroDR Detector conforms to NTC technical requirement.

Brazil

This equipment operates secondarily, that is, it doesn't benefit from protection against harmful interference, even from stations of the same type, and cannot cause interference to systems that operate primarily.

AeroDR Detector has been approved by ANA-TEL in compliance with the procedures regulated by Resolution 242/2000 and complies with the applicable technical requirements.

For more information, please visit: http://www.anatel.gov.br

Mexico

This equipment operates on a secondary basis; consequently, you must accept harmful interferences from equipment of the same type, and cannot cause interferences to systems operating on a primary basis.

1.3.5 Precautions for installing, moving, and storing

- Take note of the following when moving this device not including the AeroDR Detector:
 - Do not subject to shocks or vibration.
 - Do not start moving until the power is turned off, and operation has stopped completely.
- Do not move with the power cable or any other cable connected.
- When installing the AeroDR Battery Charger/AeroDR Battery Charger2 on a table top, observe the following:
 - Install on a base that can withstand maximum patient weight because load is inserted when setting the AeroDR Detector.
 - The contact area for the AeroDR Battery Charger/ AeroDR Battery Charger2 must be larger than the area of the AeroDR Battery Charger so that it will not fall down when the AeroDR Detector is set or when people touch it by accident.
- Install on a horizontal and stable surface.
- Do not use a base that has a surface made of slippery material such as teflon.
- Connect power cable and wires so that no one will trip.
- Install in a place easy to set the AeroDR Detector.
- Install so that the vent on the back side of the AeroDR Battery Charger2 is not blocked.

- Because connections of the X-ray device can only be made by Konica Minolta or its designated contractors, contact Konica Minolta or its designated contractors.
- Contact Konica Minolta or dealers specified by Konica Minolta to install or move this device.
- For the X-ray devices enabled to connect, contact Konica Minolta technical representatives.
- Since it is required to meet the specification provided by the X-ray device manufacturer to connect with an X-ray device, contact Konica Minolta or dealers specified by Konica Minolta.
- Take note of the following when installing or storing this device.
 - Do not install or store in a location where it may be adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, salt-air, or air containing sulfur.
 - Do not install or store in a location where it is not stable, ventilation is insufficient, the difference in light-dark is great, electromagnetic waves are generated, or where subject to vibration or shock.
- Do not install or store in a location where chemical agents are used or stored.
- Do not install this device facing up or upside down.
- Do not install the AeroDR Interface Unit, AeroDR Interface Unit2 and AeroDR Generator Interface Unit stacked on each other.



- Connect the AeroDR Interface Unit2/AeroDR Generator Interface Unit to an X-ray device that conforms to IEC 60601 or to an equivalent standard.
- Do not use access points other than those on this device.

1.3.6 Precautions regarding maintenance



- Perform the maintenance and inspection periodically. In addition to the user periodical maintenance that needs to be performed, periodical maintenance by a service engineer is also required.
- If there are stains such as body fluids, clean and disinfect.

- Based on the warranty, parts that are no longer under warranty (1 year) can be replaced for a fee.
- Turn off the power and disconnect the power plug from the wall outlet before cleaning or maintaining this device.
- Securely connect the power cable, AeroDR I/F Cable, and AeroDR UF Cable after cleaning and maintenance.
- Clean the dirt from between the protective cover and the exterior, and the terminal using a commercial plastic brush. Do not clean with sharp or hard objects.
- Take care regarding the following when disinfecting the AeroDR Detector.
 - Use ethanol for disinfection, isopropanol for disinfection, or commercial chlorine bleach, or 0.5% hypochlorite (10-fold dilution of household bleach) when disinfecting. However, bleach and hypochlorite are corrosive, so wash the bleach off well to avoid corrosion.

 If you directly apply or spray disinfecting solution on the AeroDR Detector, the solution will enter the instrument through exterior gaps, causing a failure. Dampen a lint-free, soft cloth with disinfecting solution, and use after wringing it thoroughly. Do not apply disinfecting solution onto the wired connection connector and LED when cleaning.



- Disinfecting solution is a chemical agent, so follow the precautions of the manufacturer.
- Fully charge battery once a month even if the Aero-DR Detector has not been used for a long time.

1.3.7 Precautions on service life

Service life

Name	Service life
AeroDR Detector	6 years
AeroDR Interface Unit	6 years
AeroDR Interface Unit2	6 years
AeroDR Generator Interface Unit	6 years
AeroDR Battery Charger	6 years
AeroDR Battery Charger2	6 years
AeroDR I/F Cable	6 years
AeroDR UF Cable	6 years

- The above service life is valid only if the product has been properly operated while following the precautions for use and performing the specified maintenance. (By self certification <our data>)
- The service life may differ depending on usage conditions and environment.
- Some component parts of this device are commercially available parts that have a short cycle of model changes, therefore, it might not be possible to supply service parts even within the service life. In addition, related component parts may need to be replaced to maintain compatibility at the time of model change.

1.3.8 Pediatric patients' use;

AeroDR System with P-31 does not have an X-ray generating function, and does not control X-ray generator unit.

AeroDR System with P-31 is used connecting with Xray generator unit currently used legally in the United States of America.

In case of using AeroDR System with P-31 for pediatric patients, please manage appropriately as pediatric patients receive the minimum necessary amount of Xray radiation for producing diagnostic quality images.

When using AeroDR System with P-31 for the pediatric patients, please connect only with an X-ray generator unit which has the radiation management function for the pediatric patients, and follow the instruction of X-ray generator unit for the pediatric patients.

For further assistance for the pediatric population includes neonates, please refer to the following Home Pages.

The Image Gently Back to Basics campaign materials; (http://www.pedrad.org/associations/5364/ig/?page=824)

FDA's Pediatric X-ray Imaging webpage; (http://www.fda.gov/Radiation-EmittingProducts/RadiationEmitting ProductsandProcedures/MedicalImaging/ucm298899.htm)

1.4 • R&TTE DECLARATION of CONFORMITY



DECLARATION of CONFORMITY For



Supplied by KONICA MINOLTA, INC. 1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan

Notified Body - R&TTE Directive

Product: AeroDR SYSTEM Model:AeroDR P-11, AeroDR P-12, AeroDR P-21

Technical Construction File held by KONICA MINOLTA, INC. 1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan

N/A

EN 301 489-1 V1.8.1: 2008-04

EN 301 893 V1.5.1: 2008-12

EN 301 489-17 V2.1.1: 2009-05

Standard used for comply

R&TTE Directive (Article 3.1(a) Safety) EN60950-1:2006 + Amd.11:2009 + Amd.1:2010 + Amd.12:2011 EN 62311: 2008 Exposure limit: 1999/519/EC

R&TTE Directive (Article 3.1(b) EMC)

R&TTE Directive (Article 3.2 Spectrum)

Means of Conformity

We declare under our sole responsibility that the Product (s) is conformity with the essential requirements and other relevant requirements of the Radio and Telecommunication Terminal Equipment (R&TTE) Directive (1999/5/EC).

Date of issue: April 1, 2013

Signature of Responsible Person:

R, Ushyanos

Hiroyuki Ushiroyama Manager Quality Assurance Center

The essentials of imaging





DECLARATION of CONFORMITY For



Supplied by KONICA MINOLTA, Inc. 1 Sakura-machi, Hino-shi, Tokyo, Japan 191-8511 Product: AeroDR SYSTEM Model: AeroDR P-31

Technical Construction File held by KONICA MINOLTA, Inc. 1 Sakura-machi, Hino-shi, Tokyo, Japan 191-8511

Notified Body - R&TTE Directive

N/A

R&TTE Directive (Article 3.1(a) Safety) **Standard used for comply** EN 60950-1: 2006 + Amd.11: 2009 + Amd.1: 2010 + Amd.12: 2011 EN 62311: 2008

R&TTE Directive (Article 3.1(b) EMC)

R&TTE Directive (Article 3.2 Spectrum) EN 301 489-1 V1.9.2: 2011 EN 301 489-17 V2.2.1: 2012

EN 301 893 V1.6.1: 2011-11

Means of Conformity

We declare under our sole responsibility that the Product (s) is conformity with the essential requirements and other relevant requirements of the Radio and Telecommunication Terminal Equipment (R&TTE) Directive (1999/5/EC).

Date of issue: July 16, 2013

Signature of Responsible Person:

Willace

Hiroyuki Ushiroyama General Manager Quality Assurance Operations

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Product Overview

This chapter describes the overview of this device.

2.1 • Overview of this device

This section describes the functions of this device as well as a system configuration and connection examples using this device.

2.1.1 Functions

This device consists of AeroDR Detector, AeroDR Interface Unit/AeroDR Interface Unit2, AeroDR Generator Interface Unit, AeroDR Battery Charger/AeroDR Battery Charger2, Access Point, etc. With the AeroDR Detector, diagnostic X-ray digital image data is generated by the irradiation signal and exposure from an X-ray device, and sent to the image processing controller.

Furthermore, the AeroDR Detector can be connected with (or inserted in) an AeroDR Interface Unit/AeroDR Interface Unit2 or AeroDR Battery Charger/AeroDR Battery Charger2 or removed from them.

2.1.2 System configuration and connection examples

The system configuration and connection examples are as follows.

• Basic configuration example

Number	Name	Functions
(1)	AeroDR Detector	 There are 4 types of AeroDR Detectors: AeroDR 1417HQ, AeroDR 1417S, AeroDR 1717HQ, AeroDR 1012HQ and AeroDR II 1417HQ. AeroDR Detector is of B-type Applied Parts.
(2)	AeroDR Interface Unit	 Supplies power to the AeroDR Generator Interface unit and the Access Point, and supplies power to the AeroDR Detector and charges the battery of the AeroDR Detector when an AeroDR I/F Cable or AeroDR UF Cable is used. 4 AeroDR Detectors can be connected via wireless connection and 2 via wired connection. The expansion AeroDR Interface Unit is required for connecting the third and fourth AeroDR Detectors via wired connection.
(3)	AeroDR Interface Unit2	 Supplies power to the Access Point, and supplies power to the AeroDR Detector and charges the battery of the AeroDR Detector when an AeroDR I/F Cable or AeroDR UF Cable is used. 4 AeroDR Detectors can be connected via wireless connection and 2 via wired connection. The expansion AeroDR Interface Unit is required for connecting the third and fourth AeroDR Detectors via wired connection. Relays signals between the X-ray device, the AeroDR Detector, and the image processing controller.
(4)	AeroDR Generator Interface Unit *1	Relays signals between the X-ray device, the AeroDR Detector, and the image processing controller.
(5)	AeroDR Battery Charger *1	Charges the AeroDR Detector. It also has the registration function for the AeroDR Detector. • The AeroDR 1012HQ cannot be charged and registered using the AeroDR Battery Charger.
(6)	AeroDR Battery Charger2 *1	Charges the AeroDR Detector. It also has the registration function for the AeroDR Detector.
(7)	Access Point *1	Used for wireless connection with the AeroDR Detector. *2
(8)	AeroDR I/F Cable	Used for wired connection with the AeroDR Detector. Also used for charging and registering the AeroDR Detector.
(9)	AeroDR UF Cable *1	Used when the AeroDR Detector is set in the wall stand or table.
(10)	Image processing controller	Controls the reception, management, and output of this device's image data.
(11)	AeroDR XG Cable *1	Performs signal relay between the X-ray device and the AeroDR Generator Interface Unit.
(12)	AeroDR Collimator Cable *1	Performs exposure field signal relay between the X-ray device and the AeroDR Generator Interface Unit.
(13)	AeroDR S-SRM Cable *1	Performs signal relay between the X-ray device operation panel and the AeroDR Generator Interface Unit.
(14)	S-SRM *1	Synchronizes AeroDR Generator Interface Unit and X-ray device simply. Exposure is performed using the AeroDR Generator Interface Unit.

*1 Optional product.

*2 The Access Point can also be used with commercial items.

Exposure room Wired connection Wireless connection (1) AeroDR Detector (1) AeroDR Detector X-ray device 🔹 X-ray [[Tub 4 (9) AeroDR UF Cable Wall stand (8) AeroDR (7) Access Point I/F Cable (11) AeroDR XG Cable (12) AeroDR Collimator Cable 1 5 (5) AeroDR Battery Charger (2) AeroDR Interface Unit (4) AeroDR Generator Interface Unit - Signal relay 0 ····· Power supply Hub X-ray device operation panel (10) Image processing controller

Basic connection example 1

Basic connection example 2







• S-SRM connection example 1







2.2 • Component names and functions

2.2.1 AeroDR Detector



2.2.2 AeroDR Interface Unit



The component names and functions of the AeroDR Interface Unit are as follows.

Number	Name	Functions
(1)	Top cover	Protects the internal parts.
(2)	Side cover	Protects the internal parts.
(3)	Power switch	Turns the AeroDR Interface Unit on/off.
(4)	Rear cover	Protects the internal parts.
(5)	Exhaust outlet	Exhausts internal heat.
(6)	Front cover	Protects the internal parts.
(7)	LEDs	 Displays the status of the AeroDR Interface Unit. Reference For the display patterns and status of the LEDs, refer to "4 Status (LED) Display".
(8)	Cable outlet	Outlet for various cables.
(9)	Spacer	Prevents exhaust outlet from being blocked after installation.

2.2.3 AeroDR Interface Unit2

The component names and functions of the AeroDR Interface Unit2 are as follows.



Number	Name	Functions
(1)	Exhaust outlet	Exhausts internal heat.
(2)	Top cover	Protects the internal parts.
(3)	Detector Connection LEDs	 Displays the status of the AeroDR Interface Unit2. Reference For the display patterns and status of the LEDs, refer to "4 Status (LED) Display".
(4)	Power switch	Turns the AeroDR Interface Unit2 on/off.
(5)	Rear cover	Protects the internal parts.
(6)	Side cover	Protects the internal parts.
(7)	Spacer	Prevents exhaust outlet from being blocked after installation. *No spacers may be provided on some side covers that will not come in con- tact with walls.
(8)	Front cover	Protects the internal parts.
(9)	Generator Interface LEDs	 Displays the status of the AeroDR Interface Unit2. Reference For the display patterns and status of the LEDs, refer to "4 Status (LED) Display".
(10)	Cable outlet	Outlet for various cables.
(11)	Hand switch	When S-SRM connection is adopted, a hand switch is installed in the AeroDR Interface Unit2.

2.2.4 AeroDR Generator Interface Unit



The component names and functions of the AeroDR Generator Interface Unit are as follows.

Number	Name	Functions
(1)	Top cover	Protects the internal parts.
(2)	Side cover	Protects the internal parts.
(3)	Rear cover	Protects the internal parts.
(4)	Exhaust outlet	Exhausts internal heat.
(5)	Front cover	Protects the internal parts.
(6)	LEDs	 Displays the status of the AeroDR Generator Interface Unit. Preference For the display patterns and status of the LEDs, refer to "4 Status (LED) Display".
(7)	Cable outlet	Outlet for various cables.
(8)	Spacer	Prevents exhaust outlet from being blocked after installation.
(9)	Hand switch	When S-SRM connection is adopted, a hand switch is installed in the AeroDR Generator Interface Unit.

2.2.5 AeroDR Battery Charger

The component names and functions of the AeroDR Battery Charger are as follows.



Number	Name	Functions
(1)	Rear cover	Protects the internal parts.
(2)	Slide cover	Protects the internal parts, and prevents dust from getting inside the AeroDR Battery Charger.
(3)	Top cover	Protects the internal parts.
(4)	Side cover	Protects the internal parts.
(5)	Charge/registration label	When an AeroDR Battery Charger exclusively for charge is used, a label that distinguishes the AeroDR Battery Charger exclusively for charge from an AeroDR Battery Charger that is used for charge and registration is affixed.
(6)	AeroDR Detector insert table (front)	Guide for inserting the AeroDR Detector from the front.
(7)	AeroDR Detector insert table (side)	Guide for inserting the AeroDR Detector from the side.
(8)	LEDs	Indicates the status between the AeroDR Detector and the AeroDR Battery Charger. • For the display patterns and status of the LEDs, refer to "4 Status (LED) Display".
(9)	Front cover	Protects the internal parts.
(10)	Roller	Prevents external friction when you insert the AeroDR Detector.

2.2.6 AeroDR Battery Charger2



The component names and functions of the AeroDR Battery Charger2 are as follows.

Manuality	News	Prime Allowe
Number	Name	Functions
(1)	Connector cover	Protects the wired connection connector and prevents dust from entering inside it.
(2)	Wired connection connector	Connects to the wired connection connector of the AeroDR Detector.
(3)	Front insert guide	Protects the internal parts.
(4)	Stand	Protects the AeroDR Battery Charger2 from being overturned.
(5)	Front cover	Protects the internal parts.
(6)	Side cover (right)	Protects the internal parts.
(7)	Power switch	Used to turn the AeroDR Battery Charger2 on/off.
(8)	Inlet	Connects to the power cable of AeroDR Battery Charger2.
(9)	Rear insert guide	Protects the internal parts.
(10)	Rear cover	Protects the internal parts.
(11)	Side cover (left)	Protects the internal parts.
(12)	AeroDR Detector insert table	A guide for inserting the AeroDR Detector.
(13)	LEDs	Displays the status of the AeroDR Detector and AeroDR Battery Charger2. Reference • For the display patterns and status of the LEDs, refer to "4 Status (LED) Display".
(14)	LAN connector	Connects to the Ethernet cable.

2.2.7 Access Point

The component names and functions of the Access Point are as follows.



Number	Name	Functions
(1)	LEDs	Displays the status of the Access Point. For the display patterns and status of the LEDs, refer to "4 Status (LED) Display".
(2)	10/100BASE-T(X) RJ45 port	Used for connection to the AeroDR Interface Unit/AeroDR Interface Unit2.
(3)	Antenna port	Port to attach antenna.
(4)	Antenna	Receives wireless signal.

2.2.8 AeroDR I/F Cable

The component name and function of the AeroDR I/F Cable are as follows.



(1) Spring connector

Number	Name	Functions
(1)	Spring connector	Connects to the wired connection connector of the AeroDR Detector or AeroDR UF Cable.

2.2.9 AeroDR UF Cable

The component names and functions of the AeroDR UF Cable are as follows.



Number	Name	Functions
(1)	Spring connector	Connects to the wired connection connector of the AeroDR Detector.
(2)	Wired connection connector	Connects to the spring connector of the AeroDR I/F Cable.