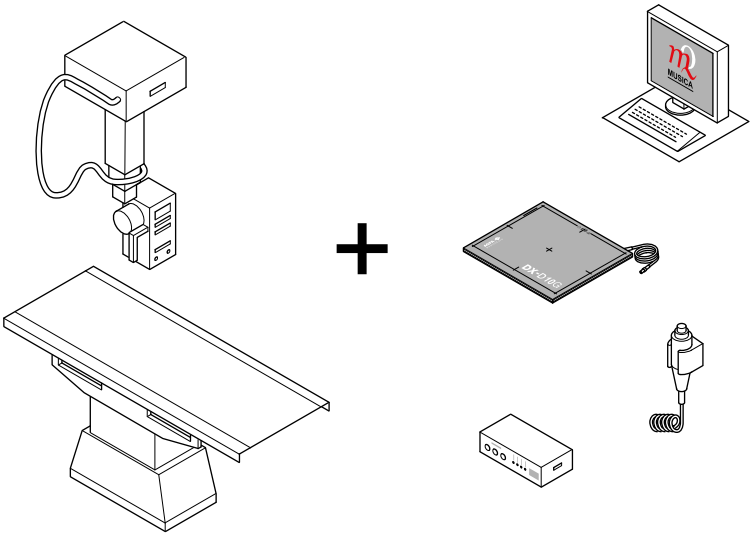
DR Generator Sync Box

5400/516

User Manual



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Legal Notice

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For more information on Agfa products, please visit medimg.agfa.com.

Published by Agfa NV

2640 Mortsel - Belgium.

Introduction to this Manual

Scope of this Manual

This manual contains information for safe and effective operation of the DR Generator Sync Box, further referred to as the device.

Warnings, Cautions, Instructions and Notes

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

Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a user, engineer, patient or any other person or can lead to a mistreatment.

Cautions are directions which, if they are not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.

This sign is typically used in combination with the warning sign when providing a specific instruction. If it is followed exactly, it should avoid the subject of the warning.

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

Disclaimer

Agfa assumes no liability for use of this document if any unauthorized changes to the content or format have been made.

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

Note In the United States, Federal law restricts this device on order of a physician for prescription use only.

Introduction

Intended Use

The DR Generator Sync Box is indicated for use as a component of the DR Retrofit Solution. The DR Generator Sync Box is making the connection between the DR detector, the MUSICA Acquisition Workstation and the X-ray generator.

Intended User

This manual is written for trained users of Agfa products. Users are considered as the persons who actually handle the equipment as well as the persons having authority over the equipment. Before attempting to work with this equipment, the user must read, understand, note and strictly observe all warnings, cautions and safety markings on the equipment.

Configuration

The DR Generator Sync Box synchronizes the exposure signal between the DR detector, the MUSICA Acquisition Workstation and the generator.

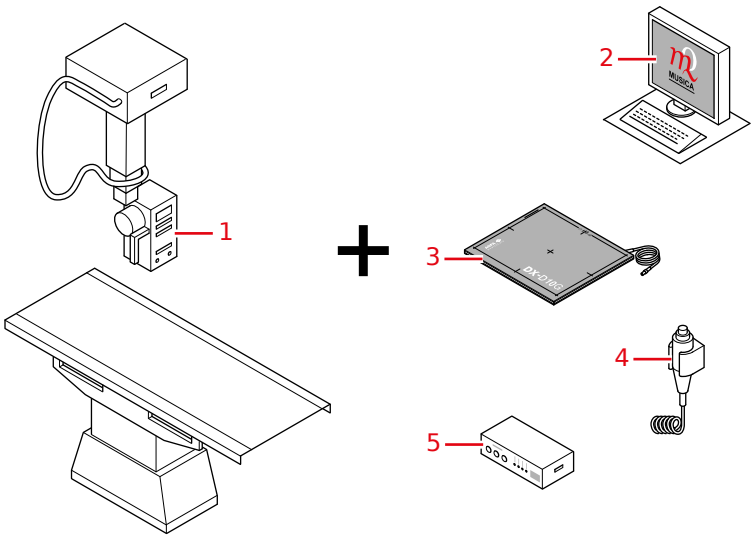
The DR Generator Sync Box supports two levels of integration with the X-ray system.

1. Integration of the exposure signal.
   - The exposure button of the X-ray system is removed or disabled and a new exposure button is connected to the DR Generator Sync Box.
2. Integration of X-ray exposure parameters.
   - The exposure button of the X-ray system is replaced by an exposure button connected to the DR Generator Sync Box.
   - X-ray parameters can be controlled using either the Software Console on the MUSICA Acquisition Workstation or the X-ray generator console of the X-ray system, depending on the configuration.

Maximum three exposure buttons can be connected to the DR Generator Sync Box. An exposure button can be a hand switch or a foot switch.

The Software Console is available on the MUSICA Acquisition Workstation and synchronizes the X-ray exposure parameters between the NX workstation and the generator.

Note Integration of X-ray exposure parameters is only supported on specific types of X-ray systems. Contact your local service representative for more information about the supported X-ray systems.



1. X-ray system
2. MUSICA Acquisition Workstation with NX application and DR Software Console or DR Detector Switch
3. DR Detector
4. Replacement exposure button
5. DR Generator Sync Box

Equipment Classification

This device is classified as following:

Table 1: Equipment classification

Class I equipment	Equipment in which protection against electric shock does not relay on basic insulation only, but includes a power supply cord with protective earth conductor. For earth reliability always plug the main power cord into an earthed mains power outlet.
Type B equipment	Not classified. The patient does not get in contact with any part of the equipment.
Water ingress	This device does not have protection against ingress of water.
Cleaning	See section on cleaning and disinfecting.
Disinfection	See section on cleaning and disinfecting.
Flammable anesthetics	This device is not suitable for use in the presence of a flammable anesthetic mixture with air, or in presence of a flammable anesthetic mixture with oxygen or nitrous oxide.
Operation	Continuous operation.

Related information

Cleaning and Disinfecting on page 18

Training

The user must have received adequate training on the safe and effective use of the system before attempting to work with it. Training requirements may vary from country to country. The user must make sure that training is received in accordance with local laws or regulations that have the force of law. Your local Agfa or dealer representative can provide further information on training.

The user must note the following information in the system documentation:

- Intended Use.
- Intended User.
- Safety Directions.

Product Complaints

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

For a patient/user/third party in the European Union and in countries with identical regulatory regimes (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Contact address:

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

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Compatibility

The system must only be used in combination with other equipment or components if these are expressly recognized by Agfa as compatible. A list of such equipment and components is available from Agfa service on request.

Changes or additions to the equipment must only be carried out by persons authorized to do so by Agfa. Such changes must comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction of the hospital.

Compliance

General

- The DR Generator Sync Box has been designed in accordance with Regulation (EU) 2017/745 on medical devices (MDR).
- IEC 62366
- ISO 14971

Safety

- IEC 60601-1
- AAMI ES 60601-1
- CSA C 22.2 No.60601-1

Electromagnetic Compatibility

- IEC 60601-1-2

Environmental Compliance

- European Council Directive 1907/2006 (REACH)
- European Council Directive 2011/65/EU (RoHS 2)
- European Council Directive 2012/19/EU (WEEE)

Connectivity

The DR Generator Sync Box is connected to the MUSICA Acquisition Workstation and the X-ray generator and replaces the interface to the original exposure button.

The DR Generator Sync exposure button is connected to the DR Generator Sync Box device.

On supported X-ray systems, the MUSICA Acquisition Workstation is connected to the X-ray system to exchange X-ray exposure parameters.

Note The connections between the components of the DR Generator Sync Box and towards the MUSICA Acquisition Workstation and the X-ray system should not be disconnected or modified.

The MUSICA Acquisition Workstation requires a 100 Mbit ethernet network to exchange information with a number of other devices.

The MUSICA Acquisition Workstation communicates with other devices in the hospital network using one of the following protocols:

- DICOM
- IHE

The MUSICA Acquisition Workstation can be connected to a RIS system (input scheduling), a PACS system (output image/data management) and to a hardcopy device (output image).

- Connectivity requirements on page 15

Related information

Configuration on page 8

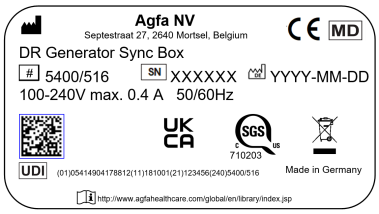
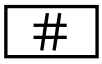
Connectivity requirements

Any kind of equipment connected to any interface must be certified according to the respective IEC standards (e.g. IEC 60950 / IEC 62368 for data processing equipment or IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the requirements for medical systems according to IEC 60601-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1. If in doubt, consult your local service organization.

Installation

Installation and configuration is performed by an Agfa trained and authorized service engineer. Contact your local support organization for more information.

Labels

 **Figure 1: Example of the type label**	The type label is located on the DR Generator Sync Box.
	In order to reduce the risk of electric shock, do not remove any covers.
	Date of manufacture
	Country of origin. The two character code on the actual label contains the country code defined in ISO 3166-1.
	Manufacturer
	Medical device
	Serial number
	Unique device identifier, in text format and in machine readable format
	Type and subtype number
	The most recent version of this document is available on http://www.agfahealthcare.com/global/en/library/index.jsp
	If the exposure button of the original system is visible, this label is attached. The user manual (this document) instructs not to use the exposure button of the original system.
	Earth (ground)

	Equipotential connector: Provides a connection between the equipment and the potential bus bar of the electrical system as found in medical environments. It is recommended to use the equipotential connection as additional safety measure.

Cleaning and Disinfecting

Cleaning and disinfecting procedures are described in the relevant modules of the device user documentation.

All appropriate policies and procedures should be followed to avoid contamination of the staff, patients and device. All existing universal precautions should be extended to avoid potential contaminations and to avoid patients coming into (close) contact with the device. Details about cleaning can be found in the following pages.

To clean the exterior of the equipment:

1. Switch off the device.
2. Remove the power plug of the socket.
3. Wipe the exterior of the device with a clean, soft, damp cloth. Use a mild soap or detergent if required but never use ammonia-based cleaner.

   Caution Make sure no liquid gets in the device.

   Note Do not open the equipment for cleaning. No components inside the device require cleaning by the user.
4. Plug the power plug into the socket.

Environmental protection

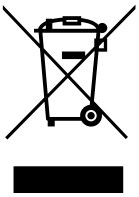


Figure 2: WEEE symbol

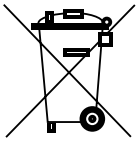


Figure 3: Battery symbol

WEEE end user notice

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

Due to the implementation into national law, specific requirements can be different within the European Member States. The WEEE symbol on the products, and/or accompanying documents means that used electrical and electronic products should not be treated as, or mixed with general household waste. For more detailed information about take-back and recycling of this product please contact your local service organization and/or dealer. The recycling of materials will help to conserve natural resources.

Caution: By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.

Battery notice

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

For battery replacements please contact your local sales organization.

Safety Directions

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

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

Warning: If the equipment is modified, appropriate inspection and testing is required to ensure continued safe use of the equipment.

Warning: To avoid risk of electric shock, do not remove any covers. Changes, additions, maintenance or repairs must be carried out by an Agfa certified field service engineer.

Warning: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Warning: To prevent unintended exposure, the position of the exposure footswitch should be such that it cannot be accidentally stepped on.

Warning: Use the replacement exposure button. The exposure button of the original system should be disabled.

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

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

- Disconnecting the DR Generator Sync Box from the mains power on page 20

Disconnecting the DR Generator Sync Box from the mains power

To disconnect the DR Generator Sync Box from the mains power, switch off the power switch or remove the power plug from the socket.

Technical Data

- DR Generator Sync Technical Data on page 20

DR Generator Sync Technical Data

Labeling	
Type	5400/516
Dimensions	
Depth	21.5 cm
Width	33.5 cm
Height	6.5 cm

Weight	3.2 kg	
Electrical connection	100-240 V AC, 50/60 Hz	
Power consumption	40 W (max. 0.4 A)	
Environmental conditions (operational)	min	max
Temperature	5 °C	35 °C
Relative air-humidity	20%	80%
Altitude	0 m (102 kPa)	3000 m (70 kPa)
Environmental conditions (storage and transport)	min	max
Temperature	-15 °C	50 °C
Relative air-humidity	20%	80%
Altitude	0 m (102 kPa)	3000 m (70 kPa)
Estimated product life	7 years	

Remarks for HF-emission and immunity

It is hereby certified that the DR Generator Sync Box has interference suppression according to the EN 55011 Class A as well as the FCC Rules CFR 47 Part 15 Class A.

This device was tested for a normal hospital environment as described above.

The user of the device should ensure that it is used in such an environment.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Warning: This device is intended for use by healthcare professionals only. This device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.

Warning: The HF-emission and immunity can be influenced by connected data cables depending on length and the manner of installation.

This device is intended for operation in the electromagnetic environment given below. The user of the device should ensure that it is used in such an environment.

RF Emission Measurements	Agreement	Electromagnetic Environment Guidelines

High frequency RF emissions in accordance with CISPR 11	Group 1	The device uses high frequency energy exclusively for its internal functions. For this reason, its high frequency RF emission is very low and it is improbable that neighboring electronic equipment will be disrupted.
High frequency RF emissions in accordance with CISPR 11	Class B	The DR Generator Sync Box is intended for use in all buildings, including living areas and areas directly connected to a public supply network that also supplies buildings that are used for domestic purposes.
Harmonic emission in accordance with IEC 61000-3-2	Class B	
Voltage fluctuations / flickering in accordance with IEC 61000-3-3	Complies	

The device is used in a professional healthcare / radiological environment. Environmental conditions are stated in the user manual.

This device was tested for a professional healthcare environment as described above. Nevertheless the HF-emission and immunity can be influenced by connected data cables depending on length and the manner of installation.

Resistance to Jamming Test	**Test level of professional medical equipment and basic EMC standards**	**Electromagnetic Environment Guidelines**
Discharge of static electricity in accordance with IEC 61000-4-2	± 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	Floors should consist of wood, concrete or ceramic tiles. The relative humidity must be at least 30%, if the floor is made of synthetic material.
Fast transient electrical disturbance variables / bursts in accordance with IEC 61000-4-4	± 2 kV mains ± 1 kV data lines	The quality of the voltage supplied should correspond to a typical commercial or clinical environment.
Impulse voltages (surges) in accordance with IEC 61000-4-5	± 1 kV line-line voltage ± 2 kV line-ground voltage	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage breakdown, short term interruptions and variations in the voltage supplied in accordance with IEC 61000-4-11	• 0% U_r for ½ period • 0% U_r for 1 period • 70% U_r (30% breakdown of U_r) for 25 periods at 0° • 0% U_r for 250 periods	The quality of the voltage supply should correspond to that of a typical commercial or clinical environment. If the user wants the device to work continuously, even when the energy supply is interrupted, it is recommended to use an energy supply free of interruptions or a battery.

Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m	Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment.
REMARK : U_r is the alternating current in the network_before the application of the test level.		

This device is intended for operation in the electromagnetic environment given below. The user of the device should ensure that it is used in such an environment.

Tests of Resistance to Disruption	**Test level of professional medical equipment and basic EMC standards**	**Electromagnetic Environment** Recommended protective distance:
Conducted high frequency disturbance variables in accordance with IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V within ISM bands	
Radiated high frequency disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	
RF communication	Refer to the section "Immunity to RF wireless communication equipment"	
		Disruptions are possible near devices that carry the following symbol: 

The field strength of stationary transmitters, such as base stations of radio telephones, mobile broadcasts for rural areas, amateur stations, and AM and FM radio transmitters, cannot be precisely predetermined theoretically. An investigation of the location is recommended, to ascertain the electromagnetic environment as a result of stationary high frequency transmitters. If the field strength of the device exceeds the test level given above, the device must be observed with regard to its normal operation at each place of use. In case of unusual performance characteristics, it can be necessary to take additional measures, such as the re-orientation of the device, for example.

This device is intended for operation in an electromagnetic environment in which the radiated high frequency disturbance variables are monitored. The user of the device can help to prevent electromagnetic disruptions by maintaining the minimum distances between portable and mobile high frequency communication equipment (transmitters) and the device as recommended below, in accordance with the maximum output power of the communications equipment. See also the section with precautions on EMC.

Recommended Protective Distances between Portable and Mobile High Frequency Communication Equipment and the Device

Rated Power of the Transmitter W	Protective Distance in accordance with RF emission Frequency m		
	150 kHz to 80 MHz $d = 1.0 \sqrt{P}$	80 MHz to 800 MHz $d = 0.3 \sqrt{P}$	800 MHz to 2.7 GHz $d = 0.3 \sqrt{P}$
0.01	0.1	0.05	0.05
0.1	0.32	0.1	0.1
1	1.0	0.3	0.3
10	3.2	1.0	1.0
The distance can be determined through the equation for each respective column. P is the rated power of the transmitter in watts (W) according to the manufacturer information on the transmitter, only for transmitters where the rated power is not mentioned in the above table. REMARK : These Guidelines may not be relevant in all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people.			

- Immunity to RF wireless communication equipment on page 25
- Precautions on EMC on page 26
- Cables, transducers and accessories on page 27
- Maintenance on EMC relevant parts on page 27

Immunity to RF wireless communication equipment

ISM Band (MHz)	**Service**	**Distance (m)**	**Immunity test level (V/m)**
300-390	TETRA 400	0.3	27
430-470	GMRS 460; FRS 460	0.3	28
704-787	LTE Band 13, 17	0.3	9
800-960	GSM 800/900; TETRA 800, IDEN 820; CO-MA 850; LTE Band 5	0.3	28
1700-1990	GSM 1800; COMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	0.3	28
2400-2570	Bluetooth; WLAN; 802.11 b/g/n; RFID 2450; LTE Band 7	0.3	28
5100-5800	WLAN 802.11 a/n	0.3	9

Precautions on EMC

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning: The DR detectors might be interfered with by other equipment.

Cables, transducers and accessories

Cables, transducers and accessories which were tested and found to comply with the collateral standard IEC60601-1-2 (EMC):

Caution: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

from	to	type	maximum length	remark
Wall outlet	DR Generator Sync box	3 x AWG18 un-shielded	3 m	mains supply cable
Exposure button	DR Generator Sync box	AWG21 unshielded	1.5 m	
PC	DR Generator Sync box	CAT 5e shielded	5 m	ethernet
PC	DR Generator Sync box	USB shielded	5 m	
DR Detector	DR Generator Sync box	10*0.25 mm^2 (AWG23)	16 m	extension cable for DR Detector
X-ray generator control box	DR Generator Sync box	10*0.25 mm^2 (AWG23)	5 m	extension cable for the console
X-ray generator control box	X-ray generator	10*0.25 mm^2 (AWG23)	16 m	extension cable for the generator

The system needs to be installed and put into service according to the EMC information provided (shielded cables).

Maintenance on EMC relevant parts

Concerning the EMC safety of the DR Generator Sync Box, no relevant parts could be inspected by the operator or by a service engineer before the end of lifetime.