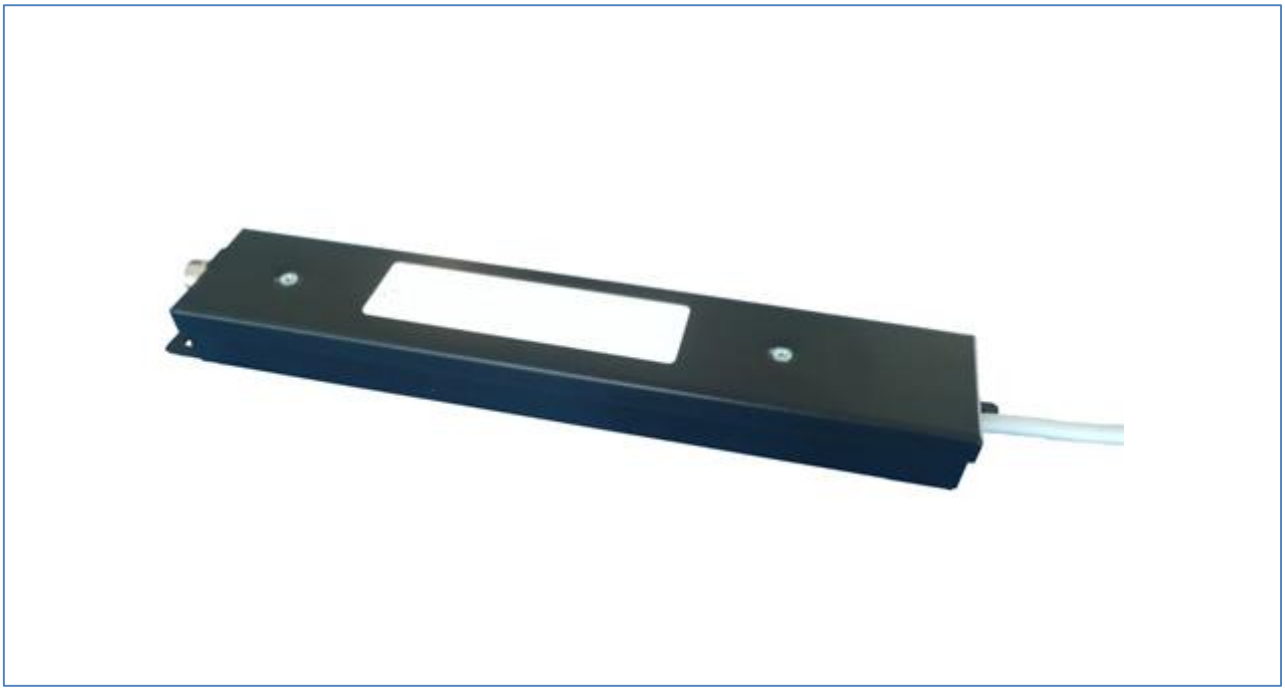

AmpMC 3-field

Intended Part numbers as listed in Table 1

CE 0120

Technical Manual

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1. Introduction

1.1. Contact information

This manual provides all the technical information necessary for the correct installation, application and maintenance of the AmpMC.

If you need additional information, need support or want to report a problem with the device, please contact your distributor or Claymount:

	Manufacturer	Distributor
Name	Claymount Assemblies B.V.	
Address	Anholtseweg 44, 7091 HB Dinxperlo The Netherlands	
Telephone	+31 (0)315 659150	
Fax	+31 (0)315 659140	
E-mail	nl.office@claymount.com	
Website	www.claymount.com	

For support and service purposes, please note the following information:

Model name:	
Part number:	
Serial number:	WO

1.2. Declaration of Conformance

Claymount Assemblies B.V. hereby declares that this product is in conformity with the essential requirements and provisions as set forth in European Union Council Directive 93/42/EEC concerning medical devices (revision 2007-09-27). See the included Declaration document.

1.3. Symbols used in this document

To ensure adequate and clear understanding of the information provided in this manual, the symbols listed below are used to indicate warnings, cautions, actions and notes that are important for correct and safe use of the device.

	**WARNING:** 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.
	**CAUTION:** Cautions are directions which, if they are not followed, can cause damage to the device described in this manual or any other equipment or goods and can cause environmental pollution.
	**NOTE:** Notes provide advice and highlight unusual points. A note is not intended as an instruction.

1.4. Abbreviations

Term	Definition
EMC	Electromagnetic compatibility
ESD	Electro Static Discharge
N.A.	Not Applicable

1.5. General warnings, cautions and notes

	**WARNING:** To avoid the risk of electric shock, this equipment must only be connected to a system isolated from supply mains according to EN-IEC-60601-1:3.1.
	**WARNING:** Do not modify this equipment without authorization of the manufacturer.

1.6. Supplied components

The device that you have purchased is packed in a transport box appropriately designed to ensure the integrity of the device. Please ensure that the contents of the package you received is intact and that there are no traces of moisture or visual damages. Otherwise, you should immediately contact your distributor or Claymount.
The transport box contains the following components:

Amount	Description	Reference
1	AmpMC	For Model and Part number see the product label on the AmpMC.
1	Technical Manual	TM20514
1	ECDoC	Declaration of conformance (CE)

1.7. Accessories

The following accessories can be ordered separately.

Description	Part Number	Suitable for
Extension cables, for use between Claymount SolidStateMC and AmpMC.		
EXTENSION CABLE, SSMC, 2.5M	12864	To connect all 3-field SolidStateMC models to AmpMC model 1001 + 1006 + 1008 + 1009. Lemo 6-pin male - Lemo 6-pin Female
EXTENSION CABLE, SSMC, 5M	12865	
EXTENSION CABLE, SSMC, 10M	12866	
EXTENSION CABLE, SSMC, 45FT	18964	
EXTENSION CABLE, SSMC, 15M	12867	
EXTENSION CABLE, SSMC, 18M	17668	
EXTENSION CABLE, SSMC, 20M	12868	
EXTENSION CABLE, SSMC, 25M	12939	
EXTENSION CABLE, SSMC, 30M	18201	
Extension cables, for use between the AmpMC and HV generator.		
EXTENSION CABLE PREAMP, 10M	13439	SubD 9-pin male - SubD 9-pin Female
EXTENSION CABLE PREAMP, 15M	13440	SubD 9-pin male - SubD 9-pin Female
EXTENSION CABLE PREAMP, 20M	13441	SubD 9-pin male - SubD 9-pin Female
EXTENSION CABLE, PREAMP HMC	17869	SubD 9-pin female - AMP 10-pin female
EXTENSION CABLE, PREAMP, 5M	13438	SubD 9-pin male - SubD 9-pin Female
Various		
Female connector 6 pin	13013	All 3-field SolidStateMC to AmpMC extension cable.
Male connector 6 pin	12799	

2. Product description

2.1. Intended Use

The AmpMC's are intended to convert an electrical current from a SolidStateMC to a voltage ramp or voltage level that can be interpreted by the Automatic Exposure Control interface of a High Voltage Generator.

2.2. Description of the device

The purpose of the Automatic Exposure Control (AEC) of an X-ray system is to obtain the correct image contrast by measuring the radiation quantity striking the film or detector.

As soon as sufficient amount of X-rays has sensitized the film or detector, the exposure end switch inside the generator disables generating more X-ray's automatically.

2.3. Principle of operation

- The conversion of electrical current from a SolidStateMC to a voltage ramp. The voltage ramp signal is proportional to the received dose of the SolidStateMC.
- To receive the field select signals (from operator via console and generator) and use the correct field of the SolidStateMC as the incoming signal.

A Claymount SolidStateMC serves as a measuring device for X-ray radiation with semiconductor components (photodiodes) as actual sensors. The ionizing effect of X-ray produces a small electrical current in the photodiodes and this current is lead to an AmpMC. The AmpMC converts the small current to a voltage signal that is proportional to the X-ray dose rate, this signal is integrated and presented as a ramp signal to the AEC controller board inside the generator and therefore represents a value for the image density.

- There is no signal available for external use about the status of the device.

2.4. Classifications

CE	IIB	93/42/EEC
Electrical safety classification	None	EN-IEC 60601-1:2006
Mode of operation	Continuous	EN-IEC 60601-1:2006
Ingress protection classification	IPX0	EN-IEC 60529
Protection	No	EN-IEC 60601-1:2006 table 6
Not intended for use in Oxygen Rich environment.		
Not suitable for Sterilization.		

2.5. Restrictions on use

The AmpMC can only be used in combination with a SolidStateMC and in a Radiography X-ray system that complies with the IEC60601-1 standard applicable at date of manufacture.

The supply lines must be limited / fused to 15W max. or the AmpMC must be mounted inside a fire enclosure.

The AmpMC is intended to be installed inside a cabinet of the X-ray system

Depending on final Assembly, additional measures may need to be taken to comply with EMC regulations.

2.6. Contraindications

The relevant contraindications for the X-ray system continue to apply (see the documentation for the X-ray system). The AmpMC does not add new contraindications on top of these.

2.7. Overview of the device

Table 1 AmpMC specifications

Model	PN#	Dimensions (mm)			Support information					Layout	Remarks
		Outside			# of fields	Connections					
						SolidStateMC		Generator			
		W	L	H		Cable (m)	Connector	Cable (m)	Connector		
1001	12860-NN[1]	42	222	21	3	None	6 pin Female	0.93	Sub-D 9p male	§ 6.1	3-field SolidStateMC preamp with single voltage ramp output
1006	14315-NN										3-field SolidStateMC preamp with single voltage ramp output and modified reset circuitry
1008	14097-NN							0.8	AMP Header 10p female / GND terminal		3-field SolidStateMC preamp with single voltage ramp output
1009	14302-NN							1.0	AMP MATE-N-LOK 14p female / GND terminal		
										Configuration of connections	
									Connector type at generator side		
								Cable length at generator side			
							Connector type at SolidStateMC side				
						Cable length at SolidStateMC side					
					# of fields that can be controlled						
				Height of AmpMC							
			Length of AmpMC								
		Width of AmpMC									

2.8. Specifications

Description	Reference
Exposure time range	≤ 4 ms to 5 s.
Fine-tuning with potentiometer	- 60% to + 150%
Input range	0.1 – 12.000 nA.
Operating voltage	+/- 12 VDC +/-5% to +/- 15 VDC +/-5% Measured at the AmpMC.
Supply current	0.1 A @ + 12 VDC 0.1 A @ - 12 VDC 0.1 A @ + 15 VDC 0.1 A @ - 15 VDC
Output signal Ramp	Positive or negative ramp 0 to 10 V @ 12 V 0 to 12 V @ 15 V Max. Load 47 kΩ
Applicable standards	EN-IEC60601-1:2006 edition 3.0 + C1 + C2 + IS1 + IS2 + A11+A1 EN-IEC60601-1-2:2007+C11 EN-IEC60601-2-54:2009+C1+C2 UL 60601-1:2003 UL certification as recognized component is only applicable when the UR symbol as in § 9.2 is visible on the product label.
Housing Material	Sheet metal
Weight	< 0.5 kg
Operation environment	Ambient temperature: +10°C to +40°C Relative humidity: 35% to 85% non-condensing Atm. Pressure: 860hPa to 1060hPa
Storage	Ambient temperature: -20°C to +60°C Relative humidity: 35% to 85% non-condensing Atm. Pressure: 860hPa to 1060hPa

[1] -NN might be added to specify customized DIL settings.

3. Installation

☞	**NOTE:** Allow system to level with room temperature before installation.

3.1. Installation requirements

⚠	**WARNING:** Installation and initial operation may only be carried out by an expert who has been trained in the field of medical diagnostic X-ray equipment.

⚠	**WARNING:** Modifications to the product are not allowed.

⚠	**WARNING:** When the enclosure is opened, ESD protective measures must be taken to prevent damage to the electronics.

⚠	**WARNING:** Always use shielded cable, the length of this cable may not exceed 30 meters.

⚠	**WARNING:** Improper grounding can cause incorrect functioning of the AmpMC

⚠	**WARNING:** Adjust the potentiometers with great caution. Using excessive force or over adjustment will result in improper functioning of the AmpMC

3.2. General Installation instructions

Position the AmpMC always outside of the active image area. The position of the AmpMC is not critical and can be mounted anywhere on the system. If the cable lengths are inadequate see the accessories list in § 1.7.

Connect the AmpMC to the control electronics in the generator by means of the connector, see § 6. The Connection diagram and plug pin layout of this cable are found under § 6.

Correct functioning of the AmpMC is guaranteed only if the cable as well as the SolidStateMC shielding is properly connected.

After the function control, the automatic exposure control is set to the correct dose, checked in all kV-ranges and for all film-foil-combinations and put into operation. This procedure has to be done according to the manual of the x-ray system.

3.2.1. Check according to the build in LED's

LED + 12 / 15 VDC:	The LED is on, when the positive supply voltage is present.
LED - 12 / 15 VDC:	The LED is on when the negative supply voltage is present.
LED – Reset:	The LED is on at reset, off at exposure.
LED's field I, field II and field III:	The corresponding LED's are on when the field is switched active.

3.2.2. Generator Switch off check

An exposure with 80 kV, 100 mA, 2 s, without any patient or phantom is released. The Automatic Exposure Control must terminate the exposure in less than 100 ms.

3.3. Necessary recurrent testing

	**WARNING:** Before granting the Automatic Exposure Control for use on patients, check the functionality of all AEC fields with a phantom.

4. Mains isolation

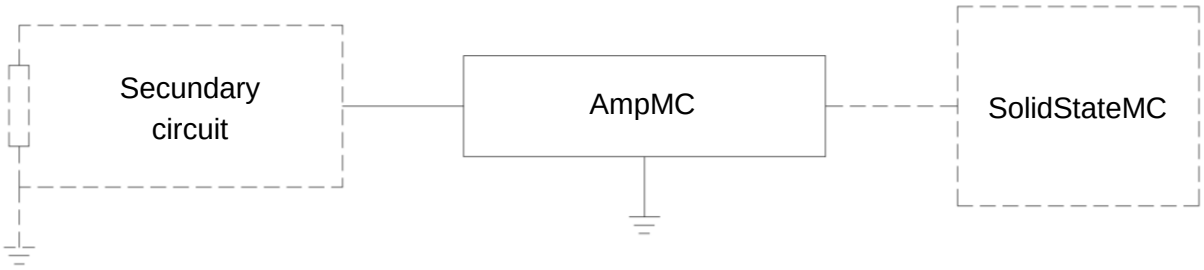


Figure 1 Means of protection

The AmpMC always needs to be connected to an X-ray system that complies with the required regulations and standards.

5. Service, maintenance and cleaning

Refer service to a qualified maintenance technician only.

AmpMC's do not require any periodic maintenance and will normally last during the lifetime of the X-ray system. For calibration see § 7 Quality Assurance.

In case of malfunction of the AEC system, the AmpMC can be checked according to the described test procedure § 5.4.

5.1. Safety precautions

When there is structural damage to the housing of the device, label the device as "out of order" and have the device repaired prior to further use.

5.2. Cleaning

Cleaning with a damp cloth is recommended. Use generally available alcohol based cleaning agents and do not soak the device with liquid.

5.3. Disinfection

Disinfection, when required, with a damp cloth with Isopropyl alcohol is recommended. Before using a disinfectant, check at a spot on the bottom of the device if the disinfectant will not damage the plastic and coated metal surfaces.

Do not soak the device with liquid.

5.4. Procedure at defects

- Exchange the extension cable (if present).
- Exchange the AmpMC

6. Device Data

Figure 2 Image of an AmpMC

6.1. 1001, 1006, 1008, 1009 – 3-field integrating amplifier

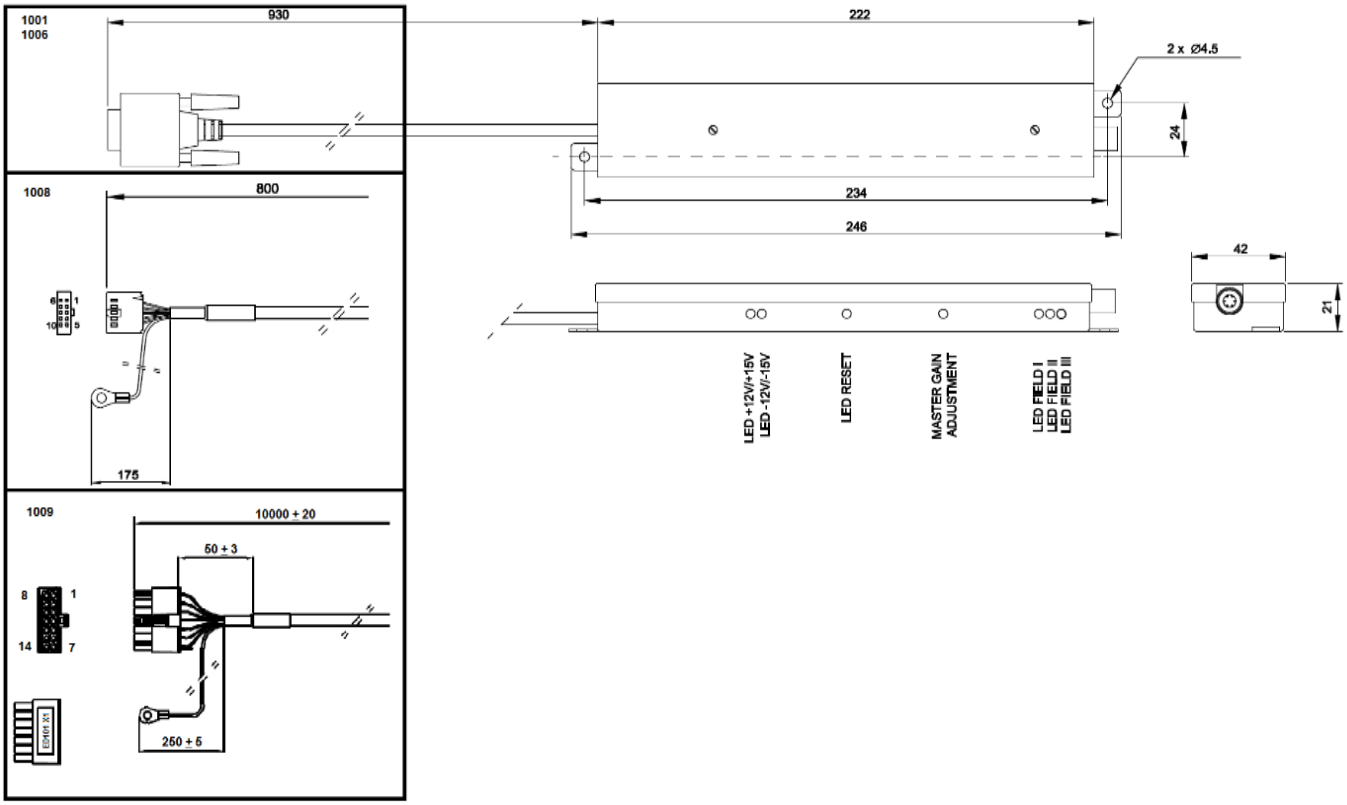


Figure 3 Layout Mechanical

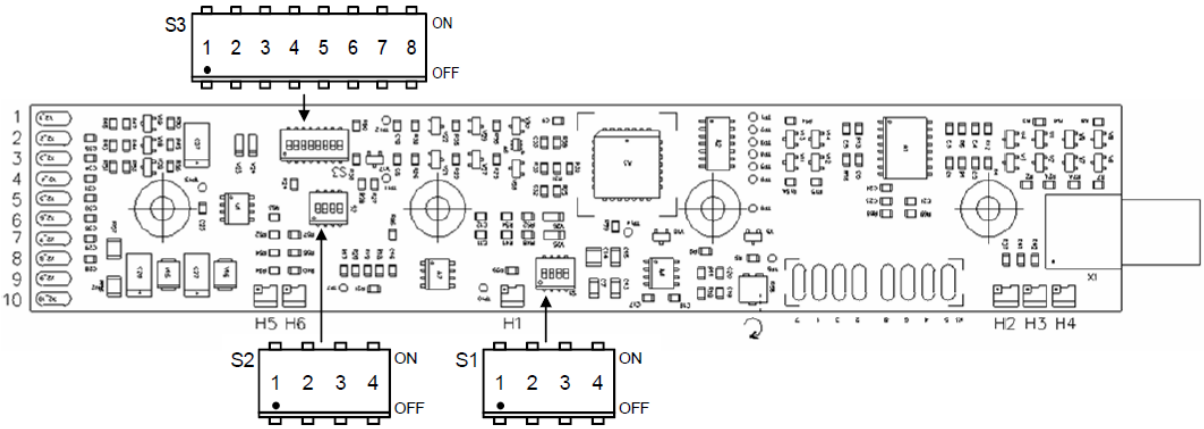


Figure 4 DIL switch location

6.1.1. Generator Interface connections

Designation (Standard)	Pin Numbers for	
	Sub D 9 pole male	Connector 10 pins
Not connected	1	1
Field II select	2	2
Field I select	3	3
Reset / exposure select	4	4
Ramp output signal	5	5
Field III select	6	6
- 12 VDC to - 15 VDC	7	7
+ 12 VDC to + 15 VDC	8	8
GND (Shield)	9	9

6.1.2. Sensitivity settings

By means of DIL-switches the configuration of the following functions is performed.

Definition of setting the DIL switches:

ON Switch closed
OFF Switch open
X Any position

The position of the DIL-switches on the PCB board is shown in Figure 4.

The sensitivity step is selected by means of DIL-switch S1. Fine adjustment in the range of - 60 % to + 150 % is performed by means of potentiometer sensitivity.

The position of the potentiometer is shown in the drawing in Figure 3.

DIL Switch S1				Sensitivity Indication		Setting code
S1.1	S1.2	S1.3	S1.4	SolidStateMC nA/µGy/Sec.	Signal V/µGy	
OFF	OFF	OFF	x	1.2 1.5 2.4	0.64 0.8 1.3	0
ON	OFF	OFF	x	1.2 1.5 2.4	0.32 0.4 0.65	1
ON	ON	OFF	x	1.2 1.5 2.4	0.16 0.2 0.33	2
Standard version						
ON	ON	ON	x	1.2 1.5 2.4	0.08 0.1 0.16	3

6.1.3. Ramp Polarity settings

The polarity of the output voltage ramp is selected by means of switches 1 and 2 of DIL-switch S2.

S2.1	S2.2	Ramp polarity	Setting code
OFF	OFF	Output open	0
ON	OFF	Positive ramp	1
Standard version			
OFF	ON	Negative ramp	2
ON	ON	Output Shorted, not allowed	-

6.1.4. Inputs reset / exposure settings

The selection of active L or H mode for reset / exposure input is performed by means of switch 3 on DIL-switch S2.

S2.3	Interface type	Function reset / exposure	Setting code
OFF	Active H	H=Exposure L=Reset	0
ON	Active L	L=Exposure H=Reset	1
Standard version			

6.1.5. Inputs for measuring field selection

The choice of active L or H mode for the field selection inputs is performed by means of switch 4 in DIL-switch S2.

S2.4	Interface type	Function Field selected	Setting code
OFF	Active H	H=Field selected L=Field off	0
ON	Active L	L=Field selected H= Field off	1
Standard version			

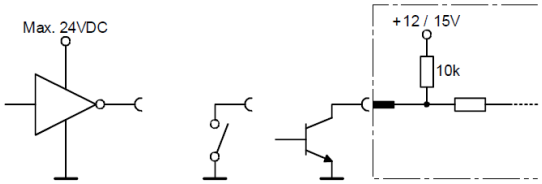


Figure 6 The connection against GND in active L mode

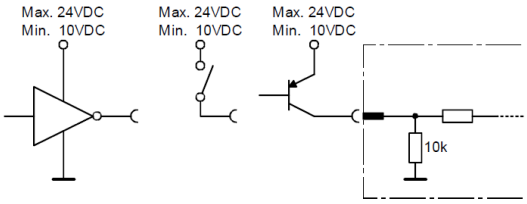


Figure 5 The connection against GND in active H mode

6.1.6. Plug pinout reset / ramp selection

The plug pinout on the SUB-D plug for reset and ramp may be changed by means of DIL-switch S3.

S3.1	S3.2	S3.3	S3.4	Ramp	Reset	Setting code
ON	OFF	OFF	ON	Pin 5	Pin 4	0
Standard version						
OFF	ON	ON	OFF	Pin 4	Pin 5	1

6.1.7. Assignment of measuring fields to the signal inputs

The plug pinout on the SUB-D plug for the measuring field selection may be assigned by means of DIL-switch S3.

S3.5	S3.6	S3.7	S3.8	Field I	Field II	Field III	Setting code
ON	OFF	OFF	x	Pin 3	Pin 2	Pin 6	0
Standard version							
OFF	ON	OFF	x	Pin 3	Pin 6	Pin 2	1
ON	ON	OFF	x	Pin 2	Pin 3	Pin 6	2
OFF	OFF	ON	x	Pin 6	Pin 3	Pin 2	3
ON	OFF	ON	x	Pin 2	Pin 6	Pin 3	4
OFF	ON	ON	x	Pin 6	Pin 2	Pin 3	5

7. Quality Assurance

An AmpMC makes part of the X-ray systems performance requirements and the adjustment procedures for the complete X-ray system are mandatory.
There are no additional QA procedures for using the AmpMC.

8. Disposal, ESD and EMC compatibility

8.1. Disposal

This device contains substances that can be hazardous to the environment and care should be taken when disposed of.

The device is marked with the following symbol:

Follow local regulations regarding disposal of devices that contain electronic parts.

8.2. ESD

	**WARNING:** The device contains sensitive electronics. Ensure that ESD protective measures are in place when the device is installed or serviced to prevent damage to the device.

8.3. EMC compatibility

The device conforms to EN 60601-1-2:2007 with performance criteria B for EMC compatibility and must be installed and put into service according to the EMC information provided in this Technical Manual (see below). Additional EMC measures may apply.

	**WARNING:** The device can be affected by communication equipment and mobile telephones.
	**WARNING:** Not taking EMC measures into account on the wiring may result in increased EMISSIONS or decreased IMMUNITY. Use e.g. shielded cable and/or ferrite core.
	**WARNING:** The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used

Below applicable tables from EN 60601-1-2:2007 are listed.

Table 1: Guidance and manufacturer's declaration – electromagnetic emissions		
The AmpMC is intended for use in the electromagnetic environment specified below. The customer or the user of the AmpMC should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The AmpMC 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	The AmpMC is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N.A.	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N.A.	

Table 2: Guidance and manufacturer's declaration – electromagnetic immunity			
The AmpMC is intended for use in the electromagnetic environment specified below. The customer or the user of the AmpMC should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N.A. ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N.A.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	N.A.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AmpMC requires continued operation during power mains interruptions, it is recommended that the AmpMC be powered from an uninterruptible 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 location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 4: Guidance and manufacturer's declaration – electromagnetic immunity

The AmpMC is intended for use in the electromagnetic environment specified below. The customer or the user of the AmpMC should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the AmpMC, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 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 the AmpMC is used exceeds the applicable RF compliance level above, the AmpMC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AmpMC.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6: Recommended separation distances between portable and mobile RF communications equipment and the AmpMC

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = [\frac{3,5}{3}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{3}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{3}]\sqrt{P}$
0,01	0.117	0.117	0.233
0.1	0.369	0.369	0.737
1	1.17	1.17	2.33
10	3.69	3.69	7.37
100	11.7	11.7	23.3

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.

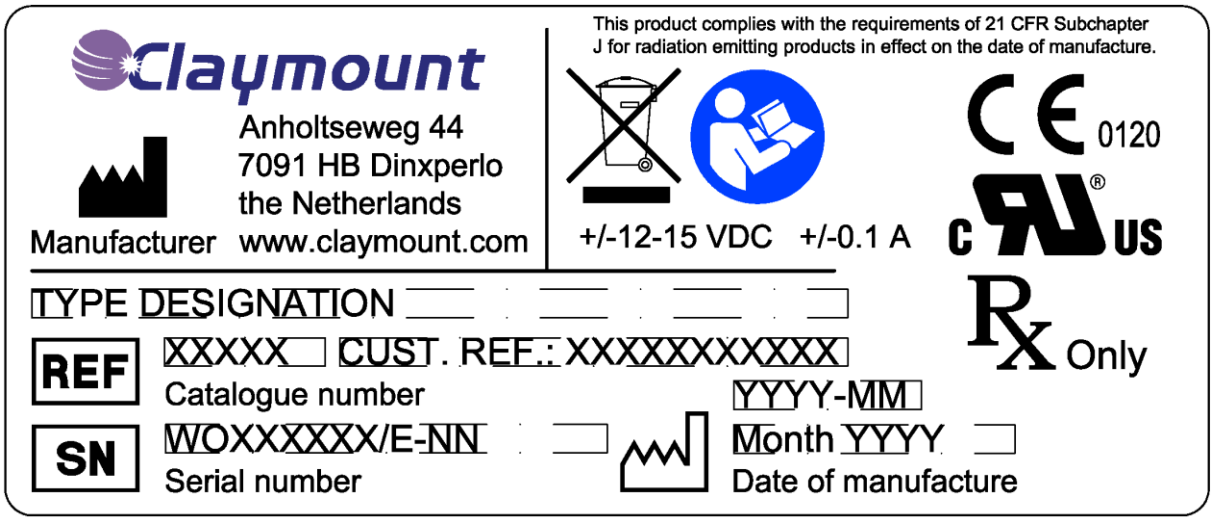
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9. Product label and symbols on the device

9.1. Product label

The product label can be found at the top side of the AmpMC.



9.2. Symbols on the device

Symbol	Explanation
	Manufacturer.
	Date of manufacture.
REF	Catalogue number.
SN	Serial number.
CE 0120	CE-mark directive 93/42/EC; conformity assessment by notified body 0120.
	Follow the instructions for use. Reading the instructions for use is mandatory for a correct and safe operation of the AmpMC.
	Identification of compliance with the provisions for EU WEEE directive.
Rx Only	For professional use only
c UL us	UL recognized component

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