

AmpMC 3-field Series

Intended Part numbers as listed in Table 1



Technical Manual



Table of Contents

Table	of Figures	3
1.	Introduction	4
1.1.	Contact information	
1.2.	Declaration of Conformance	4
1.3.	Symbols used in this document	
1.4.	Abbreviations	
1.5.	General warnings, cautions and notes	
1.6.	Supplied components	
1.7.	Accessories	6
2.	Product description	7
2.1.	Intended use	
2.2.	Description of the device	
2.3.	Principle of operation	
2.4.	Classifications	
2.5.	Restrictions on use	
2.6.	Contraindications	
2.7. 2.8.	Overview of the device	
2.0.	Specifications	9
3.	Installation	
3.1.	Installation requirements	
3.2.	General Installation instructions	
3.2.1.	Check according to the build-in LED's	
3.2.2.	Generator Switch off check	
3.3.	Necessary recurrent testing	11
4.	Mains isolation	12
5.	Service, maintenance and cleaning	12
5.1.	Safety precautions	
5.2.	Cleaning	
5.3.	Disinfection	12
5.4.	Procedure at defects	12
6.	Device Data	13
6.1.	1001, 1006, 1008, – 3-field integrating amplifier	
6.1.1.	Generator Interface connections	
6.1.2.	Sensitivity settings	
6.1.3.	Ramp Polarity settings	15
6.1.4.	Inputs reset / exposure settings	
6.1.5.	Inputs for measuring field selection	
6.1.6.	Plug pinout reset / ramp selection	
6.1.7.	Assignment of measuring fields to the signal inputs	16
7.	Quality Assurance	16
8.	Disposal, ESD and EMC compatibility	17
8.1.	Disposal	
8.2.	ESD	
8.3.	EMC compatibility	
8.3.1.	Deviations	
8.3.2.	Allowances	18
8.3.3.	Precautions	
8.3.4.	Emissions Compliance	
8.3.5.	Immunity Compliance	18

Technical Manual: TM20514-10 AmpMC 3-field Series Revision: 5.0B



9.	Product label and symbols on the device	21
9.1.	Product label and symbols on the device	21
9.2.	Symbols on the device	21
Table	e of Figures	
Figure	1 Means of protection	12
Figure	2 Image of an AmpMC	13
Figure	3 Lay-out Mechanical	13
Figure	4 DIL switch location	13
Figure	5 The connection against GND in active H mode	
-	6 The connection against GND in active L mode	
J	· ·	

All rights reserved

Although this guide is prepared with utmost care, Varex Imaging Nederland B.V. assumes no responsibility for errors or omissions.

Varex Imaging Nederland B.V. cannot be held accountable for damages of any nature arising from the use, and / or use of any options other than original Varex Imaging Nederland B.V. products.

Technical Manual: TM20514-10 AmpMC 3-field Series Revision: 5.0B



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 Varex Imaging Nederland B.V.:

	Manufacturer	Distributor
Name	Varex Imaging Nederland B.V.	
Address	Fabriekstraat 41 7005 AP Doetinchem The Netherlands	
Telephone	+31 (0)314 799 870	
E-mail	Netherlands.CNC@vareximaging.com	
Website	www.vareximaging.com	

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

Model name:	
Part number:	
Serial number:	

1.2. Declaration of Conformance

Varex Imaging Nederland 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.

<u> </u>	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.

Technical Manual: TM20514-10 AmpMC 3-field Series



1.4. Abbreviations

Term	Definition
AEC	Automatic Exposure Control
EMC	Electromagnetic compatibility
ESD	Electro Static Discharge
ME	Medical Equipment

This document contains terminology and definitions based on (international) standards. The terminology and definitions are formatted in capital letters (e.g. INTENDED USE). Terminology and definitions from the following standards are used:

Reference	Title
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-3	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-54	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

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 IEC-60601-1



WARNING:

Do not modify this equipment without authorization of the manufacturer.



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.

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 Varex Imaging Nederland B.V..

The package contains the following components:

Amount	Description	Reference
1	AmpMC	For Model and Part number see the product label on the AmpMC
1*	Documentation	Technical Manual TM20514-10 and Declaration of Conformity (CE)
1*	IFU card	Instruction for electronic download of documentation via Varex website

^{*)} One of these items must be supplied in the package

Technical Manual: TM20514-10 AmpMC 3-field Series Revision: 5.0B



1.7. Accessories

The following accessories can be ordered separately.

Description	Purpose						
Extension cables, for use between SolidStateMC and AmpMC							
EXTENSION CABLE, SSMC, 2.5M							
EXTENSION CABLE, SSMC, 5M							
EXTENSION CABLE, SSMC, 10M							
EXTENSION CABLE, SSMC, 45FT	To connect all 3-field SolidStateMC models to AmpMC model 1001 + 1006 + 1008.						
EXTENSION CABLE, SSMC, 15M							
EXTENSION CABLE, SSMC, 18M							
EXTENSION CABLE, SSMC, 20M							
EXTENSION CABLE, SSMC, 25M							
Extension cables, for use between the AmpMC and I	HV generator						
EXTENSION CABLE PREAMP, 10M	SubD 9-pin male - SubD 9-pin Female						
EXTENSION CABLE PREAMP, 15M	SubD 9-pin male - SubD 9-pin Female						
EXTENSION CABLE PREAMP, 20M	SubD 9-pin male - SubD 9-pin Female						
EXTENSION CABLE, PREAMP HMC	SubD 9-pin female - AMP 10-pin female						
EXTENSION CABLE, PREAMP, 5M	SubD 9-pin male - SubD 9-pin Female						
Various							
Female connector 6 pin	Connector without cable, solder version. To connect to SolidStateMC						
Male connector 6 pin	Connector without cable, solder version. To connect to AmpMC						



2. Product description

2.1. Intended use

The device is intended to be used in medical diagnostic applications with restrictions to human diagnostics. The device is intended to be used as accessory of an X-ray system in a professional healthcare facility environment. The device is intended to amplify and integrate the output signal of a SolidStateMC to the AEC-module of an X-ray generator. The limitations of use are specified in §2.8. The device is not intended to be used in fluoroscopy applications; near active HF Surgical Equipment or in the RF shielded room of a system for magnetic resonance imaging, where the intensity of Electromagnetic Disturbances is high.

Use, other than above, is identified as abnormal use.

The device is intended as an internal component of an X-ray system. The intended user is defined as the Service Personnel of an X-ray system.

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.

To result in a high-quality image, the AEC's exposure end switch will stop generating X-rays automatically when the demanded radiation dose on the detector is reached.

2.3. Principle of operation

The AmpMC main functions are:

- 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 field-select signals (from operator via console and generator) and use the correct field of the SolidStateMC as the incoming signal.

A 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

Subject	Classification	Reference				
CE	IIB	93/42/EEC				
Electrical safety	None	IEC 60601-1				
Electromagnetic Compatibility intended environment	Professional healthcare facility environment	IEC 60601-1-2				
Mode of operation	Continuous	IEC 60601-1				
Ingress protection	IP2X	IEC 60529				
Protection	No	IEC 60601-1 table 6				
Not intended for use in Oxygen Rich environment.						
Not suitable for Sterilization.						

Technical Manual: TM20514-10 AmpMC 3-field Series

Date of release: 2020-08-04



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 the 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

ı		nensio (mm)	ons			Support	informa	ation		
Maria I		0 1 11			Connections		ons			
Model	Outside		<u> </u>	SolidStateMC		Generator		ņọ		
	w	٦	Ŧ	# of fields	Cable (m)	Connector	Cable (m)	Connector	Lay-out	Remarks
1001	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										3-field SolidStateMC preamp with single voltage ramp output and modified reset circuitry
1008							0.8	AMP Header 10p female / GND terminal		3-field SolidStateMC preamp with single voltage ramp output
									Config	uration of connections
								Connector type at genera	ator side	е
							Cable I	ength at generator side		
						Connector type at SolidStateMC side				
					Cable length at SolidStateMC side					
				# of fie	f fields that can be controlled					
			Hei	ght of /	ht 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	IEC60601-1:2005 edition 3.0 + C1 + C2 + IS1 + IS2 + A11+ A1 IEC60601-1-2:2014 IEC60601-2-54:2009+C1+C2 + A1				
Housing Material	Sheet metal				
Weight	< 0.5 kg				
Operation environment	Ambient temperature: Relative humidity: Atm. Pressure:	+10°C to +40°C 35% to 85% non-condensing 860hPa to 1060hPa			
Storage	Ambient temperature: -20°C to +60°C Relative humidity: 35% to 85% non-condensing Atm. Pressure: 860hPa to 1060hPa				

Date of release: 2020-08-04



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 total length of this cable shall 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 chapter 6. The connection diagram and plug pin lay-out of this cable are found under chapter 6.

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

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

3.3. Check according to the build-in LEDs

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.

Technical Manual: TM20514-10 AmpMC 3-field Series Revision: 5.0B

Date of release: 2020-08-04 10/22 www.vareximaging.com



3.4. Generator Switch off check

Without a patient or phantom, a radiation exposure with 80kV, 100mA, 21 s is released. The Automatic Exposure Control must terminate the exposure in less than 100 ms.

3.5. Necessary recurrent testing



WARNING:

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

Technical Manual: TM20514-10 AmpMC 3-field Series Revision: 5.0B



4. Mains isolation

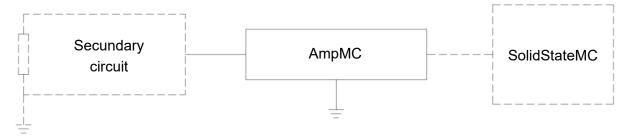


Figure 1 Means of protection

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 service technician only.

AmpMC models do not require maintenance and will last during the lifetime of the X-ray system. For calibration see chapter 7.

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 or cable 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, - 3-field integrating amplifier

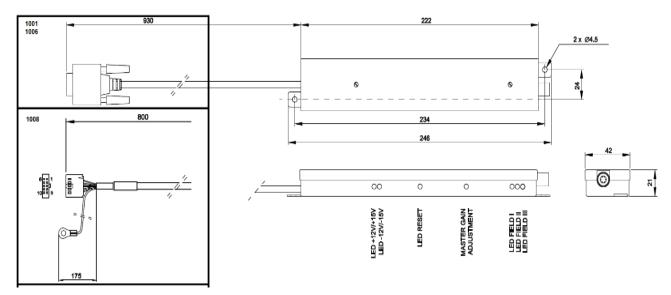


Figure 3 Lay-out Mechanical

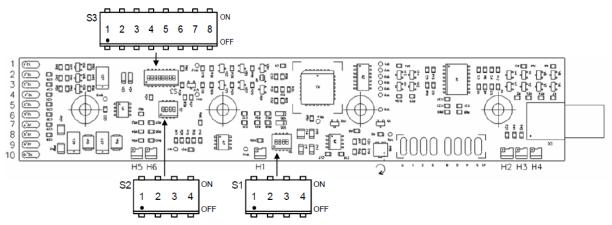


Figure 4 DIL switch location

Technical Manual: TM20514-10 AmpMC 3-field Series Revision: 5.0B



6.2. Generator Interface connections

Designation (Oten dead)	Pin Numbers for		
Designation (Standard)	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	
Not connected	N/A	10	

6.3. 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			DIL Switch S1 Sensitivity Indication			Cattina a
S1.1	S1.2	S1.3	S1.4	SolidStateMC nA/μGy/Sec.*	Signal V/μGy	Setting code	
OFF	OFF	OFF	x	1.2 1.5 2.4	0.64 0.8 1.3	0	
ON	OFF	OFF	х	1.2 1.5 2.4	0.32 0.4 0.65	1	
ON Sta	ON Indard vers	OFF	х	1.2 1.5 2.4	0.16 0.2 0.33	2	
ON	ON	ON	х	1.2 1.5 2.4	0.08 0.1 0.16	3	

^{*} depends on which SolidStateMC is used. Refer to the manual of the used SolidStateMC.

Technical Manual: TM20514-10 AmpMC 3-field Series

Revision: 5.0B



6.4. 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	Docitivo romp	1
Standard version		Positive ramp	1
OFF	ON	Negative ramp	2
ON	ON	Output Shorted, not allowed -	

6.5. Inputs reset / exposure settings

The selection of active L or active 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	4
Standard version		H=Reset	1

6.6. 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	1
Standard version		H= Field off	l

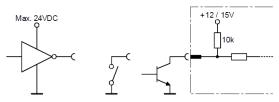


Figure 6 The connection against GND in active L mode

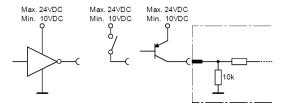


Figure 5 The connection against GND in active H mode



6.7. 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	\$3.2	\$3.3	\$3.4	Ramp	Reset	Setting code
ON	OFF	OFF	ON	Pin 5	Pin 4	0
St	andard versi	on	ON	PIII 3	PIII 4	U
OFF	ON	ON	OFF	Pin 4	Pin 5	1

6.8. 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	\$3.7	S3.8	Field I	Field II	Field III	Setting code
ON	OFF	OFF	х	Pin 3	Pin 2	Pin 6	0
Standard version			PIII 3	PIII 2	PIII 0	U	
OFF	ON	OFF	х	Pin 3	Pin 6	Pin 2	1
ON	ON	OFF	х	Pin 2	Pin 3	Pin 6	2
OFF	OFF	ON	х	Pin 6	Pin 3	Pin 2	3
ON	OFF	ON	х	Pin 2	Pin 6	Pin 3	4
OFF	ON	ON	х	Pin 6	Pin 2	Pin 3	5

7. Quality Assurance (QA)

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.

Revision: 5.0B



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 IEC 60601-1-2:2014 for EMC compatibility and must be installed and put into service according to the EMC information provided in this manual.



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 AmpMC 3-field, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



WARNING:

Not taking EMC measures into account on the wiring may result in increased EMISSIONS or decreased IMMUNITY. IEC60601-1-2:2014 must be followed for being complaint with EMC guidelines.



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:

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.



NOTE:

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

8.4. Deviations

No deviations from IEC60601-1-2:2014 are applied.

Technical Manual: TM20514-10 AmpMC 3-field Series Revision: 5.0B



8.5. Allowances

No allowances from IEC60601-1-2:2014 are used.

8.6. Precautions

Precautions to be taken to prevent adverse events to the PATIENT and the OPERATOR due to Electromagnetic Disturbances are listed in the column "Electromagnetic environment – guidance" in the tables below.

8.7. Emissions Compliance

Guidance and manufacturer's declaration – Electromagnetic emissions					
The AmpMC 3-field is intended for use in the Electromagnetic environment specified below. The customer or user of the AmpMC 3-field should assure that it is used in such an environment.					
Emissions test	Compliance	Electromagnetic environment - guidance			
RF emissions group CISPR 11	Group 1	The AmpMC 3-field 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 class CISPR 11	Class A	The EMISSIONS characteristics of AmpMC 3-field make it suitable for use in industrial areas and hospitals (CISPR 11 class			
Harmonic emissions IEC 61000-3-2	Not Applicable	A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services.			
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	The user might need to take mitigation measures, such as relocating or re-orienting the equipment."			

8.8. Immunity Compliance

Guidance	and manufacturer's declaration	- Electromagnetic immunity - ENCLOSURE PORT			
	The AmpMC 3-field is intended for use in the Electromagnetic environment specified below. The customer or user of the AmpMC 3-field should assure that it is used in such an environment.				
Immunity test	Compliance Test level	Electromagnetic environment - guidance			
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 %.			
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See next table below	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches)			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.			

Technical Manual: TM20514-10 AmpMC 3-field Series

Revision: 5.0B



Guidance and manufacturer's declaration – Electromagnetic immunity – Compliance Test Levels for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency	Band	Service ^{a)}	Modulation	Maximum power	Distance	IMMUNITY TEST LEVEL
(MHz)	(MHz)			(W)	(m)	(V/m)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460; FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710			5 b			
745	704 – 787	LTE Band 13, 17	Pulse Modulation b)	0,2	0,3	9
780			217 Hz			
810		GMS 800/900;	Dada a Madadatiana b)			
870		TETRA 800; iDEN 820;	Pulse Modulation b)			
930			18 Hz		0,3	28
1 720		GSM 1800;	Pulse Modulation b)			
1 845	4 700 4	CDMA 1900;	Pulse Modulation 9			
1 970	1 700 – 1 990	GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	DECT; Band 1, 3, 217 Hz		0,3	28
2 450	2 400 – 2 570	Bluetooth; WLAN 802.11 b/g/n; RFID 2450;	Pulse Modulation ^{b)} 217 Hz	2	0,3	28
		LTE Band 7				
5 240			Pulse Modulation b)			
5 500	5 100 – 5 800	WLAN 802.11 a/n	217 Hz	0,2	0,3	9
5 785			21/11/2			

^{a)} For some services, only the uplink frequencies are included.

b) The carrier is modulated using a 50 % duty cycle square wave signal.



Guidance and manufacturer's declaration - Electromagnetic immunity - Power and Signal PORTs

The AmpMC 3-field is intended for use in the Electromagnetic environment specified below. The customer or user of the AmpMC 3-field should assure that it is used in such an environment.

Ampine 3-neiu should assure that it is used in such an environment.				
Immunity test	Compliance Test level	Electromagnetic environment - guidance		
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 AC and DC power ports ± 1 kV signal ports 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.		
Surges Line-to-line IEC 61000-4-5	Not Applicable	The AmpMC 3-field is intended to be supplied by a secondary IEC60601-1 compliant AC or DC power supply.		
Surges Line-to-ground IEC 61000-4-5	Not Applicable			
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V ^{a)} 0,15 MHz – 80 Mhz 6 V ^{a)} in ISM bands between	Field strengths from fixed RF transmitters, as determined by an Electromagnetic site survey ^{c)} , should be less than the compliance level in each frequency range. Interference may occur near equipment marked with the following symbol:		
	0,15 MHz and 80 MHz ^{b)} 80 % AM at 1 kHz			
Voltage dips IEC 61000-4-11	Not Applicable	The AmpMC 3-field is intended to be supplied by a secondary IEC60601-1 compliant AC or DC power supply.		
Voltage interruptions IEC 61000-4-11	Not Applicable			

a) r.m.s. before modulation is applied

NOTE

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

Technical Manual: TM20514-10 AmpMC 3-field Series

Revision: 5.0B

^{b)} The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

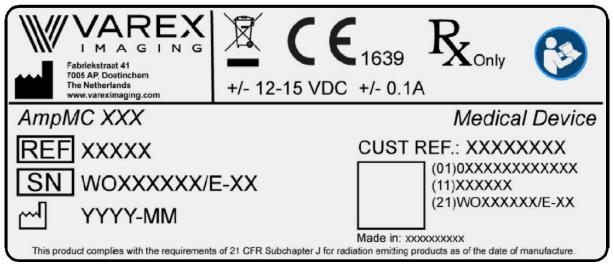
c) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the Electromagnetic environment due to fixed RF transmitters, an Electromagnetic site survey should be considered. If the measured field strength in the location in which the AmpMC 3-field is used exceeds the applicable RF compliance level above, the AmpMC 3-field 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 3-field.



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.
\sim	Date of manufacture.
REF	Catalogue number.
SN	Serial number.
C E ₁₆₃₉	CE-mark directive 93/42/EC; conformity assessment by notified body 1639.
③	Follow the instructions for use. Reading the instructions for use is mandatory for a correct and safe operation of the AmpMC.
X	Identification of compliance with the provisions for EU WEEE directive.
FC	Identification of compliance with FCC 47 CFR Part 15 (optional feature)
$ m R_{ m Only}$	For professional use only

Technical Manual: TM20514-10 AmpMC 3-field Series

Revision: 5.0B



Contact details

Varex Imaging Nederland B.V.

The Netherlands t +31 314 799 870

Netherlands.CNC@vareximaging.com

U.S.A.

t +1 847 279 5100 f +1 630 271 9995

Americas.CNC@vareximaging.com

Varex Imaging Americas Corp.

Varex Imaging Philippines Inc.

Philippines

t +63 49 5024 520

t +63 49 5024 521

f +63 49 5024 500

f +63 2 8076 472

Philippines.CNC@vareximaging.com

Varex Imaging Technology (Beijing) Co., Ltd.

China

t +86 10 6780 2708

t +86 10 6780 2129

f +86 10 6780 2170

China.CNC@vareximaging.com

© 2021 by Varex Imaging Nederland B.V.

All Rights reserved. No part of this document may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission of Varex Imaging Nederland B.V.

Technical Manual: TM20514-10 AmpMC 3-field Series

Revision: 5.0B