Instructions for Installation and Use for Automatic Exposure Control Chamber (AEC Chamber)

REF 140 00 13

REF 141 00 18

REF 141 00 20

REF 142 00 13

REF 143 00 06

REF 145 00 44

REF 145 00 45

REF 145 00 97

REF 151 00 18

REF 151 00 21

REF 151 00 22

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1. Safety

1.1 General warning and safety information

These instructions for use apply to the following AEC chamber product group versions:

- REF 140 00 13,
- REF 141 00 18,
- REF 141 00 20,
- REF 142 00 13,
- REF 143 00 06,
- REF 145 00 44,
- REF 145 00 45,
- REF 145 00 97,
- REF 151 00 18,
- REF 151 00 21,
- REF 151 00 22

- Read through these instructions for use in full.
- Retain the instructions for use for later reference.
- Failure to comply with the instructions for use could result in injuries or damage to the product.
- These instructions for use are intended exclusively for qualified specialist personnel.
- The AEC chamber may only be used for the intended purpose. Modifications of the device are not allowed.
- Do not perform any servicing work while the AEC chamber is in use.
- The AEC chamber is a sensitive accessory for medical devices and therefore must be handled with care. The original or equivalent quality packaging must be used for transportation and returns.
- To prevent deformation, no pressure is to be exerted on the measuring chamber.
- The cable and the connector must not be placed on top of the chamber in the packaging.
- Observe the warning and safety information regarding electromagnetic compatibility (chapter 9: Warning and safety information regarding electromagnetic compatibility).
- All serious incidents that have occurred in connection with the medical device must be reported to the manufacturer and the local authority responsible.
- If the packaging of the automatic exposure chamber was damaged, opened before use or was exposed to environmental conditions that go beyond those specified, the functionality of the automatic exposure chamber must be checked carefully and, if necessary, sent back to the manufacturer.

1.2 Explanation of symbols

Symbol	Meaning
	Manufacturer
	Follow instructions for use (white symbol on blue background!)
 YYYY-MM	Date of manufacture
	Attention
	Catalog number
	Keep dry
	Serial number
	Humidity limitation
	Temperature limitation
	Atmospheric pressure limitation
CE 0197	CE mark (European approval symbol with the identification number of the notified body)
	Symbol for separate collection of electrical and electronic equipment
	Instructions for use

2 Description of the AEC chamber

2.1 Intended use

The AEC chamber is an accessory for X-ray systems (projection radiography). The AEC chamber provides a signal proportional to the image receptor dose and, in conjunction with the AEC in the X-ray system, allows X-ray imaging with optimal diagnostic image quality with minimal patient radiation exposure. The AEC chamber is designed for continuous operation in professional health care facilities (clinics, hospitals, medical practices).

The intended user and the intended patient are defined by the intended use of the X-ray system.

There are no known contraindications or side effects.

2.2 Functional description

The AEC chamber is an accessory for X-ray systems (projection radiography).

The AEC chamber is constructed as an ionization chamber (air-filled parallel plate chamber with one or more measuring fields). The ionization chamber converts the intensity of the X-radiation into a current. The current is converted into an electrical signal by an amplifier, which also acts as an integrator. The electrical signal is transmitted to the X-ray system. The electrical signal is proportional to the image receptor dose and, in conjunction with the AEC in the X-ray system, allows X-ray imaging with optimal diagnostic image quality and minimal patient radiation exposure.

2.3 Material information

The AEC chamber essentially consists of two polycarbonate plates (parts suitable for contact), which are printed with ink on the inside and secured around the edge with a galvanized frame covered with a PVC adhesive tape. Inside are polyethylene, graphite and thin silver coated electrodes on plastic films. The electronic printed circuit board amplifier is an integral component of the AEC chamber.

2.4 Service life

The AEC chamber is designed for a service life of 10 years. The AEC chamber may no longer be operated if

- electrical and mechanical safety is no longer guaranteed,
- connectors or cables are damaged, or
- contacts on the connector are bent.

If the intended service life of the AEC chamber is exceeded, safe operation can no longer be guaranteed.

3 Installation

3.1 General preparation and safety information for installation

Installation may only be carried out by qualified specialist personnel from the X-ray system manufacturer.

Check that the product is in perfect condition before use. Damage can lead to injuries and impair performance. Check the cable for damage. Check that the connector is in perfect condition and for cleanliness between the contacts.

The amplifier cover is made up of a metallic screen connected to the electronics ground.

The ionization chamber and the amplifier must be installed with contact protection and isolation (isolation from the mains in compliance with protection class II).

The cable must be routed through the screen to the signal ground on the generator side. On the amplifier side, the connector must be installed with isolation. The cable shield may not be used as a protective ground conductor. A protective extra low voltage must be used.

The AEC chamber can be used with the following X-ray systems:
The AEC chamber can be used as an accessory for X-ray systems if the X-ray systems meet the specifications for the mechanical and electrical interfaces stipulated by VacuTec Meßtechnik GmbH. These specifications can be found in the corresponding data sheets for the individual AEC chamber types and are also included in the technical data in these instructions for use (see chapter 7: Technical data and chapter 8: Electronics information).
The X-ray systems must comply with the legal requirements for medical devices (e.g. the EN 60601-1; EN 60601-2-54 standards). Final testing is carried out in the X-ray system and is the responsibility of the system manufacturer.

3.2 Installation

The VacuTec ionization chamber is to be connected to an AEC that guarantees a voltage supply with protective extra low voltage. The supply circuit for the AEC chamber must be designed in such a way that the isolation from the mains meets the requirements of protection class II and the power loss in case of faults is limited to less than 15 W.
The pin assignment in the connector for connection to the AEC (interface to the generator) can be found in the data sheet supplied.
The AEC chamber is in the beam path, always between the patient and the imaging system.
The AEC chamber is installed as described in the installation instructions supplied by the manufacturer of the relevant X-ray system. The AEC chamber has a 5 mm wide frame, which can be used for attachment. Any pressure, mechanical damage and twisting of the AEC chamber during installation must be avoided. If an anti-scatter grid is used, it must always be fitted in the beam path in front of the AEC chamber.

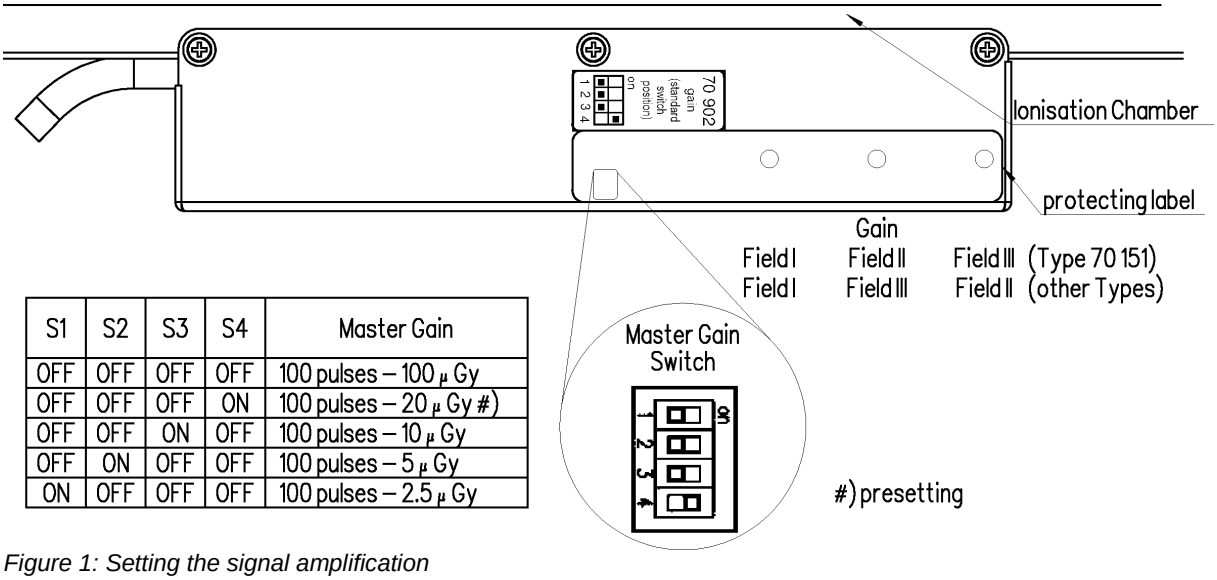
3.2.1 Chamber electronics

The electronics consist of the signal amplifier, operating voltage generation for the ionization chamber, and the measuring field selector switch. The charge generated by the X-ray radiation in the measuring chamber is digitized in the amplifier and processed based on the measuring field selected. It is possible to choose between 5 sensitivity levels using 4 DIL switches. The DIL switches are accessible through an opening in the amplifier housing. The digital measuring signal is transmitted to the AEC in the X-ray system via a cable (see data sheet supplied for connector assignment), where the cut-off-signal for the X-ray tubes is generated. In addition, this cable carries the supply voltage to the amplifier and the control signals for the measuring field selection. The supply voltage (see also chapter 7 Technical data) must be a protective extra low voltage (PELV) from the AEC.

By default, the control signals and the RESET are set to “low-active”. An analog ramp signal can be generated by connecting a ramp module (see section 7.3.2). Additional information is provided in chapter 8.

3.2.2 Settings on the amplifier

The output signal (pulse count or ramp voltage) is calibrated according to the dose. The manufacturer default setting is customer-specific. Other settings can be selected, as shown in the table (Figure1: Setting the signal amplification). The sensitivity of the entire VacuTec AEC chamber with amplifier is calibrated during manufacture so that the measuring fields have the same sensitivity and therefore no further settings are necessary on the amplifier.



S1	S2	S3	S4	Master Gain
OFF	OFF	OFF	OFF	100 pulses – 100 µ Gy
OFF	OFF	OFF	ON	100 pulses – 20 µ Gy #)
OFF	OFF	ON	OFF	100 pulses – 10 µ Gy
OFF	ON	OFF	OFF	100 pulses – 5 µ Gy
ON	OFF	OFF	OFF	100 pulses – 2.5 µ Gy

Figure 1: Setting the signal amplification

3.3 Application

The AEC chamber is an accessory for X-ray systems (projection radiography) and does not have any control or visualization features of its own. It is commissioned, used, and shut down using the X-ray system. The AEC chamber does not generate any system messages, error messages, or fault messages.

4 Preparation

The AEC chamber is located inside the X-ray system. No cleaning, disinfection or sterilization of the AEC chamber is required.

5 Maintenance and repair

The AEC chamber requires no specific maintenance. The X-ray system checks and ensures the functioning of the AEC chamber. Refer to the instructions for use for the X-ray system.
Any repairs may only be carried out by VacuTec Meßtechnik GmbH. Please contact the manufacturer.

6 Disposal

The AEC chamber contains electronic components and must be disposed of in compliance with the applicable requirements in the relevant country.

7 Technical data

7.1 General technical data

Energy range / tube voltage	40 kV to 150 kV
Dose rate range*	0.5 µGy/s to 1000 µGy/s
Exposure dose range*	1 µGy to 100 µGy
Exposure time range	1 ms to 10 s
Attenuation factor	< 1.04
Aluminum equivalent*	< 0.75 mm aluminum
Sensitivity tolerance between measuring fields (calibration by manufacturer)	≤ 5 %
Protection rating (IEC 60529)	IP 20
AEC chamber supply voltage (from X-ray system)	+12 V to +16 V
Power consumption	max. 2 W
Start-up time	120 s
Digital output	Differential signal (RS 422), pulse width 2 µs
Supply connection	Protective extra low voltage
Protection class	Protection class II
When using the ramp module:	
Ramp module supply voltage (from X-ray system)	-12 V to -16 V and +12 V to +16 V
Power consumption (-12 V to -16 V)	max. 0.2 W
Power consumption (+12 V to +16 V)	max. 0.5 W
Ramp module output	0 V to 10 V

*) The dose measurement (air Kerma in the unit Gy) is carried out immediately downstream of the measuring chamber with X-ray radiation quality RQA 5 in compliance with IEC 61267 (2005) / DIN EN 61267:2009:1.

7.2 Additional technical data

Type	Document reference	Revision
Data sheet for REF 140 00 13	140DB13E	B
Data sheet for REF 141 00 18	141DB18E	B
Data sheet for REF 141 00 20	141DB20E	B
Data sheet for REF 142 00 13	142DB13E	B
Data sheet for REF 143 00 06	143DB06E	B
Data sheet for REF 145 00 44	145DB44E	B
Data sheet for REF 145 00 97	145DB97E	A
Data sheet for REF 151 00 18	151DB18E	B
Data sheet for REF 151 00 21	151DB21E	B
Data sheet for REF 145 00 45	145DB45E	B
Data sheet for REF 151 00 22	151DB22E	B

7.3 Components for the AEC chamber

Only add-on components specified for the medical device may be used. The use of different cables or ramp modules than those specified or provided by the manufacturer of this device can result in increased electromagnetic interference emissions or reduced electromagnetic immunity of the device and leads to defective operation.

List of components and spare parts:

REF	Type	Document	Revision
Extension cable BAK dig. Sub-D 9p			
REF 902 00 19-15	Length = 15m	902DB19E	B
REF 902 00 19-16	Length = 16m		
REF 902 00 19-20	Length = 20m		
Extension cable BAK dig. RJ45			
REF 902 00 30-02	Length = 2m	902DB30E	B
REF 902 00 30-05	Length = 5m		
REF 902 00 30-10	Length = 10m		
REF 902 00 30-15	Length = 15m		
REF 902 00 30-20	Length = 20m		
RJ45 - Coupler			
REF 902 00 41	Modular coupler	902DB41E	B
Ramp module			
REF 902 00 11	Ramp module (70 902)	902DB11E	B
REF 902 00 11-N	Ramp module (70 902)		
REF 902 00 13	Ramp module (70 902)	902DB13E	B
REF 902 00 42	Ramp module (70 902)	902DB42E	B
REF 902 00 48	Ramp module (70 902)	902DB48E	B
Spacer			
REF 145 00 27	Spacer	902DB27E	B

7.3.1 Extension cable

Extension cables up to 20 m in length for connection to the AEC can be supplied.

7.3.2 Ramp module

The digital output signal can be converted into an analog ramp signal of 0 to 10 V. A ramp module in the form of a 9-pin Sub-D connector is available for this purpose, and is connected at the input to the AEC. 100 pulses generate a ramp voltage of 10 V.

7.3.3 Spacer

To install the 6 mm thick VacuTec ionization chamber in chamber mountings with a width of 12 mm, four plastic spacers are used, and are attached to the chamber frame with screws and allow isolated installation of the chamber.

7.4 Operating conditions

Temperature	+10 °C to +40 °C
Air pressure	65 kPa to 106 kPa
Humidity	10 % to 90 % relative humidity, non-condensing

7.5 Transport conditions

Temperature	−40 °C to +60 °C
Air pressure	50 kPa to 106 kPa
Humidity	10 % to 90 % relative humidity, non-condensing

7.6 Storage conditions

Store the AEC chamber in its original packaging until commissioning.

Temperature	−40 °C to +60 °C
Air pressure	50 kPa to 106 kPa
Humidity	10 % to 90 % relative humidity, non-condensing

8 Electronics information (basic information, start-up process, level, measuring signals, timing)

8.1 Basic information

The AEC chamber provides a digital signal that is proportional to the image receptor dose. The measurement information is transmitted in the form of pulses. A pulse corresponds to a particular dose, according to the selected sensitivity. Achievement of the cut-off dose can be identified by counting the pulses. A ramp module is available to provide the conventional analog interface. In this module, the digital pulse signals are converted into an analog ramp signal from 0 V to 10 V.
Because of the transmission technology used, the digital version provides increased interference immunity. To utilize this advantage, when using the ramp module it must be installed close to the AEC and the measurement information must be transmitted digitally.

8.2 Start-up process

During the X-ray system start-up process, undefined levels can occur for both the supply voltages and the signals for controlling the AEC chamber. For the supply voltages, depending on the capacitive load the time before the nominal values are reached can be several milliseconds (t_{PO}).
To prevent undefined statuses, a start-up delay of 300 ms is integrated into the internal AEC chamber control. After a further initialization time of 1 ms, the chamber electronics switch to a WAIT status. In WAIT status, any radiation occurring does not produce a measuring signal (see Figure 2)
The first time the control signal changes – either a change to the measuring field selection or a RESET signal – the chamber electronics are immediately switched to active status. They remain active until switched off.

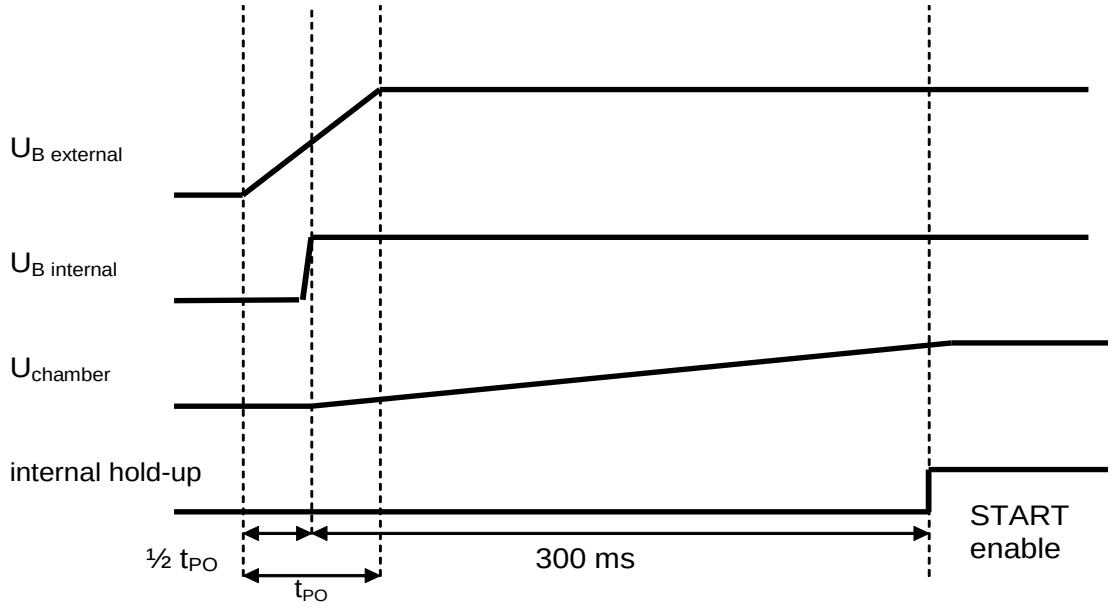


Figure 2: Behavior of voltage levels over time

To operate the AEC chamber in a stable operating condition, a start-up time of 2 minutes must be observed.

8.3 Voltage supply and control signal levels

The wiring of the components is shown in the following overview.

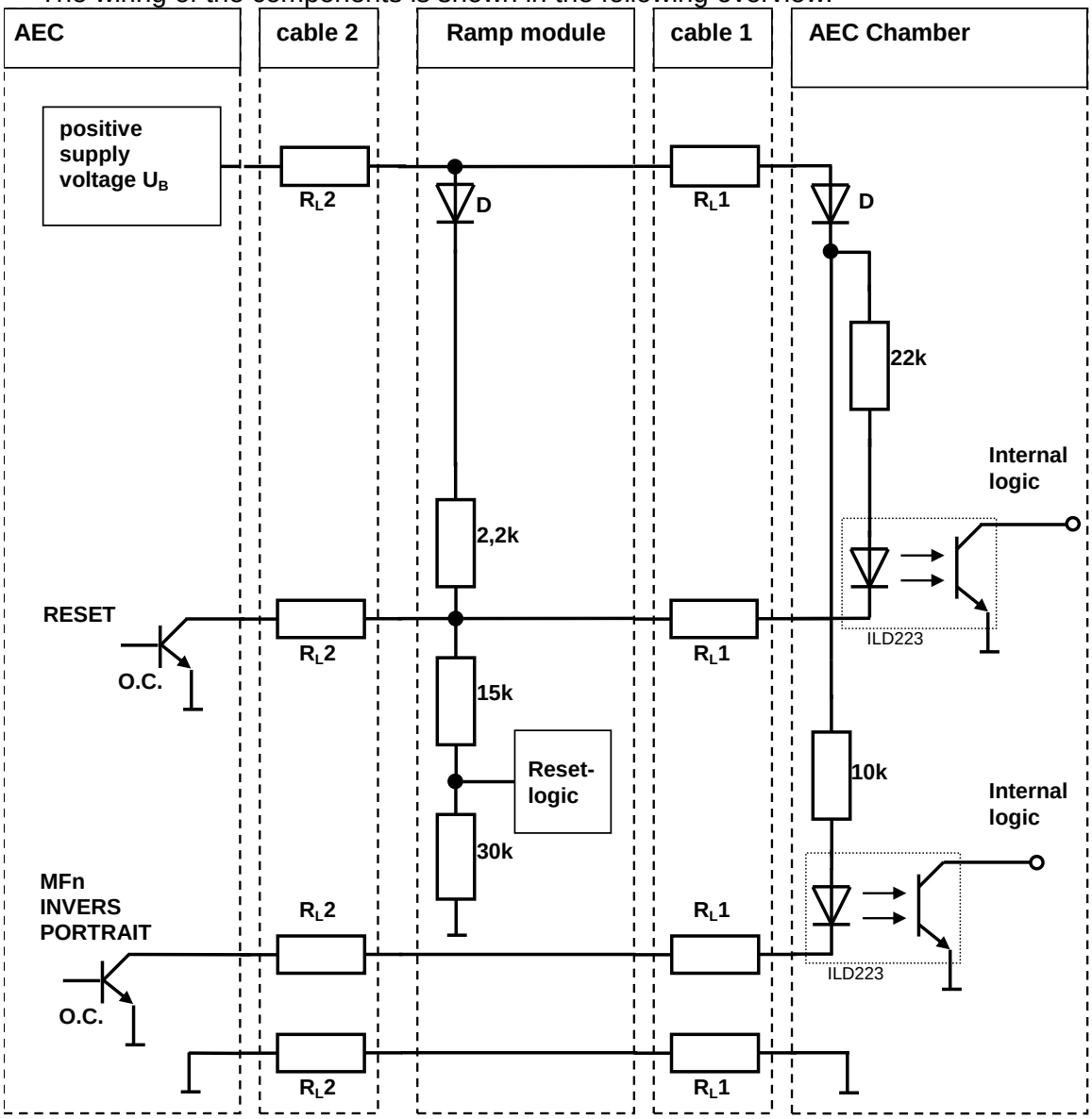


Figure 3: Wiring of components

Cable 1	Cable between AEC chamber and ramp module
Cable 2	Cable (as short as possible) between ramp module and AEC
D	Reverse polarity protection diode (voltage drop approx. 0.3 V)
R_L1 and **R_L2**	Line resistance (depending on type and length of cable)
MFn, INVERSE, **PORTRAIT**	Control signals for measuring field selection
O.C.	Open Collector output

Inside the AEC, low side switches (open collector or open drain outputs) as well as changeover switches between ground and positive supply voltage can be used for control.

The corresponding levels are:

LOW	0 V or <1 V
HIGH	Positive supply voltage or open.

8.4 Measuring signals

The following overview outlines the conversion of the measuring signals.

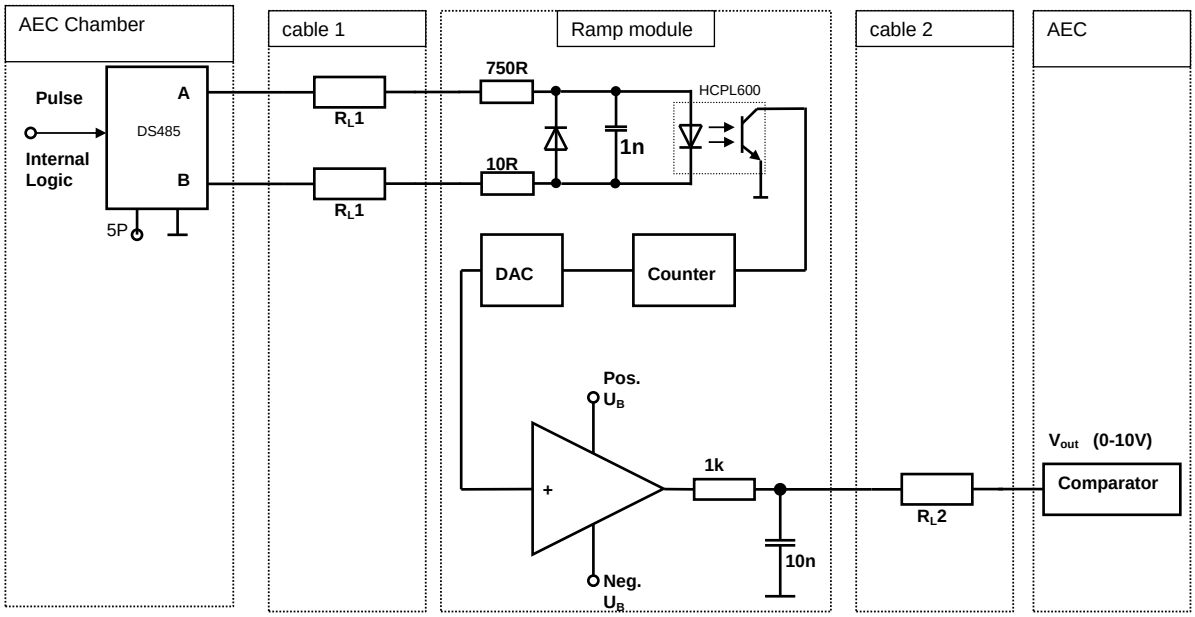


Figure 4: Processing the measuring signals

The pulse signal is output as a differential signal. This ensures a high interference immunity.

When using the digital interface in the AEC, using the input circuit as in the ramp module is recommended.

8.5 Timing of the measuring sequence

The control signals are static signals and are electrically isolated. The optical couplers used (ILD223) filter out peaks and thus guarantee high interference immunity. For the timing, it is important to consider that the H/L edge is delayed by around 200 µs and the L/H edge by around 900 µs. There must be a corresponding time interval (t_{START}) between switching of the control signals and application of the radiation.

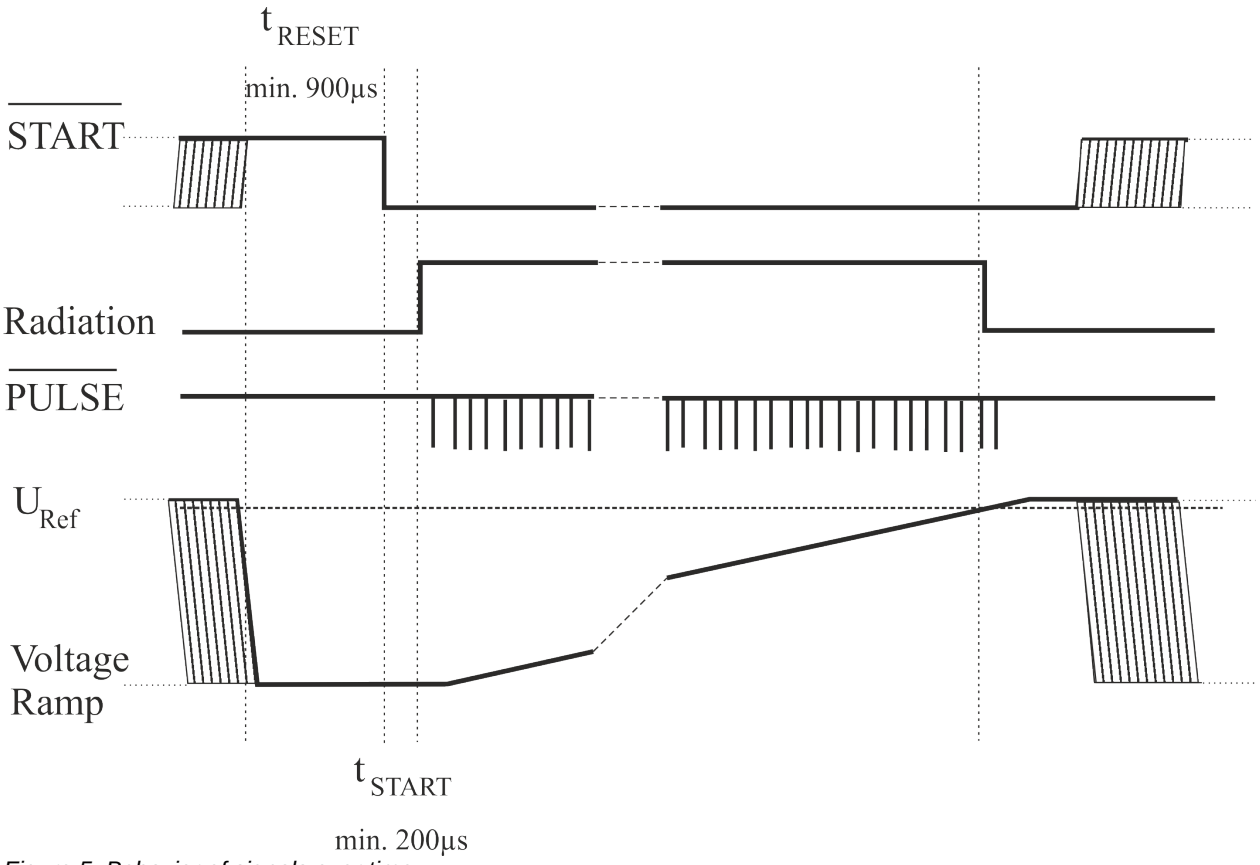


Figure 5: Behavior of signals over time

9 Warning and safety information regarding electromagnetic compatibility

9.1 Warning and safety information regarding electromagnetic compatibility

The AEC chamber is designed for continuous operation in professional health care facilities (clinics, hospitals, medical practices).

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.

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 AEC chamber or the ramp module, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Sources of proximity magnetic fields (RFID readers, surgical swab recognition systems, devices used for position detection in e.g. cath labs, etc.) must not be used at a distance of less than 15 cm from the exposure machine chamber or the ramp module. Non-observance can lead to a reduction in the operating properties of the automatic exposure chamber in the form of additionally generated measuring signals.

9.2 Electromagnetic interference emissions

Emission limits	Compliance
Radiated RF emissions according to CISPR 11	Group 1, Class B

9.3 Electromagnetic immunity

Electromagnetic immunity tests	IEC 60601-1-2 test level	Compliance level
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 8 kV discharge	± 8 kV discharge
	± 15 kV air discharge	± 15 kV air discharge
Radiated RF EM fields according to IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz	3 V/m
Proximity fields from RF wireless communications equipment according to IEC 61000-4-3	27 V/m 385 MHz	27 V/m
	28 V/m 450 MHz, 810 MHz – 3.7 GHz	28 V/m
	9 V/m 710 MHz – 780 MHz 5.24 GHz – 5.785 GHz	9 V/m
Electrical fast transients (bursts) according to IEC 61000-4-4	± 1 kV signal input/output lines	± 1 kV signal input/output lines
Conducted disturbances inducted by RF fields according to IEC 61000-4-6	3 V (6 V in ISM bands) 0.15 MHz – 80 MHz	3 V (6 V in ISM bands)

Rated power frequency magnetic fields according to IEC 61000-4-8	30 A/m	30 A/m
Close proximity magnetic fields according to IEC 61000-4-39	65 A/m, 134.2 kHz 7.5 A/m, 13.56 MHz	--- a) 7.5 A/m
a) According to EN 60601-1-2:2015 + A1:2021, Annex E.9, the following special condition for the intended use of X-rays can be applied: During exposure to X-rays, nobody is in the vicinity of the automatic exposure chamber with the exception of the patient . The use of sources of proximity magnetic fields can thus be ruled out. The types of magnetic field interference sources to be expected in the close proximity are specified in Appendix A (general explanation and justification for 8.11).		