DAP Measurement System

KermaX-*plus*® Chamber

Model Types:

120-131 ETH

120-131 OEM CAN

120-131 HS/RS485

120-131 MICRO

120-131 MIC CAN

120-131 ZKCANO

OEM Manual

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Notice

This OEM (Original Equipment Manufacturer) Manual is an integral part of the **KermaX-*plus*®**. To ensure proper use of this product, please read this manual carefully and keep it for the future reference. Do not carry out any adjustment or procedure other than those described in the manual. The attempt to do so may result in hazardous situation such as fire, explosion or electric shock to patient, operator, or service engineer.

KermaX-*plus*® and its accessories must not be used for any other purpose than described in the accompanying documentation (intended use). Violation will result in loss of warranty.

IBA Dosimetry GmbH does not accept liability for injury to personnel or damage to equipment that may result from misuse of this equipment, failure to observe the hazard notices contained in this manual, or failure to observe local health and safety regulations.

IBA Dosimetry GmbH shall under no circumstances be liable for incidental or coincidental damage arising from use of the equipment described in this document.

Several key functions of the **KermaX-*plus*®** and its associated components are protected by international patents.

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Table of Contents

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1. Introduction

1.1. Intended Use

The **KermaX-*plus*®** is designed to be installed in diagnostic X-ray units (attached at the collimator) and is intended to be used for the measurement of Dose Area Product (DAP), DAP rate, and exposure time for standard and paediatric procedures and long time fluoro applications.

The system and its accessories must not be used for any other purpose than described in the accompanying documentation (intended use).

1.2. Product Description

The **KermaX-*plus*®** chambers are rectangular transparent ionization chambers with integrated electronics to be used in one measuring mode to determine Dose Area Product (DAP), DAP rate, and exposure time. The integration into the system is customer specific. The chamber is attached to the output opening of the X-ray collimator.

The communication Interface, which provide DAP measurement Data, is based on client-server network model with different topology, which are RS-485, CANopen and Ethernet each with RJ45-Interface.

The **KermaX-*plus*®** device as Slave, Server, or Consumer component, depending on the used communication object, provides function or service to the Master, Client or Producer which initiates requests for such services and is able to receive all measured data from the **KermaX-*plus*®** and to control the **KermaX-*plus*®** device. The **KermaX-*plus*®** system is answering all request with certain response telegrams.

1.3. About this Manual

This manual contains information necessary to use the **KermaX-*plus*®** DAP Measurement system. It describes safety information, functionalities, and applications of the **KermaX-*plus*®** device.

To ensure proper use of this product, please read this manual carefully and keep it for future reference. Do not carry out any adjustment or procedure other than those described in the manual. The attempt to do so may result in hazardous situation such as fire, explosion or electric shock to the patient, operator, or service engineer.

The operator must be trained in the proper operation of the product.

NOTICE

IMPORTANT NOTICE

PICTURES AND SCREENSHOTS

All numbers and selections displayed in pictures and screenshots are only examples and no recommendations for settings or entries.

1.3.1. Conventions

The functions of the device, dialog captions and dialog text are indicated by **bold** font.

Examples: **Settings, Field size**.

Referrals to chapter and section headings in this manual are indicated by *italic* font.

Examples*: Notice, Technical Specifications*.

Throughout this OEM manual, hazardous situations or operations are identified by DANGER, WARNING, CAUTION and NOTICE. They are indicated by specific signs and colors, described below:

Sign	Meaning
⚠ DANGER	DANGER indicates a hazardous situation, which, if not avoided, **will** result in death or serious injury of the operator or patient.
⚠ WARNING	WARNING indicates a hazardous situation, which, if not avoided, **could** result in death or serious injury of the operator or patient.
⚠ CAUTION	CAUTION, used with a safety alert symbol, indicates a hazardous situation, which, if not avoided, could result in minor or moderate injury of the operator or patient.
CAUTION	CAUTION, without the safety alert symbol, used to address issues related to possible hardware damage.
NOTICE	IMPORTANT NOTICE used to address operational issues not related to personal injury or hardware damages.

1.3.2. Intended User

This manual is intended for personnel with the following expertise:

Area	Expertise
Installation	Experts
Start-up, operation, and shutdown	Experts Trained personnel
Maintenance	Experts
Troubleshooting	Experts

Trained personnel:
Any personnel who have received a training for using this medical device as described in this User's Guide by the expert or other trained personnel.

Experts:
Assigned person by IBA Dosimetry who received a specific training for this medical device as described in this User's Guide.

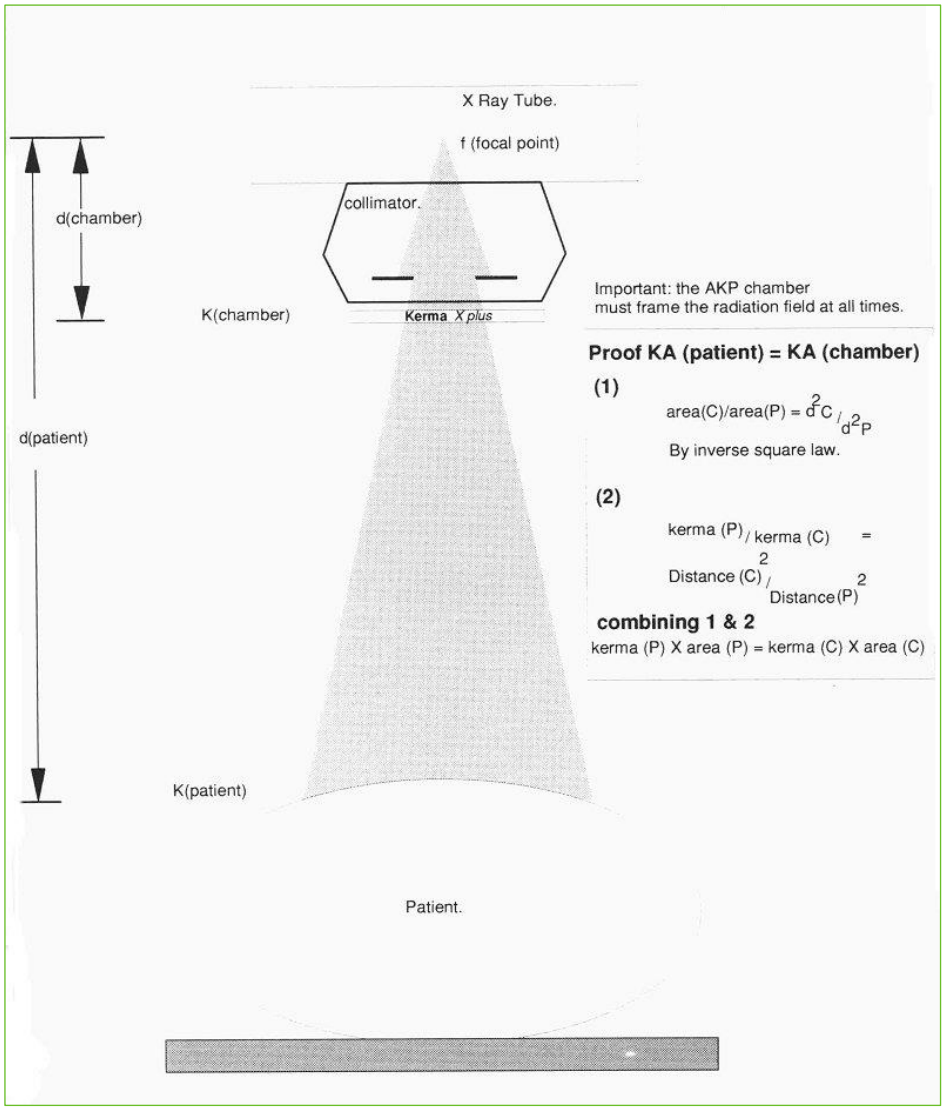
1.3.3. Symbols Used

The following symbols are used on the product and in this manual:

	Consult the User's Guide before use
	The device meets the essential requirements of Regulation (EU) 2017/745 on medical devices.
	UL Recognized Component, E352291. Investigated to: • ANSI/AAMI ES60601-1 (2012) • CAN/CSA-C22.2 No. 60601-1 (2014) • IEC 60601-1 (2012)
	Symbol for Class II Equipment
	DC current
	Energy dependence, rated range of X-ray source voltage.
	Radiation filter, quality equivalent filtration
	Interference may occur in the vicinity of equipment marked with this symbol
	The users are not allowed to change the original factory values of the parameters in the setup menus of the displays with this warning sign
	Warning; Electricity
	Recycling
	Separate collection of electrical and electronic devices in accordance with EU Directive 2012/19/EU: Do not dispose of the device with normal domestic waste. Keep separate from domestic waste and dispose in an environmentally safe way in compliance with local regulations.
	Manufacturer: this symbol shall be accompanied by the name and the address (incl. country) of the manufacturer
	Manufacturing date: this symbol is accompanied by a date to indicate the date of manufacture in the format YYYY-MM-DD
	Serial Number
	Catalogue Number
	Medical Device

1.4. DAP Measurement

The **KermaX-*plus*®** indicates the product of dose and radiation field area in air irrespective of patient distance from the X ray tube as shown in the figure below. This is a convenient phenomenon, which allows a remote collimator mounted chamber to measure the Air Kerma Product (AKP) respectively Dose Area Product (DAP) as it is more commonly known in the patient plane. There are numerous published papers on DAP reference levels and their relationship to short term radiation injury and long-term risk for different examinations, thus avoiding the need for additional calculations.



Principle of DAP Measurement

If the real time display of DAP values and perhaps the DAP rate is available, the physician will rapidly become familiar with factors which affect DAP levels. Learning to keep the radiation field collimated to the area under investigation can have a remarkable influence on total examination DAP (up to 50% reduction in some cases). Using fluoroscopy for the minimum period can also show similar reductions.

2. Health and Safety Information

2.1. General

The purpose of this chapter is to identify the hazards associated with the equipment. This information is presented by displaying all safety and rating labels, which are attached to the equipment, and by providing instructions to avoid the associated hazards.

To ensure proper use of this product, please read this manual carefully and keep it for future reference. Do not carry out any adjustment or procedure other than those described in the manual. The attempt to do so may result in hazardous situation such as fire, explosion or electric shock to the patient, operator, or service engineer. The operator must be trained in the proper operation of the product.

NOTICE

IMPORTANT NOTICE

ALL PERSONNEL MUST READ THIS CHAPTER

All personnel must read this chapter and be fully aware of its contents before commencing installation work and before operating or servicing the **KermaX-*plus*®**.

If the **KermaX-*plus*®** is used in a way not specified in this OEM manual, the protection provided by the equipment may be reduced.

2.2. Important Information

This manual is part of the measurement system for the Dose Area Product, **KermaX-*plus*®** and is needed to ensure the correct functioning of this device. The **KermaX-*plus*®** including all the accessories must not be used for any other purpose as described in this manual.

CAUTION

CAUTION

WITHDRAWN FROM SERVICE IF AN INVOLVING HAZARDOUS INCIDENT

If this measuring unit is involved or associated directly or indirectly with a hazardous incident, it needs to be withdrawn from service instantly. Report the details to your dealer or the manufacturer immediately.

NOTICE

IMPORTANT NOTICE

PATENTS

Several features of the **KermaX-*plus*®** and its components are subject to filed patent applications.

NOTICE

IMPORTANT NOTICE

DO NOT MODIFY THIS PRODUCT

Modifications to this product or the content of this manual will invalidate the product warranty and may compromise a safe operation. Therefore, do not, under any circumstances, make any changes to the product or its components.

2.3. User Responsibility

The personnel, using the **KermaX-*plus*®** to record the Dose Area Product; carry the full responsibility to judge each measurement result critically.

The **KermaX-*plus*®** should be stored in a clean, dry environment. Protect it from mechanical and thermal stress, dust, and unnecessary moisture.

CAUTION

CAUTION

WET DEVICES

Devices on which moisture (condensation) has developed because of temperature changes must not be used unless they have been completely dried.

2.4. Regulations

The installer and operator are responsible for complying with all local regulations regarding installation and operation of the **KermaX-*plus*®**.

Please be advised that other mobile electronic devices, e.g., cellular telephones, exceeding the established emission limits in the EMC standard may disrupt the function of the device.

CE mark:

This medical device is labeled with a CE mark and complies to Regulation (EU) 2017/745 on medical devices. Its design guarantees provision to comply with all recommended standards, as with IEC 60601-1-2 for electromagnetic compatibility (EMC), on the level of the system component. The overall safeguard of EMC test, radiation protection and other safety features of the X-ray system and the respective test results must be guaranteed and documented by the system manufacturer.

National regulations:

In all countries, the legally established regulations are to be observed.

Legally required tests:

All legally required tests must be performed at the prescribed time intervals, e.g., constancy test according to the X-ray ordinance (§116 StrlSchV) in the Federal Republic of Germany, e.g., tests based on DHHS guidelines (**D**epartment of **H**ealth and **H**uman **S**ervices) where applicable.

2.5. Safety Precautions

NOTICE

IMPORTANT NOTICE

LIABILITY

As manufacturer, IBA Dosimetry GmbH will not be held responsible for the safety features, reliability, and performance of the system if:

- The system is used in a manner other than that specified in the operating manual.
- Installation, upgrades, resetting, or repairs are performed by unauthorized personnel.
- Components affecting product safety are not replaced with original IBA Dosimetry GmbH spare parts.

- The **KermaX-*plus*®** should only be used by personnel which fulfils the following criteria:
  - Understanding of the functions and the limitations of the device as they relate to the measurement of radiation output.
  - Knowledgeable about safety procedures to be observed when working with radiation sources.
  - Competence of the security requirements of radiation and the relevant standards like IEC 60601-1 and others.
  - Experience with the use of measuring systems for the Dose Area Product
- Prior to the use of the measuring system, the correct connection between the chamber and the accessories must be ensured. The user must check the general functionality and security of the chamber as well as all the connection cables (also for mechanical damages).
- The **KermaX-*plus*®** must be used in a fire secured, clean, dry, and climatic room. Protect it from mechanical and thermal pressure as well as dust and unneeded humidity.

CAUTION

CAUTION

USING ONLY DRY CHAMBERS

If condensation is built up in the chamber because of temperature changes, the system must be dried completely and should not be used.

- The **KermaX-*plus*®** is not designed for patient contact in its intended use.
- Do not remove any signs or labels of the **KermaX-*plus*®**. If labels become unreadable, the corresponding parts must be sent back to the manufacturer, to be identified and to be relabelled.
- Never open the chamber device to avoid contact with hazardous high voltage inside.

⚠ WARNING

WARNING

HIGH VOLTAGE

Because of the high voltage, there is a risk of life!

- The **KermaX-*plus*®** is not waterproof. If there is a risk of spray, device must be covered and protected sufficiently.

- The chamber is not completely sealed, due to the special mounting situation. When the device is mounted and then used, make sure, that no foreign substances get into the measuring chamber. Any foreign subjects could lead to errors.
- Because of the high sensitivity of the measuring chamber, vibrations or touching the chamber could cause partial discharge, which could lead to a wrong measuring result.

  This is the reason, why it must be guaranteed in the C-shaped system, that those impulses are only evaluated during the exposure

2.5.1. Device Handling

- Before using the system, the operator must ensure that the chamber and all accessories are in proper working condition. The user must verify the general functionality, safety, and condition of the device and cables.
- Neither the **KermaX-*plus*®** chamber nor any peripheral device must be used in direct contact to the patient.
- Do not remove any labels from parts of the system components or its accessories.
- Do not open the chamber device to avoid contact with hazardous high voltage.
- The housing of the chamber device is not waterproof. When the risk of splashing fluid is present, mount it under auxiliary covers.
- The **KermaX-*plus*®** requires a voltage in the range of 15 - 24 V DC ±20%, which is normally provided by a power supply with 4kV isolation according to IEC 60601-1. Connecting the chamber to another external power supply shall only be done with the approval and under the sole responsibility of the manufacturer of the diagnostic X-ray machine. The range and type of the voltage provided shall be checked and, if necessary, discussed with IBA Dosimetry GmbH.

⚠ WARNING

WARNING

ENSURE A SECURE INSTALLATION

When mounting the chamber and its accessories (holder, filter, etc.) on an X-ray machine, make sure the devices are locked securely in place to prevent falling of the device when the collimator rotates. It may damage the device or cause personal injuries.

2.5.2. Protection from Fluids

Do not allow fluids to enter the converter either during normal operation or during cleaning and disinfection as this may damage the system or cause a system malfunction.

2.5.3. Radiation Protection

Please adhere to the following recommendations to keep the absorbed dose for the patient as low as possible:

- When available, always use the automatic dose rate and / or exposure control since these contribute considerably to the reduction of radiation exposure for the patient and the operator.
- Collimate the exposure field as small as possible or use the automatic collimation if available.
- Keep the fluoroscopic time as short as possible.
- Protect the patient using gonad shields or lead lined rubber covers when using radiation for examinations near the reproductive organs.
- Wear protective clothing when working in the examination area.
- Use a radiation monitoring badge or a pen dosimeter.
- Maintain the maximum possible distance from the source of radiation.
  Maintain the maximum possible focus-skin-distance.
- Be aware that certain materials can lead to increased dose exposure, e.g., parts of a patient table, when located in the beam path.
- Components that are brought into the beam path, e.g., patient table, will attenuate radiation and may degrade image quality.

2.5.4. Combination with Other Systems

In the interest of safety do not attach any products / components to the **KermaX-*plus*®**.

The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- Use of the accessory in the patient vicinity
- Evidence that the safety certification of the accessory has been performed in accordance with the appropriate IEC 60601-1 harmonized national standards

2.5.5. Use of Accessories

⚠ CAUTION

CAUTION

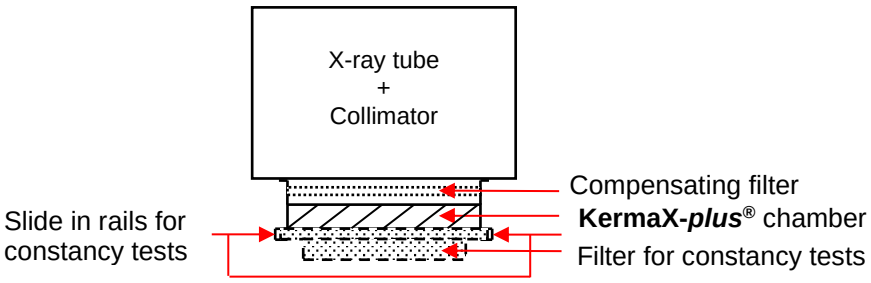
ACCESSORIES AND SPARE PARTS

No other accessories and spare parts than those provided or approved by the manufacturer must be used, otherwise operator safety, specified measuring accuracy, and interference free operation cannot be guaranteed. Violation of this prescription will result in loss of warranty

IBA Dosimetry GmbH cannot be held liable for any damages resulting from the use of accessories or consumables that are not provided or approved by the manufacturer.

2.5.5.1. Positioning of Compensating Filters

Special accessory holders to slide-in of compensating filters, e.g., pediatrics or shoulder filters, in patient operation only **over** the **KermaX-*plus*®** are available (3.1.2 Optional components for)



⚠ WARNING

WARNING

USING FILTER IN CONSTANCY TEST

In patient operation never slide in filters in the “slide-in rails for constancy tests"!

2.5.5.2. Constancy Test

⚠ WARNING

WARNING

FALLING DEVICE

Strictly follow the following instruction and take extreme care when installing the testing device. The device may fall due to improper installation and cause personal injury.

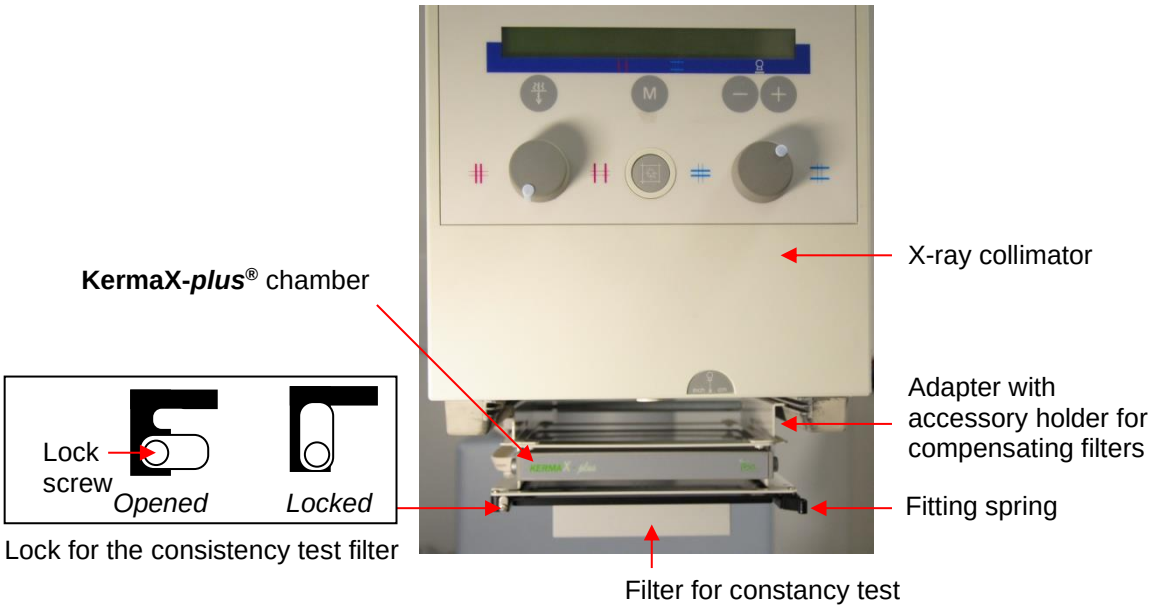
⚠ WARNING

WARNING

LOCK THE DEVICE IN PLACE

To prevent devices falling, ensure the accessory holder, chamber, and filter, etc., are properly locked in place with screws, fitting springs or locking mechanism when mounting them.

1. It is only allowed to use filters with a maximum of 1 kg in the “slide-in rails for constancy tests”, e.g., the DEDX detector from IBA Dosimetry GmbH.
2. The “slide-in rails for constancy tests” must only be used for constancy tests.
3. It is not allowed to perform tube movements, e.g., during tomography, with filters fitted to the “slide-in rails for constancy tests”.
4. Open the Lock for the consistency test filter by loosening the lock screw and turning it to the horizontal position to open the left rail; press the fitting spring to open the right rail. Slide in the filter; then release the fitting spring and turn the lock to the vertical position and tighten the screw. Installing the filter for consistency test into the “slide-in rails for constancy tests" is only permitted in the horizontally oriented and stationary tube.



An example of settings for constancy test

5. The width of the filter plate must be 176 mm or 167 mm depending on the collimator tail spacing. The filter may not to be deformed and may have a maximum tolerance of + 0.5 mm and – 0.25 mm relative to the nominal dimension.
6. The locking screws always must be fixed on both sides.
7. Daily control of the adapter that it is tightly installed and not damaged mechanically. If necessary, replace the adapter.
8. Positioning of compensating filters as described above.

⚠CAUTION

CAUTION

ENSURE FITTING SPRING IN PROPER WORKING CONDITION

Check the fitting spring regularly that it has not become loose for locking the safeguard lever.

2.6. Electromagnetic Compatibility (EMC)

The electromagnetic environment of intended use is the professional healthcare facility environment, except for the RF shielded room of a medical electrical system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.

(See chapter Intended Use).

Due to electromagnetic disturbances, the measurement performance of dose area product meter can be degraded or lost.

NOTICE

IMPORTANT NOTICE

OPERATING IN NEAR OF HF SURGICAL EQUIPMENT

The Operation of **KermaX-*plus*®** equipment in a HF-SURGICAL ENVIRONMENT is generally excluded. Its use in such Environment the manufacturer of the diagnostic X-ray machine carries the full and entire responsibility to evaluate the correct operating and measurement of the **KermaX-*plus*®** equipment.

NOTICE

IMPORTANT NOTICE

OTHER EQUIPMENT CLOSE TO THE OPERATING DEVICE

The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

NOTICE

IMPORTANT NOTICE

USE OF ACCESSORIES, TRANSDUCERS AND CABLES

The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of the **KermaX-*plus*®** could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

NOTICE

IMPORTANT NOTICE

USE OF PORTABLE RF COMMUNICATIONS EQUIPMENT

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 **KermaX-*plus*®**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

2.6.1. Electromagnetic emissions compliance

Manufacturer's declaration – electromagnetic emissions		
Phenomenon	**Basic EMC standard or test method**	**EMISSIONS class and group**
radiated RF EMISSIONS <1GHz	CISPR 11 [b)]	Class B Group 1
Harmonic distortion	IEC 61000-3-2 [a)]	not applicable, no connection to public mains network.
Voltage fluctuations and flicker	IEC 61000-3-3 [a)]	not applicable, no connection to public mains network.

[a)] This test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEMS used there will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard.

[b)] Mains conducted EMISSION not tested; direct connection to PUBLIC MAINS NETWORK not possible

2.6.2. Electromagnetic Immunity compliance

Manufacturer's declaration – electromagnetic immunity ENCLOSURE PORT		
Phenomenon	**Basic EMC standard or test method**	**IMMUNITY TEST LEVELS**
ELECTROSTATIC DISCHARGE [a)]	IEC 61000-4-2	severity level 3 Contact discharge: ± 6 kV Air discharge: ± 8 kV
Radiated RF EM fields [b)]	IEC 61000-4-3	3 V/m [g)] 80 MHz – 2,7 GHz [c)] 80 % AM at 1 kHz [d)]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	see chapter 2.6.3
RATED power frequency magnetic fields [e)] [f)]	IEC 61000-4-8	30 A/m [h)] 50 Hz or 60 Hz

a) This test applies to various external parts of the complete dose area measurement equipment which may be touched by the OPERATOR during a normal measurement (i.e., not to those parts of the IONIZATION CHAMBER and MEASURING ASSEMBLY that are normally exposed in the radiation beam).

b) The interface between the PATIENT physiological signal simulation, if used, and the ME EQUIPMENT or ME SYSTEM shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT or ME SYSTEM.

c) ME EQUIPMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

d) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

e) Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

f) During the test, the ME EQUIPMENT or ME SYSTEM may be powered at any NOMINAL input voltage, but with the same frequency as the test signal.

g) Before modulation is applied.

h) This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

Manufacturer's declaration – electromagnetic immunity Input d.c. power PORT		
Phenomenon	**Basic EMC standard or test method**	**IMMUNITY TEST LEVELS**
Electrical fast transients / bursts [a) g)]	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line [a) b) g) k)]	IEC 61000-4-5	severity level 3; 1.2/50 (8/20) µs LtL: ±1.0 kV
		not applicable EUT is intended to be used with Power Supply which complies the Surge requirements
Surges Line-to-ground [a) b) g) k)]	IEC 61000-4-5	severity level 3; 1.2/50 (8/20) µs LtG: ±2.0 kV
		not applicable EUT is intended to be used with Power Supply which complies the Surge requirements
Conducted disturbances induced by RF fields [a) c) d) i)]	IEC 61000-4-6	3 V [h)] 0,15 MHz – 80 MHz 6 V [h)] in ISM bands between 0,15 MHz – 80 MHz [j)] 80 % AM at 1 kHz [e)]
Electrical transient conduction along supply lines [f)]	ISO 7637-2	not applicable

a) The test is applicable to all d.c power PORTS intended to be connected permanently to cables longer than 3 m.

b) All ME EQUIPMENT and ME SYSTEM cables shall be attached during the test.

c) INTERNALLY POWERED ME EQUIPMENT is exempt from this test if it cannot be used during battery charging, is of less than 0,4 m maximum dimension including the maximum length of all cables specified and has no connection to earth, telecommunications systems, any other equipment or a PATIENT.

d) The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) For ME EQUIPMENT and ME SYSTEMS intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems.

g) Direct coupling shall be used.

h) r.m.s., before modulation is applied.

i) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

j) The ISM (industrial, scientific and medical) bands between 0,15 MHz 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.

k) Severity level 3 is only applicable for **KermaX-plus® 120-131** ETH

Manufacturer's declaration – electromagnetic immunity Signal input/output parts PORT		
Phenomenon	**Basic EMC standard or test method**	**IMMUNITY TEST LEVELS**
ELECTROSTATIC DISCHARGE [e]	IEC 61000-4-2	severity level 3 Contact discharge: ± 6 kV Air discharge: ± 8 kV
Electrical fast transients / bursts [b] [f]	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Surges Line-to-ground [a] [j]	IEC 61000-4-5	severity level 3; 1.2/50 (8/20) µs LtG: ±2.0 kV
		not applicable No outdoor output line
Conducted disturbances induced by RF fields [b] [d] [g]	IEC 61000-4-6	3 V [h] 0,15 MHz – 80 MHz 6 V [h] in ISM bands between 0,15 MHz – 80 MHz [i] 80 % AM at 1 kHz [c]

[a] This test applies only to output lines intended to connect directly to outdoor cables.

[b] SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

[c] Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

[d] Calibration for current injection clamps shall be performed in a 150 Ω system.

[e] Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.

[f] Capacitive coupling shall be used.

[g] If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

[h] r.m.s., before modulation is applied.

[i] The ISM (industrial, scientific and medical) bands between 0,15 MHz 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.

[j] Severity level 3 is only applicable for **KermaX-plus® 120-131** ETH

2.6.3. Immunity to proximity fields from RF wireless equipment

Manufacturer's declaration – IMMUNITY to RF wireless communications equipment						
Test frequency [MHz]	**Band** [a] [MHz]	**Service** [a]	**Modulation** [b]	**Maximum power** [W]	**Distance** [m]	**IMMUNITY TEST LEVEL** [V/m]
385	380 –390	TETRA 400	Pulse modulation [b] 217 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 217 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

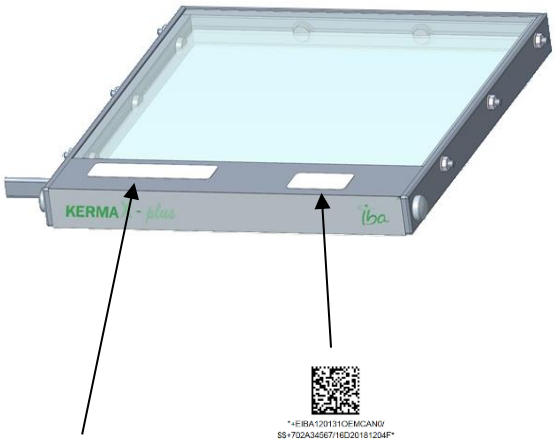
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

2.7. Labels

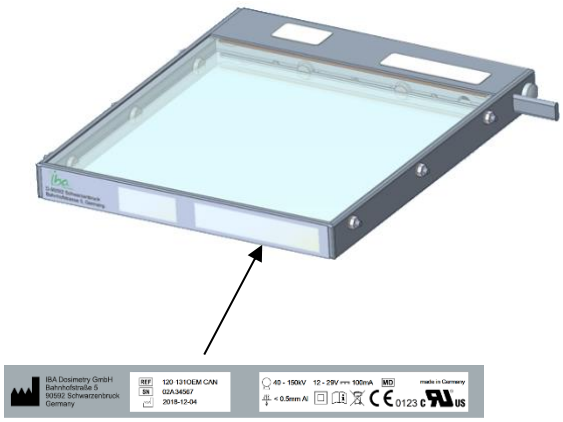
The label indicates the identification and electrical ratings. Another label indicates the device model number and serial number. They are located on the rear side of the chamber.

An example is shown below:



OEM specific label

UDI label
(acc. ANSI/HIBC Supplier Labeling Standard)



ID label

NOTICE

IMPORTANT NOTICE

UL RECOGNIZED COMPONENT MARK

The **KermaX-*plus*®** is mark as UL Recognized Component. The Model Types are listed in the UL File Number E194025 and E352291.

2.8. Regulatory Requirements

The **KermaX-*plus*®** fulfils the requirements of the Medical Device Regulation (EU) 2017/745 and is a medical device class IIb according to annex VIII classification rule 10.

In accordance with the performance requirements of IEC 60580:2019, the **KermaX-*plus*®** is classified as FIELD-CLASS dose area product meter.

The quality management system in IBA Dosimetry GmbH is certified according to EN ISO 13485:2016.

The following standards apply:

- IEC 60580:2019
- UL 2601-1 and UL 60601-1 ed.1
- CSA C22.2 No. 601.1
- IEC 60601-1:2005+A1:2012
- IEC 60601-1-2:2014
- ANSI/AAMI ES 60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- CSA CAN/CSA-C22.2 No. 60601-1:14

The **KermaX-*plus*®** is manufactured by:

IBA Dosimetry GmbH
Bahnhofstrasse 5
DE-90592 Schwarzenbruck
Germany

NOTICE

IMPORTANT NOTICE

UL RECOGNIZED COMPONENT MARK

The **KermaX-*plus*®** is marked as UL Recognized Component and the Model Type is listed in the UL File Number E352291 and E194025.

NOTICE

IMPORTANT NOTICE

COMPLY WITH ALL LOCAL REGULATIONS

The installer and operator are responsible for complying with all local regulations regarding installation and operation of the **KermaX-*plus*®** measurement system with its accessories.

The overall safeguard of EMC test, radiation protection and other safety features of the X-ray system and the respective test results must be guaranteed and documented by the system manufacturer.

RoHS and REACH Compliance:

The products specified have been designed and manufactured in compliance with the following specifications:

- Compliant with the European Union **RoHS** (**R**estriction **o**f **H**azardous **S**ubstances) Directive, 2011/65/EU as amended by Commission Delegated Directive (EU) 2015/863 (RoHS 3).
- Compliant with the European **REACH** (**R**egistration, **E**valuation, **A**uthorization and Restriction of **CH**emicals) Regulation, EC No. 1907/2006.
- Compliance with the specification has been verified by internal design controls. We reserve to ourselves making use of the exception for medical devices as defined in EU Directive 2012/19/EU on **W**aste **E**lectrical and **E**lectronic **E**quipment (**WEEE**).

3. System Description

3.1. Standard Components

3.1.1. DAP Chambers

The **KermaX-*plus*®** chambers are rectangular, transparent ionization chambers with integrated electronics and connection cable with RJ45 plug, having a DAP resolution of 0.01 µGym² and different communication Interfaces (see Chap. 1.2 Product Description). They are available in two sizes:

- Standard size, dimension: 179 × 156 × 17 mm; active area : 140 × 140 mm
- Compact size, dimension: 158 × 134.5 × 17 mm; active area : 115 × 115 mm

Based on the chamber with or without center cross, the chambers are classified into two groups:

KermaX-*plus*® with Part No.:

Chambers without center cross:

Name	Standard Size	Compact Size	Interface
120-131 ETH	x		Ethernet
120-131 OEM CAN	x		CAN
120-131 HS/RS485	x		RS485-Serial
120-131 MICRO Rev02		x	RS485-Serial
120-131 MIC CAN		x	CAN

Chambers with center cross and special mounting frame:

Name	Standard Size	Compact Size	Interface
120-131 ZKCANO	x		CAN

3.1.2. Optional components for **KermaX-*plus*®**

- Power pack

  Part No.: 120805
  12080600 [*only Ethernet Chamber*]
  Input: 100-240 VAC, 50/60 Hz
  Output: 15 VDC

  Including one power line:

  Part No.: 12080501, Euro plug
  12080502, UK plug
  12080503, US plug
  12080504, no plug

  Part No.: 12080602 [*only Ethernet Chamber*]
  passive PoE injector box (for mounting), shielded RJ45 socket, DC socket ∅ 5,5/2,1mm

  Part No.: 12080601 [*only Ethernet Chamber*]
  passive PoE injector cable adapter, unshielded RJ45 socket, DC socket ∅ 5,5/2,1mm

- AKP-cable, with Y-connector

  Part No.: 120900105, 5 m / 16 ft
  120900106, 6 m / 20 ft
  120900112, 12 m / 40 ft
  120900118, 18 m / 50 ft
  120900124, 24 m / 80 ft
  (Other lengths are available on request.)

- USB Converter
  [*only Serial Interface Chamber*]

  Part No.: 12080800
  Converter including cable

  Part No.: 12080803
  USB cable only

- Serial Converter RS485 to RS232
  [*only Serial Interface Chamber*]

  Part No.: 120104501#001
  Converter RS485/232
  full duplex

- Line Filter

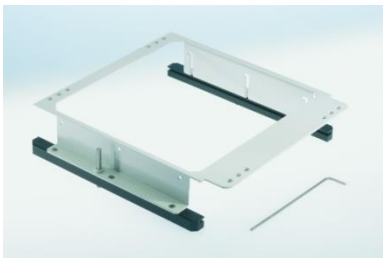
  Part No.: 12080700
  for Serial Interface Chamber

  Part No.: 12080650
  for CAN Interface Chamber

- Adapters with accessory holder for standard size chambers

  Part No.: 120103030,
  Dist. between collimator rails 176 mm

  Part No.: 120103040,
  Dist. between collimator rails 167 mm



- Adapters with accessory holder including extension rails for standard size chambers

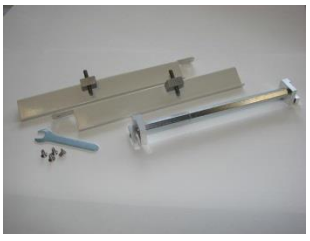
  Part No.: 120103031,
  Dist. between collimator rails 176 mm

  Part No.: 120103041,
  Dist. between collimator rails 167 mm

- Pair of extension rails for accessory holder for standard size chambers

  Part No.: 120103033,
  Dist. between collimator rails 176 mm

  Part No.: 120103043,
  Dist. between collimator rails 167 mm



➤ Pair of rails for chamber

Part No.: 120131020
For standard size chambers
Dist. between collimator rails 176 mm

Part No.: 120131021
for standard size chambers
Dist. between collimator rails 167 mm
Rails fixed on KermaX-plus®

Part No.: 1201310211
For standard size chambers
Dist. between collimator rails 167 mm
Retrofit

Part No.: 1201310225
For standard size chambers
Customized for Ralco R225 collimator

Part No.: 120131015
For compact size chambers
Dist. between collimator rails 150 mm,

Part No.: 120131042
For compact size chambers
Dist. between collimator rails 146 mm

Part No.: 120AMXGE
For compact size chambers
Customized for GE AMX4 (with locking system)

Part No.: 120OPTIMA200
For compact size chambers,
Customized for GE OPTIMA200

NOTICE

IMPORTANT NOTICE

SPECIAL ADAPTORS

IBA offers a variety of special adapters. Please contact us at IBA Dosimetry GmbH. See contact information in Section 8.7.1.

4. Unpacking and Installation

4.1. Unpacking

NOTICE

IMPORTANT NOTICE

PERSONNEL QUALIFICATIONS

Only qualified personnel is permitted to unpack, install and operate the **KermaX-*plus***®.

NOTICE

IMPORTANT NOTICE

TRANSPORTATION

During transportation the **KermaX-*plus***® should be adequately protected in the originally supplied or equivalent packing.

NOTICE

IMPORTANT NOTICE

DOCUMENTATION

The documentation supplied with the **KermaX-*plus***® consists of this manual and the factory calibration certificate.

4.2. Installation

4.2.1. Installing the Chamber in the X-Ray Machine

Slide the chamber into the lower accessory rails of the collimator. Ensure that even if the collimator shutter is fully open that no shadows from the chamber frame are visible in the light field.

For chambers integrated into the X-ray collimator, please refer to the respective instruction manual from the collimator manufacturer.

CAUTION

CAUTIONS

SAFETY PRECAUTIONS

When installing the device, please observe the safety precautions described in Section 2.5 Safety Precautions.

CAUTION

CAUTION

TURN OFF THE POWER BEFORE CONNECT/DISCONNECT THE CHAMBER

Do not connect/disconnect the chamber to/from the X-ray machine when the power is turned on. It may damage the electronics.

CAUTION

CAUTION

DO NOT EXCEED THE ACTIVE AREA OF THE CHAMBER

The size of the radiation field at the surface of the centered chamber may not exceed the active area of the chamber (see Chapter 9, Technical Specifications).

NOTICE

IMPORTANT NOTICE

REFERENCE DIRECTION OF INICIDENT RADATION

The central beam direction of incident radiation must be orthogonal to the Chamber surface.

CAUTION

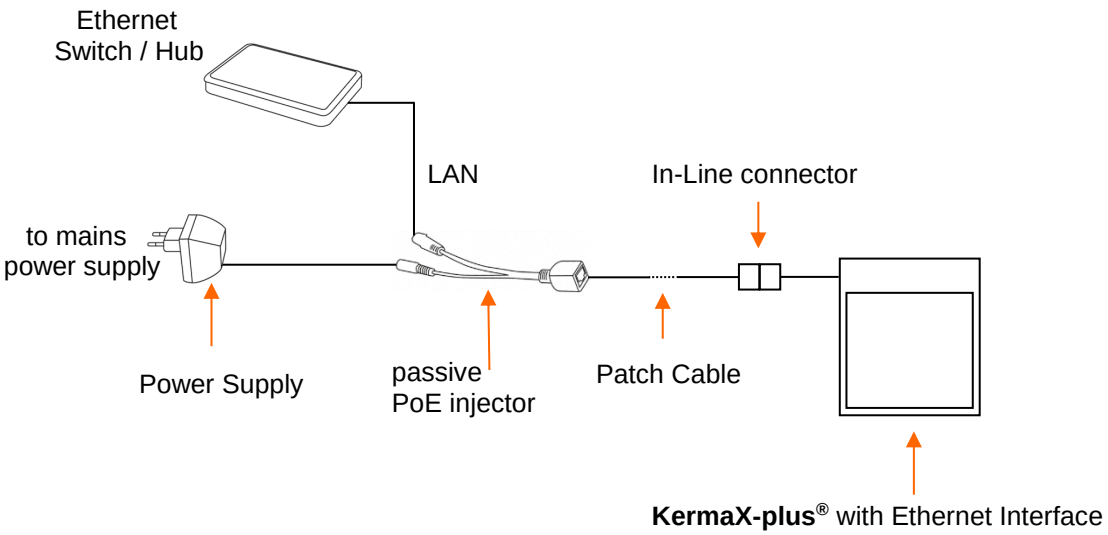
CAUTION

DO NOT USE DAMAGED KERMAX-PLUS® PARTS

Do not use damaged parts.

4.2.2. Electrical Configuration of **KermaX-*plus*®** with Ethernet Interface

Configuration of the **KermaX-*plus*®** measuring system with Ethernet Interface consists of the following minimum components:



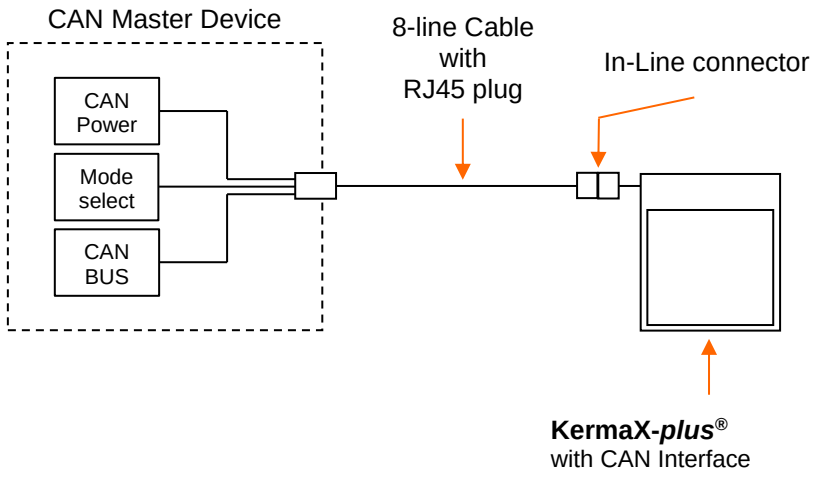
*Configuration of **KermaX-plus®** system with Ethernet Interface*

The setup procedure:

1. Connect chamber cable to the PoE injector (POE socket) with the help of the inline connector plug an approved network cable (CAT5 STP/SFTP or better).
2. Connect the power supply to the PoE Adapter (DC socket).
3. Connect the power supply to the mains. Make sure that the power supply is appropriate for medical Equipment and accordingly UL resp. IEC 60601 certified (see Chap. 2.5.1).
4. Connect the LAN (Network Interface) to PoE Adapter (RJ45 socket)

4.2.3. Electrical Configuration of **KermaX-*plus*®** with CAN Interface

Configuration of the **KermaX-*plus*®** measuring system with CAN Interface consists of the following minimum components:



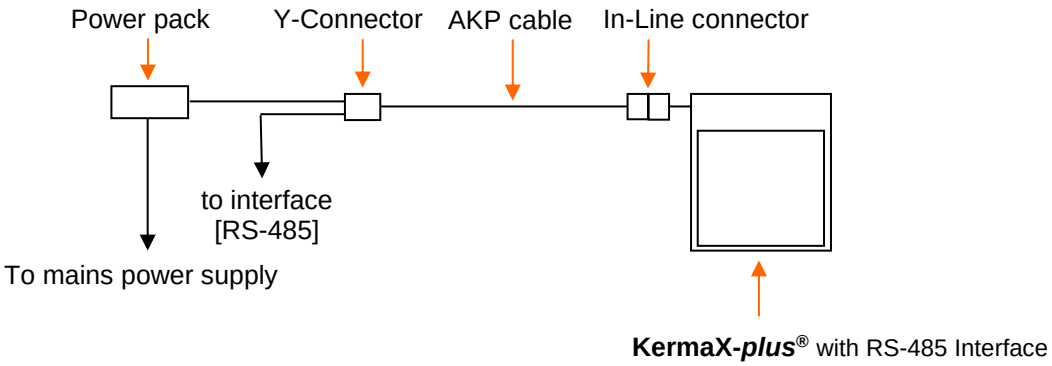
*Configuration of **KermaX-plus**® CAN Interface*

The setup procedure:

1. Connect chamber cable to the CAN Master Device socket either directly or with an extension cable connection with the help of the modular connector plug.
2. Make sure that the CAN power supply is appropriate for medical Equipment and accordingly UL resp. IEC 60601 certified (see Chap. 2.5.1).

4.2.4. Electrical Configuration of **KermaX-*plus*®** with RS-485

Configuration of the **KermaX-*plus*®** measuring system with RS-485 Interface consists of the following minimum components:



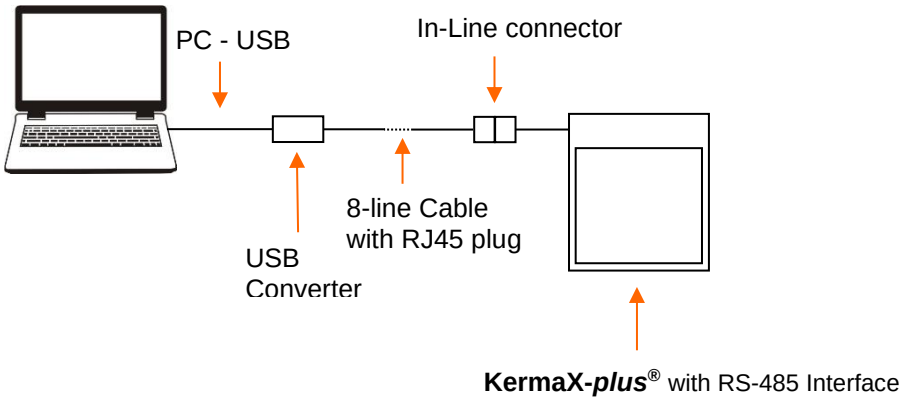
*Configuration of **KermaX-plus**® system with RS-485 Interface*

The setup procedure:

1. Connect chamber cable to the AKP cable connections with the help of the modular connector plug and the Y-connector.
2. Connect the power pack to the Y-connector of the AKP cable.
3. Connect the power supply to the mains. Make sure that the power supply is appropriate for medical Equipment and accordingly UL resp. IEC 60601 certified (see Chap. 2.5.1).
4. Connect the computer / generator to the Y-connector.

4.2.5. Electrical Configuration of **KermaX-*plus*®** with RS-485 with USB Converter

Configuration of the **KermaX-*plus*®** measuring system with RS-485 Interface and USB Converter consists of the following minimum components:



*Configuration of **KermaX-plus**® system with RS-485 Interface and USB Converter*

The setup procedure:

1. Connect chamber cable to the extension cable connections with the help of the modular connector plug and in-line connector.
2. Connect the extension cable to the RJ45 socket of USB converter.
3. Connect the USB Converter to PC with the provided USB cable.

For more Information see the appropriate USB Converter Manual.

NOTICE

IMPORTANT NOTICE

USB CONVERTER DRIVER

The use of the USB Converter for **KermaX-*plus*®** system required a FTDI Driver.

NOTICE

IMPORTANT NOTICE

POWER TO KERMAX-PLUS® MEASURING SYSTEM

The **KermaX-*plus*®** measuring system is powered through the USB converter from the USB port of the computer and required about 400mA current from USB Port.

CAUTION

CAUTIONS

USB CABLE – PROPER FUNCTION OF CONVERTER

For a proper functioning of the USB converter and consequently the **KermaX-*plus*®** system only use the cable supplied with the converter or use one which fulfills the specifications above.

CAUTION

CAUTION

Power Supply

Use the UL 60601 & IEC 60601-1-2:2014 approved power supply only.

CAUTION

CAUTION

TURN OFF POWER BEFORE CONNECT/DISCONNECT THE CHAMBER

Do not connect/disconnect the chamber to/from the system when the power is turned on. It may damage the electronics.

⚠ CAUTION

CAUTION

RESPONSIBILITY

The integrator takes the full and entire responsibility of integrating/ installing **KermaX-*plus*®** measuring systems.

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5. Measurement

1. Before starting a measurement, check the System and Error State to be ready for measurement (see also section 6.1).
2. Reset the last measurement values for new a session resp. study.
3. Make an exposure and read out the measured values with corresponding command.

⚠CAUTION

CAUTION

DO NOT EXCEED THE ACTIVE AREA OF THE CHAMBER!

The size of the radiation field at the surface of the centered chamber may not exceed active area of the chamber (see Chap. 9,Technical Specifications).

⚠CAUTION

CAUTION

MAXIMUM AIR KERMA RATE / DAP RATE

The maximum Air Kerma rate at the chamber position and DAP rate must not be exceeded (see Chap. 9.1 Specifications).

⚠CAUTION

CAUTION

RECALIBRATION / VERIFICATION

If a compensating filter is used behind the measuring chamber and before the patient the indicated level must be adjusted accordingly. The absorption of the table top when available should be compensated if the chamber is installed below the examination table.

NOTICE

IMPORTANT NOTICE

DAP CORRECTION FACTOR PROCEDURE

The measurement procedure for determination of DAP Correction Factor is described in Chap.6.5 Recalibration.

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6. Quality Assurance

6.1. System Test (Stability Check)

To check the functionality and stability of the DAP-measurement system, a test signal can be activated by software command from the X-ray unit. The activation of this test in the DAP measurement system will only happen if the high voltage inside the chamber is within the correct range resp. no device error occurs.

6.1.1. Test Value

The test command activates a test charge in the amplifier of the connected chamber. Afterwards the chamber returns a value of 10000 (≙100.00µGym²) ±20 % which should be evaluated through the user (resp. X-Ray unit).

NOTICE

IMPORTANT NOTICE

PERFORMING STABILITY TEST

The stability test should be performed before each measurement session.

6.2. Calibration Check

NOTICE

IMPORTANT NOTICE

FIRST CHECK

The DAP measuring system is calibrated by the manufacturer prior to shipment and a copy of the Calibration Certificate is included with the documentation. As a rule, the first check of the calibration normally takes place at the time of installation.

CAUTION

CAUTION

ABSORBER CORRECTION

The DAP system is calibrated without an absorber. Consider each correction that could be necessary to take into account the local conditions.

If a compensating filter is used (e.g. behind the measuring chamber or in a cosmetic cover of the X-ray tube), the indicated level must be adjusted accordingly (*see Chap. 6.5 Recalibration*).

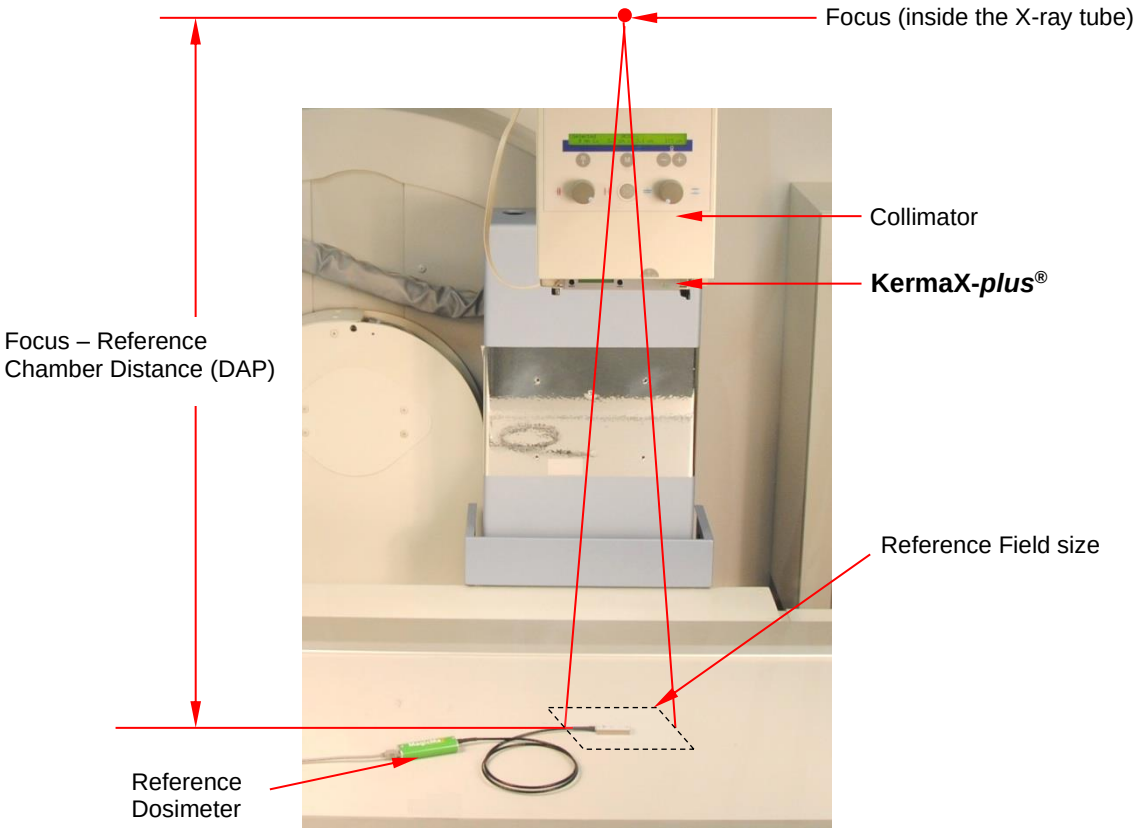
The absorption of the table top when available should be compensated if the chamber is installed below the examination table.

6.2.1. Measurement Setup

To ensure correct measurements, the operator should check the systems compliance with the calibration conditions in the table below.

Reference Conditions for Calibration	
Air humidity	50 % (relative humidity, no condenstation)
Air pressure	1013 hPa
Field size	5 x 5 cm at chamber level (max. 9 x 9 cm)
Stabilization time	< 15 minutes
Temperature	20 °C
Radiation Quality	100 kV (RQR 8, IEC 61267)

*Meaurement Setup for the DAP verification of the **KermaX-plus**®*



6.2.2. Calibration Check procedure

1. Switching on the X-ray machine, the **KermaX-*plus*®** system is switched on simultaneously (depending on the wiring/connecting of the system) and can measure after about 20 seconds. Only after the specified stabilization time, the system measures within the specifications
2. Perform a stability check as described in previous chapter 6.1 System Test (Stability Check).
3. Irradiated field size parameters should be set at the control console resp. collimator device. It is recommended to collimate an average size of the irradiated field of the active chamber surface.
4. Determine the reference field area. It is the size of the surface area on the reference point level (e.g., table top, grid assembly) which is orthogonal to the central beam direction. This is the location of the reference dosimeter.

   For a more accurate field size determination, it is recommended to exposure an X-ray film or a fluoroscopic screen.

   If an iris shutters / collimators are used, the area formula for regular polygons shall be applied.
5. Put the reference dosimeter on the reference point level.
6. Exposure parameters should be set at the control console and an X-ray exposure released. In order to make a valid comparison with the manufacturer's calibration (see Table above, reference conditions), the radiograph must be made using 100 kV.
7. After the exposure has been released, take note of the results displayed on both measuring devices.

   e.g., reference dosimeter display: $2703\ \mu Gy$
   KermaX-*plus*®: $33.90\ \mu Gym^2$
8. Comparison of the reference dose area product (*reference dose x reference field area*) and **KermaX-*plus*®** measured dose area product:

$$\frac{100\% \times 33.90\ \mu\,Gym^2}{2703\ \mu\,Gy \times 0.012 m^2} - 100\% = 4.51\%$$

   KermaX-*plus*® value which are about 4.51% higher which is still within tolerance. The manufacturer's tolerance is ± 5%.

NOTICE

IMPORTANT NOTICE

AIR DENSITY CORRECTION

Due to sensor option (built-in air-density correction sensor) of the **KermaX-*plus*®** and variable reference sensors, air density correction for the chamber and / or the reference detector may be indicated for best accurateness (section 7 Air Density Correction).

6.3. Test the drift of indicated values

6.3.1. Positive drift

During absence of radiation, and after resetting the DAP meter, the indicated values should be not more than 1 count for at least 1 hour.

After the stabilization time is elapsed and a new Background compensation is completed (activated by software command), check this by reading after 15 min, 30 min, 45 min and 1 h after the DAP meter was reset, and with no resetting or compensation adjustment during the test.

NOTICE

IMPORTANT NOTICE

INFLUENCE OF ENVIROMENTAL CONDITIONS

Make sure that there is no moisture in chamber cavity, the operating conditions are met, and no vibrations occur (e.g., movement of system).

6.3.2. Negative drift

Perform the system test (Section 6.1 System Test (Stability Check)) and repeat this test measurements separated in 5min intervals; the indicated values should not more deviate than 2% from each other.

After the stabilization time is elapsed and a new Background compensation is completed (activated by software command), check this by reading after 5 min, 10 min, 15 min, 20min after the stability check of the DAP meter was initialized.

6.4. Test tolerance and interval

The radiological and electrical calibration of the DAP-measuring system is already done by IBA Dosimetry.

The check of the calibration can be done on-site by a competent person or in our calibration laboratory at IBA Dosimetry. The calibration value is saved in the chamber

The following tests should be done in regular intervals to ensure the functionality of the device.

Suggested timetable and tolerance for tests:

Type of test	Frequency	Tolerance
Evaluation and routine testing	maintenance and essential modification of X-ray unit	± 20 %
Stability check (System test)	Monthly	± 20%
Check of calibration	• at installation • every 2 years • any case following a repair	± 5%
Drift of indicated values	Maintenance	1 count @ positive Drift Test 2% @ negative Drift Test

NOTICE

IMPORTANT NOTICE

MAINTENANCE CHECKS

The maintenance checks specified here are only recommendations. Please review and observe national and international laws for the country of use together with the local safety regulations.

6.5. Recalibration

NOTICE

IMPORTANT NOTICE

RECALIBRATION

The change of calibration should only be carried out in exceptional cases when really justified. The DAP measuring system is calibrated by the manufacturer and the corresponding calibration certificate is part of the delivery.

If the DAP exceeds the tolerance defined in previous Chap.6.4, please contact Customer Service Dept., IBA Dosimetry GmbH for recalibration.

NOTICE

IMPORTANT NOTICE

THE FACTORY CALIBRATION CANNOT BE CHANGED BY USER

The user cannot change the factory calibration value of the chamber because it is stored in the chamber memory chip. Only the DAP correction factor can be adjusted.

With the Recalibration you have the possibility to adjust the DAP for the plane in which the radiation is incident on the patient in case where absorbing materials (e.g., cosmetic cover), absorbers are permanently or temporarily present between the ionization chamber and the patient.

The procedure for determination of DAP correction factor is in general the same as which is described in chapter *6.2 Calibration Check*. To correct the deviation from Calibration Check it is necessary to read out and recalculate the DAP correction factor. The new calculated factor needs to be stored by software command. For details, please refer to respective interface description.

An example with a +4,51% deviation (*see Chap. 6.2.2 Calibration Check procedure*):

readout DAP correction factor: $1.00\ (\text{Default Value})$

KermaX-*plus*® deviation factor: $\frac{100\%}{(100\%+4{,}51\%)} = 0.957$

new DAP correction factor: $0.957 \times 1.00 = 0.957$

NOTICE

IMPORTANT NOTICE

AIR DENSITY CORRECTION

Due to sensor option (built-in air-density correction sensor) of the **KermaX-*plus*®** and variable reference sensors, air density correction for the chamber and / or the reference detector may be indicated for best accurateness (section 7 Air Density Correction).

NOTICE

IMPORTANT NOTICE

DEVIATIONS TO EXPECTED MEASUREMENTS

If you observe significant deviations from the expected results, please verify that no additional absorption is located in the beam (e.g., table top, additional filters). In addition, please verify that the DAP correction factor of the **KermaX-*plus*®** is set according to your system design.

⚠ CAUTION

CAUTION

DATA EVALUATION RESPONSIBILITY

If the **KermaX-*plus*®** is integrated into a system and used for data collection of Dose Area Product (DAP), the manufacturer carries the full and entire responsibility to critically evaluate the results of each measurement.

7. Air Density Correction

The **KermaX-*plus*®** DAP meter is available with an optional built-in sensor (temperature and air pressure) for automatically correction of air density fluctuation in the ionization chamber.

If this functionality is not enabled, the user must follow the procedure described in following Chapter.

7.1. Air Density Fluctuation in the Ionization Chamber

The ionization current is proportional to the density of air in the measuring volume of ionization chamber. According to the thermal equation of state for ideal gases, the Air density ρ is proportional to the quotient of pressure p and temperature T. It follows immediately, the correction for the influence of air density:

$$k_\rho = (p_0 / p) \cdot (T / T_0)$$

The reference values of air pressure and temperature are:

$$p_0 = 1013\text{hPa}$$
$$T_0 = 293{,}15\text{K}$$

If necessary, using k_ρ to the DAP reading correction:

$$D_{dap} = M_{dap} \cdot k_\rho$$

For example, at a temperature of T = 23°C (296,15K) and an air pressure of p = 990hPa is the correction of the displayed DAP M_{dap} by 3.4%.

7.2. Correction Overview

Due to built-in air-density correction sensor and variable reference sensors, air density correction for the chamber and / or the reference detector may be indicated for best accurateness.

DAP Chamber / Reference detector	enabled built-in sensor	disabled built-in sensor
Semiconductor detector	no action	correct DAP chamber value[1]
Ionization chamber	correct reference chamber value[1]	no action

[1] Temperature measurement should be done as close as possible to the corresponding chamber

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8. Service and Technical Support

8.1. Warranty

8.1.1. Warranty, General

IBA Dosimetry GmbH warrants the **KermaX-*plus*®** system and the associated accessories to be immaculate during the 12 months of warranty. In case of defects, IBA Dosimetry GmbH will decide whether to repair or to exchange the system.

The following information must be attached to claim for warranty:

- an error description
- date of purchase
- the model number of the device
- the serial number of the device

The costs for packing and shipping the goods back to the manufacturer are at the owner's expenses unless otherwise agreed upon in writing prior to shipment.

Any damages caused during the shipment of the returned goods are at the owner's expenses. On receipt of the goods the manufacturer will carry out an inspection to confirm the problem is covered by warranty conditions. If the case is not covered, the owner will receive a quote for repair.

The terms of this warranty do not affect the owner's statutory rights under applicable national or local legislation or claims against a local supplier arising from a sale or purchase contract. Claims of this nature should be addressed to the supplier.

Enhancements, modifications, or repairs may only be done by IBA Dosimetry GmbH or by trained personnel with sufficient knowledge and skill who are authorized by IBA Dosimetry GmbH.

IBA Dosimetry GmbH is not liable for damages caused from the use or operation, which is not approved by the manufacturer and not described in this manual.

8.1.2. Warranty, Limitations

The warranty does not cover the following:

- Periodic checks, calibrations, or preventive maintenance.
- Defects which result from modifications without the manufacturer's written approval.
- Damage resulting from normal wear.
- Damage resulting from improper use or handling including, but not limited to, the dropping or the incorrect installing of the product.
- Accidents, damages, or disasters which are beyond the manufacturers control including, but not limited to lightning, fire, public disturbances, and improper ventilation.
- Damages due to the transportation of the system.
- Incorrect cleaning

NOTICE

IMPORTANT NOTICE

RESPONSIBILITY, PROFESSIONAL PRACTICE

It is the OEM's responsibility to follow the guidance given in this OEM manual and to use established professional practice to ensure the product is in usable condition and is being used correctly. This manual is not intended for the use by end users.

8.2. Maintenance of **KermaX-*plus*®**

The **KermaX-*plus*®** has no user serviceable parts which can be classified as replaceable material. The power supply and cables can be changed at any time since this component does not have any influence on the calibration.

The **KermaX-*plus*®** was designed to give long and reliable service and does not require special maintenance. In case the device becomes defective a repair should not be attempted but the faulty component once identified should be replaced by authorized and qualified service engineers. The respective part numbers are given in the system components section of this manual.

CAUTION

CAUTION

REPLACING PARTS

Switch off the supply voltage and remove the external power lead from the system when replacing any parts.

NOTICE

IMPORTANT NOTICE

LOCATION OF CALIBRATION DATA

The factory calibration value is stored in the chamber memory and cannot be changed by the user.

NOTICE

IMPORTANT NOTICE

DAILY CONTROL OF ADAPTER

The accessory adapter as described in Chap. 2.5.5 needs to be checked daily to ensure that it is tightly installed and not damaged mechanically. If necessary, replace the adapter.

8.3. Cleaning and Disinfection

The external parts of the **KermaX-*plus*®** should be carefully cleaned with a soft, dry, dust free cloth. If necessary, you can clean the device using a soft, dust free cloth that has been immersed in a small quantity of pure alcohol. Under no circumstances should chemically cleaning supplies or other materials be used. When cleaning please observe the following:

- Switch OFF the system and disconnect the line voltage prior to cleaning or disinfection.
- Never spray the system with cleaning solutions. Do not allow fluids or cleaning solutions to seep into the system since it may cause damage to the equipment.

- All parts coming into contact with patients must be cleaned before each use. Clean the parts with a damp cloth, or cleaning, use pure alcohol.
- Do not use abrasive cleaners, organic solvents, and cleansers containing spot removers, etc. due to possible material incompatibility.
- Disinfectant sprays should generally not be used. The spray can seep into the system and safety features can no longer be guaranteed.
- Sprays could cause damage to electrical parts or create a flammable air / vapour mixture.
- Phenol based disinfectants and chlorine releasing preparations can weaken materials and are generally not recommended.

⚠CAUTION

CAUTION

INCORRECT CLEANING CAN REDUCE THE LIGHT PERMEABILITY

Incorrect cleaning can lead to a reduction of the light permeability of the chamber or other malfunctions.

8.4. Troubleshooting

The following troubleshooting table may help in resolving problems.

Problem	Possible Causes
Interface is not functioning	1. Check the inter connections by disconnecting and reconnecting the cables. 2. Check the communication with another computer and Interface application (Terminal program).
Wrong DAP value indicated	1. Check whether the X-ray beam is penetrating the chamber correctly. 2. Check the field size setting. 3. Remove additional filtration. 4. Compare indicated values with independent dosimeter as described in the verification procedure. 5. If none of the above remedies help return the chamber to the factory for service and repair.
No DAP count during irradiation	1. Check collimator opening. 2. Check if chamber is connected and powered.
Random counting without radiation	1. Check for humidity in chamber. Dry for 24 hours and retry. 2. Check for electrical interference. If necessary, call service engineer.
Light field distortion	1. Check for dirty chamber plates dirty and clean as per cleaning instructions.
Test value changes	1. Check if ambient temperature is too high or too low. 2. Check once more when normal working temperature is reached.
Calibration error	1. Check for additional absorber in the beam and remove. 2. Check if the same beam quality as for the previous calibration was used.

8.5. Safety Inspection

This device does not require safety inspection.

8.6. Disposal and Recycling

This measuring device and its components contain electronic modules.

RECYCLING

None of the parts mentioned above may be disposed by the general house or hospital waste disposal system. Please observe all local regulations governing the disposal of your system. The end-user is responsible for complying with all local regulations regarding the removal of the product from service. To avoid environmental damage and/or injury and if you have no facility to convert the device to electronic waste at the end of its life cycle, please return it to IBA Dosimetry GmbH . We will ensure an environmentally correct recycling.

In the interest of complying with legal requirements concerning the environmental compatibility of our products (protection of natural resources, avoidance of waste) we endeavor to reuse components and to return them to the production cycle. We guarantee the functioning, quality and life of these components by taking extensive quality assurance measures, just as for factory-new components.

The **KermaX-*plus*®** contains materials which can be detrimental to the environment. For this reason, the proper disposal of the **KermaX-*plus*®** according to the regulations of national law and in view of protecting the environment must be ensured. This is guaranteed by returning the **KermaX-*plus*®** to the manufacturer.

Materials Used:

Part	Material
Shielding of electronics	tinned steel plate or Aluminum
KermaX-*plus*® transparent material	Polycarbonate
KermaX-*plus*® inside frame	ABS
KermaX-*plus*® outside frame	ABS
Screws	Nylon

8.7. Technical Support

8.7.1. Contact for Technical Support

If you need technical support, please contact the local IBA Dosimetry GmbH Service Department:

Europe, Middle East, Africa

(24/7) +49 9128 607 38

+49 9128 607 38

service-emea@iba-group.com

German Speaking Support

+49 9128 607 911

USA, Canada, Latin America

(24/7) +1 786 288 0369

service-usa@iba-group.com

Asia Pacific

(24/7) +65 3129 2472

service-apac@iba-group.com

+65 3129 2472

Chinese Speaking Support

+86 400 0422 367

IBA Dosimetry Service

8.7.2. Reporting Complaints

The Quality Management system of IBA Dosimetry GmbH includes a routine to handle any reported complaints.

All complaints about the product should be report to any representative of IBA Dosimetry GmbH or directly to the technical support (see the contact information in the above section.

8.7.3. Returning Device for Repair, Maintenance, or Calibration

Procedure for shipping the device to the factory:

- Call or email to our Customer Service to explain the problem
- The Service personnel will generate an RMA (Return Material Authorization) number. You will receive a filled RMA Form with the RMA number and provided information by e-mail or fax.
- Place the RMA Form into the package and ship the device to the address below:

  Customer Service Department
  IBA Dosimetry GmbH
  Bahnhofstrasse 5
  DE-90592 Schwarzenbruck
  Germany

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9. Technical Specifications

CAUTION

CAUTION

MAXIMUM AIR KERMA RATE / DAP RATE

The maximum DAP rate must not be exceeded.

9.1. Specifications of **KermaX-*plus*®**

Item	Characteristic
Active area	square area: 140 x 140 mm [*Standard size*] square area: 115 x 115 mm [*Compact size*]
Radiation quality *(IEC 60580)*	40 - 150 kVp
Electrode Spacing	7 mm
Energy dependence *(40 – 150 kV)*	± 8 %
Quality equivalent filtration ➤ Al attenuation equivalent ➤ Al HVL equivalent *(Methode of Measurement IEC 60522:1999)*	0,31mm Al / 70kV / 2,5mm Al 0,14mm Al / 70kV / HVL 2,5mm Al
Air Kerma rate range *(at the position of the Chamber)*	12 µGy/s – up to 2 Gy/s
DAP measurement range	0.1 – 99999999,99 µGym² 0.1 – 42949672,94 µGym² [*With CAN Interface*]
DAP resolution	0.01 µGym²
DAP rate measurement range	0.1 – 9000 µGym²/s
DAP rate resolution	0.01 µGym²/s
Irradiation time resolution	0.5 ms
min. Measuring time	> 0.01 s
Stabilization time	< 15 min
Startup time	30 s
Combined measurement uncertainly *(IEC 60580)*	25 %
Optical transparency	≥ 75 %
Field size	65 mm² – 19600 mm² [*Standard size*] 65 mm² – 13225 mm² [*Compact size*]

Item	Characteristic
Chamber voltage	410 V ± 10%
Power supply	+15 – +24 V_{DC} ± 20%, 100 mA +15 – +24 V_{DC} ± 20%, 300 mA [***KermaX-plus®*** *with ETH Interface*]
Power consumption	< 3 W < 5 W [***KermaX-plus®*** *with ETH Interface*]

9.2. Interface Specification

Interface	Specification
CAN	• CANopen Interface according CiA Draft Standard 301 and CiA Profil 412 Part 6 “Dose measurement system” • Node ID and Baud rate see Table Chap. 9.5.2 • CAN Termination default set in Chamber (*configurable by manufacturer*)
Ethernet	• IPv4 • Integrated IEEE 802.3 MAC and 10BASE-T / 100BASE-TX • Full/Half duplex with auto-negotiation • Auto MDI/MDIX • Unique MAC address • ARP, ICMP, UDP, TCP/IP support • DHCP client or static IP assignment • Default gateway support
RS-485	• point to point connection • serial port settings: – Bits per second *38400* – Data bits: *8* – Parity: *None* – stop bits: *1* – Flow control: *None*

9.3. Environmental Conditions and Requirements

Operational Condition	Range
Ambient temperature	+10°C – +70°C
Atmospheric pressure	700 hPa – 1060 hPa
Relative humidity range	20% – 75% (without condensation)
Transportation and Storage Conditions	**Range**
Ambient temperature	-20 °C – +70 °C
Atmospheric pressure[1]	700 hPa – 1060 hPa
Relative humidity range[2]	10% – 95% (without condensation)

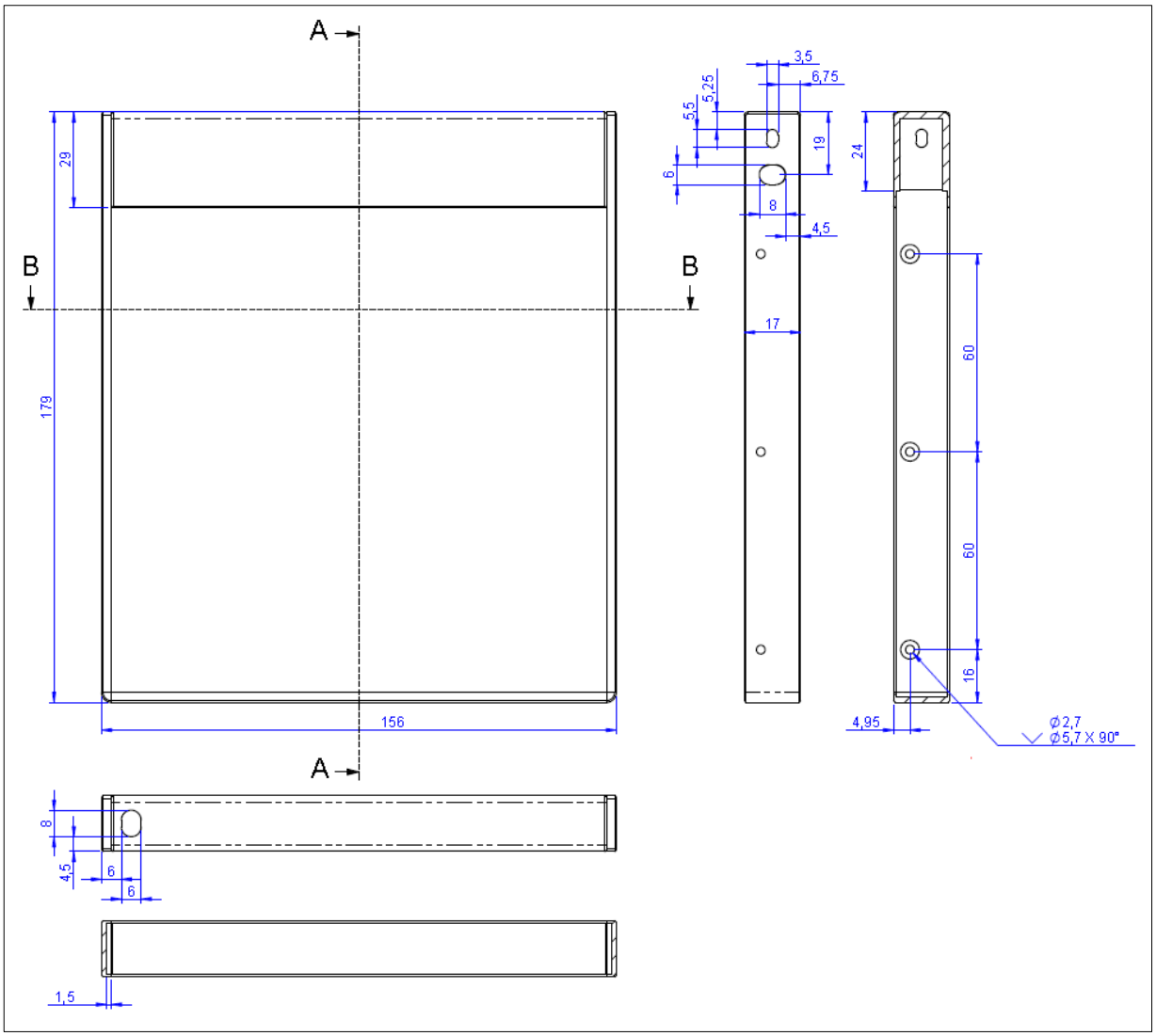
[1] For 120-131 ZKCANO: 500 hPa – 1060 hPa
[2] For 120-131 ZKCANO: 0% - 95%

9.4. Dimensions and Weight

9.4.1. **KermaX-*plus*®** standard size

Item	Value
Dimension (L x W x H) [mm]	179 x 166* x 17
Weight [g]	app. 225

* Including mounting bolts

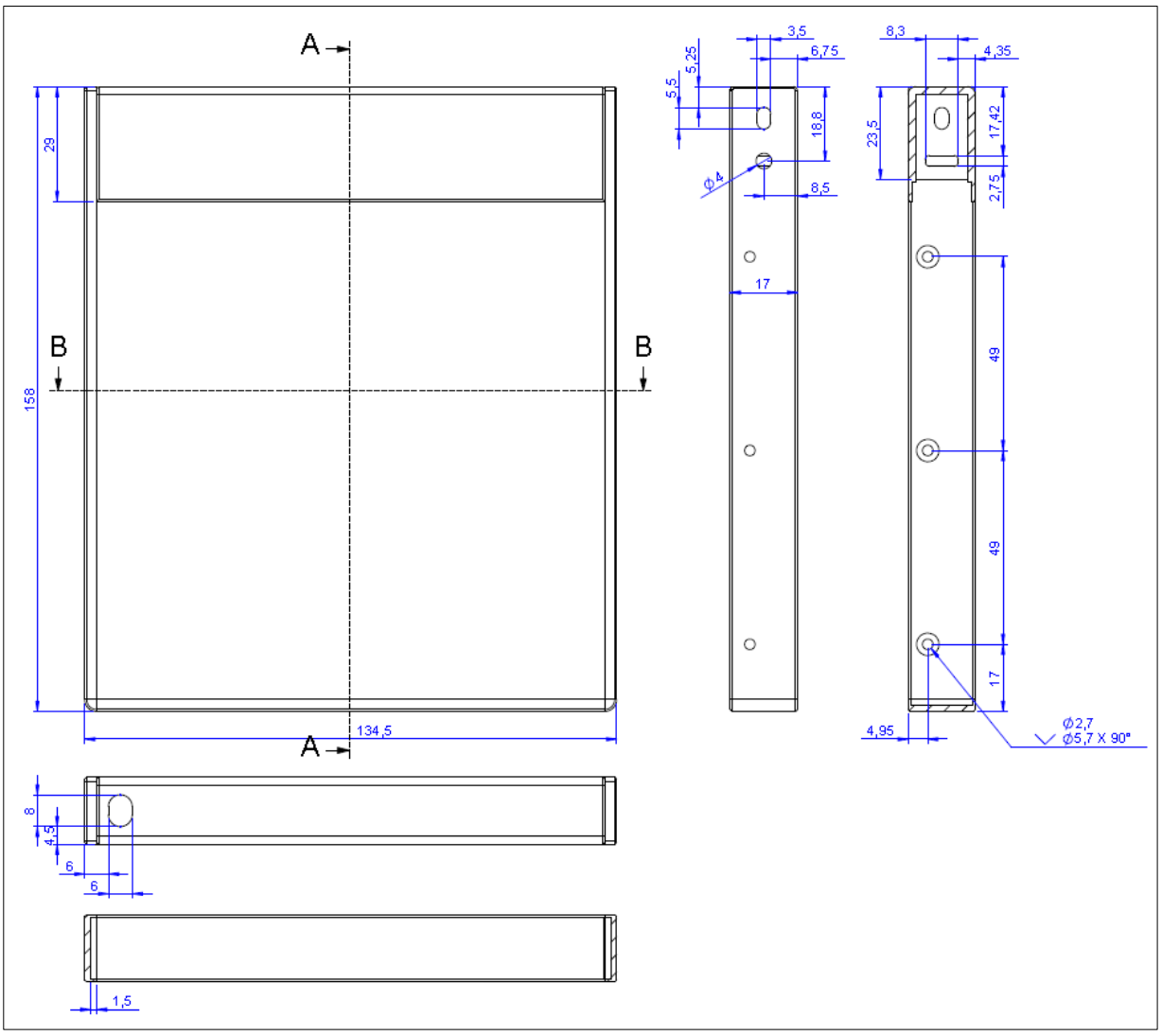


Drawing mechanical Dimensions standard Housing [tolerance ISO 2768 m]

9.4.2. **KermaX-*plus*®** compact size

Item	Value
Dimension (L x W x H) [mm]	158 x 144,5* x 17
Weight [g]	app. 195

* Including mounting bolts



Drawing mechanical Dimensions compact Housing [tolerance ISO 2768 m]

9.5. Pin assignment for the RJ45 8 pin Plug

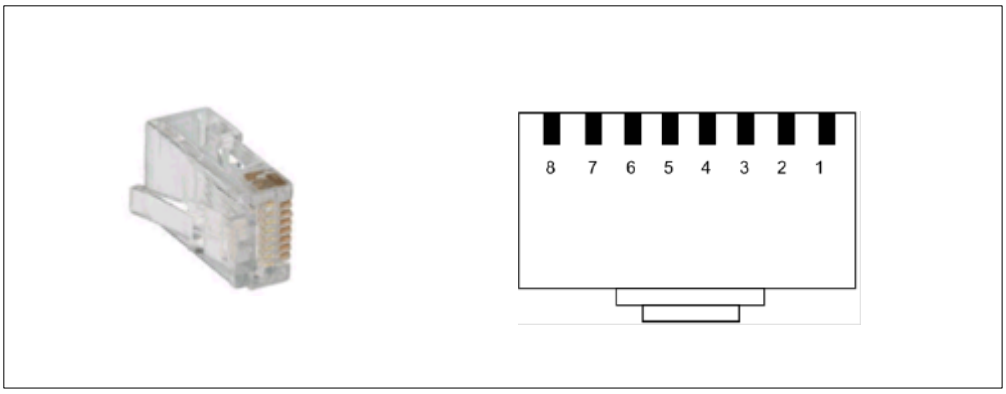


Figure RJ45 Plug

9.5.1. Ethernet Interface

The RJ45 pinout complies to EIA/TIA-568A/568B and IEEE Std 802.3at™-2009 (Alternative B)

PIN	Signal	Description
1	RX+	Receiver +
2	RX-	Receiver -
3	TX+	Transmitter +
4	DC+	PoE positive Terminal
5	DC+	PoE positive Terminal
6	TX-	Transmitter -
7	DC-	PoE negative Terminal
8	DC-	PoE negative Terminal

NOTICE

IMPORTANT NOTICE

BRIDGE RECTIFIER IMPLEMENTED

A bridge rectifier is implemented on the **KermaX-*plus*®** with Ethernet Interface electronic board. Therefore, the DC to the chamber is independent of the polarity of the supply voltage.

9.5.2. CAN Interface

PIN	Signal	Description
1	CAN_H	CAN Bus Line high
2	CAN_L	CAN Bus Line low
3	CAN_GND	Ground CAN Bus / DAP Chamber power supply
4	MODE BIT 0	Node ID/Baud Rate configuration
5	MODE BIT 1	Node ID/Baud Rate configuration
6	MODE BIT 2	Node ID/Baud Rate configuration
7	MODE BIT 3	Node ID/Baud Rate configuration
8	CAN_V+	positive power supply

CAN Node ID Configuration

Node ID	Baud rate [kBit/s]	Mode Bits *			
		Bit3	Bit2	Bit1	Bit0
0x1F	125	0	0	0	1
0x59	500	0	0	1	0
0x1B	125	0	0	1	1
0x5B	500	0	1	0	0
0x1E	125	0	1	0	1
0x1D	125	0	1	1	0
0x1C	125	0	1	1	1
0x58	500	1	0	1	0

* Negative logic, 1 = CAN_GND Potential

9.5.3. RS-485 Interface

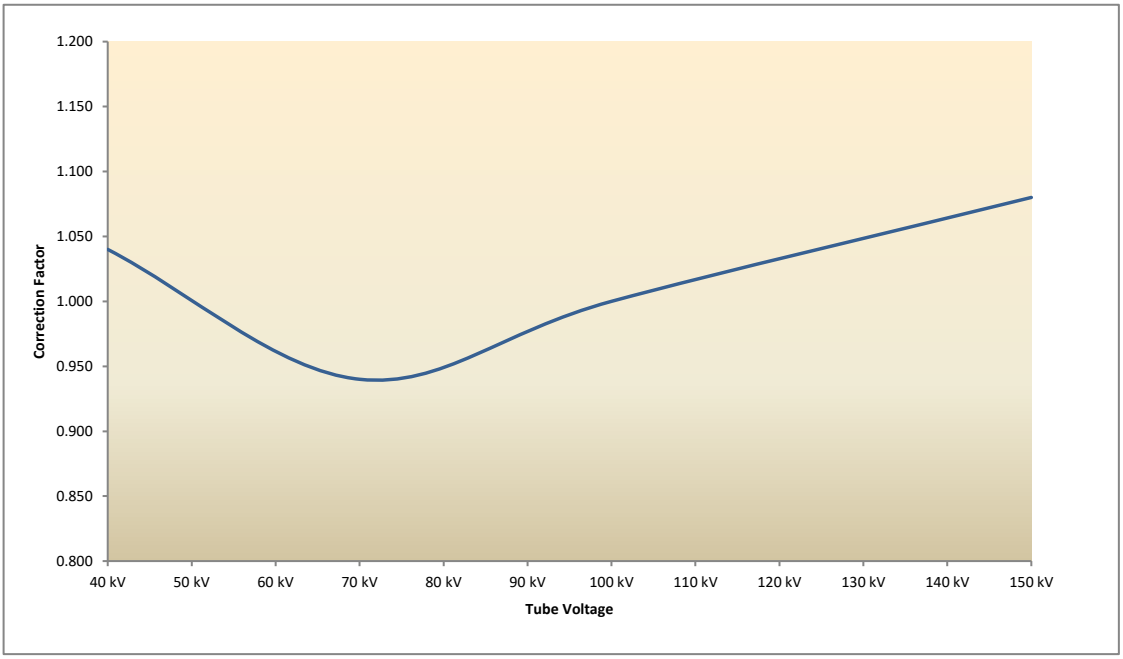
PIN	Signal	Description
1	Serial A	Receiver
2	NC	not connected
3	DC+	DC Voltage +
4	GND	Ground, DC Voltage -
5	Serial B	Receiver
6	Serial Z	Transmitter
7	NC	not connected
8	Serial Y	Transmitter

9.6. Typical energy dependence

The DAP measuring device is calibrated without any absorber (see Table Reference Conditions for Calibration, Section 6.2, Calibration Check).

In the following sections is the table for typical correction factors in dependence from tube voltage with 2,5mm Al Filtration:

Tube voltage											
40 kV	50 kV	60 kV	70 kV	80 kV	90 kV	100 kV	110 kV	120 kV	130 kV	140 kV	150 kV
1,04	0,97	0,95	0,94	0,96	*0,97*	*1,00*	*1,02*	*1,03*	*1,04*	*1,06*	*1,08*



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