Instructions for use

for dose area product measuring system

VacuDAP 2004 OEM

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General warning and safety information:

These instructions for use include the relevant data sheets corresponding to the REF specified on the product rating plates, see *Table 3 List of applicable documents.*

Read through the instructions for use in full. Ensure that the instructions for use are available at all times near to the product for later reference. Failure to comply with the instructions for use could result in injuries or damage to the product.

- The measuring system must only be used for the intended purpose.
- Do not perform any servicing work, e.g. repairs, while the measuring system is in use.

Introduction

Despite the ongoing development of X-ray technology and the reductions in required radiation dose achieved, X-ray diagnostics remains a significant source of radiation exposure for humans. For this reason, the European directive 2013/59/EURATOM stipulated recording and documentation of the patient dose in radiological procedures, as well as the use of diagnostic reference levels. The VacuDAP 2004 OEM measuring system makes this easy.

The VacuDAP 2004 OEM measuring system is used to determine the dose area product (DAP) and the dose area product rate.

The measuring system consists of a transparent rectangular ionization chamber with integrated detector electronics and an analysis unit integrated into the X-ray system. The measuring chamber transfers calibrated pulses to the generator interface. These are counted and displayed by the X-ray system control unit. The generator manufacturer implements the generator interface and the measured value display in the X-ray system control unit. **Operation** of the entire measuring system, made up of the measuring chamber and analysis unit, and any changes to set values are **not** covered by these instructions for use.

The VacuDAP 2004 OEM is intended for standard radiological procedures.

Symbols used:

Symbol	Meaning
	Follow instructions for use (white symbol on blue background!)
	Attention
	This symbol indicates additional information. This additional information is intended to improve understanding or make operation easier.
CE 0197	CE mark (European approval symbol with the identification number of the notified body)
	Manufacturer
 YYYY-MM	Date of manufacture
REF	Catalogue number
SN	Serial number
	Keep dry
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Separate collection of electrical and electronic equipment
	The device meets the requirements of protection class II
	The device is operated using DC current
	Quality equivalent filtration

Contents

1 General user information

1.1 Intended use

The VacuDAP dose / dose area product measuring system is an accessory for diagnostic X-ray systems (radiography and radioscopy) and is intended for monitoring the patient dose in radiological applications. The VacuDAP dose / dose area product measuring system is a secondary measuring device for recording the dose area product, dose area product rate, irradiation time and, where applicable, air kerma and air kerma rate at the reference point during radiological examinations on the patient.

The values determined are compared with diagnostic reference levels for diagnostic and interventional X-ray applications.

The indicated air kerma and air kerma rate at the reference point are the basis for calculation of the skin dose during radioscopy.

The VacuDAP dose / dose area product measuring system is designed for continuous operation in professional health care facilities (clinics, hospitals, medical practices).

The intended patient is defined by the intended use of the X-ray system.

There are no known contraindications or side effects. The VacuDAP dose / dose area product measuring system must not be used to control the generator, nor for primary determination of the characteristic data for X-ray systems.

1.2 Classification

In line with Directive 93/42/EEC on medical devices, the dose area product measuring chamber in the VacuDAP 2004 OEM is a Class I active medical device with measuring function.

The measuring system is intended for continuous operation.

The measuring system must not be used in potentially explosive areas of rooms used for medical purposes or in an oxygen-enriched environment.

1.3 Electromagnetic compatibility (EMC)

The measuring system complies with the electromagnetic compatibility (EMC) requirements of IEC 60601-1-2 (EN 60601-1-2).

Medical electrical equipment is subject to special precautionary measures in terms of EMC. During installation and commissioning of the measuring system, the EMC information in *Chapter 8* must be observed.

To ensure immunity to electrostatic discharge (ESD), the connector of the measuring chamber must be installed inaccessible. Otherwise, REF 953 00 90 (ESD protection set) must be used, see *Installation instructions for the generator manufacturer*.

Portable and mobile HF communication equipment can influence medical electrical equipment.

1.4 Protection against electric shock

The measuring chamber is supplied with power by the X-ray system via the interface cable. Only secondary circuits in protection class II may be used for the supply.

The following symbol for protection class II must be printed on the power supply:

1.5 Accessories

Only genuine parts may be used for the measuring system, or parts that meet the specifications stipulated by the manufacturer (see *Chapter 7 Additional equipment and components*).

1.6 Handling, transportation, shipping, storage

The ionization chamber, including integrated electronics, is a highly sensitive measuring device and must therefore be handled with the utmost care.

The original or equivalent quality packaging must be used for transportation and returns.

Due to the risk of damage, no mechanical pressure may be exerted on the light-transparent electrodes in the measuring chamber.

This device must not be modified without the approval of the manufacturer.

During transportation and storage, the following ambient conditions must be ensured:

Temperature	-20 °C ... +60 °C
Rel. humidity	10 % ... 80 % (max. 20 g/m^3; non-condensing)
Air pressure	50.0 kPa ... 106.0 kPa

1.7 Cleaning

No cleaning of the measuring chamber is required.

1.8 Usage conditions

The dose area product measuring chamber is only to be used in enclosed rooms.

In no case may liquid penetrate into the device. This can lead to damage to the product.

The following ambient conditions must be ensured during operation:

Temperature	+10 °C ... +40 °C
Rel. humidity	10 % ... 80 % (max. 20 g/m^3; non-condensing)
Air pressure	80.0 kPa ... 106.0 kPa

If the relative humidity is greater than 80 %, a film of moisture can be precipitated on the ionization chamber and the electrical terminals. Under some circumstances, this can lead to incorrect measuring results.

1.9 Service life

The expected service life of the measuring system is 10 years, provided the intended storage and usage conditions are observed (see *Chapter 1.6* and *Chapter 1.8*) and the specified maintenance and calibration is carried out (see *Chapter 4 Preventive maintenance and testing*).

1.10 Disposal

The dose area product measuring chamber contains electronic components and must be disposed of or returned to the manufacturer in compliance with the applicable national regulations (e.g. electrical equipment ordinance, directive 2011/65/EU (RoHS II)).

2 Preparations for operation

2.1 Preparation

The packaging material is to be removed carefully. If any damage to the components is identified, the supplier or manufacturer must be contacted without delay. Damaged components must not be installed.

2.2 Supply voltage

The measuring system is supplied with a voltage in the range 15 V to 24 V DC by the X-ray system.
The supply must comply with protection class II.

The voltage supply must comply with the requirements of IEC 60601-1 (EN 60601-1) and guarantee reliable isolation resulting in 2 MOPP (means of patient protection).

The power supply to the measuring chamber must be limited to a power of < 15 W.

Connecting the measuring chamber to an X-ray system creates an ME system. The specific requirements of IEC 60601-1 (EN 60601-1) must be observed

The electronic modules of the measuring system have internal reverse polarity protection.

2.3 Installation

Installation of the measuring chamber must be carried out by specialist personnel like in *Installation instructions for the generator manufacturer* described.

2.4 Functional check

Before starting the functional check, all components of the measuring system must be at room temperature.

The measuring chamber has an automatic POWER-ON TEST, which checks the function of the ionization chamber and all electronic components. The test is evaluated by the generator analysis unit. Further details can be found in the information supplied by the generator manufacturer.

2.5 Checking the calibration

After installation of the measuring chamber, its calibration must be checked under installation conditions (see *Chapter 4.4 Overall calibration check*).

2.6 Stabilization time

The ionization chamber is a highly sensitive detector, which has to settle and stabilize once the chamber voltage is connected to ensure that the performance characteristics specified in the *data sheet* are provided. The time required to do this is known as the stabilization time.

Unless otherwise specified in the ionization chamber data sheet, a stabilization time of 3 minutes is required.

The measuring chamber is also ready for measurement during this stabilization time.

2.7 Factory calibration

The VacuDAP 2004 OEM measuring chamber has been calibrated by the manufacturer in compliance with EN 60580 with a calibrated reference device (IEC 61674) and corresponds to all the data set out in the *data sheet*.

The calibration is carried out **with no additional absorber** in the beam path between the measuring chamber and the patient at 70 kV, 100 mAs and **total filtration** o **2.5 mm aluminum**.

To correctly measure the dose area product, no other accessories, such as absorbers or apertures may be inserted into the beam path between the ionization chamber and the patient.

If an absorber is permanently located in the beam path between the ionization chamber and the patient, this must be taken into account in the dose area product measurement.

This calibration depends significantly on the beam quality (X-ray tube voltage, filtration, additional absorber).

Using a calibration factor, **recalibration** can be carried out by authorized personnel. Further details can be found in the information supplied by the generator manufacturer.

The value of the calibration factor for an additional absorber of 0.5 mm aluminum has been determined by type testing and is specified in the *data sheet*.

2.8 Shutting down

The measuring system is completely controlled by the X-ray generator. It is shut down by the generator.

3 Device description

3.1 General

The VacuDAP 2004 OEM measuring system can be used to determine the dose area product (DAP) and the dose area product rate (DAP rate).

The light-transparent measuring chamber is installed in the collimator or fitted in the accessory rails at the beam exit window of the beam limiting device and has no influence on routine operation.

Compared to the entrance dose, measurement of the dose area product enables the variable influence quantities of dose rate, exposure time and the field size used to be taken into account. The X-ray radiation detected by the ionization chamber is registered and transferred to the counter unit as calibrated pulses. The rate of these count pulses (frequency) corresponds to the dose area product rate.

3.2 Measuring chamber and measuring principle

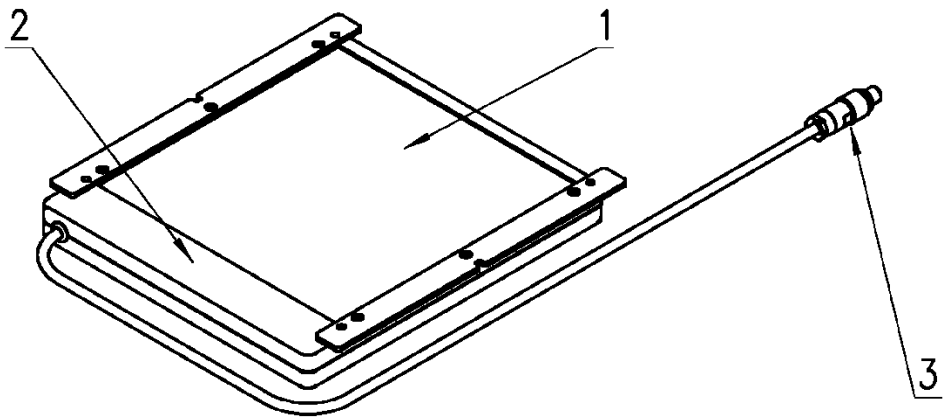

Figure 1: Measuring chamber for the VacuDAP 2004 OEM measuring system

The X-ray radiation produces charge carriers in the ionization chamber (1), which are proportional to the product of the dose and the irradiated area of the ionization chamber. These small measuring currents are amplified and digitalized by the integrated electronics (2). The detector electronics have a pulse interface (3). For interference immunity reasons, the pulse is transferred differentially to the generator interface (RS-422).

The transparent ionization chamber is intended for use on X-ray systems with light beam diaphragm. The measuring chamber has a very compact design and also contains the detector electronics. This electronics module includes the chamber voltage generation, a charge amplifier, and a microprocessor.

The digitalized measuring signal is transferred using the interface cable.

4 Preventive maintenance and testing

4.1 General

The vented ionization chamber and the detector electronics are not subject to any wear under normal operating conditions.

To ensure high measuring accuracy, the operational safety and functional capability should be checked at the specified intervals as part of maintenance of the X-ray system, as set out in the German X-ray ordinance (RöV). Measurement of the patient leakage currents should be conducted.

4.2 Testing stability

The stability of the overall system is tested regularly as part of the POWER-ON TEST. Details of performing and evaluating the system test can be found in the information supplied by the generator manufacturer.

4.3 Monitoring for drift of indicated values

A check for drift of indicated values can be performed after the stabilization time (see *Chapter 2.6 Stabilization time*) using the following method:

1. Reset the display
2. Defined irradiation of the measuring system with typical X-ray system settings
3. Note the indicated value after a response time of 3 seconds
4. Leave the measuring system in MEASURING mode for an idle time of at least one hour with no further irradiation
5. After this time, read off the second indicated value and compare it to the first indicated value

The second indicated value may deviate from the first indicated value by a maximum of 1 mGy*cm².

If it deviates by more than this and the issue persists even after drying the ionization chamber, the measuring chamber needs to be checked by the manufacturer (see *Chapter 5.2 Service and repairs*).

4.4 Overall calibration check

The dose area product measuring chamber in the VacuDAP 2004 OEM measuring system has been calibrated using a calibrated reference device (IEC 61674) in compliance with EN 60580 prior to delivery (see *Chapter 2.7 Factory calibration*).

The overall check on the measuring system should be performed at least every two years.

Logging all test conditions, measured values, and calibration factors is recommended.

To check the calibration of the VacuDAP 2004 OEM measuring system, the dose area product is determined as the numerical product of the cross-sectional area of the useful beam and the measured dose (air kerma) in the cross-sectional plane, with both variables measured in turn at the same distance from the focal spot. The dose area product determined is compared with the indicated value on the VacuDAP 2004 OEM measuring system. Further details of performing the calibration and any necessary recalibration can be found in the information supplied by the generator manufacturer.

5 Eliminating faults

5.1 Fault elimination instructions

Evaluation of the POWER-ON TEST enables a fault that has occurred to be localized. Further details can be found in the information supplied by the generator manufacturer.

Possible fault conditions on the measuring chamber are shown in *Table 2*.

Fault	Meaning	Fault elimination instructions
$TEST_{ACTUAL}$ = 0	• No supply voltage • Interface cable defective • Measuring chamber defective	• Check supply voltage • Check interface cable • Send measuring chamber for repair
$TEST_{ACTUAL}$ = 10	• Detector electronics OK; no signal from ionization chamber	• Send measuring chamber for repair
$TEST_{ACTUAL}$ outside TEST range	• Test function not completed without errors	• Check that the TEST value on the test certificate matches the comparison parameter $TEST_{NOMINAL}$ • Repeat the TEST function after drying the measuring chamber (at a max. of 50 °C). • Send measuring chamber for repair
Pulse output permanently active	• Chamber voltage failed	• Briefly disconnect voltage supply for measuring chamber • If fault recurs: Send measuring chamber for repair

Table 2: Measuring chamber fault conditions

5.2 Service and repairs

Necessary checks and repairs after malfunctions have been indicated are only to be performed by the manufacturer or authorized service personnel. The required service documents are provided to these people.

In case of queries, please have the following data to hand:

- SN for measuring chamber (see rating plate)
- REF for measuring chamber (see rating plate)

Defective systems or components are to be returned to the manufacturer in original or equivalent packaging, with a description of the fault enclosed.

6 List of applicable documents

The applicable documents are listed in *Table 3*. The technical data can be found in the valid data sheets for the components, as specified on the rating plate.

Document		**File**	**Revision**
	Installation instructions for the generator manufacturer	DAP-II-03_VD-2004-E_C	C
REF 156 00 07	Data sheet	156DB07E_B	B
REF 156 00 10	Data sheet	156DB10E_C	C
REF 157 00 10	Data sheet	157DB10E_B	B
REF 157 00 12	Data sheet	157DB12E_B	B
REF 157 00 15	Data sheet	157DB15E_B	B

Table 3: List of applicable documents

7 Additional equipment and components

A selection of the additional equipment and components available for the VacuDAP 2004 OEM measuring system is shown in *Table 4: Additional equipment and components*.

A complete list of suitable additional equipment and components, corresponding to the mechanical and electrical interfaces of the respective measuring system, is available on request.

Designation	Catalogue no.	Comment
Cable XYm	REF 953 00 73-XY	Adapter cable Triad to Sub-D (available length: 6 m, 15 m, 20 m, 22 m, 25 m, 30 m)
Cable XYm	REF 953 00 74-XY	Connection cable Triad -> open (available length: 10 m, 15 m, 20 m, 25 m)
Cable Triad->RJ45 0,1m	REF 953 00 47	Adapter cable Triad to RJ45, length: 10 cm
ESD Protection Set	REF 953 00 90	ESD Protection Set for Triad connector

Table 4: Additional equipment and components

8 Information on electromagnetic compatibility (EMC)

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

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 dose / dose area product measuring system VacuDAP, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic emissions	
Emission limits	**Compliance**
Conducted and radiated RF emissions according to CISPR 11	Group 1, Class B

Electromagnetic immunity		
Electromagnetic immunity tests	**IEC 60601-1-2 test levels**	**Compliance levels**
Electrostatic discharge according to IEC 61000-4-2	± 15 kV air	± 15 kV air [1)]
Radiated RF EM fields according to IEC 61000-4-3	3 V/m 80 MHz - 2,7 GHz	3 V/m 80 MHz - 2,7 GHz
Proximity fields from RF wireless communications equipment according to IEC 61000-4-3	27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz - 2,45 GHz 9 V/m 710 MHz - 780 MHz 5,24 GHz - 5,785 GHz	27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz - 2,45 GHz 9 V/m 710 MHz - 780 MHz 5,24 GHz - 5,785 GHz
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) 0,15 MHz - 80 MHz
Rated power frequency magnetic fields according to IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz
[1)] this test does not apply to parts of the ionization chamber and measuring assembly that are normally exposed in the radiation beam, in accordance with the requirements of IEC 60580		