Instructions for use

for dose area product measuring system

VacuDAP - OEM

VacuTec Meßtechnik GmbH
Dornblüthstraße 14a
D-01277 Dresden
Germany

CE 0197

Tel.: +49 - (0) 351 - 3 17 24 - 0
E-mail: info@vacutec-gmbh.de
www.vacutec-gmbh.de

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 2 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 - OEM** measuring system is intended for simultaneous determination of the dose area product, dose area product rate, and irradiation time. The system is suitable for measuring and recording the radiation exposure of a patient during radiological diagnostic procedures.

The VacuDAP OEM can be used for pediatric and standard 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 VacuDAP - OEM is a Class I active medical device with measuring function.

The measuring system is intended for continuous operation.

The device is not suitable for use in an environment containing combustible mixtures.

1.3 Electromagnetic compatibility (EMC)

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

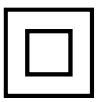
Medical electrical equipment is subject to special precautionary measures in terms of EMC. During installation and commissioning of the measuring system, the EMC information in *Chapter 8* must be observed.

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

1.4 Protection against electric shock

The measuring system is supplied with power by the generator 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 and the electronics are highly sensitive components of a measuring system and, as a result, must 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 to the ionization chamber, no mechanical pressure may be exerted on the light-transparent electrodes in the measuring chamber.

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

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

1.7 Cleaning

No cleaning of the measuring chamber is required.

1.8 Usage conditions

The measuring system 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.

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.

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

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 1.5* and *Chapter 1.7*) and the specified maintenance and calibration is carried out (see *Chapter 4 Preventive maintenance and testing*).

1.10 Disposal

The measuring system 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 10 V to 30 V DC by the X-ray generator. 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 generator 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, overvoltage protection, and overload protection.

2.3 Installation

Installation of the measuring device must be carried out by specialist personnel.

For high dose applications, the measuring electronics must be protected from scattered radiation.

The measuring chamber is pushed into the accessory rails at the beam exit window of the beam limiting device using the guide rails.

Different guide rails and adapters are available in dimensions corresponding to the different widths of the support rails.

Ensure that the correct rail width and length is used, so that the measuring chamber is stable and securely attached.

During electrical installation, correct terminal assignment must be ensured (see *data sheet*).

The cable must be routed in a way that guarantees reliable strain relief. The cable must not restrict the free movement of the moving parts.

2.4 Functional check

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

The measuring system has an automatic POWER-ON TEST, which checks the function of the ionization chamber and all electronic parts.

After installation of the measuring system, its calibration must be checked under installation conditions (see *Chapter 4.5 Overall calibration check*).

2.5 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 same applies to the analog section of the electronics. The time required to do this is known as the stabilization time.

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

The required stabilization time can be found in the *data sheet*.

2.6 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 - OEM measuring system is used to determine the radiation exposure of a patient in radiological diagnostics. The following measured variables are determined simultaneously:

- Dose area product (DAP, cumulative)
- Dose area product rate (DAP rate)
- Irradiation time (cumulative)

The measured values are available as an ASCII log at the serial interface.

3.2 Measuring system layout and measuring principle

The transparent ionization chamber is intended for use on X-ray systems with light beam diaphragm. It has a very compact design and also contains all of the measuring electronics. The VacuDAP - OEM measuring system is connected to the host computer, which requests the measured data, via an interface cable.
In addition, parameters and settings can be changed from the host computer. Detailed information on programming the serial interface can be found in the *Data interface installation instructions*.

The active area of the ionization chamber always detects the entire radiation field. The signal current I_{DAP} produced by X-ray radiation is proportional to the product of the irradiated area and the air kerma rate.
The signal current I_{DAP} is amplified, digitalized, and evaluated in the electronics. The `RESET` command starts cumulation of the dose area product and irradiation time values.

3.3 Communication with the host computer

The measuring system has a serial interface (RS485, half-duplex, no galvanic isolation), which is connected to the host computer. Alternatively, various interface converters are offered (see *Chapter 7 Additional equipment and components*). Further information on the required settings for the interface and for communication can be found in the *Data interface installation instructions*.

Connecting the measuring system to a PC creates a two-node IT network. This connection can lead to unknown risks. The responsible organization must identify, analyze, evaluate, and manage these risks.

Subsequent changes to the IT network can lead to new risks and thus require additional analyses.

Changes to the IT network include the following:

- Changes to the IT network configuration
- Connection of additional components to the IT network
- Removal of components from the IT network
- Updating devices connected to the IT network
- Upgrading devices connected to the IT network

3.4 Measured value transfer format

The VacuDAP - OEM measuring system simultaneously determines the measured values for the cumulative dose area product (DAP), dose area product rate (DAP rate), and irradiation time. The measured data transmitted and the units of measure are set using firmware parameters. The default configuration for the transfer format and the units of measure is set out in the *data sheet*.

3.5 Energy dependence compensation

The response of the ionization chamber depends on the X-ray tube voltage (see *data sheet*). The maximum change in the response stipulated in EN 60580 of ±8 % in the range 50 kV to 150 kV is fully met.

To further increase the measuring accuracy, the measuring system can automatically correct the change in the response of the X-ray tube voltage. To do this, the host computer must always set the `tube voltage` parameter to the current X-ray tube voltage (see *Data interface installation instructions*).

3.6 Temperature compensation

The response of the vented ionization chamber depends on the air density, which in turn is influenced by temperature and the absolute atmospheric pressure (see *data sheet*). The measuring system automatically compensates for the temperature dependency of the response. The influence of the absolute atmospheric pressure can also be corrected by the user by following the instructions in the *data sheet*.

3.7 Switching on

After connecting the supply voltage, the VacuDAP - OEM initializes the serial interface, sends information about the measuring system, and starts the Power-On test. The switch on behavior (timing) is described in detail in the *Data interface installation instructions*.

After the Power-On test, the measuring system is ready to measure.

3.8 Test function

The test function tests that all components of the measuring system, including the ionization chamber, are functioning correctly. A current test value is determined and compared with a nominal test value determined in the factory. If the current test value is within a tolerance range, the test function is classed as having been performed successfully. In case of error, the system sends an error message.

The test function is started automatically (Power-On test) when the measuring system is switched on. It can also be repeated later using the `TEST` command (see *Data interface installation instructions*).

After the test function, the measuring system is ready to measure again.

3.9 Reset function

The reset function (`RESET` command, see *Data interface installation instructions*) sets the cumulative measured values for the dose area product and irradiation time to zero.

After the reset function, the measuring system is ready to measure again.

3.10 Measuring mode

The VacuDAP - OEM measuring system has two measuring modes: *High resolution* and *High rate*.

In *High resolution* measuring mode, the digital resolution of the measuring system is ten times higher than in *High rate* measuring mode. The *High resolution* mode is especially recommended for pediatric applications, while *High rate* measuring mode is used for very high dose area product rates. These very high dose area product rates can occur if large irradiation fields are used in conjunction with a high air kerma rate (high X-ray tube voltage and current values). The digital resolution and the rated range of use for both measuring modes can be found in the *data sheet*.

If the maximum dose area product rate is exceeded, the measuring system generates the fault code for excessive dose area product rate (see *Chapter5. Fault elimination*).

Which of the two measuring modes is best suited for the planned application should be verified.

4 Preventive maintenance and testing

4.1 General

The vented ionization chamber and the 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.

4.2 Testing stability

The stability of the overall system is tested regularly as part of the Power-On test. The test function can be called up again at any time using the `TEST` command.

4.3 Monitoring for drift of indicated values

A check for drift of indicated values can be performed after the stabilization time (see *Chapter 2.5 Stabilization time*) using the following method:

1. Call up the RESET function
2. Defined irradiation of the measuring system with typical X-ray system settings
3. Note the measured value after a response time of 3 seconds
4. Leave the measuring system in standby 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 one digit (last digit displayed) per hour of idle time.

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

4.4 Factory calibration

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

This calibration is carried out at 70 kV, 100 mAs, and total filtration of 2.5 mm aluminum. During calibration, the Above table calibration parameter is changed.

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

The measuring system has a second Below table calibration parameter, which is used when using an additional absorber (e.g. patient table). The Below table calibration parameter is factory set for the additional absorber specified in the *data sheet*. The `POSITION` parameter can be used to switch between the two calibrations (see *Data interface installation instructions*).

If the second calibration parameter is used, it must be ensured that the factory calibration for the additional absorber (Al equivalent value, see *data sheet*) corresponds to the actual operating conditions.

4.5 Overall calibration check

The overall check on the VacuDAP - OEM measuring system must be carried out under installation conditions. To check the measuring system calibration, the dose area product is determined as the numerical product of the cross-sectional area of the useful beam and the measured air kerma. The air kerma is determined using a calibrated independent measuring device.

The independent value determined is compared with the indicated values on the X-ray system.

> The overall check on the measuring system should be performed at least every two years. Logging all test conditions, measured values, and Above table (or Below table) calibration parameters is recommended.

The following requirements must be met:

- Set the useful beam field size at the position of the VacuDAP – OEM to approx. 100 cm²
- Measure air kerma with uncertainty ≤ 5 % (keep influence of back scatter to a minimum)
- Setting on X-ray system: X-ray tube voltage 70 kV, select an X-ray tube current and irradiation time that results in three-digit measured values being displayed on the X-ray system

> If measurements are normally carried out *with* and *without* additional absorbers, the check and any recalibration must be performed separately for the two calibration parameters (see *Chapter 4.4 Factory calibration*).

The following procedure is recommended for checking the calibration:

1. Determine the field size A' with X-ray film, in a typical position for patients
2. Measure the air kerma K' with an independent measuring device in this position and simultaneously determine the dose area product $K \cdot A$ with the VacuDAP - OEM
3. Calculate the deviation of the dose area product $F_{K \cdot A}$ indicated value from the comparison value:

$$F_{K \cdot A} = \frac{K \cdot A}{K' \cdot A'}$$

If the deviation is in the range ± 10 %, i.e.

$$0{,}9 \leq F_{K \cdot A} \leq 1{,}1$$

no recalibration is required. If a greater deviation has been identified, the new calibration parameters Above table $_{new}$ (and Below table $_{new}$) are calculated as follows:

$$\text{Above table}_{\text{new}} = F_{K \cdot A} \cdot \text{Above table}_{\text{old}}$$

How to read and change the current calibration parameter is explained in the *interface description*.

> After changing the calibration parameter, the calibration check must be repeated.

5 Eliminating faults

5.1 Fault codes and fault elimination instructions

Fault code		Meaning	Fault elimination instructions
Bit	decimal		
1	2	• TEST warning	• No significant influence on measuring function • Repeat TEST function after stabilization time
2	4	• Excessive dose area product rate warning	• Dose area product measured values may have been determined as too low, as the upper limit of the rated range of use for dose area product rate has temporarily been exceeded • Ensure that the rated ranges of use set out in the data sheet are observed • Change the measuring mode to *High Rate* (see *Chapter 3.10 Measuring mode*)
3	8	• Zero check error	• X-ray radiation was active during RESET function • Radiation off, repeat RESET
4	16	• TEST fault	• TEST function defective • Check nominal test values • If fault recurs: Send measuring system for repair (see *Chapter 5.2 Service and repairs*)
5	32	• Chamber voltage failed	• Switch measuring system OFF and back ON • If fault recurs: Send measuring system for repair (see *Chapter 5.2 Service and repairs*)
6	64	• Firmware error	• Switch measuring system OFF and back ON • If fault recurs: Send measuring system for repair (see *Chapter 5.2 Service and repairs*)

Table 1: Fault codes

Further information can be found in the *interface description*.

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 and REF of VacuDAP – OEM (see *rating plate*)
- Description of fault (if necessary fault message)

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

6 List of applicable documents

The applicable documents are listed in *Table 2*. The technical data can be found in the valid data sheets for the components, as specified on the rating plate.

Document		File	Revision
	Data interface installation instructions	DAP-II-11_VD-OEM-Interface-V1.6-E_C	C
REF 156 00 13	Data sheet	156DB13E_B	B
REF 156 00 15	Data sheet	156DB15E_B	B
REF 156 00 18	Data sheet	156DB18E_B	B
REF 158 00 10	Data sheet	158DB10E_B	B
REF 158 00 12	Data sheet	158DB12E_B	B
REF 158 00 13	Data sheet	158DB13E_B	B
REF 158 00 15	Data sheet	158DB15E_B	B

Table 2: List of applicable documents

7 Additional equipment and components

A selection of the additional equipment and components available for the VacuDAP measuring system is shown in *Table 3: 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
Connecting cable MediSnap XYm	REF 943 00 40-XY	Connecting cable (available length: 6 m, 15 m, 20 m, 25 m, 30 m, 36 m)
Cable MediSnap->open XYm	REF 943 00 44-XY	Connecting cable (available length: 6 m, 15 m, 20 m, 25 m)
Interface cable RS232 XYm	REF 952 00 61-XY	Interface cable RS-232 (available length: 2,5 m, 3 m, 5 m, 6 m, 15 m, 20 m, 25 m, 30 m)
CAN-BUS Converter sub-D	REF 952 00 65	Adapter RS485 to CAN-BUS, sub-D
CAN-BUS Converter RJ45	REF 952 00 66	Adapter RS485 to CAN-BUS, RJ45
USB-Converter	REF 952 00 67	USB Converter
USB-Converter	REF 952 00 68-XY	USB Converter with cable length XY m
Plug-in power supply VacuDAP (EU)	REF 950 00 57	Plug-in power supply with primary plug EURO
Plug-in power supply VacuDAP (UK)	REF 950 00 58	Plug-in power supply with primary plug UK
Plug-in power supply VacuDAP (US)	REF 950 00 59	Plug-in power supply with primary plug Nord America / Japan
Plug-in power supply VacuDAP	REF 950 00 75	Plug-in power supply with exchangeable primary plug (available primary plugs UK, US, AU, EU, CN)

Table 3: 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
Voltage fluctuations and flicker according to IEC 61000-3-3	Complies

Electromagnetic immunity		
Electromagnetic immunity tests	**IEC 60601-1-2 test levels**	**Compliance levels**
Electrostatic discharge according to IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact [1)] ± 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	± 2 kV mains input ± 1 kV signal input/output lines	± 2 kV mains input ± 1 kV signal input/output lines
Surges according to IEC 61000-4-5	± 1 kV line-to-line	± 1 kV line-to-line
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
Voltage dips according to IEC 61000-4-11	0 % U_T; ½ cycle at 0, 45, 90, 135, 180, 225, 270, und 315 degree 0 % U_T; 1 cycle 70 % UT; 25/30 cycles at 0 degree	0 % U_T; ½ cycle at 0, 45, 90, 135, 180, 225, 270, und 315 degree 0 % U_T; 1 cycle 70 % UT; 25/30 cycles at 0 degree
Voltage interruptions according to IEC 61000-4-11	0 % U_T; 250/300 cycles	0 % U_T; 250/300 cycles [2)]
[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 [2)] if uninterrupted operation is required, additional measures must be taken by the responsible organization		