

# KermaX<sup>®</sup> *plus* DDP

Duo display system



**User Manual**

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## NOTICE



This Operating Manual is an integral component part of the dose - surface - product measuring system KermaX<sup>®</sup> *plus* DDP and should always be kept in the proximity of the actual measuring system. This Operating Manual is required, in order to ensure the correct function and operation of the KermaX<sup>®</sup> *plus* DDP system. The KermaX<sup>®</sup> *plus* DDP system together with its accessories may be used for no other purposes other than those specified in this Operating Manual.

The use of the KermaX<sup>®</sup> *plus* DDP and every other system described in this document, the resulting data, as well as the verification of the data before clinical use, is the sole responsibility of the user. Iba Dosimetry accepts no responsibility for personal injury or damage to devices due to faulty operation, neglect of the danger warnings in this Operating Manual, or local health and safety regulations. No part of this Operating Manual may be translated or reproduced in any way without the express written consent of the company Iba Dosimetry.

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Several key functions of the KermaX<sup>®</sup> *plus* DDP and its component accessories are protected by International Patents.

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**Please take note of this important symbol. Emphasized notes in this manual are important for the correct operation of the device and should be read carefully.**

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# Intended Use

## 1. Security and General Information

### 1.1. General Information

#### Important message:

The user must ensure that before running the measuring system that this Operating Manual has been read and fully understood. The KermaX<sup>®</sup> *plus* DDP is a medical product of the class IIb. By initial start-up and subsequent use of this device and / or its associated accessories, all applicable National and International regulations are to be observed. If the KermaX<sup>®</sup> *plus* DDP is involved in connection with an incident pertaining to local or international Medicine Product Law, then the system must immediately be taken out of operation, and the manufacturers or the local representative of Iba Dosimetry informed about the incident in detail.

### 1.2. Responsibility of the user

#### Data evaluation responsibility

Those who use the KermaX<sup>®</sup> *plus* DDP for the collection of data about dose surface product, carry the full and entire responsibility to critically evaluate the results of each measurement.

#### Repairs, Accessories

Enhancements, modifications or repairs may only be implemented by Iba Dosimetry or persons who possess sufficient knowledge and expertise and are authorized by Iba Dosimetry. For repairs, only spare parts supplied or authorized by the manufacturer may be used. Disregard of the above can lead to a malfunction of the measuring instrument and subsequent errors in the readings. Failure to observe any of these conditions will automatically void the manufacturer's warranty.

### Safety Precautions

1. The KermaX<sup>®</sup> *plus* DDP should only be operated by users, who fulfil the following criteria:
  - ↳ Have an understanding of the functionality and the limitations of the equipment.
  - ↳ Possesses expert competence concerning current safety regulations about sources of radiation and the relevant legal regulations.
  - ↳ Have experience in operating dose surface product measuring systems.

🔧 Are electro-technical specialists

2. Before using the KermaX<sup>®</sup> *plus* DDP the correct connection of the chamber and its component accessories must be established. The operator must examine the general functionality and security of the chamber, the display unit and its cable connections (also for physical damage).

3. The KermaX<sup>®</sup> *plus* DDP must be operated in a fire-protected, clean, dry and, if possible, air-conditioned environment. Protect it against excessive mechanical and thermal loads as well as dust and unnecessary humidity.



**Note:**

**If condensation should form in the chamber due to a change of temperature, then the system is to be dried completely and may not be operated again until such action has been taken.**

4. Neither the KermaX<sup>®</sup> *plus* DDP or its components and/or accessories (e.g. the attached chambers) are intended to be used directly in contact with the patient.

5. Do not remove any labels / type identification markings from the KermaX<sup>®</sup> *plus* DDP or from its accessories. If type identification markings become illegible, the parts concerned must be returned to the manufacturer for correct identification and in order to be re-marked.

6. Never open the KermaX<sup>®</sup> *plus* DDP or the attached measuring chambers. There are no user serviceable parts.



**Caution high voltage – Danger of Electrocution!**

7. The KermaX<sup>®</sup> *plus* DDP and the attached chambers are not waterproof. If a risk of immersion or splashing exists, then all system components must be sufficiently covered up and protected.

8. The KermaX<sup>®</sup> *plus* DDP requires a power supply within the range of 15 - 29 V DC. For this purpose a power pack is supplied. If the chamber should be operated with a different external power supply, then this should only take place with the agreement of the X-ray unit manufacturer. The responsibility lies exclusively with the operator or user of the equipment. In any case the power supply should be checked beforehand. In the case of any doubt you should contact the manufacturer, Iba Dosimetry.



**Please consider the safety-relevant legal regulations!**

## 1.3. International Standards

Iba Dosimetry GmbH operates a certified quality management system according to EN ISO 13485 / 07.2003

KermaX<sup>®</sup> *plus* is a medical device class IIb in accordance with the Medical Device Directive 93/42 EEC.

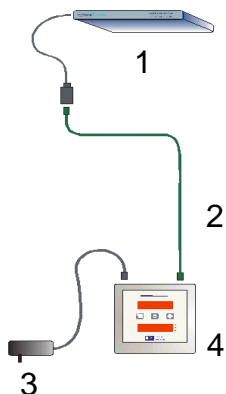
## 2. Use of the KermaX<sup>®</sup> *plus* DDP

### 2.1. Intended use

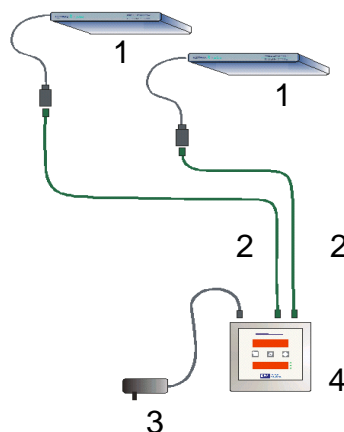
The KermaX<sup>®</sup> *plus* chambers 120-131 OEM HS, 120-131 OEM 120-131 HS, 120-12X have been designed for the determination of the level of the dose surface product (DAP) during an X-ray examination. The KermaX<sup>®</sup> *plus* DDP serves to display the levels measured by these chambers and in particular to record the radiation dose received by the patient.

### 2.2. System Components

#### 2.2.1. General System

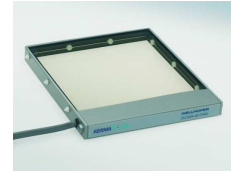


KermaX<sup>®</sup> *plus* DDP S(ingle)



KermaX<sup>®</sup> *plus* DDP D(ouble)

- (1) Ionisation Chamber  
(Illustrated here is the 120-131  
version) with integrated electronics  
and an AKP cable.



- (2) AKP cable and Y-Connector.



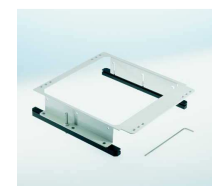
- (3) Power Pack.



- (4) Control / Display Unit  
KermaX<sup>®</sup> *plus* DDP



- (5) Adapter Frame



- (6) or Extension Rails



## 2.2.2. Control / Display Unit KermaX<sup>®</sup> plus DDP

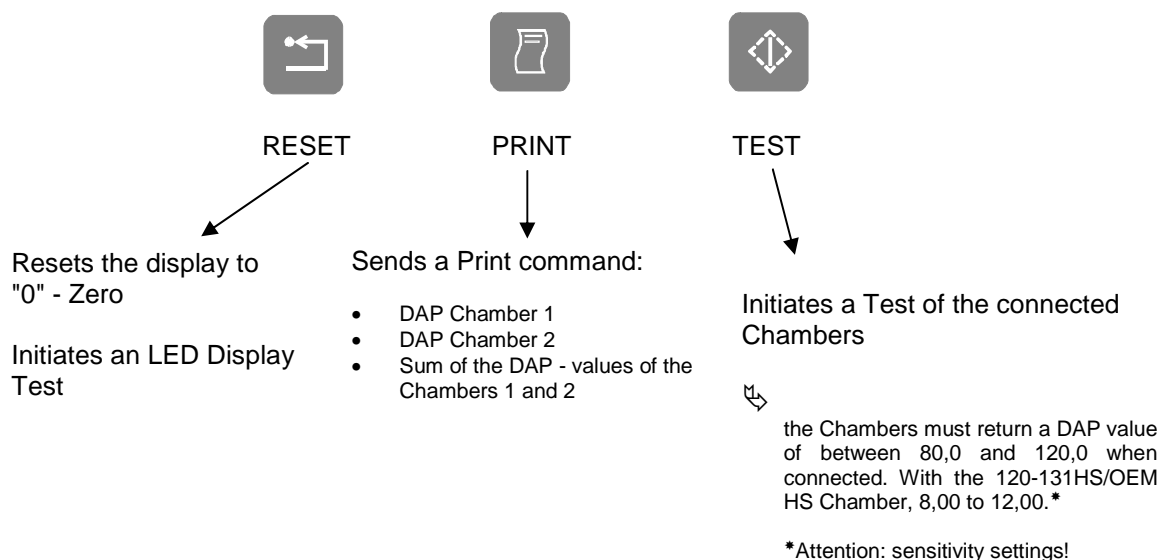
The Control / Display Unit is equipped with two identical measuring chamber inputs (RJ 45 sockets) for the connection of the ionisation chambers described in chapter 2. These inputs are marked CH1 and CH2. Additionally the device is equipped with a 9 pin D-Sub socket for the connection of a printer and also an RS 232 socket (marked RJ 45) for the serial communication with an external computer.

Input Chamber 1	Input Chamber 2	Printer output	RS 232
(CH 1)	(CH 2)		(RS 232)



KermaX<sup>®</sup> plus DDP – rear view

Das KermaX<sup>®</sup> plus DDP has two LED displays and three push-button actuators. Their functions are described below:





## 2.3. Assembly & Installation Instructions

### 2.3.1. KermaX<sup>®</sup> *plus* DDP S

1. 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 are visible in the light field.
2. Connect the chamber using the 12m long connecting cable (AKP cable) with the KermaX<sup>®</sup> *plus* DDP (using the socket CH1).
3. Connect the RJ 45 plug of the supplied power supply with the socket CH2.
4. Connect the power supply to the mains.
5. Carry out a system check in accordance with the following chapter.

### 2.3.2. KermaX<sup>®</sup> *plus* DDP D

1. Slide the chambers into the lower accessory rails of the collimators. Ensure that even if the collimator shutters are fully open that no shadows from the measuring chambers are visible in the light fields.
2. Connect the chambers with the KermaX<sup>®</sup> *plus* DDP by means of two, 12m long connecting cables (AKP cables) using the sockets CH1 and CH2.
3. Connect the RJ 45 plug of the power supply to the RS 232 socket.
4. Connect the power supply to the mains.
5. Carry out a system check in accordance with the following chapter.



If a supplemental filter is used behind the measuring chamber, then the level indicated must be adjusted accordingly. If the KermaX<sup>®</sup> *plus* DDP is installed in a below-table X-ray Unit, then generally speaking, a re-calibration and / or verification of the calibration must be carried out (see chapter "recalibration").

**Do not exceed the maximum dose surface product rate!**

**The size of the radiation field at the surface of the centred chamber may not exceed 146 mm X 146 mm.**

## 2.4. Taking Measurements

After switching on, the system is ready for use after 10 s. However, in order to achieve thermal equilibrium it is essential that a warm-up time of 15 minutes will have elapsed in order that the attached chambers can operate to within the tolerances given in the Technical Specification.



Immediately before each measurement is made it is necessary to push the RESET button once.

After pressing the RESET button the KermaX<sup>®</sup> *plus* DDP is ready for use. The operator is now able to measure the dose surface product and / or the dose surface rate.

## 2.5. Environmental Conditions

The following environmental conditions must be observed in order for the measuring device to operate to within the specified tolerances.

### 2.5.1. Working

Temperature:	between +10 °C and +50 °C,
Air humidity:	between 30% and 75% without condensation,
Air pressure:	between 700 hPa and 1060 hPa.

### 2.5.2. Storage / Transportation

Temperature:	between +10 °C and +50 °C,
Air humidity:	between 30% and 75% without condensation,
Air pressure:	between 700 hPa and 1060 hPa.

## 2.6. System Inspection

### 2.6.1. General Information

After the initial installation (Acceptance Test) and thereafter once a month, the operator should carry out an inspection of the KermaX<sup>®</sup> *plus* DDP.

### 2.6.2. Execution

Press the TEST button



↗ The KermaX<sup>®</sup> *plus* DDP resets itself automatically and generates a test signal in the amplifier of the connected chambers. Afterwards the connected chambers should show a DAP value between 80,0 and 120,0. With 120-131 HS chambers 8,00 - 12,00 (scythe 10 adjust)

Press the "RESET" button



Briefly all LED - display elements must light up and reset all indicator values to "0" - Zero.

**In the event that a test returns a value outside of the given tolerances you will have to carry out a recalibration of the system.**

## System configuration

### 2.7. General Information

The system can be configured to operate with a one or two-channel display.

- One (1) channel on: (only one chamber attached) corresponds to KermaX<sup>®</sup> *plus* DDP-S

The KermaX<sup>®</sup> *plus* DDP shows in the upper display the dose surface product of Channel 1 and in its lower display, either the dose surface product rate or the exposure time, measured with Chamber 1.

- Two (2) channels on: (two chambers attached) corresponds to KermaX<sup>®</sup> *plus* DDP - D

The KermaX<sup>®</sup> *plus* DDP indicates in the upper display the dose surface product of Channel 1 and in the lower display the dose surface product of Channel 2.

The status of the lower display is indicated by one of three adjacent LEDs. In order to use the KermaX<sup>®</sup> *plus* DDP the supplied power pack must be connected either to the chamber connection CH2 or to the RS 232 socket.

Additionally, the KermaX<sup>®</sup> *plus* DDP (Master) allows for the connection of a second device (Slave) which will always accurately display the same value as the *Master* DDP.

The *Slave* can be connected with an Interface-cable to the RS 232 socket. In this case, power is now supplied through the *Master* DDP and therefore the system can no longer be connected to a computer.

### 2.8. Setup

It is possible, to deliver separate results from two individual chambers (connected to CH1 and CH2).

- Dose surface product in  $\mu\text{Gym}^2$
- Dose surface product rate in  $\mu\text{Gym}^2/\text{s}$

- Time indicator in ms

Data from the two channels can be individually displayed, one DDP on the upper LED display, the other on the lower LED display. The unit of measurement of the displayed value is indicated by one of three LEDs located to the right of the lower display.

## 2.9. Selection of the parameters for each display

First of all, the user must activate the LED display set-up program. This is done by depressing the pushbuttons RESET, PRINT and TEST simultaneously. In this case, the pushbutton RESET must be pressed slightly before the other buttons.

Subsequently the following characteristics / parameters can be changed:

- ❖ Settings for LED display 1 (DISP-1)
- ❖ Settings for LED display 2 (DISP-2)
- ❖ Printer selection
- ❖ COM – status settings
  - You have the choice of being able to switch the RS232 interface on, or off, for COM connections.
- ❖ Sensitivity (Resolution) settings\*
  - It is possible to change the position of the decimal point on the LED display and therefore the sensitivity.



**\* Warning! This change may only be carried out by Iba Dosimetry or its locally approved representative. A change is only necessary when the display resolution is altered as a result of using different (High Sensitivity) chambers (see chapter 8).**

- ❖ ID – Number setting
  - The ID number can be read on every label attached to the device so that the user can determine exactly which KermaX<sup>®</sup> plus DDP is in use.

After the set-up process has begun, the following announcement appears on the upper display:

d	I	S	P	-	1	
---	---	---	---	---	---	--

*This announcement means - "the system is ready to configure the LED display 1"*



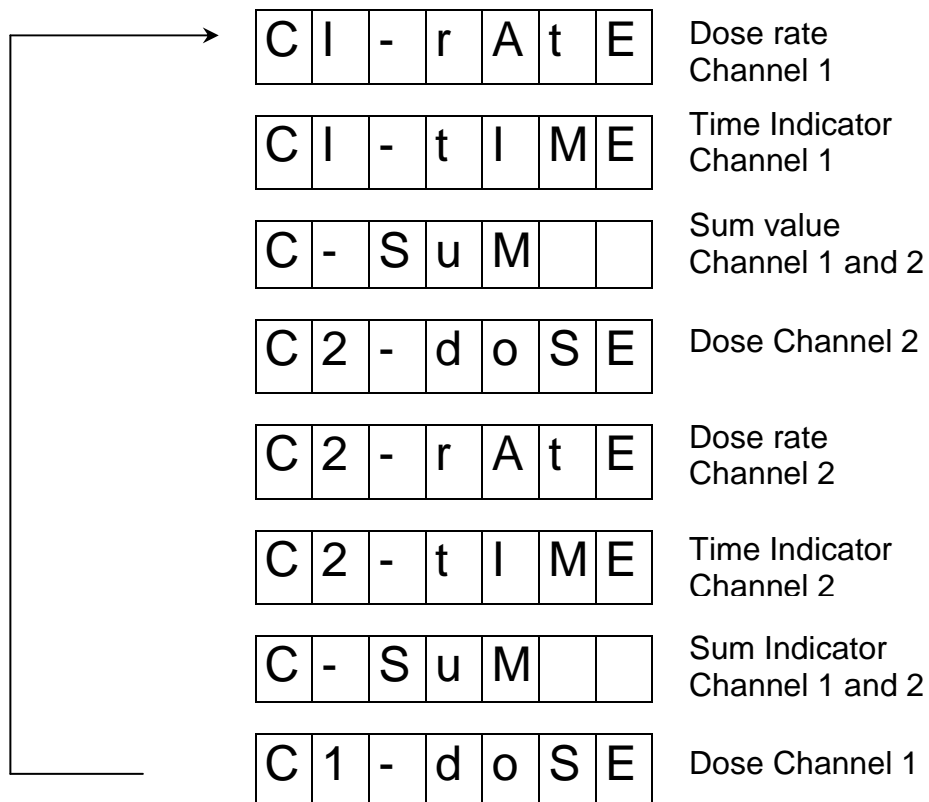
When the RESET button is pushed, the system will show the current setting for the LED display 1.

C	I	-	d	o	S	E
---	---	---	---	---	---	---

Dose Channel 1



When the TEST button is pushed several times in succession the following settings which are available for LED display 1 are shown.



To select one the settings in the display push the RESET button when that setting is displayed.

When the configuration for the LED display 1 is complete the following announcement appears in the LED display 1:

d	I	S	P	-	2	
---	---	---	---	---	---	--

*This announcement means - "the system is ready to configure the settings of LED display 2."*

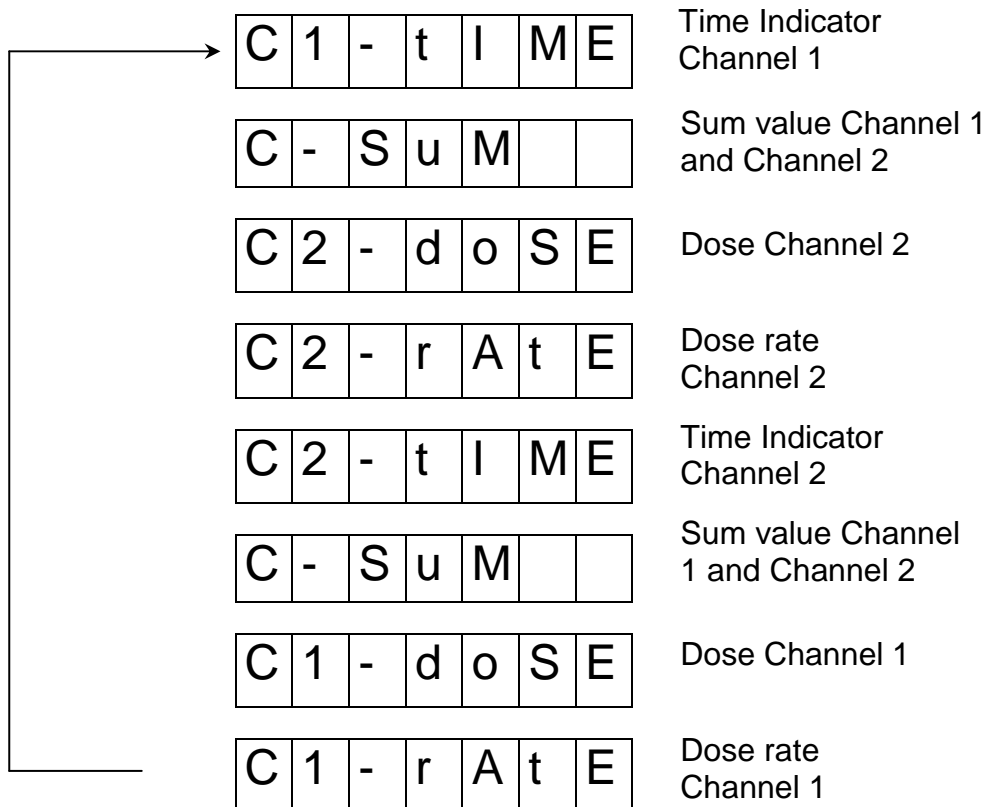


When the RESET button is pushed, the system shows the current settings for the LED display 2:

C	I	-	r	A	t	E
---	---	---	---	---	---	---



When the TEST button is pushed several times in succession the following settings which are available for LED display 2 are shown:



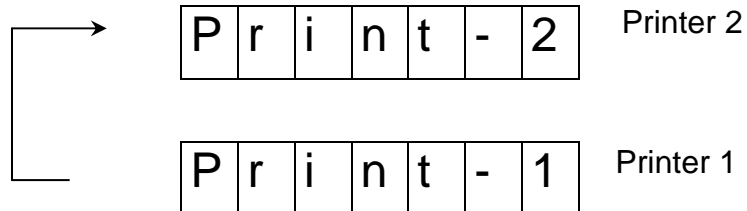
To select one the settings in the display push the RESET button when that setting is displayed.

When the configuration for the LED display 2 is complete the activated printer setting is shown.

P	r	i	n	t	-	1
---	---	---	---	---	---	---



The user can change this configuration, by pushing the TEST button.



A printer will selected when the RESET button is pushed.

**Note:**

If the user selects Printer 1 (standard setting), the system will support the label printer *Star DP8340S*. In this case the DIP switches on the printer must be configured as follows:

ON



OFF

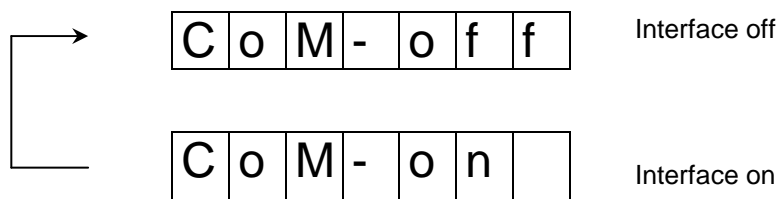
When a printer has been selected, the current setting for the RS 232 interface is displayed as either "on" or "off"

Example:

C	O	M	-	o	n	
---	---	---	---	---	---	--



The user can change this configuration by pushing the TEST button.



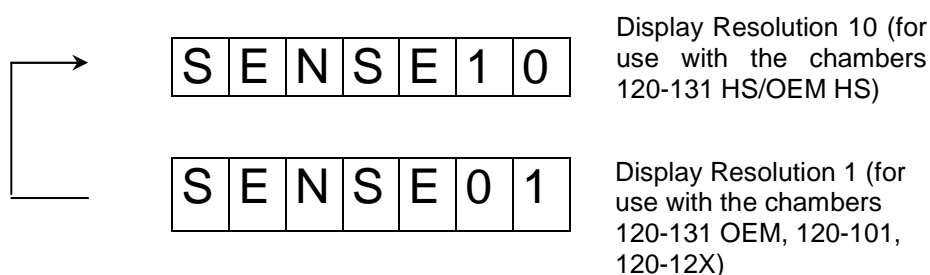
When the RESET button is pushed, the following text appears in the display:

e.g.:

S	E	N	S	E	0	1
---	---	---	---	---	---	---



The user can change this configuration by pushing the TEST button.



In order to select one of the sensitivity values it is always necessary to push the RESET button!

After the user has selected the sensitivity factor he / she can additionally set the ID number (beginning from 0 to 7) for the KermaX<sup>®</sup> plus DDP



Example:

I	D	-	1			
---	---	---	---	--	--	--



The user can change this configuration by pushing the TEST button.

I	D	-	2				ID – Nummer 2
I	D	-	3				ID – Nummer 3
I	D	-	4				ID – Nummer 4
I	D	-	5				ID – Nummer 5
I	D	-	6				ID – Nummer 6
I	D	-	7				ID – Nummer 7
I	D	-	0				ID – Nummer 0
I	D	-	1				ID – Nummer 1



When the user pushes the RESET button the current ID number will be selected and the set-up process is terminated.

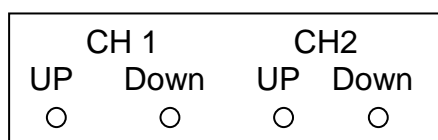
### 3. Calibration



The following calibration procedure should only be carried out only in exceptional cases when really justified. The DAP measuring system is calibrated by the manufacturer prior to shipment and a copy of the Calibration Test Certificate is included with this documentation. As a rule, a verification of the calibration normally takes place at the time of installation.

#### 3.1. Calibration of the Test Value

With the help of the KermaX<sup>®</sup> *plus* DDP original factory test results (Calibration Test Certificate - included with this documentation), the original test values can be recreated if required. On the right hand side of the housing of the KermaX<sup>®</sup> *plus* DDP are four access holes. Located behind each of these openings is a pushbutton, which can enable the user to raise or lower the values measured by the chamber/s connected to the measuring device. With each push of a button (UP - increase) or (Down - decrease) the value will change by approximately 0.5% assuming that the button is pressed for at least 200ms.



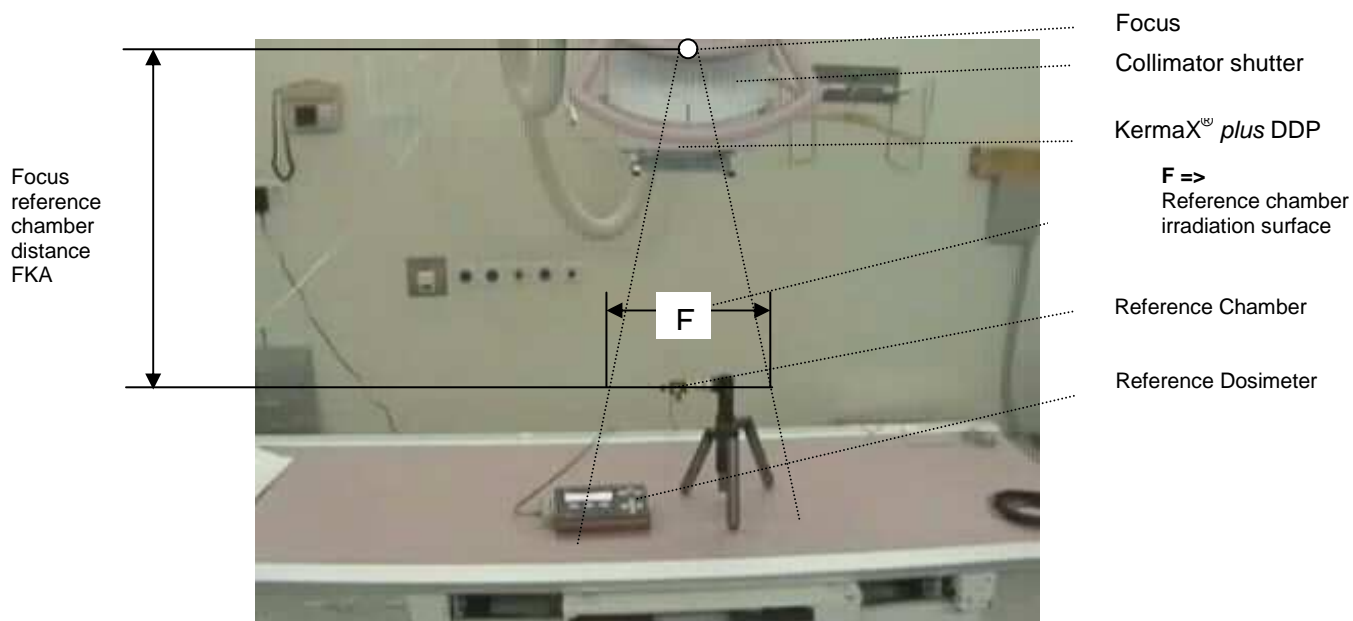
Right side of the housing of the KermaX<sup>®</sup> *plus* DDP

#### *Example:*

If the test value of the chamber amounts to 1 75.0 (7.50 with HS chambers), it is necessary to push the UP button of the chamber 1, -50 times. Afterwards the test value displayed should be approximately 100,0 (10,00 in a HS system). At any time the change can be viewed by pressing the TEST pushbutton.

### 3.1.1. Preparation for Calibration

In the illustration below the set-up for the calibration of the KermaX<sup>®</sup> *plus* DDP is depicted.



Set-up for the execution of the Calibration

### 3.1.2. Carrying out the Calibration

#### Routine Procedure

- a) The Display should be reset to Zero (0) by pushing the RESET button. Following this, a test should be carried out as previously described in ([see 2.5.2](#)). The results of this test should be noted down.
- b) Now the surface area of the light beam at the level where it is projected (orthogonal to the middle beam direction) must be determined. The measuring point of the reference chamber must also be located within this area.

✎ Switch on the light beam and measure the length and breadth of the projected light field with a ruler. The surface area is determined by the multiplication of the two values.

*Note:*

- A more accurate method is to produce an x-ray (radiograph) at the same level as the Reference Chamber and subsequently measure the surface area of the exposed film surface.
- c) Photographic parameters should be set at the control console and an X-ray (emission release) made. In order to make a valid comparison with the manufacturer's Test Calibration the radiograph must be made using 100KV.

- d) After the radiograph (emission release) has been made, read and take note of the results displayed on both measuring devices.

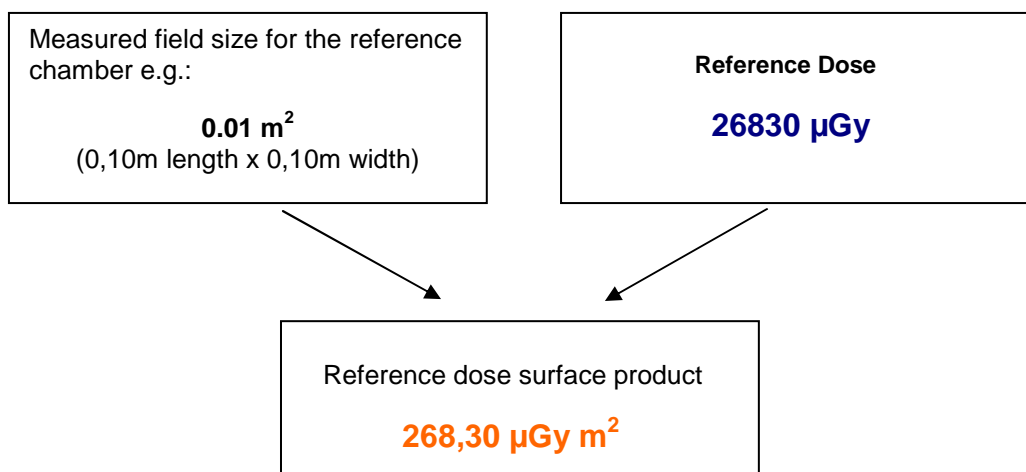
e.g.: Reference Dosimeter display: **26830  $\mu\text{Gy}$**

Display KermaX<sup>®</sup> *plus*: **281.5  $\mu\text{Gy}\cdot\text{m}^2$**

Note:

- If a semi-conductor chamber is used as the reference system, then the display of the KermaX<sup>®</sup> *plus* DDP measuring system must be adjusted to compensate for the ambient air pressure and temperature.

- e) Reference dose surface product calculation:



- f) Comparison of the reference dose surface product and the KermaX<sup>®</sup> *plus* DDP dose surface product:

$$\frac{100\% \times \mathbf{281.5 \mu\text{Gy}\cdot\text{m}^2}}{\mathbf{268,30 \mu\text{Gy m}^2}} - 100 = \mathbf{4,92 \%}$$

- g) Result:

The KermaX<sup>®</sup> *plus* DDP shows in this case a value of 4.92% more. In order to correct this deviation the DOWN button for the appropriate channel (on the side of the *KermaX plus DDP*), must be pushed approx. x10 times ([see 3.1](#)) in order to re-adjust the measuring instrument (each depression of the key results in an approx. 0,5% change).

- h) Check that the test value is within the given tolerances, 100,0  $\pm$  5 % (10,00 with a 120-131 HS chamber), when the TEST button is pressed on the KermaX<sup>®</sup> *plus* DDP.

- i) If the test values are ok press the RESET button and the KermaX<sup>®</sup> *plus* DDP is now ready to start taking measurement readings.

#### 4. KermaX<sup>®</sup> plus DDP Technical Specification

Number of chamber inputs:

2

##### Display Resolution:

- Dose surface product display
  - ↳ in combination with the chambers 120-131OEM, 120-12X 0.1  $\mu\text{Gy m}^2$
  - ↳ in combination with the chambers 120-131 HS / 120-131 OEM HS 0.01  $\mu\text{Gy m}^2$
- Dose surface product display
  - ↳ in combination with the chambers 120-131, 120-12X 0.1  $\mu\text{Gy m}^2 / \text{s}$
  - ↳ in combination with the chambers 120-131 HS / 120-131 OEM HS 0.01  $\mu\text{Gy m}^2 / \text{s}$
- Irradiation time 50 ms

##### Measuring range:

- Minimum measurable dose surface product:
  - ↳ in combination with the chambers 120-131, 120-131 OEM, 120-12X 0.1  $\mu\text{Gy m}^2$
  - ↳ in combination with the chambers 120-131 HS / 120-131 OEM HS 0.01  $\mu\text{Gy m}^2$
- Maximum measurable dose surface product:
  - ↳ in combination with the chambers 120-131, 120-131 OEM, 120-12X 999999,9  $\mu\text{Gy m}^2$
  - ↳ in combination with the chambers 120-131 HS / 120-131 OEM HS 99999,99  $\mu\text{Gy m}^2$
- Minimum measurable dose surface product rate:
  - ↳ in combination with the chambers 120-131, 120-12X, 120-131 OEM 0.1  $\mu\text{Gy m}^2 / \text{s}$
  - ↳ in combination with the chambers 120-131 HS / 120-131 OEM HS 0.01  $\mu\text{Gy m}^2 / \text{s}$
- Maximum measurable dose surface product rate:
  - ↳ in combination with the chambers 120-131 30000,0  $\mu\text{Gy m}^2 / \text{s}$
  - ↳ in combination with the chambers 120-131 HS – 120-131 OEM HS 3000.00  $\mu\text{Gy m}^2 / \text{s}$
  - ↳ in combination with the chambers 120-101, 120-12X 1000.0  $\mu\text{Gy m}^2 / \text{s}$

## 5. Regular Maintenance:

The following routine maintenance checks should be carried out as specified below in order to ensure the trouble free operation of the measuring device:

Test	Frequency.	Tolerance
Automatic Self Test	Monthly	8,00 – 12,00. (at 120-XXX HS chambers 80.0 – 120.0)
Instrumentation Control	Every 5 years	+/- 15 % Absolutely accuracy
Dose surface product measurement with Filter	Whenever there is a maintenance inspection / Constancy Test of the X-ray unit	+/- 30 % of the reference value

↳ Filters can be test bodies employed in the maintenance inspection / Constancy Test of the X-ray unit.

↳ The same Filter must always be used in the same place when a measurement is taken in this way.

Light field

Monthly

### **Note:**



The maintenance checks specified here are only recommendations. National & International laws for the country of use together with local legal regulations must always be observed.

## 6. Customer Relations

### 6.1. Complaints

Product queries and complaints are dealt with according to the established procedures of the Iba Dosimetry quality assurance system. Customers should send their query or complaint, in writing, directly to the following address:

Iba Dosimetry GmbH  
Bahnhofstrasse 5  
D-90592 Schwarzenbruck  
Germany

Telephone ☎: +49 9128 607-0, Fax 📠: +49 9128 607-10  
Email ✉: [info@iba-dosimetry.com](mailto:info@iba-dosimetry.com)

We endeavour to resolve all customer queries or complaints in the shortest time possible. Items covered by guarantee / warranty will be repaired or replaced within 21 working days.

## 7. Warranty

### 7.1. Conditions

IBA DOSIMETRY GmbH guarantees for a period of 12 months from date of purchase the error free operation of the KermaX<sup>®</sup> *plus* DDP together with its component accessories. In the event of a defect IBA DOSIMETRY GmbH shall decide whether the system will be replaced or repaired free of charge. The following data must be included for a possible claim under warranty:

- Description of the defect / error
- The date of purchase
- The model number of the device
- The serial number of the chamber

Postage and packaging costs will be paid for by the owner unless otherwise first agreed in writing with IBA DOSIMETRY GmbH. Costs incurred as a result of damage to the equipment caused during transit will be the responsibility of the owner.

Subject to change  
VD UM KermaX<sup>®</sup> *plus* DDP 003