Radcal®

# Model PDC
# Patient Dose Calibrator

# Instruction Manual

MADE IN GERMANY FOR RADCAL UNDER THE FOLLOWING
PATENT: PAT NO. 7,413,345

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## Note.

The system automatically defaults to the “Low Rate” mode and when the rate is too high, an error message “OVERRATE” will be displayed. The mode should then be changed to “High Rate”.

## Attention.

The PDC cannot be switched on when the battery charger is connected. Always disconnect the battery charger before using the system.

## Important.

Throughout this manual the following words are given a specific meaning and the reader should be aware of their significance.

> *Attention*; Used where there is a risk of damaging the PDC by incorrect handling or operation error.
>
> *Note*; Used where information is provided to aid better understanding of the PDC or its use.

# CONTENTS

## General user information

*Attention*. This section contains essential information that is required for the safe use of the Patient dose Calibrator (PDC)

**Application**
The Patient Dose Calibrator PDC has been designed for checking the calibration of dose area product meters and air kerma meters used in patient dosimetry. It can also be used to establish reference dose and dose area product levels for specific examinations and to check the consistency and behaviour of automatic exposure control systems.

**Classification**
The Patient Dose Calibrator PDC is not a medical device; it is a laboratory measuring instrument and should not be used with patients.

The protection afforded by the housing of the PDC corresponds to IP41 (IEC 60529).

The device is not suitable for application in proximity of combustible substances.

**Electromagnetic compatibility (EMC)**
This laboratory measuring instrument complies with the international standard IEC 60601-1-2 and meets the EMC protection requirements for medical devices.
Portable and mobile HF communication systems may affect electrical measuring devices.
The Patient Dose Calibrator was designed to power off if exposed to electro-static discharge (ESD).

**Protection against electric shock**
The Patient Dose Calibrator PDC is powered by an internal lithium ion (Li-ION) battery pack. For charging the battery a special charger unit for medical devices with safety extra-low voltage (SELV) features is used.
When charging the internal lithium ion battery pack only use the charger supplied with the instrument or a replacement obtained from the manufacturer.

**Handling, transport, shipping**
The ionization chamber and electronic system are highly sensitive components and must be handled with care.
For transport and return shipment the original or an equivalent packaging must be used.
During transport the following ambient conditions must be maintained.

Temperature 0°C - 50°C
Relative air humidity 10% - 80% (max. 20 g/m3; non-condensing)

**Cleaning**
When cleaning the ionization chamber no abrasive cleaners and no organic solvents or cleaning agents containing solvents (e.g. petroleum ether, alcohol) must be used.
The enclosure of the PDC can be cleaned by wiping with a damp cloth containing a mild washing-up liquid solution.

**Storage, conditions of application**
Nominal range of application with regard to temperature and relative air humidity can be found in the Technical specification on page 15.
A relative air humidity exceeding 80% can cause precipitation of condensate on the ionization chamber and electrical connections. This will lead to increased leakage current. Where the PDC might have been exposed to excessive humidity, the risk of such insulation failures can be reduced by drying the ionization chamber at an elevated temperature (max. 50°C).

A relative air humidity exceeding 80% can cause precipitation of condensate on the ionization chamber and electrical connections. This will lead to increased leakage current. In order to eliminate such insulation failures, the ionization chamber may be dried at an increased temperature (max. 50°C).

**Disposal**
The device contains a lithium ion battery pack and electronic components. It must be disposed of in accordance with the applicable national regulations or returned to the manufacturer.

## System description

### Introduction

The PDC is designed to function as a stand-alone battery powered instrument. Its application can be extended by connection to a PC computer running the optional software package (see separate software user manual). A support stand is provided to elevate the PDC above structures that might add scattered radiation to a primary beam measurement.
The PDC has been designed for use with a patient equivalent phantom when measuring entrance or image receptor doses. This is not included in the system package.

### Construction

The PDC consists of an ion chamber assembly, electronic printed circuit board incorporating displays, a switch panel and battery.
The components are housed within a protective housing that incorporates a beam alignment target.
*Note*. There are no user accessible components within the housing.

### The Ion chamber

The ion chamber is suspended within the protective housing to minimize disturbance during positioning the PDC in the radiation beam. The chamber consists of central and outer active areas. Dose measurement uses the central area only whilst both areas are used for DAP measurement.

### The radiation target

A target assembly is provided to assist with alignment to the radiation beam.
*Attention*. When making dose measurements the radiation field size must exceed the red 10cm diameter area.
Where a light field is not available a matrix of radio-opaque markers are provided for alignment with a fluoroscopic image. The markers are placed at points of major intercept on the target and are illustrated by red dots.

### The Electronic system

The PDC uses a micro controller to manage and process instructions and measurement data. A common high voltage generator is used to energize both sections of the ion chamber. The system incorporates three independent electrometers that are permanently coupled to collector plates of the ion chamber. Their functions are:
1. Central area
2. Outer area, low sensitivity
3. Outer area, high sensitivity

The electrometer outputs are continuously sampled by the processor.

The operator can use the mode switch to select dose or DAP display, both are available during or following a X-ray exposure.
When the system senses radiation the display automatically indicates dose or dose area product rate. At the end of an exposure the display indicates the accumulated dose or dose rate.
The user can manually set the display to zero at any time with the rest switch. For convenience there is an automatic zero function (default setting, auto zero 15 seconds after the end of a radiation exposure).
The system performs an automatic test routine when switched on. This involves a display test, electrometer test, battery check and electrometer auto zero.
The battery is charged with a charger that is supplied with the system and when charged provides 8 hours of operation.
If the system is not used for a prolonged period (default value 15 minutes) it is automatically switched off.

**Computer connection**
When connected to a PC running the optional software package control is via the computer and with the exception of the power on/off button all PDC located controls are disabled. Please see the software manual for more details.

## Preparations for operation

**Preparation**
The PDC should be carefully removed form its packing case and inspected. If any damage to the components is found, the supplier or manufacturer should be contacted. Damaged components must not be used.

**Charging the battery**
The Patient Dose Calibrator is delivered with a basic state of charge of the internal battery of approximately 25 %. The actual state of charge is displayed during the test function.
It is recommended that the battery is fully charged before first use. Plug the charger into the PDC first then into the wall.

*Attention.* When charging the Patient Dose Calibrator, use only the original charger or a manufacturer supplied replacement!

*Note*. When the battery is fully charged the PDC will function for a minimum of 8 hours. To charge a completely exhausted battery takes about two hours.

*Note*. If the PDC battery is completely flat, when the charger is plugged in its yellow charging indicator lamp fails to glow until the load on the power supply is reduced after about 30 minutes of charging.

**Power-on test**
*Note.* Prior to use, all components of the measuring system should have been adapted to room temperature.
The measuring system includes an automatic power-on test during which the function of the ionization chamber and all electronic systems are checked.

**Stabilization time**
The ionization chamber is a highly sensitive detector which must stabilize following application of the ionization potential in order to meet the specified performance, see page 15 of this manual. The same applies to the analogue portion of the electronic system.
The period of time required for this process is known as the stabilization time.
The measuring system is however operational during this stabilization time.
The required stabilization time for the ion chamber can be found on page 15 of this manual.

**Operation**

*Attention*. The PDC – Patient Dose Calibrator should only be used by personnel who are authorized to use sources of diagnostic medical X-radiation and are acquainted with these instructions.

*Note* These instruction apply only to the PDC when used without a computer running the application software being connected.

**Switching on the device**
A short press of the button marked ON/OFF will switch the PDC on.
The display shows the following sequential information:

***Radcal***

- The device name:

***Patient Dose Calibrator***

- Software version (x.xx)

***PDC x.xx***

- A test of all indicator LED's and a digit test of the display is then performed.

Thereafter the power-on test sequence starts:

***TEST***

The required time for the power-on test is displayed.
Three test values (T1 –T3) are then displayed and internally evaluated. At the end of the power-on test a battery check is carried out and the
The percentage of residual charge of the battery is displayed.

After the power-on test the zero current is checked:

***ZC-CHECK***

The required time for the zero current check is displayed.
The zero current check takes place over the period that was indicated.

***RESET***
***O.K.***

The PDC's internal microprocessor switches the measuring range to "low rate" and the measuring mode to "dose area product". This is indicated by turning on the LED "low rate" and the LED for the dimension unit "µGy· m²"

Readiness for use is shown in the display as

***0.00***

**RESET function**
The RESET function resets the display of measured dose area product and air kerma regardless of the selected display mode.
A short press of the reset (test) button starts the RESET function.

The PDC incorporates an Auto-Reset at a default time of 15 seconds following a measurement or other operation. The auto reset time can be adjusted or disabled via the PCD software (see separate manual).
*Note*. After expiration of the Auto-Reset the PDC resets the display of dose area product and air kerma automatically to zero. If a subsequent exposure is measured prior to Auto-Reset it will be added to the dose area product and air kerma already displayed (commonly know as accumulate mode).

**TEST function**
The TEST function checks that all the components of the measuring system are functioning correctly.
In the course of this, three test values are determined and compared to factory-set nominal reference values. If the current test values are within an accepted tolerance range, the TEST function has been performed successfully. In case of failure, an error message is displayed.
At the end of the power-on test a battery check is carried out and the percentage state of charge is displayed.
When the PDC is switched on, the TEST function is started automatically (power-on test). The test function can be used at any time by pressing the reset (test) button for 2 seconds (until “RESET” on display changes to “TEST”). If the button is pressed for a longer period the TEST function will be cancelled.

**Display mode**
The Patient Dose Calibrator provides two display modes “dose area product” and “air kerma”. The selected display mode is indicated by the LED together with the selected dimension unit.

When X-rays are detected the display indicates “dose area product rate” or the “air kerma rate” and the measured quantity is indicated by the corresponding LED. Following termination of the exposure the accumulated “dose area product” and “air kerma” is displayed.

To change the display mode press the mode selection button and confirm the function has been completed by inspection of the indicator LED’s.
It is possible to toggle between dose and dose area product following a measurement.
*Note* The field sized must be greater than 10 cm diameter to display a valid dose reading. By dividing the displayed DAP by the dose, it is possible to derive the approximate radiation field area.

**Measuring range**
The PDC can measure Dose, Dose Rate, DAP and DAP Rate. The DAP and DAP Rate have either low or high dose rate range.
When in the dose area product display mode the PDC has two ranges "low rate" and "high rate". The selected rate is indicated by the corresponding LED. The rated range of use for each is given on page 15 of the Technical specifications.

***Note*** **The system automatically defaults to the "Low Rate" mode and when the rate is to high, an error message "OVERRATE" will be displayed. The mode should then be changed to "High Rate".**

To change the measuring range press the range button and confirm the function has been completed by inspection of the indicator LED's.
*Note*. The measured values are displayed as floating point numbers.

**Low battery indicator**
The LED "low battery" is turned on when the state of charge of the internal lithium ion battery is less then 20%. In this condition the device will be operable for at least one hour. When the battery is completely exhausted the device switches off automatically.

**Switching off the device**
By pressing the on/off button for minimum two seconds, the device is switched off.
*Note*. The PDC incorporates an auto power off feature. The system is switched off automatically after 15 minutes of inactivity (default time, the time can be changed via the PC software).

## Dose and dose rate measurements
Depress the 'Mode' button until the 'mGy' indicator is illuminated. Make sure that the x-ray field size is larger than the red 10 cm diameter circle area indication on the PDC cover. Set the exposure to be greater than 1 second. Ensure that the display reads zero. Press the 'Reset' button to clear any erroneous readings caused by movement. The dose rate will be immediately displayed during the exposure and the dose is displayed following the exposure. The software can be used to capture the exposure dose rate. Note that the high and low range mode does not affect the dose and dose rate functions. The PDC readings will self-clear in 22 seconds or can be manually cleared by pressing the 'Reset' button.

## DAP and DAP Rate measurements
Depress the 'Mode' button until the 'uGy*$m^2$ ' indicator is illuminated. Make sure that the x-ray field within the 30x30 cm area indication on the PDC cover. The field can be any shape as long as it is within the 30x30 cm area indication. Select 'low rate' for expected exposures from 1 uGy*$m^2$ /min to 10 mGy*$m^2$ /min. Select 'High range' for exposures exceeding 2 mGy*$m^2$ /min. Set the exposure to be greater than 1 second. Ensure that the display reads zero. Press the 'Reset' button to clear any erroneous readings caused by movement. The DAP dose rate will be displayed immediately during the exposure and the DAP is displayed following the exposure. The software can be used to capture the exposure DAP rate. The PDC readings will self-clear in 22 seconds or can be manually cleared by pressing the 'Reset' button.

## Trouble Shooting

**Fault correction table**

| Error message | Meaning | Suggested action |
|---|---|---|
| ***ZC-ERROR*** | * Zero check error | * X-radiation was active during RESET function.<br>-> Radiation off, repeat RESET.<br>* In case of repeated occurrence: contact service. |
| ***TE-ERROR*** | * TEST error | * One of the Test values is out of the tolerance range.<br>-> Switch measuring system OFF and ON again.<br>* In case of repeated occurrence: note the displayed test-values and contact your Radcal representative. |
| ***OVERRATE*** | * maximum dose-rate is exceeded | * ->Change the measuring range to “high rate”, RESET; repeat measurement |
| ***LOW RATE*** | * Below minimum dose-rate | * ->Change the measuring range to “low rate”, RESET; repeat measurement |
| ***OVERFLOW*** | * Display range (accumulated value) is exceeded | * DAP > 99 999 999 µGy*m² or AK > 99 999 999 mGy<br>-> RESET; repeat measurement. |
| ***TW-ERROR***<br>***EE-ERROR***<br>***HV-ERROR*** | * Electronic error | * Electronic error was detected.<br>-> Switch measuring system OFF and ON again.<br>* In case of repeated occurrence: note the displayed test-values and contact your Radcal representative. |

## Technical specifications

Notes:
All technical data is valid for the ambient conditions as defined in IEC 60580.
Only values given with tolerance ranges or limits are guaranteed.
All other values are for information only.
Subject to change without prior notice.

**Ionization chamber**
Response, 700 pC / µGy·m²
Leakage current, < 0.1 pA
Response versus radiation quality, ± 3 %
(50 kV …150 kVp, norm. to 100 kVp; according to IEC 60580)
Equivalent filtration, (70 kV) 0.6 mm Al
Active area,
Dose area product maximum, (300 x 300) mm²
Air kerma minimum 100 X 100 $mm^2$ (at center of chamber assembly)
Chamber polarization potential, 300 V
Distance between electrodes, 10.5 mm
Stabilization time, 3 min

**Measuring system**
Digital resolution,
Dose area product, 0.01 µGy·m²
Dose area product rate, 1 µGy·m²/min
Air kerma, 0.001 mGy
Air kerma rate, 0.1 mGy/min
Display range,
Dose area product, 0.01 - 99 999 999 µGy·m²
Air kerma, 0.001 - 99 999 999 mGy

**System performance**
Rated range of use.
Tube voltage, 40 - 150 kV
Dose area product rate, (low rate range)
1 – 1 X $10^4$ µGy·m²/min
Dose area product rate (high rate range)
2 X $10^3$ – 9 X $10^5$ µGy·m²/min
Air kerma rate, 0.2 - 9 X $10^3$ mGy/min.
Operating atmospheric pressure range, 80.0 - 106.0 kPa
Operating temperature range, +10 - +40) °C
Air humidity 10 - 80 %
Relative humidity, max. 20 g/m³

| Accuracy. | | |
|---|---|---|
| DAP | ± 10% | Inclusive of all uncertainties i.e. temperature, pressure rate, |
| Air kerma | ± 10% | area and beam quality |
| | | |
| DAP | ± 7.5% | Under reference conditions |
| Air kerma | ± 7.5% | 10 mGy/min, 15 x 15 cm field, 80 kVp, 2.5 mm Al filtration. |

**Power supply**

Internal rechargeable battery pack Li-ION, 2 cells Panasonic CGR18650CF (UL 1642)
Nominal voltage, 7.2 V
Nominal capacity, 2.25 Ah
Maximum charge, voltage 8.2 V
Maximum charge, current 2.5 A
Number of charge/discharge cycles, > 500
Operation time (initial state of charge= 100 %), > 8 h

**General**

Serial interface USB (virtual COM)
Protection class (acc. IEC 60529) IP 41
Weight 2.32 kg
Dimension (length x width x height) 350 mm x 410 mm x 35 mm

## Support Elevation Stand

- **Foam Elevation Support Stand fits inside the interior of the Carry Case lid**

Horizontal Elevation Use

Vertical Elevation Use

**Warranty for the Model PDC - Patient Dose Calibrator**

Radcal warrants that, in the event that any defects in material or workmanship should develop within one year of the date of shipment, the company assumes full responsibility for servicing equipment of its manufacture without charge upon return of the equipment to Radcal, with shipping costs prepaid by the customer. Costs to return-ship to customer by ground transportation will be paid by Radcal if the repairs are warranty-applicable. This warranty excludes batteries.
Radcal shall not be held liable for damages or delays caused by defects beyond making repairs or furnishing replacement parts, nor shall Radcal be liable for any defective material replaced without Radcal's consent during the period of this warranty. Radcal reserves the right to perform warranty services at its own factory.

**Non-Warranty Repairs**

The calibration of this instrument was correct within specified limits when the instrument left our factory. Radcal cannot be responsible for injury or damage resulting from improper use or calibration errors which develop subsequent to our shipment of the instrument.
If Radcal determines that a fault has been caused by misuse, abnormal operating conditions, or repairs by unauthorized personnel during the warranty period, repairs and shipping costs will be billed at normal rates.
If the equipment is found to be in proper working condition, Radcal will return-ship the equipment at customer expense.

## Declaration of Conformity

| | |
|---|---|
| **Manufacturer's Name:** | Radcal 426 West |
| **Manufacturer's Address:** | Duarte Road Monrovia, CA 91016 U.S.A. |

| | |
|---|---|
| **Declares that the Product** | Patient Dose Calibrator |
| **Product Name:** | PDC-01 |
| **Model Number(s):** | All |
| **Product Accessories:** | |

**Conforms to the following Product Specification:**

**EMC: ***

EN 61326-1 (2013) Group 1 Class B
EN 61000-4-2
EN 61000-4-3
EN 61000-4-4
EN 61000-4-6
EN 61000-4-5
EN 61000-4-11
EN 61000-3-2
EN 61000-3-3

**PERFORMANCE:**

IEC 61674

The product herewith complies with the RFI-emissions requirements and immunity requirements and carries the CE marking accordingly.

E. MacIntosh
Technical Manager
August 29, 2019

* Tested with 3m USB cable