# Warranty and Service Policy

## Introduction

This document outlines the warranty and service policy between RADIOMETER and its subsidiaries and distributors.

In this document RADIOMETER encompasses Radiometer Medical ApS (RMED); Radiometer Medical Aps Distribution Center in Poland (RMED PL); Radiometer Basel AG (RBSL); and Radiometer California, Inc (RCAL) hereafter, in this document, these entities will be collectively referred to as RADIOMETER.

Where differences exist between these three entities (RMED, RMED PL, RBSL and RCAL), these differences will be clearly identified.

## Validity

This version is valid as of September 1, 2024, and replaces all previous information regarding this matter.

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# 1 Warranty Policy

## 1.1 Limited Warranty

RADIOMETER warrants that the products supplied from RADIOMETER are free from defects in components and workmanship.

The duration of the warranty period for the various types of products and services are given below.

The warranty is limited to the replacement of defective parts of the product and does not cover any associated costs or expenses, such as, hourly expenses (travel and labour) and freight charges.

## 1.2 Warranty Disclaim

RADIOMETER cannot provide or verify instrument performance specifications and accept warranty claims if the recommended maintenance procedures are not performed or if accessories other than those recommended by RADIOMETER are used, unless the customer or producer of the accessories can show that these accessories match the quality of the accessories recommended by RADIOMETER and do not in any way affect the overall system performance and specifications.

Warranty claims for parts which suffer from physical damage, unauthorised attempted repair, or exposure to conditions other than those specified by RADIOMETER (e.g., temperature, humidity, line voltage outside specified limits, electrostatic discharge) will not be accepted.

## 1.3 Analyzers & Monitors

All analyzers, and TCM4 series instruments, from RMED and RCAL are covered by a warranty of 18 months from our invoice date. In the case of RCAL, the period begins on the date the sales invoice is issued from RCAL.

All TCM5 series instruments are covered by a warranty of 15 months from the time of production.

All PeriFlux6000 instruments from Perimed are covered by a warranty of 24 months from the date the sales invoice is issued from Perimed.

## 1.4 Spare parts

Spare (service) parts are covered by an 18-month warranty from our invoice date.

When claiming credit, the sales subsidiary or distributor must provide the invoice date for the spare part to Radiometer. If an invoice date is not provided to RADIOMETER, then the warranty period for the spare part is set to start at the invoice date for the analyser (hence, reduced or no warranty, depending on analyzer age).

Parts, which are replaced on a regular basis as part of a preventive maintenance plan, are covered by an “Out of the box” warranty. That is, the warranty is limited to defects observed at the time of installation of the part. These parts are listed in the maintenance schedule of the Operator’s Manual, or are included in, for example, the Yearly Service Kit (e.g., tubing, washers, O-rings, air filters etc.).

## 1.5 Analyzer and Monitor Factory Repair

Repairs carried out at the factory are covered by a six-month warranty from the date of invoice. The warranty is limited to the parts replaced.

Refer to Service Policy for the conditions for returning an analyzer or monitor for repair at the factory at RADIOMETER.

## 1.6 Electrodes and Probes, General

The warranty period for this category of consumables depends on the type as outlined below.

Each electrode and probe are marked with either a two-letter or a two-digit code indicating the time of production. Please refer to paragraph 8 for an interpretation of the production codes.

For electrodes covered by an 18-month warranty from the date of production, please refer to paragraph 9 for a conversion of production code to expiry of warranty.

## 1.7 Electrodes and Probes, Detailed (ABL8XX and TCM4XX)

***Glass Electrodes (pH, $pCO_2$, tc-$pCO_2$, and tc-$pO_2$/$pCO_2$ )***

These electrodes are covered by an 18-month warranty from the date of production.

RADIOMETER ensures that there will be a minimum of 13 months warranty period remaining when shipped.

***Reference, $pO_2$, tc-$pO_2$, and Metabolite Electrodes***

These electrodes are covered by an 18-month warranty from the date of production.

RADIOMETER ensures that there will be a minimum of 10 months warranty period remaining when shipped.

***Ion-Selective Electrodes***

These are covered by an 18-month warranty from our invoice date.

RADIOMETER ensures that these electrodes are shipped within four years following production.

***RBSL TC sensors***

These TC sensors are coved by a warranty of 15 months from the time of production in RBSL.

## 1.8 Other Consumables and Accessories

Consumables and accessories, which have a limited durability, are covered by a warranty period ranging from 1 to 48 months following production depending on the type of accessory. The warranty period is equal to the expiration date printed on the product (the expiration date is the last day of the month printed).

In general, we ensure that at least half of the warranty period is left when the product is shipped. There are, however, a few exceptions:

| Product | Minimum warranty remaining at shipment |
|---|---|
| PICO 70 | 13 months |
| Few Calibration and Test Cartridges for AQT | Varies with type of cartridge |

Consumables and accessories are marked with a two-letter code indicating the time of production. Please refer to paragraph 8 for an interpretation of the production codes.

## 1.9 Point of Care data management products

All Point of Care data management products are covered by 12 months warranty, from invoice date. The warranty cover that the products will function substantially in accordance with the functions and features described in the documentation delivered with the product.

## 1.10 How to Claim Warranty Credit

Please follow the instructions outlined in “Procedures for Claiming Credit and Returning Parts” (section 3).

In general, a credit claim can only be acknowledged when the claim is accompanied by sufficient information enabling RADIOMETER to evaluate the claim as stated in the above instructions.

# 2 Service Policy

## 2.1 Introduction

This section outlines the policies and procedures, which must be followed by Subsidiaries and Distributers when servicing RADIOMETER products.

Exceptions from the service policy are not allowed, unless special permissions or instructions have been given in writing beforehand, by RADIOMETER.

## 2.2 RADIOMETER Responsibilities

It is the responsibility of Radiometer to:

- Maintain the Warranty and Service Policy document, which details the policies, procedures and requirements that apply to subsidiaries/distributors.
  The Warranty & Service Policy document is distributed as follows:
    - Attachment to Distributor Agreement
    - Emailed to subsidiaries/distributors (General Manager and Service Manager) upon release of a new version. Subsidiaries/distributors to sign-off on receipt and local distribution/training.
    - Posted on the official RADIOMETER site
- Create and maintain Service documentation and IT specialist guides, which details procedures for installation, check, maintenance, troubleshooting, repair, and verification of products. Subsidiaries/distributors to sign-off on receipt and local distribution of new versions of service documentation.
- Create and maintain training material for training field service engineers and IT specialists. The training material is based on the service documentation and IT specialist guides
- Provide training courses for field service engineers and IT specialists at RADIOMETER and at subsidiary/distributor. RADIOMETER keeps a record of participants, and the participants receive a certificate to document their participation
- Create and maintain a certification program for both new hire and existing employees, evaluating skills and knowledge to repair and maintain Radiometer Solutions.
  Record and document the certified engineers.
- Provide 2nd level support for subsidiaries/distributors
  The service requests are evaluated to ensure that those that meet the definition of a complaint or represents an event of potential health hazard or adverse event are reported as a Quality Complaint and handled accordingly

## 2.3 Subsidiaries and Distributors Responsibilities

It is the responsibility of the Subsidiary and Distributer to:

- Establish policies, procedures, and metrics to ensure compliance with requirements given by RADIOMETER and local requirements
- Ensure that all staff are fully aware of their obligations and reporting requirements
- Ensure confidentiality of personal data (any information that might lead to identification of a person, e.g. name, date of birth, ID number) while installing and servicing device products and under no circumstances share any such data with RADIOMETER unless it has been fully anonymized prior to the transfer
- Ensure all staff are aware of the health risks related to exposure to biological agents and are trained in the applicable safety controls
- Ensure that Field Service Engineers use the most recent versions of the service documentation made available through the official RADIOMETER channels. Further, the subsidiaries/distributors must be able to document that this is the case.
- Install RADIOMETER products (including IT systems) at customer sites, and to service and maintain these products
- Ensure that the products are installed and configured in compliance with specifications
- Plan and conduct service visits
- For CRM users: File either a CASE Type “Pre-Installation” or “Installation” in CRM and attach the electronic file containing the test and inspection data.
  For non-CRM users: No action.
- Establish and maintain installation and service records of all device products (both instruments and IT products), which must include:
    - Name of the product installed or serviced
    - Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used
    - The date of installation or service
    - The individual(s) installing or servicing the product
    - Details of the work performed
    - The current software version
    - If changes made do not impact patient results QC is not required. It is mandatory to describe the rationale.
    - The test and inspection data
        - The data must be stored as electronic file (picture of the QC printouts, or the Data Log, or AQURE QC (Revision 1.1, or above) documentation)

    - Data must be readily available, and RADIOMETER must be able to access independently
- Train customers in basic troubleshooting
- Review any customer contact and service record and ensure that those that:
    - Fall under the definition of a complaint (see separate paragraph),
    - Represent an event of potential health hazard or adverse event (see separate paragraph), and
    - Represent unresolvable issues

  are escalated through the proper systems to RADIOMETER.

## 2.4 Repair Level

The repair level outlines the extent to which it is allowed to dismantle a product in the process of troubleshooting and repairing. This level is limited for several reasons such as: the need for specialized test equipment, special environmental requirements etc., and is optimized in relation to cost of parts, time of repair etc.

The repair level for each specific product is indicated in the respective service manuals in the "General Information", “Dismantling and Replacements”, and "Spare Parts List" sections.

## 2.5 Classification of items

### 2.5.1 Definition of an accessory

An item that is added to an instrument. For example: the printer for the ABL9, the mixer for the ABL80, USB connected barcode readers, third party printers etc.

### 2.5.2 Definition of a consumable

Any item that is consumed. Electrodes, assays, sensors & solutions (liquids). For example: ABL9, ABL80 & ABL90 sensor cassettes and solution packs, QC, tHb cal solution, protein remover, ABL7/8xx: electrodes and solutions, QC, tHb cal solution, protein remover, AQT90 assays, solutions, LQC, Cleaning solution TCM sensors, membrane kits

### 2.5.3 Definition of a spare part

Any part that can be changed on an instrument. Some parts must only be changed by a RADIOMETER certified Service engineer (requires tools and equipment or special procedures - these parts are listed in Service manual). Some parts can be ordered by the customer (such as pump tubes, inlet gasket/probes)

## 2.6 Non-original Parts

*Spare Parts, consumables and Accessories in General*

In order to ensure the reliability and durability and operation in accordance with technical specifications of our products, we have set up instructions which state that only original RADIOMETER parts, or parts approved by RADIOMETER must be used.

The policy, which is stated in appendix "Policy For Use of Non-Original Parts”, concerns both spare parts, consumables and accessories.

*Refilling of Gas Cylinders*

For safety reasons RADIOMETER subsidiaries/distributors must either

- Return empty cylinders to RADIOMETER for refilling, or
- Have a local manufacturer who has an authorization for refilling the cylinders supplied by RADIOMETER carry out the refilling. The manufacturer must have the equipment necessary to ensure that the refilling is carried out according to our specifications.

Customers who do not purchase gasses through the RADIOMETER subsidiary/distributor must be urged to do so explaining the dangers of unauthorized refilling.

## 2.7 Availability of Spare Parts and Accessories

It is in general our policy to stock accessories and spare parts for discontinued products for at least five years from the announcement of the discontinuation (Support Period).

For spare parts this is, however, limited to items which are subject to wear and tear during normal operation of the analyzer.

***The following types of spare parts will normally not be stocked:***

- Items such as internal frames, panels, and brackets and cosmetic items such as outer panels, etc.

The appendix “Support Status" gives an overview of the stocking situation for spare parts for the various analyzers. These lists will be updated on a regular basis.

***Limitation***
The technologies used in our products develop very fast. New types of components are introduced and earlier are discontinued (often without

notice).
This is a potential threat and may reduce the support period for some components or assemblies.

## 2.8 Analyzer Repair (at RADIOMETER)

The general policy is that the subsidiary/distributor must repair analyzers locally.

All technical cases concerning problems to which the subsidiary/distributor requires assistance from RADIOMETER, e.g. analyzer repairs, must be reported as a Quality Complaint Type 1 (see Section 4).

The Quality Complaint Type 1 documents the nature of the problem, the actions taken to solve the problem, as well as the observations and results obtained by the local service engineer during the attempt to repair. On occasion, an unusual experience may occur that cannot be expediently resolved in the field. On these rare occasions, return of the analyzer to RADIOMETER for failure investigation and repair may be requested.

A clear agreement must be met and signed between the sales subsidiary or distributor and RADIOMETER prior to returning an analyzer for investigation and repair. The decision to return an analyzer to RADIOMETER for investigation is made by RADIOMETER (responsible for the investigation).

If the product is under warranty, the repair will be carried out at no charge. Otherwise, the subsidiary/distributor will be invoiced for the labour and parts according to the current price list.

RBSL repairs a limited number of in and out of warranty products; refer to section 3.22 for list of items eligible for repair.

The TCM5 has only limited repairs that can be done in the field. In the case of factory repairs, please refer to the TCM5 repair process.

## 2.9 Types of Spare Parts

***Ordinary Spare Parts (components)***

This category contains primarily components or smaller assemblies, which cannot be repaired and re-used, or it is not economically advantageous to do so.

Defective parts of this category are eventually discarded.

***Trade-in Spare Parts (modules) RMED:***

Trade-in parts can be repaired at the factory. This category mainly consists of larger printed circuit boards but also includes some mechanical and optical assemblies such as gas mixers and spectrometers.

The Trade-in Arrangement involves a trade-in discount resulting in an exchange price of 33.33% of the full net price as follows:

- When purchasing a replacement part, we invoice the full net price, 100%.
- When receiving the defective part, we issue a credit note equal to 66.67% of the full net price (100% if in warranty).

An important prerequisite for the Trade-in Arrangement is that for each defective part returned to RMED for repair and resale a similar part (with the same part number) is purchased.

*All RADIOMETER Products*

We do NOT issue trade-in credit for parts, which are originating from analyzers, which have been traded in and/or scrapped.

***All RADIOMETER Analyzers and Upgrade Modules***

These items are not included in the Trade-in Arrangement and cannot be returned for credit in case of defects. They must be repaired locally using the spare parts available for servicing.

***Other RADIOMETER Parts***

There is a small group of parts, which do not fit into any of the above categories. For these parts we offer a trade-in like discount as follows:

- Repairable parts, primarily very large and expensive assemblies, for which the exchange price is determined on basis of the cost of repair.
- Not repairable parts, primarily small and inexpensive assemblies for which the commercial value is very high, but the cost is very low.

For these parts we invoice 100% at the purchase, and issue a credit note equal to the full price less an exchange price.

## 2.10 Electrostatic Discharge Protection

In order to ensure the reliability and durability of our analyzers, we have set-up procedures for protecting the ESD sensitive parts (section 15). Parts such as printed circuit boards and integrated components may be damaged if handled incorrectly during storage and service. The damage is not visible, and the damaged parts may not fail immediately but several months later. “Electrostatic Discharge (ESD) Protection” describes in detail the procedures, which must be followed in connection with the servicing of analyzers and the handling of ESD sensitive parts.

## 2.11 USB flash drive usage - recommended practice

Radiometer recommends that every USB flash drive is scanned for malicious software, prior to connecting the USB flash drive to the analyzer. Radiometer further recommends that every USB flash drive is scanned after removal from the analyzer.

Radiometer recommends that the instructions in section 12 are followed in all situations.

# 3 Procedures for Claiming Credit and Returning Parts

## 3.1 Introduction

This chapter describes the procedures for claiming credit and for what is to be done with the parts for which credit has been claimed. The actual procedure is in section 3.23-3.30 whereas various definitions and requirements are stated below.

## 3.2 Product support structure

| Product | Supported by |
|---|---|
| AQT90 FLEX | RMED |
| ABL80 (all models) | RCAL |
| ABL800 (all models) | RMED |
| ABL9 | RCAL |
| ABL90 (all models) | RMED |
| Periflux 6000 | RMED (Perimed) |
| TCM4 series | RMED |
| TCM5 series | RMED (Plexus) |

## 3.3 Procedure for RMED products

All claims for credit must be forwarded to RMED using Form 2015, “Credit Claim Note” (CCN). The CCN form is implemented as a template in EXCEL and is to be filled in and E-mailed to the subsidairies/distributors contact person in RADIOMETER Shipping by the person authorized by the subsidairies/distributors management.

Some fields in the form are automatically filled in upon entry of “Part #”, that is “Description”, “Category”, “Trade-In”, and “SPE”.

Some fields change color upon entry of “Part #” and “Reason for Credit”, that is “Lot/Serial #”, “Exchange Date”, Analyzer Serial #”, “Invoice Date”, “Installation Date”, “Quality Complaint Type 1/FA #”, “Trade-In”, and “SPE”. The following colors may appear:

| Color | Interpretation |
|---|---|
| Green | Mandatory input field. |
| White | Voluntary input field. |
| Black | Not possible to enter data. |

### *Time Limits for Credit Claims for RMED Products*

Credit will be granted only if the following time limits are fulfilled:

- The credit claim note (CCN) must be received at RADIOMETER within **ONE MONTH** after the repair has been performed.
- Parts, which according to standard procedures are to be returned to RADIOMETER (see “Parts Flow” and subsequent paragraphs below), must be shipped to RADIOMETER within **ONE MONTH** after the repair.
- Consumables, accessories and service parts required for return to RADIOMETER must be received, or a valid proof of shipment provided within one month following the report of this failure to RADIOMETER. Valid proofs of shipment include a tracking number or air waybill number.
- If, after one month, RADIOMETER has not received the product or been provided proof of shipment, the complaint file will be closed and no credit will be issued.

See also “Returning parts, important” and “Priority Parts” below.

### *Required Documentation for RMED Products*

Credit can only be issued for parts listed on a Credit Claim Note (CCN) including the required information.

In addition, a Service Report or Service Work Order stating the following information must accompany each defective item, which is returned to RADIOMETER:

- Reported symptom
- Service engineer’s observations
- Troubleshooting and corrective actions.

For Sensor Cassettes (SC) and Solution Packs (SP):

- Quality Complaint Type 2
- Failure event documentation

### *Exception for Radiometer subsidiaries*

RMED will not issue a credit note on the following item types:

- Sensor Cassette and Solution Packs related to Quality Complaints Type 2.

These items are reimbursed based on the QT2 complaint reporting.

## 3.4 Procedure for RCAL Products

The following steps describe the actions to perform when requesting warranty credit to RCAL. **Please note that RCAL does not use a CCN form.** Credit requests are made using one of the following forms:

- SNDX PER (Product Experience Report) for
  - any consumable not associated with a Quality Complaint Type 1
  - any consumable or spare part associated with a logistics complaint due to damage during shipment.
- SNDX Credit Request Form for
  - any spare part associated with a service work order
  - any consumable or spare part associated with a Quality Complaint Type 1

You may request a SNDX Credit Request Form by sending an email to warrantycredit@sendx.com.

### *Exception for Radiometer subsidiaries*

RMED will not issue a credit note on the following item types:

- Sensor Cassette and Solution Packs related to Quality Complaints Type 2.

These items are reimbursed based on the QT2 complaint reporting.

When submitting a credit request to RCAL, the requestor shall:

- Itemize these requests in the appropriate form (SNDX PER or SNDX Credit Request Form)
- Collect any additional required documentation per section 3.6.
- Send any SNDX PER and documentation to warrantycredit@sendx.com for crediting.
- Send any SNDX Credit Request form to warrantycredit@sendx.com for crediting.

When receiving a credit request, RCAL shall:

- Identify if the request is from a Radiometer entity and is related to a Quality Complaint Type 2 for Sensor Cassettes or Solution Packs. If this is the case, NO credit note will be issued for these Sensor Cassettes or Solution Packs for Type 2 Complaints.
- Assign a Credit ID to the received SNDX PER or SNDX Credit Request Form. In some cases, a single Credit ID may be assigned to a group of PER's that have been received from the same requestor.
- Email the Credit ID to the requestor. The Credit ID can be used to trace the eventually received credit to the original credit request.
- Provide warranty credit for sensor cassettes based on the number of tests remaining on the sensor cassette at the time of failure.
- Provide warranty credit for solution packs based on the full transfer price.
- Provide warranty credit for spare parts based on the full transfer price provided the failure occurred within the defined warranty period (see section 1.4).

### *Overview of forms to use for crediting of RCAL products*

| Product Type | Case Type | SNDX PER | SNDX Credit Request Form |
|---|---|---|---|
| Sensor Cassette or Solution Pack | Non-Quality Complaint Type 1 | X | |
| | Logistics | X | |
| | Quality Complaint Type 1 | | X |
| Spare Parts | Non-Quality Complaint Type 1 | | X |
| | Logistics | X | |
| | Quality Complaint Type 1 | | X |

### *Required information for crediting of RCAL products*

Note: This required information is for crediting purposes only. Refer to Section 4.0 Complaint Handling for specific information required for complaint handling purposes.

When using the **SNDX PER**, the required information: (Send to warrantycredit@sendx.com)

Sensor Cassette and Solution Pack failures not associated with a Quality Complaint Type 1 (to be itemized in the **SNDX PER**)

- Part Number
- Lot Number
- Tests Remaining (sensor cassettes only)
- RMED Invoice Number (original invoicing number)
- Site (original location from which the item was shipped)

Logistics Reports for damage during shipment (to be itemized in the Logistics Report tab of the **SNDX PER**):

- Quantity
- Part Number
- Lot Number (sensor cassette and solution pack only)

- Serial Number (spare parts only)
- RMED Invoice# (original invoicing number when applicable)
- Site (original location from which the item was shipped when applicable)
- RCAL Shipment#
- Distribution Site

When using the **SNDX Credit Request Form**, the required information is: (Send to warrantycredit@sendx.com)

Spare Parts associated with a Quality Complaint Type 1 or service work order (to be itemized under Spare Parts tab)

- Part Number
- Part Description
- Spare Part Original Install Date
- Spare Part Replacement Date
- Spare Part Serial Number
- Analyzer Serial Number from which the part was removed (when applicable)
- Analyzer type
- RMED Invoice# (original invoicing number)
- Site (original location from which the item was shipped)
- CRM SWO Number (when applicable)
- Quality Complaint Type 1 reference (when the spare part is associated with a Quality Complaint Type 1)

Sensor Cassettes and Solution Packs associated with a Quality Complaint Type 1 (to be itemized under Sensor Cassette_Solution Pack tab)

- Part Number
- Lot Number (sensor cassette and solution pack only)
- Tests Remaining (sensor cassette only)
- RMED Invoice Number (original invoicing number)
- Site (original location from which the item was shipped)
- Quality Complaint Type 1 reference

### *Time Limits for credit claims for RCAL products*

Credit will be issued only if the SNDX PER or SNDX Credit Request Form are received at RCAL within the following time limits:

- Sensor cassettes and solution packs: no later than 60 days after the failure occurred
- Spare parts: no later than 30 days after the spare part was replaced

## 3.5 Call-back Stock

The call-back stock is a stock area at your end for stocking defective parts replaced under warranty, but which are not to be returned to RADIOMETER according to the rules stated in these procedures.
These parts are to be stocked for two months after claiming credit.

RADIOMETER is required by the authorities to perform a failure investigation in case e.g., the failure rate for a particular part shows a significant upward trend. The call-back stock ensures that the parts are readily available for such an investigation.

RADIOMETER Shipping will keep track of the contents of your call-back stock and will let you know:

- If parts are to be returned for failure investigation during the two months storage period.
- When and which parts may be discarded after the two month period

## 3.6 Returning Parts, Important

The following general requirement apply for returning parts:

- Parts exposed to human blood must not be returned to RADIOMETER unless we have specifically requested them back for investigation. The packaging for such parts must be marked as hazardous material according to local regulations.
- Parts and instruments that have been exposed to dangerous biological agents other than blood, must not be returned to Radiometer and will not be requested for return for investigation.
- All parts returned to RMED or RMED PL must ALWAYS be sent be ATT: RMED Shipping – even if they are addressed to specific individuals or departments in RMED.
- All parts returned to RADIOMETER must be packed in its original packaging or packaging, which provides similar protection to prevent shipping damages.
- All parts returned to RADIOMETER must be shipped to the location from where they were originally invoiced (RMED/RMED PL). Shipping must approve any deviation to this.

## 3.7 Priority Parts

The parts listed below are categorized as priority parts:

- Parts requested back in a Quality Complaint Type 1
- Parts requested back from the call-back stock

These parts must ALWAYS be returned to RADIOMETER as soon as possible and latest within **ONE WEEK** after the receipt of the return request – disregarding the “Time limits for warranty credit claims” stated above.

Further, to speed up the handling at our end both the outer shipping boxes containing such parts and the inner packaging MUST be marked with a label stating:

“PRIORITY RETURN”

Furthermore, the papers must be marked with the:

- Quality Complaint Type 1 reference if applicable
- Name of recipient at RADIOMETER

## 3.8 Subsidiary/Distributor Input area

The information to be filled in on the CCN in the subsidairy/distributor input area, "Distributor", “Select type of Credit Claim”, and Distributor Input”, is required for evaluating whether a credit claim is valid or not.

Missing information will result in the credit claim to be rejected.

### 3.8.1 Subsidiary/Distributor

The identification information includes:

| Input Field | Description | Include When |
|---|---|---|
| Subsidiary/Distributor | Name of subsidiary/distributor | Always |
| Credit Claim Note # | Subsidiary’s/Distributor’s internal reference number | Always |
| Created Date/Initials | Created Date and initials for person creating the CCN | Always |

### 3.8.2 Select Type of Credit Claim

Eight different types of credit claims are defined as listed in the table below. The type of CC divides the parts for which credit is claimed into eight groups.

**IMPORTANT:** Each CCN may only contain parts from one of these groups.

| Type of CC | Parts Flow |
|---|---|
| Return to RADIOMETER | Goods to be returned to RADIOMETER. |
| Call-back stock | Goods to be put on Call-back stock. |
| Buy Back | Goods that RADIOMETER has agreed beforehand to buy back e.g., excess stock. |
| Return keys | Specific for claiming credit for Option keys.<br>Credit will not be issued for the Basic key, but it must be returned to obtain credit for Option keys. |
| Quality Complaints Type 1 – Return to RADIOMETER ***)** | Goods, relating to a Quality Complaint Type 1, that RADIOMETER has requested to be returned for investigation. |
| Quality Complaints Type 1 – Call-back stock ***)** | Goods, relating to a Quality Complaint Type 1, that RADIOMETER has not requested to be returned for investigation. |
| FAN – Return to RADIOMETER ***)** | Goods, relating to a FAN, that RADIOMETER has requested to be returned. |
| FAN – Call-back stock/Discarded ***)** | Goods, relating to a FAN, that RADIOMETER has requested to be put on Call-back stock or to be discarded. |

*) These types are to be selected **ONLY** in case the parts flow or the credit differs from the standard policy (e.g., when parts, which are normally to be put on call-back stock, are requested back for investigation).

### 3.8.3 Reason for Credit

The reason for claiming credit for each individual part must be stated on the CCN. The following reasons for claiming credit apply:

| Reason for credit | Use when |
|---|---|
| WAR | The defective part is in warranty |
| DOW | The defective part is out of warranty, but included in the Trade-in Arrangement |
| SPE | The part is included in the lists of "Special Parts" below. The parts are identified automatically when entering the part #.<br>These parts may be in or out of warranty. |
| 2ND | The part exchanged was installed less than 12 months ago in an analyzer, which is now out of warranty. |
| DEP | The part is a deposit item, e.g., refillable gas bottles.<br>The parts are identified automatically when entering the part #. |
| STOCK | The part was defective from stock |
| BUY | RADIOMETER has agreed beforehand to buy back parts, e.g., excess stock |
| OOW | Used only for out of warranty parts returned for investigation as per request in a Quality Complaint Type 1. |

### 3.8.4 Basic Information

The basic information required for each individual item is stated in the following table:

| Input Field | Description | Include When |
|---|---|---|
| Reason for credit | States the reason for claiming credit for the part as per above | Always |
| Part # | Part number of claimed item | Always |
| Description | Description of claimed item | Appears automatically |
| Category | Categorizes the part in terms of e.g., spare part or accessory and in terms of tracing method. | Appears automatically |
| QTY | Quantity of identical items | Always |
| Lot/Serial Number | Lot, serial number, or expiry code of item | The field is green |
| Exchange date | Exchange date for defective item | The field is green.<br>Required if analyzer is in warranty and for 2nd repairs. |
| Analyzer Serial # | Serial number of analyzer | The field is green.<br>Required if analyzer is in warranty. |
| Invoice Date | Date the analyzer was invoiced to subsidiary/distributor | The field is green.<br>Required if analyzer is in warranty. |
| Installation Date | Installation date for the now defective item | The field is green.<br>Required for 2nd (3rd etc.) repair where an installed item breaks down within the 12 months warranty period |
| Site | The distribution center from which you received the item (DK/PL) | Always |
| RMED Invoice # | States the original invoice number from RADIOMETER | Always – see 3.11.4.1 |
| Quality Complaint Type 1 / FA # | State the Quality Complaint Type 1 reference or FA number | The field is green. |
| Trade-In | Indicates if the part is included in the Trade-In Arrangement | Appears automatically |
| SPE | Indicates if the part is listed as a Special Part | Appears automatically |
| Remarks | Free text field | Voluntary input field, which may be used both by the subsidiary/distributor and RADIOMETER Shipping |

#### 3.8.4.1 Statement of original invoice

Due to legal requirements RADIOMETER cannot provide a credit note without reference to the original invoice number.

For parts trade-in parts with no original invoice number, you must provide the original invoice number for the instrument from which the trade-in part is taken.

## 3.8.5 RADIOMETER Input Area

The information to be filled in on the CCN in the RADIOMETER input area, "RADIOMETER" and “RADIOMETER Evaluation”, is explained below.

## 3.8.6 RADIOMETER

The RADIOMETER reference information includes:

| Input Field | Description | Include When |
|---|---|---|
| RADIOMETER Reference # | RADIOMETERs internal reference number | Always |
| Evaluation Date/Initials | Date of evaluation and initials of person performing the evaluation<br>(for Call-back and Discard CCNs this indicates completion of CCN) | Always |
| Completed Date | Date for completion of Return CCN<br>(Credit Note issued) | Always |

## 3.8.7 RADIOMETER Evaluation

The evaluation for credit for each individual part will be stated on the CCN. The following results apply (mostly identical to “Reason for credit” above:

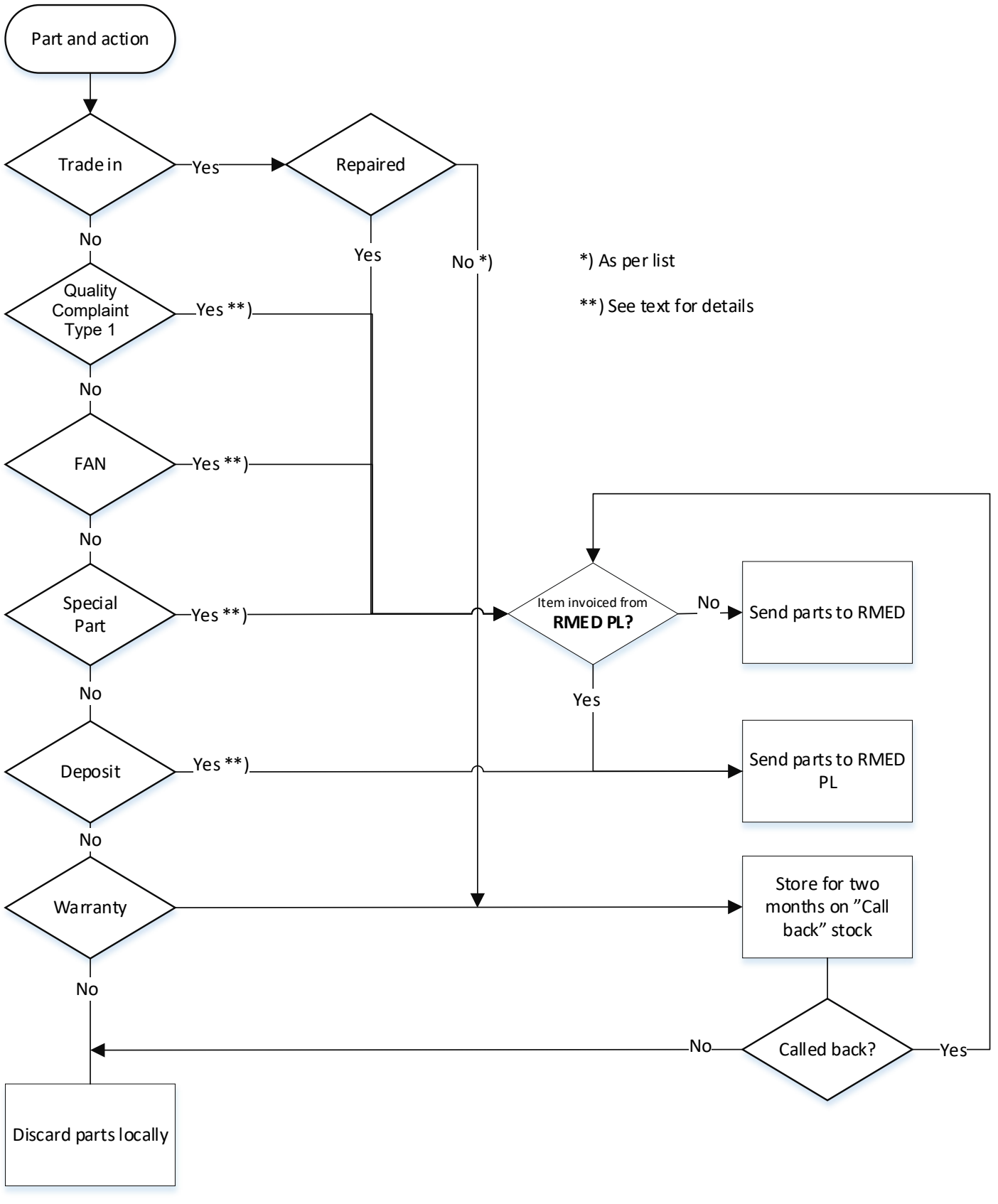
| Evaluation for credit | Used when |
|---|---|
| WAR | The defective part is in warranty |
| DOW | The defective part is out of warranty, but included in the Trade-in Arrangement |
| SPE | The part is included in the lists of “Special Parts” below. |
| 2ND | The part exchanged was installed less than 12 months ago in an analyzer, which is now out of warranty. |
| DEP | The part is a deposit item, e.g., refillable gas bottles. |
| STOCK | The part was defective from stock |
| BUY | RADIOMETER has agreed beforehand to buy back parts, e.g., excess stock |
| OOW | Based on the information available the part is judged to be out of warranty. |

## 3.8.8 Credit and No Credit

These columns are used for indicating the conclusion of the evaluation. For each part on the CCN either “Credit” or “No Credit” is checked.

## 3.9 Parts Flow

The parts flow, that is, which parts are to go where is detailed in the flow diagram below.



## 3.10 Return to RADIOMETER

The following parts must always be returned to RADIOMETER for one or the other reason (standard procedure):

| Parts | Explanation |
|---|---|
| Trade-In (still repaired) | Parts, which are included in the Trade-in Arrangement for Modules, primarily major PCBs and mechanical/optical modules, which are repaired at the factory and then re-sold. |
| Quality Complaint Type 1 | These parts (in or out of warranty) must be returned **IF** requested back to enable a failure investigation in connection with an open Quality Complaint Type 1.<br>Credit will only be issued for in warranty parts.<br><br>Parts, which are NOT requested back for investigation:<br>• Must be stored on the call-back stock (if in warranty)<br>• May be discarded locally (if out of warranty).<br>No credit is issued for these parts. |
| FA | In case the FA involves exchange of parts the FA will instruct you what to do with the parts (return, put on call-back stock, or discard).<br><br>In case the FA involves credit for parts, the CCN must reference the FA number, the part number, and lot or serial number. |
| Special parts | This category contains a few parts, which do not fall into any of the other categories. See details below. |
| Deposit | Empty gas cylinders, which are to be returned for refilling. See details below. |
| Buy back | This could be any type of goods. |

## 3.11 Put on Call-Back Stock

The following parts must always be put on the call-back stock:

| Parts | Explanation |
|---|---|
| Warranty | All parts, which are exchanged under warranty, and which do not fall into any of the above categories. |

## 3.12 Discard Locally

The following parts may be discarded locally:

- All parts, which do not fall into any of the above categories
- Parts on the call-back stock when the two months storage period has elapsed. RADIOMETER Shipping will inform you when which parts may be discarded.
- Parts, which under normal circumstances are to be returned or put on call-back stock, if RADIOMETER beforehand has requested or accepted the goods to be discarded.
- Waste containers, which have been installed and used on an analyzer and thus contain blood waste.

## 3.13 Special Parts, Credit

This category contains a few parts, which are eligible for credit even though they according to the general policy are not.

These parts are:

| Part No. | Description | RADIOMETER action |
|---|---|---|
| 902-564<br>902-778<br>903-044<br>903-111<br>903-722<br>903-723<br>903-724<br>903-725 | TCM4 Series Modules | When purchasing a replacement part, an out of warranty defective part will be credited 100% less an exchange fee |

If parts are in warranty, put “WAR” on the CCN for “Reason for claiming credit”. If out of warranty, put “SPE” on the CCN.

## 3.14 Special Parts, Return

This category contains a few parts, which must be returned to RADIOMETER even though they according to the general policy should not.

These parts are:

***Always return (in and out of warranty):***

| Part No. | Description | RADIOMETER action |
|---|---|---|
| 367-683 | Basic Key ABL800 | Full credit for option keys if re-ordered *) |

*) Ensure that the serial number of the analyzer in question is stated both on the replacement order for ordering new basic and option keys and on the CCN.
Ensure that the replacement order number is stated in Remarks on the CCN.
Note that credit for option keys on the CCN will only be issued if they are on the replacement order. Basic keys are not eligible for credit.

**In general**
If parts are in warranty, put “WAR” on the CCN for “Reason for claiming credit”. If out of warranty, put “SPE” on the CCN.

## 3.15 Deposit Parts, Return

Below listed deposit parts may **only** be returned to RMED (DK).

| Part number |
|---|
| 962-092 |
| 962-139 |
| 962-140 |
| 962-141 |
| 962-160 |
| 962-161 |

## 3.16 The Actual Workflow

The paragraphs below outline the whole workflow for credit claims, which involves the following steps:

| Step | Action | Type of Parts Flow | | |
|---|---|---|---|---|
| | | Return | Call-back | Discard |
| 1 | You fill in a CCN and mail it to us | ✓ | ✓ | ✓ |
| 2 | We add our reference number, evaluate the credit claim, and mail the CCN back to you | ✓ | ✓ | ✓ |
| 3 | We issue the credit note | N/A | ✓ | ✓ |
| 4 | You ship the parts to RADIOMETER | ✓ | N/A | N/A |
| 5 | We issue the credit note upon receipt of the parts | ✓ | N/A | N/A |

## 3.17 Credit claim requirements

### 3.17.1 To Claim Credit You Must

The following tables outline the whole workflow for claiming credit, handling of parts, and issuing credit notes.

**Important:** Be sure to comply with the time limits stated on the previous pages.

| Step | Action |
|---|---|
| **1.** | Collect e.g., last two weeks exchanged parts. |
| **2.** | Sort the exchanged parts into the eight groups as indicated in the “Type of Credit Claim” described above. |
| **3.** | For each of the groups of parts fill in one Credit Claim Note (CCN), Subsidiary/Distributor Input area only.<br>That is, fill in one CCN for the parts to be returned to RADIOMETER, fill in another CCN for the parts to be put on the Call-back stock, and so forth. |
| **4.** | E-mail the CCNs to your contact person at RADIOMETER Shipping.<br>Then wait for a reply from RADIOMETER (with ref. numbers for the CCNs). |

### 3.17.2 We Will (Upon Receipt of CCN)

Upon receipt of a Credit Claim Note we will:

| Step | Action |
|---|---|
| **1.** | Fill in the RADIOMETER part of the CCN, e.g. issue a reference number for each CCN. |
| **2.** | Perform the evaluation of the data entered on the CCNs and fill in the "RADIOMETER Evaluation" part.<br>The evaluation will take place within 72 hours after the receipt of the CCNs. |
| **3.** | Issue a credit note for each CCN for parts, which are not to be returned to RADIOMETER. |

### 3.17.3 You Must (Upon Receipt of evaluated CCN)

Upon receipt of an evaluated Credit Claim Note you must (Return Goods only):

| Step | Action |
|---|---|
| **1.** | Pack the parts to be sent to RADIOMETER together with a copy of the corresponding CCN. |
| **2.** | Take notice of the confirmed return address (RMED / RMED PL) |
| **3.** | Ship the parts. |

### 3.17.4 You Must (upon receipt of credit note)

For the goods to be put on call-back stock or to be discarded you must upon receipt of the credit notes:

| Step | Action |
|---|---|
| **1.** | Put the parts to be stored on the Call-back stock into a box together with a copy of the corresponding completed CCN (including the reference number received from RADIOMETER) and then store the box. |
| **2.** | Discard the parts to be discarded. |

### 3.17.5 We Will (upon receipt of parts)

Upon receipt of returned parts we will:

| Step | Action |
|---|---|
| **1.** | Verify that the returned goods match the information on the corresponding CCN. |
| **2.** | In case of a mismatch between the issued credit note and the received goods, our action depends on the nature of the mismatch as follows:<br>**Parts listed on the CCN and received:**<br>We will issue a credit note.<br>**Parts not listed on the CCN are found among the returned goods:**<br>We will ask you to submit a new CCN for the “excess” parts. |

## 3.18 Return Parts from Call-back Stock

From time to time we will request that parts on the Call-back stock are returned to us, e.g. to perform a failure investigation. In case parts are requested back:

***We will:***

| Step | Action |
|---|---|
| **1.** | Send an E-mail detailing which parts are requested back including references to the CCNs concerned. |

***You must:***

| Step | Action |
|---|---|
| **1.** | Pull the parts requested back to RADIOMETER from the Call-back stock. |
| **2.** | Include a copy of our return request indicating the name of the recipient at RADIOMETER with the parts. |
| **3.** | Pack the parts for shipment and stick a “PRIORITY RETURN” label both onto the inner packaging and the outer box. |
| | **The parts requested back must be shipped within one week from the receipt of the E-mail requesting the parts back.** |

***Upon receipt of the parts we will:***

| Step | Action |
|---|---|
| **1.** | Check the contents of the box against our records (Call-back stock) and our return request. |
| **2.** | If parts requested back are missing in the shipment (e.g. because they cannot be found on the Call-back stock, we will issue an invoice for the missing parts. |

## 3.19 Return Quality Complaints Type 1 Parts

From time to time we will request that parts referred to in a Quality Complaint Type 1 are returned to us to perform an investigation. In case parts are requested back:

***We will:***

| Step | Action |
|---|---|
| **1.** | Put a request for the return in the Quality Complaint Type 1. |

***You must:***

| Step | Action |
|---|---|
| **1.** | Include the Quality Complaint Type 1 ID with the parts and the name of the complaint handler |
| **2.** | Pack the parts for shipment and stick a “PRIORITY RETURN” label both onto the inner packaging and the outer box. |
| **3.** | Update the Quality Complaint Type 1 with information about shipping (e.g. track and trace number) |
| | **The parts requested back must be shipped within one week from the receipt of the request.** |

# 4 Complaint Handling

## 4.1 Introduction

This chapter describes the procedures for handling a complaint, how to assess whether a complaint involves a potential health hazard (potentially reportable event, e.g. discrepant results/measurement errors), and which data to collect. Radiometer subsidiaries, Sales Offices, and distributors are responsible for collecting the required documentation and reporting complaints to RADIOMETER.

The subsidiaries/distributors Quality System must include SOPs/Instructions to comply with the procedures given in this chapter.

Subsidiaries are responsible for ensuring all relevant employees (for example: Field Service Engineers and service employees) are trained in the "Complaint handling training" available on Coursemill.

RADIOMETER trends all Quality Complaint Types, and CAPAs are initiated when needed.

**Handling of Quality Complaints for Distributors without access to Radiometer CRM**

Distributors without access to Radiometer CRM are only excepted for the parts in this chapter that requires interaction with Radiometer CRM. All other parts must be obeyed.

All non-CRM-distributors must report Quality Complaints to RADIOMETER by sending an email to RMED Customer Complaints Department (CustomerComplaint@radiometer.dk). RMED Customer Complaints Department will then document the complaint in CRM as appropriate. RMED Customer Complaints Department (or other Radiometer designated unit) will communicate with distributor via email if more information is required to handle the complaint.

Specifically for reporting Quality Complaints Type 2 (QCT2s); To allow distributors to only submit QCT2s to one Radiometer department and to ensure smooth handling of credit claims, ISD distributors shall only report QCT2s to ISD via isd@radiometer.dk. ISD will then handle credit claims and ensure that QCT2s are forwarded to Customer Complaint Department for registration in CRM.

Up to 50 QCT2s may be reported in one email. Send an email (to isd@radiometer.dk) attached with:

- "QCT2 Submission" form completed with one row for each QCT2 (form can be found on Global Service Library - Warranty and service policies - All Documents)
- One analyzer printout or Credit Claim Form for each QCT2
- NB! For Radiometer to issue credit, all QCT2s should be reported to Radiometer within 30 days from complaint receival.

## 4.2 Complaint Definition

The general definition of a complaint is as follows:

- A complaint is defined as any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, usability, effectiveness, packaging or performance of a product after it is released for distribution.

Complaints can originate from several sources including but not limited to:

- Customer via phone, fax, mail, e-mail, or in person
- Service phone calls or on-site visits
- Scientific articles or conferences, clinical research
- Social media

All complaints must be documented upon receipt.

Information is collected and complaint is immediately* reported into the Complaint Management System. The reported information must include:

- Product name and identification** (e.g., software version, part no., item no., serial no., lot no., UDI)
- Date complaint received (date when any Radiometer subsidiary/Sales Office/Distributor first receives information that there is a complaint from a user)
- Awareness date for complaint evaluated as potential health hazard/PHH or potential reportable
- Complainant name, address, phone number
- Nature and details of the complaint (incident-specific information such as values and units of measured results, information about patient/user injury etc.)
- Description of any actions taken to solve the customer's problem

*) No later than **12 hours** for Potential Health Hazards/Potential Reportable Events (e.g., discrepant results/measurement errors) and no later than **24 hours** for other Quality Complaints Type 1

**) A unique identification shall be reported if possible. If not, other identification must be given in order to be able to look up UDI.

**Quality Complaint Types**

Quality Complaint Type 1:

All Quality Complaints which require additional investigation by RMED/RCAL/RBSL/RSUZ. Any complaint that represents an Adverse Event constitutes a subset of the Quality Complaint Type 1 and is clearly identified.

Quality Complaint Type 2:

Quality Complaint concerning known problems related to specific consumables resolved with no additional investigation required.

This comprises complaints on Sensor Cassettes and Solution Packs for ABL9, ABL80, and ABL90 which are resolved by replacement.

Escalate to a Quality Complaint Type 1 if any Potential Health Hazard/Potential Reportable Event is suspected (see section 4.3).

Quality Complaints Type 2 must be completed in CRM within 60 days of receival from customer. If a complaint exceeds the timeframe, the reason must be documented via a justification in the related Case record in CRM. Complaints containing a justification for exceeded timeframe must be re-assessed at least every 30 days and a new justification must be added to the related Case record.

Quality Complaint Type 3:

Quality Complaint which is resolved by a Field Service Engineer/RSUB with no additional investigation required.

Escalate to a Quality Complaint Type 1 if any Potential Health Hazard/Potential Reportable Event is suspected (see section 4.3).

Classify complaint as Quality Complaint Type 2 if Field Service Engineer/RSUB replaced Sensor Cassette/Solution Pack that meets definition of a Quality Complaint Type 2.

Quality Complaints Type 3 must be completed in CRM within 90 days of receival from customer. If a complaint exceeds the timeframe, the reason must be documented via a justification in the complaint record in CRM. Complaints containing a justification for exceeded timeframe must be re-assessed at least every 30 days and a new justification must be added to the Quality Complaint Type 3 record.

Logistics Quality Complaint:

Issue reported by customer related to distribution, transportation, warehousing, or order processes which are discovered prior to installation of equipment or unpacking of consumables. These shall be reported to shipping at RADIOMETER.

Escalate to a Quality Complaint Type 1 if any Potential Health Hazard/Potential Reportable Event is suspected (see section 4.3).

**Quality Complaint timelines:**

| **Type** | **Timeline** |
|---|---|
| **QCT1** | From Case **Received On** to **Created on** (escalation):<br>• Potential Reportable Events/Health Hazards: maximum **12 hours**<br>**NB! For PHH complaint provide Awareness date**<br>If awareness date is later than received date, it is required to provide justification, to understand the difference between received date and awareness date.<br>• All other QCT1: maximum **24 hours** |
| **ALL** | From **Received On** to **Closed Date**:<br>• QCT1-PHH: maximum **60 calendar days**<br>• QCT1-Non-PHH: maximum **90 calendar days**<br>• QCT2: maximum **60 calendar days**<br>• QCT3: maximum **90 calendar days**<br>If exceeded, justification must be documented, and the complaint must be re-assessed every 30 calendar days and update the justification accordingly |

Examples of Quality Complaints include but are not limited to:

- Devices performing outside specifications
- Analyzers/monitors presenting false high or low parameters
- Patients affected or injured, e.g., TC electrode burn, needle stick, blood spray
- Usage errors, e.g., problems using the Needle Shield Device

Examples that are not complaints (e.g., service support):

- Inquiries that are linked to user manuals
- Advice/help how set-up analyzers, use certain features etc.
- Help on maintenance issues etc.

## 4.3 Potential Health Hazard (PHH) / Reportable Event, Identification

Address the questions in the table to determine if the complaint is a reportable event or potential health hazard (PHH).

| **Question** | **Instruction** |
|---|---|
| Was the product even remotely connected with a reported death? | Select YES, if any factual information indicates that death has occurred in connection with an event that involves a Radiometer product.<br>If not, select NO. |

| Question | Instruction |
|---|---|
| Was the product even remotely connected with a reported injury? | Select YES, if any factual information indicates that any persons have suffered injury (regardless how serious) in connection with an event that involves a Radiometer product.<br>If not, select NO. |
| Did the hospital need to make an intervention to avoid death or injury? | Select YES, if any factual information indicates that an unusual intervention had to be performed to avoid maltreatment of a patient in connection with an event that involves a Radiometer product.<br>If not, select NO. |
| Did any person need additional hospitalization? | Select YES, if any factual information indicates that a person has been admitted to hospital or incurred prolonged hospitalization in connection with an event that involves a Radiometer product.<br>If not, select NO. |
| Caused by use error or malfunction and reoccurrence in similar products is likely to cause harm? | Select YES, if any factual information indicates that if the use error or malfunction happens again, it can potentially be a health hazard?<br>If not, select NO.<br>Examples of complaints that should have a “YES” includes (but is not limited to):<br>- Incorrect measurement, discrepant results.<br>- Sample lost<br>- Delayed treatment<br>- Rusty needle on sampler<br>- Compromised sterile barrier<br>- Dust or particles inside the sterile barrier<br>- Missing heparin brick<br><br>Software related<br>- Sample mix-up<br>- Patient mix up<br>- Rounding issues<br>- Unit issues<br>- Crashed<br>- Irresponsive/freezing analyzer<br><br>If not, select NO. |

## 4.4 Adverse Event

An adverse event is an event associated with a medical device or in-vitro diagnostic medical device that has led to death, serious injury or indirect harm of a patient, user or other person or a malfunction which upon recurrence (if the error/malfunction occurred again) on the device or a similar device would be likely to cause or contribute to a death or serious injury. With recurrence (near incidents) means similar incidents where the patient/user outcome might be different e.g. resulting in injury or death. This includes e.g., measuring errors where no impact on patient management was reported. It is therefore important that all information that has or could have impacted patient/user safety are reported as Quality Complaint Type 1 with a “yes” in PHH assessment.

Such events must be reported to RADIOMETER ***IMMEDIATELY*** (without any delay that could not be justified) but **no later than 12 hours after awareness** by the subsidiary/distributor of the event. Awareness date is the earliest date when an organization (any associate of RADIOMETER or a Radiometer manufacturing site or subsidiary including, e.g., field service engineers) receive information that reasonably suggests* that the event is potential health hazard (PHH) and or potentially reportable (e.g. on site, by phone or e-mail)

*) Information that reasonably suggests means any information, including professional, scientific, or medical facts, observations, or opinions that would cause organization to come to a reasonable conclusion that a device has caused or may have caused or contributed directly or indirectly to harm or injury for the patient/user of the device.

If preliminary information suggests there is a potential health hazard, the awareness date will be the same as the received date. If Radiometer initially determines that an event does not represent a PHH and then later obtains new information that impacts or changes the previous determination, then reassessment of PHH evaluation is performed. In this situation, where awareness date is later than received date, it is required to provide justification, to understand the difference between received date and awareness date.

It is stressed that reporting of adverse events/PHH cases **MUST**:

- Accurately describe the relevant **FACTS** and **DATA**
- Add specific data related to the complaint (e.g., result value and unit, number of patients, comparison results).
- Include a copy of any written message from the customer
- Refrain from any speculations/guesses related to the cause of the event reported.
- Refrain from any speculations/guesses about potential effects of the event.

## 4.5 Reportable Event, Investigation

If determined that the complaint is a potentially reportable event (health hazard), then it is important to collect as many details of the incident as possible. Use ***Vigilance Investigation Form*** **(Guide-00197)** and ***AQT Data Collection Guide*** to supplement the following:

- Did the product fail to meet its specifications? Answer for each type.
    - Failure (breakage, wear out, etc.)
    - Manufacturing (assembly, testing, label mix-up, dimensions, etc.)
    - Malfunction (unexpected behaviour)
    - Improper or inadequate design (hardware issues)
    - Improper or inadequate design (software issues)
    - Labelling (inaccurate, incomplete, or misleading information)
    - Packaging (incorrect content, damage etc.)
    - Use error (including misuse, lack of training, etc.):
    - Was the device used for other purposes than those specified in the ‘intended use’ for the device?
    - Did the user follow the instructions for use in manuals or inserts?
    - Was the user aware of relevant warning/caution notices in the instructions for use?
    - Had the user received proper training for the device?
- Incident date (event date) – date when the event/malfunction/error occurred
- Clinical information is required in order to report it correctly to the relevant authorities.
    - Was the device used for treatment or diagnosis during incident?
    - Is there a relation between the event and the product?
    - Did the hospital need to make an intervention in order to avoid maltreatment, injury or death?
    - Did any person need additional treatment or prolonged hospitalization because of the event?
    - Please inform the patient’s age, weight, sex, symptoms, and diagnose (or general medical condition) at the time of the event.
    - The outcome for the patient of any maltreatment or injury, delayed treatment, or death suspected/confirmed to be related to the incident.
    - If there was an incident, did the hospital report it to the authorities? (Provide report)
    - The customer complains about false high or false low results, missing results, patient mix-up etc.
- Additional information for the AQT90 FLEX events: (see further in the ***AQT Data Collection Guide***)
    - Specifically, for the TnI results:
        - Was the user aware that the patients rise and/or fall should be monitored, according to the international guidelines for interpretation of TnI results? (See http://www.radiometer.com/en/topics-in-poc-testing/cardiac-markers-guidelines)
        - Had the user received proper training for interpreting results from the device?

If a complaint is reportable, RADIOMETER is responsible for the reporting to and follow-up with authorities.

The ***Vigilance Investigation Form (Guide-00197)*** and ***AQT Data Collection Guide*** are available for download from RMEDs official download site, Global Services Library.

## 4.6 Service Call Activities

For handling and documenting the complaint, then be sure to document:

Complaint:
What is the complaint about, i.e., error messages, symptoms, etc.?

Investigation:
What has been investigated and what were the results?

Correction:
Which actions were taken to correct the problem (i.e., replacements, adjustments, etc.)?

Test performed:
Which tests were done to verify correct performance of the analyzer, apart from QC?

All tests passed:
If the answer is “No”, then describe which further actions will be taken.

## 4.7 Quality Complaints Type 1 Handling

CRM Escalated Complaint must be used for reporting Quality Complaints Type 1 (QCT1):

- All Quality Complaints which require additional investigation by RMED/RCAL/RBSL/RSUZ.
- All Quality Complaints which are neither a Quality Complaint Type 2 nor 3.
- Any complaint that represents an Adverse Event constitutes a subset of the Quality Complaint Type 1 and is clearly identified.
- Any situation which may potentially evolve into a product liability claim against RADIOMETER
- Systematic errors, e.g., complaints suggesting that a whole production lot is involved or where the same issue is found in several units.
- Quality Complaints Type 3 which could not be solved locally within a reasonable time and effort using the Service Manual shall be escalated to a Quality Complaint Type 1.
- Cases which RADIOMETER specifically asked for initiation of a QCT1 (e.g., if a Quality Complaint Type 3 should be reclassified)

- OOB (Out-Of-Box) errors: Errors relating to the instrument that occur upon unpacking/installing or within 72 hours of installation. CRM users to file Case type “Pre-Installation“ or “Installation”. Consumables are not in scope for OOB.

All relevant and available information shall be included in the reporting of the complaint.

In case of prolonged CRM failure (more than 4 hours), Quality Complaints Type 1 must be reported to the Customer Complaint Department at Radiometer Medical by other means such as email (customercomplaint@radiometer.dk) or phone.

The following are NOT QCT1s:

- Enquiries and questions concerning functionality of analyzers/monitors etc.
- Wishes in relation to e.g. functionality or documentation (please contact RMED TPS&S)

### 4.7.1 RADIOMETER Quality Complaint Type 1 processing

QCT1s are evaluated and assigned to relevant departments for investigation and identification of Corrective Actions. The following will be documented in the QCT1:

1. Investigation performed and any conclusions reached
2. Decisions on CAPA initiation: If there is a Corrective Action, its reference number is noted in the complaint and the complaint will be completed

### 4.7.2 Reply to Customer

It is the responsibility of the Subsidiary/Distributor to reply and document any response to the customer.

## 4.8 Quality Complaints Type 2 handling

Quality Complaints Type 2 (QCT2) shall be reported in CRM in the QCT2 module.

Complaint-specific field report printouts (or Failure Report download files) may be attached to the complaint record in CRM, or otherwise it must be archived locally by the Radiometer subsidiaries, Sales Offices, and distributors.

Any correspondence with the customer must be archived locally by the Radiometer subsidiaries, Sales Offices, and distributors. All SCs and SPs reported as QCT2 should be discarded after replacement.

QCT2s concern known and investigated issues for the SC and SP which are solved by replacing the SC or SP. Hence, no further investigation is needed for individual QCT2s. Lists of error codes related to known issues are available in Global Services Library - Warranty and service policies - All Documents (sharepoint.com)

QCT2s must be completed in CRM within 60 days of receival from customer. If a QCT2 exceeds the timeframe, the reason must be documented via a justification in the related Case record in CRM. QCT2s containing a justification for exceeded timeframe must be re-assessed at least every 30 days and a new justification must be added to the related Case record.

If there is a Potential Reportable Event/Potential Health Hazard, or any unknown problem occurs, the complaint must be reclassified and reported as a Quality Complaint Type 1.

## 4.9 Quality Complaints Type 3 handling

Quality Complaints Type 3 (QCT3) concerns only known problems for which established investigation and pre-defined solutions via Service Manual/IFU exist. QCT3s shall be reported immediately in CRM via a case with Complaint Type = Complaint Type 3, and the following information:

- Product name
- Unique product identification, e.g., version, serial no., lot no., UDI, Software version, part no., item no.
- Date complaint received (date when Radiometer subsidiary/Sales Office/Distributor becomes aware of the complaint)
- Complainant name, address, phone number (available from the Related Account)
- Nature and details of the complaint

A Service Work Order (SWO) shall also be created in the associated CRM case.

The Quality Complaint Type 3 is resolved by FSE with no additional investigation required. If a problem cannot be resolved or if there is a Potential Reportable Event/Potential Health Hazard, the complaint must be re-classified to a Quality Complaint Type 1.

QCT3s shall be completed within 90 days of receival from customer. If a QCT3 exceeds the timeframe, the reason must be documented via a justification in the case in CRM. Complaints containing a justification for exceeded timeframe must be re-assessed at least every 30 days and a new justification added to the Quality Complaint Type 3 record.

## 4.10 Product Liability Claim

Any situation, which may potentially evolve into a product liability claim against RADIOMETER must immediately be reported to RADIOMETER as Quality Complaint Type 1.

Upon receipt of such report RADIOMETER will as soon as possible inform about which steps should be taken in relation to involving lawyers, RADIOMETERs insurance company etc.

## 4.11 VET90 Complaint Handling

VET90 (i.e., VET90 analyzer and its consumables) is a product sold exclusively to the VET industry and therefore it is not considered to be a medical device. Despite not being a medical device RMED has decided that any customer complaint related to VET90 must be reported to RMED via the usual channel, i.e., in CRM as Quality Complaint Type 1, 2 or 3.

All customer complaints related to VET90 must follow the regular complaint process, including complaint definitions, as is described in this chapter, with exception to the following fields in CRM:

- Related Portfolio Product: Ensure that Related Portfolio Product is “VET90”. This is important in order for RMED to identify that complaint is related to a VET product.
- Potential Health Hazard fields: The meaning of the regular PHH evaluation is health hazard towards humans. Thus, for VET90 related complaint “No” must be answered to all regular PHH questions.
- For VET90 QCT1, field “Details of Complaint”: Copy/paste and detail the following questions:
  1. Did the incident cause harm to the user of the analyzer and/or accessories or exposed the user to a hazard?
  2. Did the incident cause harm to the animal patient (cat/dog) or expose the animal patient (cat/dog) to a hazard?
  3. Did the incident cause damage to property?”

# 5 Corrective Actions and Updates

## 5.1 Introduction

This chapter defines the types of corrective actions and updates, describes the contents of the documents used for communicating the corrective actions and updates, and describes the procedures for implementing corrective actions and updates in the field.
Further, it describes the effectiveness check which is performed by RADIOMETER for corrective actions.

The subsidiaries/distributors Quality System must include SOPs to ensure compliance with the procedures given in this chapter.

## 5.2 Definitions

### 5.2.1 Stock Recovery

A stock recovery is used by RMED to request subsidiaries to typically put potentially affected product located on their local inventory in quarantine while RMED is investigating a potential issue with the product. Product located on subsidiaries inventory is under RADIOMETER’s control. A stock recovery cannot be used for product located at distributors or customers’ stock as it is not under RADIOMETER’s control.
Actions stated in a Stock Recovery are always mandatory.

### 5.2.2 Field Action (FA)

A Field Action is an action that is being taken with regards to distributed products to recall or correct a product, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device:

- may be hazardous to health
- may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety
- may not meet the requirements of standards or regulations.

**Field Action - Typical scenarios:**

FAs may be performed in many ways depending on the actual case. Two typical scenarios are listed below:

**Scenario 1 (recall of consumable):**

- **FA** is distributed to subsidiaries and distributors to inform customers about an issue using a Customer Advisory Letter (CAL). Subsidiaries and distributors are required to:
  - Translate CAL to local language(s) and submit translated CAL to RMED
  - Generate list of affected customers and affected product per customer per country using the Field Action Effectiveness Data Sheet and submit to RMED
  - Distribute CAL to local customers and confirm to RMED using the proper FAC
  - Collect Recall Response Form or other objective evidence of the response from local customers and submit proper FAC indicating the percentage of customers responding to the CAL to RMED. Details including Recall Response Form or other objective evidence of the response from local customers is filed locally.

**Scenario 2 (information and corrective action):**

- **Revision 1** of FA is distributed to subsidiaries and distributors to inform customers about an issue using a Customer Advisory Letter (CAL).
  Subsidiaries and distributors are required to:
  - Translate CAL to local language(s) and submit translated CAL to RMED
  - Generate list of affected customers and affected product per customer per country using the Field Action Effectiveness Data Sheet and submit to RMED
  - Distribute CAL to local customers and confirm to RMED using the proper FAC
  - Collect Recall Response Form or other objective evidence of the response from local customers and submit proper FAC indicating the percentage of customers responding to the CAL to RMED.
    Details including Recall Response Form or other objective evidence of the response from local customers is filed locally.

- **Revision 2** of FA is distributed to correct an issue (e.g. by upgrading the analyzer software)
  Subsidiaries and distributors are required to:
  - Translate Revision 2 CAL to local language(s) and submit translated Revision 2 CAL to RMED
  - Generate list of affected customers and affected product per customer per country using the Field Action Effectiveness Data Sheet and submit to RMED (the list may have changed since revision 1 of FA)
  - Visit all local customers to perform corrective action including handing over the Revision 2 CAL and confirm to RMED using the proper FAC and the completed Field Action Effectiveness Data Sheet (input to consolidated effectiveness data)

### 5.2.3 Effectiveness Check

RMED must be able to demonstrate the effectiveness of a Field Action. If an FA involves more actions, e.g., communicated via different revisions of a FAN (as in scenario 2 above), the effectiveness of the FA (with detailed effectiveness data) at RMED is measured on the final action only.
Effectiveness data for temporary/intermediate actions must be filed at the subsidiaries and distributors.

The effectiveness data includes:

- A complete list of affected customers and affected product per customer (the latter including e.g., serial numbers of analyzers, quantity/lot of bottles/boxes)
- For each affected customer and affected product, the list must indicate which affected product has had the agreed countermeasures implemented

The effectiveness of a FA is measured as follows: Percentage of affected product that has had the agreed countermeasures implemented.

The effectiveness data must be available per individual country and consolidated globally.

Affected product is any product manufactured within the product limitation, which are affected by the issue described in the FA.

### 5.2.4 Technical Update (TU)

A Technical Update (TU) is used for actions taken in the field, which do not fall into the definition of a FA.

The TU is used primarily for product improvements and new features, preparation of products for e.g., new consumables or hardware, and to secure use of current features.

## 5.3 Contents of Documents

### 5.3.1 Stock Recovery:

The following documents exist:

- **E-mail:** Used by RMED to define what the potentially affected product is and to typically put the potentially affected product located on their local inventory in quarantine until further notice.

### 5.3.2 Field Action (FA) Documents:

The following documents exist:

- **Customer Advisory Letter (CAL):** Used by RMED to define the contents of any written information to be provided to the customers as a part of a Field Action. The text is translated by the subsidiary and distributor to the local language and presented with the subsidiary's or distributor's letterhead.
  The last page of the customer advisory letter is a Recall Response Form that the customer must return to the subsidiary/distributor to acknowledge the receipt of the letter.
- **FAN: Field Action Notice (FAN):** Used by RMED to explain the issue, the corrective action required as well as the completion date for the Field Action to the subsidiaries and distributors. Furthermore, it states the user actions as well as regulatory requirements.
- **Field Action Confirmation (FAC):** Must be used by the subsidiaries and distributors to confirm the completion of the external actions. Since the FA may involve more individual actions (see typical scenarios below) there may be more FACs per FA.
- **Field Action Effectiveness Sheet:**
  Used by RMED to specify which information and to which detail the subsidiaries and distributors must provide to RMED to demonstrate the effectiveness of a FA (see below). In the case where a subsidiary or distributor covers more countries the subsidiary or distributor must compile one sheet per country. The sheet is to be submitted to RMED upon completion of the FA locally.

- **Frequently Asked Questions (FAQ):** May be used by RMED to answer any questions that the subsidiaries and distributors may have or customers may ask the in relation to the Field Action. It must be assessed if it is necessary or appropriate to prepare a FAQ in each specific case. The FAQ may relate to all technical and practical aspects of a Field Action.
- **Field Action document package (external):** Is the common term for the entire package that is to be sent to the subsidiaries and distributors, consisting of FAN, CAL, FAC, Field Action Effectiveness Sheet, and possible FAQ.

### 5.3.3 Technical Update (TU) Documents:

The following documents exist:

- **Technical Update (TU):** Used by RMED to explain the background, define which updates the subsidiaries and distributors are to perform and if they are mandatory or recommended, and setting the deadline for the updates (mandatory updates only).
- **Technical Update Confirmation (TUC):** Must be used by the subsidiaries and distributors confirm the completion of the updates (mandatory updates only).
- **Customer Information Letter (CIL):** Used by RMED to inform the customer about the major new features and changes to be implemented on the product. The text is translated by the subsidiary or distributor to the local language and presented with the subsidiary's or distributor's letterhead. It must be assessed if it is necessary or appropriate to prepare a CIL in each specific case.

## 5.4 Procedural Description

### 5.4.1 Stock Recovery:

**The following procedure applies:**

- Upon receipt of the Stock Recovery e-mail subsidiaries must confirm by return e-mail that the product has been quarantined locally, including the number of affected products that has been quarantined
- Upon completion of the investigation of the potential issue with the product RMED informs subsidiaries about the conclusion of the investigation, RMED may:
    - Decide to initiate a Field Action, or
    - Communicate to the subsidiaries how to proceed with respect to the product on local quarantine

### 5.4.2 Field Action:

**The following procedure apply:**

| Step | Action |
|---|---|
| **1.** | RMED e-mails the FA to the relevant Subsidiaries and Distributors.<br>The receivers are designated persons within the Subsidiaries and Distributors organization (the persons responsible for carrying out the corrective actions). |
| **2.** | Upon receipt the receiver must return an email with the text “Received” to document that the FA document package has been received. |
| **3.** | The distributors/subsidiaries must email the material below to RMED within the timeframe stated in the FAN document:<br>• A complete list of affected customers and affected product per customer (the latter including e.g., serial numbers of analyzers, quantity/lot of bottles/boxes). The Field Action Effectiveness Data Sheet is used for this. The list must be separated by country for subsidiaries/distributors serving more countries.<br>• Copies of the translated customer advisory letter to the customers<br>This information is required for establishing the effectiveness of the FA and for reporting the corrective actions to the local authorities. |
| **4.** | The distributors/subsidiaries plan the implementation of the corrective actions as described in the FAN document.<br>**The distributors/subsidiaries must ensure that the implementation is completed for all affected customers/product within the timeframe stated in the FAN document.** |
| **Note** | In some countries the corrective action for FAs must not be initiated before the local authorities have approved it. |
| **5.** | The distributors/subsidiaries implement the required corrective actions. |
| **6.** | Distributor/subsidiary follow up.<br>Affected customers must confirm the receipt of the customer advisory letter, and in some cases also that requested corrective actions have been performed. This is done by completing and submitting the sign-off sheet (Recall Response Form) of the customer advisory letter to the distributor/subsidiary.<br>Distributors/subsidiaries must contact customers not responding at least three times using different ways of communication, e.g., e-mail, phone, mail, visit, and document the attempts of contact. |
| **Note** | A FA may involve more corrective actions, which must be completed and confirmed to RMED on different Dates.<br>The follow up, completion of corrective actions, and confirmation to RMED applies to all corrective actions. |

7. Not later than on the completion date stated in the FAN document the distributors/subsidiaries must submit an e-mail to RMED, including the appropriate FAC (filled in and signed) and filled in e.g., Field Action Effectiveness Data Sheet. This is to confirm that the corrective actions required in the FA have been completed.
   The filled in e.g., Field Action Effectiveness Data Sheet documents for each affected customer/product that the affected product that has had the agreed countermeasures implemented **and provides the effectiveness data**.

   Please see the table below for an overview of material that must be submitted to RMED.

**!** **Timing**

The completion dates for implementing the corrective actions as stated in the FAN document have been set considering the extent of the work involved, the severity of the issue, and the fact that local authorities request the corrective actions to be carried out in a timely manner.

***It is very important that the corrective actions are completed and confirmed to RADIOMETER (using the FACs) not later than the completion date stated.***

Local authorities may question the subsidiaries/distributors course of action in the case that the deadline is exceeded.

### 5.4.3 Technical Update

**The following procedure apply:**

| Step | Action |
|---|---|
| **1.** | RADIOMETER e-mails the TU to the relevant Subsidiaries and Distributors.<br>The receivers are designated persons within the Subsidiaries and Distributors organization (the persons responsible for carrying out the updates). |
| **2.** | Upon receipt the receiver must return an email with the text “Received” to document that the document package has been received. |
| **3.** | For mandatory TUs only:<br>The distributors/subsidiaries plan the implementation of the update as described in the TU document.<br>The distributors/subsidiaries must ensure that the implementation is completed within the timeframe stated. |
| **4.** | The distributors/subsidiaries implement the required update. |
| **5.** | For mandatory TUs only:<br>Not later than on the completion date stated in the TU document the distributors/subsidiaries must submit an e-mail to RMED, including the TUC (filled in and signed).<br>This is to confirm that the update required in the TU has been completed. |

# 6 Policy for Use of Non-Original Parts

## 6.1 Objective

To ensure operation of RADIOMETER instruments in accordance with technical specifications using only original RADIOMETER parts, or parts approved by RADIOMETER.

## 6.2 Summary

The subsidiary/distributor should always use original RADIOMETER spare parts and accessories. Normally, RADIOMETER will not approve of the use of non-original parts if original parts are available from RADIOMETER.

In rare exceptions RADIOMETER may approve of the use of non-original parts, for exceptional economic, technical, legal or other reasons.

This instruction outlines the procedure for obtaining approval for use of non-original parts, if, exceptionally, this is needed.

## 6.3 Application Procedure

The following procedure should then be followed:

Fill in the enclosed approval sheet and send it to RADIOMETER, TPS&S

The sheet must contain all pertinent information about the non-original part and its intended use in a RADIOMETER instrument.

Of particular importance is: name and address of manufacturer; legal entity within the company to whom legal and regulatory questions can be addressed; technical approvals, both local and international of the non-original part.

Attach technical specifications of the part. If a formal supplier evaluation has been carried out, the result should also be attached

## 6.4 Approval

If RADIOMETER can approve of the use of the non-original part or the vendor in question, the approval sheet will be signed by: Director QA Operations, R&D Manager, and Manager, Technical Documentation, RADIOMETER, and returned to the subsidiary/distributor.

The approval sheet is numbered and filed in the Technical Documentation Department.

## 6.5 Violation of the Policy

If it is determined that a RADIOMETER subsidiary/distributor supplies non-original parts to customers and if the requirements in this policy have not been strictly followed, RADIOMETER may revoke the warranty for analyzers or spare parts with which the non-original part has been connected.

## 6.6 Application and Approval Form

The form, which is to be filled in by the subsidiary/distributor in connection with applying for permission to use a non-original part, is on the next page.

**No._____**

# Approval for use of non-original part

RADIOMETER grants the following approval for the use of a non-original part as a substitute for an original RADIOMETER part:

| | |
|---|---|
| **Subsidiary/Distributor** | |
| **Non-original part**:<br>Manufacturer:<br>(Name and address)<br>Code-no.:<br>Legal entity<br>Price in local currency:<br>Technical approval by local authorities:<br>Technical specifications:<br>Result of supplier evaluation: | |
| The non-original part is to be used in the following instruments:<br>Description of use:<br>Original RADIOMETER part number: | |
| **Conditions for RADIOMETER approval**: | |
| **Approval is valid until:** | |
| **Approved by:**<br>Director QA Operations<br>R&D Director<br>Manager, Technical Documentation | <br>Date: .<br>Date: .<br>Date: . |

# 7 Spare part Policy for Standard PC Components

## 7.1 Objective

The objective of this paragraph is to:

- Expand on the “Policy for Use of Non-Original Parts” specifically for standard PC components.
- Outline the policy for enhancing analyzers including standard PC components.

## 7.2 Non-Original Parts

**Background**

Most components within the PC Module are standard PC components and are as such often available through PC and Electronics stores "around the corner".

These components are available in numerous brands and types and at widely different prices in different countries throughout the world.

This may result in a desire to purchase the components locally either due to convenience or price.

**Policy**

The "Policy for Use of Non-Original Parts” covers all Radiometer analyzers and as such also the standard PC components, such as e.g. DVD and HDD, Main Board, and RAM.

**The policy states that it is not allowed to use non-original parts unless the use beforehand has been approved by RADIOMETER.**

RADIOMETER cannot guarantee the analyzers performance specifications and safety and cannot accept any warranty claims in case non-original parts are used.

Approval of any part is based on tests verifying that the actual component performs correctly in our application (such as PC Module with software). However, due to the amount of different brands and types available and the pace at which they are discontinued and replaced by new ones, it is not possible and economically feasible for our supplier of e.g. the PC Module to offer such verification tests for these parts.

**Definition of non-original standard PC components**

The definition of non-original parts for standard PC components if not different from that of other components.

Any part not purchased through RADIOMETER is regarded as being non-original.

## 7.3 Enhancement

**Background**

The technology for computer systems develops extremely fast resulting in new and more powerful components constantly being introduced and earlier less powerful being discontinued. Such components are e.g. hard disk, CPU, Main Board, CD/DVD drive, and RAM.

Over the lifetime of a product, such as the ABL800FLEX, numerous changes and enhancements to the PC components will take place.

Some enhancements will inevitably result in new components not being compatible with previous ones.

From time to time we will be faced with customers wishing their PC Module to be enhanced to improve its performance.

**Policy**

The policy for enhancements of PC components is as follows:

- *Subsidiary/Distributor/Customer driven enhancement*

In general, enhancements to new and more powerful components to improve the performance of the PC Module should not be performed and will not be subsidized by RADIOMETER.

- *RADIOMETER driven enhancement*

For non-standard PC components (primarily Main Boards), we shall, as long as possible, continue to supply the original components to avoid costly upgrades in the field.
Once the original Main Board becomes unavailable, we will instead deliver a new type of Main Board. Please note that such a changeover to a new type may result in other parts needing to be exchanged due to incompatibility - this causes the cost of repair to increase.

Standard components have a tendency to become larger and faster over time, often without a price increase.
We will deliver "the current standard" which means that an original, e.g., hard disk in most cases will be replaced by a larger type. Such enhancements are only subject to extra charges in case the cost increases.

# 8 Interpretation of Two-letter and Two-digit Production Codes

## 8.1 Interpretation of two-digit production codes

Two-digit production codes are used for marking consumables and accessories to identify the year and quarter of production. These codes are primarily used for products that do not have a specific expiry date.
The production code may be used for stock management (first in – first out) and to determine which lots are produced after a certain lot.

The table below converts a two-digit production code into the year and month of production.

| Production code | Time of production | Production code | Time of production | Production code | Time of production | Production code | Time of production |
|---|---|---|---|---|---|---|---|
| 01 | N/A | 26 | Q4 2031 | 51 | N/A | 76 | Q2 2027 |
| 02 | Q4 2019 | 27 | N/A | 52 | Q4 2029 | 77 | N/A |
| 03 | Q4 2032 | 28 | Q1 2017 | 53 | Q1 2033 | 78 | Q2 2019 |
| 04 | Q1 2021 | 29 | Q1 2022 | 54 | Q2 2021 | 79 | Q2 2024 |
| 05 | Q3 2031 | 30 | Q1 2035 | 55 | Q3 2029 | 80 | Q4 2033 |
| 06 | Q1 2028 | 31 | N/A | 56 | Q2 2026 | 81 | N/A |
| 07 | N/A | 32 | Q4 2025 | 57 | N/A | 82 | Q2 2025 |
| 08 | Q3 2018 | 33 | Q3 2032 | 58 | Q4 2018 | 83 | Q1 2034 |
| 09 | Q3 2023 | 34 | Q4 2020 | 59 | Q4 2023 | 84 | Q2 2020 |
| 10 | Q3 2034 | 35 | Q2 2030 | 60 | Q2 2035 | 85 | Q3 2027 |
| 11 | N/A | 36 | Q4 2028 | 61 | N/A | 86 | Q2 2031 |
| 12 | Q4 2024 | 37 | N/A | 62 | Q1 2025 | 87 | N/A |
| 13 | Q2 2033 | 38 | Q2 2018 | 63 | Q3 2035 | 88 | Q4 2017 |
| 14 | Q4 2026 | 39 | Q2 2023 | 64 | Q1 2020 | 89 | Q4 2022 |
| 15 | Q3 2030 | 40 | N/A | 65 | Q2 2028 | 90 | Q4 2034 |
| 16 | Q1 2026 | 41 | N/A | 66 | Q3 2026 | 91 | N/A |
| 17 | N/A | 42 | Q4 2019 | 67 | N/A | 92 | Q3 2025 |
| 18 | Q2 2017 | 43 | Q2 2032 | 68 | Q3 2017 | 93 | Q1 2032 |
| 19 | Q2 2022 | 44 | Q3 2021 | 69 | Q3 2022 | 94 | Q3 2020 |
| 20 | Q4 2035 | 45 | Q1 2030 | 70 | N/A | 95 | Q4 2027 |
| 21 | N/A | 46 | Q1 2031 | 71 | N/A | 96 | Q1 2027 |
| 22 | Q3 2024 | 47 | N/A | 72 | Q3 2028 | 97 | N/A |
| 23 | Q2 2034 | 48 | Q1 2019 | 73 | Q3 2033 | 98 | Q1 2018 |
| 24 | Q2 2029 | 49 | Q1 2024 | 74 | Q4 2021 | 99 | Q1-2023 |
| 25 | Q4 2030 | 50 | N/A | 75 | Q1 2029 | | |

# 9 Expiry of Warranty for Certain Electrodes

## 9.1 Conversion of two-letter production code into Date of expiry of warranty

For electrodes covered by an 18-month warranty from the day of production, the table below translates the two-letter production code into the corresponding date for expiry of warranty.

The warranty expiry date is the last day of the month.

| Code | Exp. Date | Code | Exp. Date | Code | Exp. Date | Code | Exp. Date | Code | Exp. Date |
|---|---|---|---|---|---|---|---|---|---|
| AB | NOV 2010 | DB | JUL 2012 | IC | MAY 2021 | MC | MAR 2023 | SK | JAN 2017 |
| AH | DEC 2010 | DF | JUN 2026 | ID | JUN 2021 | MD | APR 2023 | SP | FEB 2017 |
| AI | JAN 2011 | DG | JUL 2026 | IE | JUL 2021 | ME | MAY 2023 | SR | MAR 2017 |
| AM | FEB 2011 | DH | AUG 2012 | IJ | AUG 2021 | MJ | JUN 2023 | ST | APR 2017 |
| AP | MAR 2011 | DI | SEP 2012 | IL | SEP 2021 | ML | JUL 2023 | SV | MAY 2017 |
| AR | APR 2011 | DK | OCT 2012 | IQ | OCT 2021 | MQ | AUG 2023 | UB | JUN 2017 |
| AT | MAY 2011 | DM | NOV 2012 | IR | NOV 2021 | MR | SEP 2023 | UK | JUL 2017 |
| AV | JUN 2011 | DN | DEC 2012 | IU | DEC 2021 | MS | OCT 2023 | UN | AUG 2017 |
| AW | JUL 2011 | DP | JAN 2013 | IY | JAN 2022 | MU | NOV 2023 | UP | SEP 2017 |
| BA | JUN 2019 | DR | FEB 2013 | JB | MAY 2014 | MX | DEC 2023 | UR | OCT 2017 |
| BC | JUL 2019 | DT | MAR 2013 | JH | JUN 2014 | MY | JAN 2024 | UT | NOV 2017 |
| BD | AUG 2019 | DU | AUG 2026 | JK | JUL 2014 | NA | FEB 2024 | UV | DEC 2017 |
| BE | SEP 2019 | DV | APR 2013 | JM | AUG 2014 | NC | MAR 2024 | WB | JAN 2010 |
| BH | JUL 2025 | DW | MAY 2013 | JN | SEP 2014 | ND | APR 2024 | WD | FEB 2010 |
| BI | AUG 2025 | DX | SEP 2026 | JP | OCT 2014 | NE | MAY 2024 | WE | MAR 2010 |
| BJ | OCT 2019 | DY | OCT 2026 | JR | NOV 2014 | NJ | JUN 2024 | WJ | APR 2010 |
| BL | NOV 2019 | DZ | NOV 2026 | JT | DEC 2014 | NL | JUL 2024 | WL | MAY 2010 |
| BN | SEP 2025 | EB | JUN 2013 | JV | JAN 2015 | NQ | AUG 2024 | WQ | JUN 2010 |
| BP | NOV 2027 | EC | DEC 2026 | JW | FEB 2015 | NR | SEP 2024 | WR | JUL 2010 |
| BQ | DEC 2019 | ED | MAR 2027 | KA | FEB 2022 | NU | OCT 2024 | WS | AUG 2010 |
| BR | JAN 2020 | EE | APR 2027 | KC | MAR 2022 | NY | NOV 2024 | WU | SEP 2010 |
| BS | FEB 2020 | EF | MAY 2027 | KD | APR 2022 | PA | DEC 2024 | WY | OCT 2010 |
| BU | MAR 2020 | EH | JUL 2013 | KE | MAY 2022 | PC | JAN 2025 | XB | JAN 2018 |
| BV | OCT 2025 | EI | AUG 2013 | KF | OCT 2027 | PD | FEB 2025 | XK | FEB 2018 |
| BW | NOV 2025 | EK | SEP 2013 | KJ | JUN 2022 | PE | MAR 2025 | XP | MAR 2018 |
| BX | APR 2020 | EM | OCT 2013 | KL | JUL 2022 | PJ | APR 2025 | XR | APR 2018 |
| BY | MAY 2020 | EN | NOV 2013 | KQ | AUG 2022 | PL | MAY 2025 | XT | MAY 2018 |
| CB | AUG 2011 | EP | DEC 2013 | KR | SEP 2022 | PQ | JUN 2025 | XV | JUN 2018 |
| CG | DEC 2025 | ER | JAN 2014 | KS | OCT 2022 | RB | FEB 2016 | YB | JUL 2018 |
| CH | SEP 2011 | ET | FEB 2014 | KU | NOV 2022 | RC | JAN 2027 | YH | AUG 2018 |
| CI | OCT 2011 | EV | MAR 2014 | KX | DEC 2022 | RE | FEB 2027 | YI | SEP 2018 |
| CJ | JAN 2026 | EW | APR 2014 | KY | JAN 2023 | RF | DEC 2027 | YK | OCT 2018 |
| CK | NOV 2011 | FK | JUL 2027 | LB | MAR 2015 | RH | MAR 2016 | YM | NOV 2018 |
| CM | DEC 2011 | HA | JUN 2020 | LH | APR 2015 | RI | APR 2016 | YN | DEC 2018 |
| CN | JAN 2012 | HC | JUL 2020 | LI | MAY 2015 | RK | MAY 2016 | YP | JAN 2019 |
| CP | FEB 2012 | HD | AUG 2020 | LK | JUN 2015 | RL | SEP 2007 | YR | FEB 2019 |
| CR | MAR 2012 | HE | SEP 2020 | LM | JUL 2015 | RM | JUN 2016 | YT | MAR 2019 |
| CS | FEB 2026 | HJ | OCT 2020 | LN | AUG 2015 | RN | JUL 2016 | YV | APR 2019 |
| CT | APR 2012 | HL | NOV 2020 | LP | SEP 2015 | RP | AUG 2016 | YW | MAY 2019 |
| CU | MAR 2026 | HQ | DEC 2020 | LR | OCT 2015 | RS | JUN 2027 | ZK | AUG 2027 |
| CV | MAY 2012 | HR | JAN 2021 | LT | NOV 2015 | RT | SEP 2016 | ZA | SEP 2027 |
| CW | JUN 2012 | HU | FEB 2021 | LV | DEC 2015 | RV | OCT 2016 | | |
| CY | APR 2026 | HY | MAR 2021 | LW | JAN 2016 | RW | NOV 2016 | | |
| CZ | MAJ 2026 | IA | APR 2021 | MA | FEB 2023 | SB | DEC 2016 | | |

# 10 Support Status

The Support Status list has been divided into three lists depending on the stocking situation for the individual analyzer.

## 10.1 Still In Production

The analyzers on this list are still being produced and sold for which reason all spare parts are available for servicing.

**List of Instruments**

***Analyzer***

| | |
|---|---|
| ABL9 | Blood Gas System |
| ABL800 BASIC | Blood Gas System |
| ABL800 FLEX | Blood Gas System |
| ABL90 FLEX | Blood Gas System |
| ABL90 FLEX PLUS | Blood Gas System |
| AQT90 FLEX | Immunoassay Analyzer |
| PeriFlux6000 | Monitoring System |
| TCM4 | Series Monitoring System (391-880) |
| TCM5 Basic | Monitoring System |

## 10.2 Discontinued but Supported

This list includes analyzers, which have been discontinued, but we are still producing accessories and spare parts, which are subject to tear and wear.

**List of Instruments**

| ***Analyzer*** | | ***Discontinuation Date (YYYY.MM.DD)*** | ***Support Expires (YYYY.MM.DD)*** |
|---|---|---|---|
| ABL80 FLEX | Blood Gas System | 2022.12.31 | 2027.12.31 |
| ABL80 FLEX CO-OX | Blood Gas System | 2022.12.31 | 2027.12.31 |
| TCM4 | Monitoring System (hardware platform 391-876) | 2006.03.16 | N/A |
| TCM4 | Monitoring System (hardware platform 391-878) | 2008.06.03 | N/A |

* For a limited number of markets this date is different.

## 10.3 Support Expired

This list includes analyzers for which the support period has already expired, that is, no accessories and spare parts are available anymore.

**List of Instruments**

| ***Analyzer*** | | ***Expired (YYYY.MM.DD)*** |
|---|---|---|
| A7401 | Gas Supply Rack | N/A |
| A7405 | tc Calibration Unit | 1998.12.31 |
| ABC1 | Acid-base Cart | N/A |
| ABC2 | Acid-base Cart | 2002.02.28 |
| ABC70 | Acid-base Calculator | N/A |
| ABC73 | Acid-base Calculator | N/A |
| ABL1 | Acid-base Laboratory | N/A |
| ABL2 | Acid-base Laboratory | 2000.02.29 |
| ABL3 | Acid-base Laboratory | 2003.02.28 |
| ABL30 | Acid-base Analyzer | 2007.04.01 |
| ABL300 | Acid-base Laboratory | 2007.04.01 |
| ABL330 | Acid-base Laboratory | 2007.04.01 |
| ABL4 | Acid-base Laboratory | 2003.02.28 |
| ABL5 | Blood Gas System | 2019.12.31 |
| ABL50 | Blood Gas System | 2015.01.31 |
| ABL500 | Blood Gas System | 2015.01.31 |
| ABL505 | Blood Gas System | 2015.01.31 |
| ABL510 | Blood Gas System | 2015.01.31 |
| ABL520 | Blood Gas System | 2015.01.31 |

| | | |
|---|---|---|
| ABL555 | Blood Gas System | 2019.12.31 |
| ABL70 | Blood Gas System | 2004.09.30 |
| ABL77 | Blood Gas System | 2018.04.30 |
| ABL700 | Series Blood Gas System | 2020.12.31 (2021.06.30) |
| ABT1 | Acid-base Training Aid | N/A |
| AME1 | Astrup Micro Equipment | N/A |
| AMT1 | Astrup Micro Tonometer | N/A |
| BAT | Battery Unit for OXI | 2006-12-31 |
| BEU1 | Blood Gas Electrode Unit | N/A |
| BGA3 | Blood Gas Analyzer | N/A |
| BMS1 | Blood Micro System | N/A |
| BMS2 | Blood Micro System | N/A |
| BMS2mk2 | Blood Micro System | 1996.12.31 |
| BMS3 | Blood Micro System | N/A |
| BMS3mk2 | Blood Micro System | 1998.12.31 |
| BPH1 | Blood pH Analyzer | 1996.12.31 |
| BPH2 | Blood pH Analyzer | 2003.02.28 |
| BPH5 | Blood pH System | 2008.08.01 |
| CMT10 | Chloride Titrator | 2003.02.28 |
| D616 | Thermostatted Cell | 2003.02.28 |
| DCA1 | Dissociation Curve Analyzer | N/A |
| E5021 | pH Micro Electrode Unit | N/A |
| ECU1 | Electrode Conditioning Unit | 2003.02.28 |
| EML100 | Electrolyte Metabolyte Laboratory | 2008.08.01 |
| EML105 | Electrolyte Metabolyte Laboratory | 2015.01.31 |
| FLM2 | Flame Photometer | N/A |
| FLM3 | Flame Photometer | 2003.02.28 |
| GAA1 | Gas Analysis Apparatus | N/A |
| GMA1 | Gas Mixing Apparatus | N/A |
| GMA2 | Precision Gas Supply | 2002.02.28 |
| HEM1 | Hemolyzer | N/A |
| ICA1 | Ionized Calcium Analyzer | 2002.02.28 |
| ICA2 | Ionized Calcium Analyzer | 2003.02.28 |
| KNA1 | Sodium-Potassium Analyzer | 2002.02.28 |
| KNA2 | Sodium-Potassium Analyzer | 2003.02.28 |
| NPT7 | Series Blood Gas System | 2014.12.31 |
| OSM1 | Oxygen Saturation Meter | N/A |
| OXI | Pulse Oximeter | 2006.12.31 |
| OSM2 | HEMOXIMETER | 2009.12.31 |
| OSM3 | HEMOXIMETER | 2011.12.31 |
| PHA860 | pH meter Tester, Service Tool | N/A |
| PHA930 | $pO_2$ Module | N/A |
| PHA931 | $pCO_2$ Module | N/A |
| PHA850 | Electrode Tester | 1993.12.31 |
| PHA927 | Gas Monitor | N/A |
| PHA928 | Oxygen Monitor | N/A |
| PHA932 | $pO_2$ Module | N/A |
| PHA933 | $pCO_2$ Module | N/A |
| PHA934 | $pO_2$ Module | N/A |
| PHA935 | $pCO_2$ Module | N/A |
| PHA936 | SBC Module | N/A |
| PHM22 | pH Meter | N/A |
| PHM27 | pH Meter | N/A |
| PHM71 | Analog Acid-base Analyzer | N/A |
| PHM72 | Digital Acid-base Analyzer | N/A |

| | | |
|---|---|---|
| PHM71mk2 | Analog Acid-base Analyzer | N/A |
| PHM72mk2 | Digital Acid-base Analyzer | N/A |
| PHM73 | pH Blood Gas Monitor | 2002.02.28 |
| PHM75 | Clinical pH Meter | 2002.02.28 |
| PRS1 | Strip Printer | N/A |
| PRS10 | Alpha Printer | N/A |
| PRS11 | Ticket Printer | N/A |
| PRS12 | Alpha Printer | 2003.02.28 |
| PRS15 | Printer | 2008.08.01 |
| REC | Recorder | 2011.12.31 |
| RIS1 | Interface System | 2003.02.28 |
| SBC1 | Standard Bicarbonate Apparatus | N/A |
| TCA1000 | Power Supply | 1998.12.31 |
| TCA1100 | Power Supply | 1998.12.31 |
| TCA1200 | Power Supply | 1998.12.31 |
| TCC3 | Calibration Unit | 2011.12.31 |
| TCM1 | tc Oxygen Monitor | 1990.12.31 |
| TCM101 | tc Calibration Unit | 1990.12.31 |
| TCM2 | tc Oxygen Monitor | 1998.12.31 |
| TCM20 | tc Carbon Monitor | 1998.12.31 |
| TCM200 | Recorder and Power Supply | 1998.12.31 |
| TCM3 | $pO_2/pCO_2$ Monitoring System | 2011.12.31 |
| TCM30 | Oxygen Monitoring System | 2011.12.31 |
| TCM4 | Monitoring System (hardware platform 000-152) | 2011.12.31 |
| TCM4 | Monitoring System (hardware platform 000-154) | 2011.12.31 |
| TCR2 | tc Recorder | 1990.12.31 |
| TCR3 | tc Recorder | 1998.12.31 |
| TNC1 | Turntable/Conditioner | 2002.02.28 |
| TOSCA500 | Monitor | 2020.05.24 |
| VTS13 | Water Circulation Thermostat | N/A |

# 11 Electrostatic Discharge (ESD) Protection

## 11.1 Objective

To prevent damage to electronic circuitry caused by electrostatic discharge (ESD).

### 11.1.1 Concerns Whom?

Service and warehouse personnel at RADIOMETER Subsidiaries/distributors worldwide.

It is the responsibility of the subsidiaries/distributor's service/quality assurance manager that these procedures are followed.

### 11.1.2 Which Situations?

Maintenance, checkout and adjustments, replacements and repairs, which imply removing of the instrument case and exposing of the electronics by use of tools. When unpacked PC-boards and electronic components are being touched.

### 11.1.3 Concerns What?

RADIOMETER instruments, PC-boards and semiconductors.

### 11.1.4 Definitions

- *ESD protected area***.** Work benches on which electrostatic sensitive devices are handled, i.e. where instrument electronics are exposed or touched and PC-board assemblies are being repaired, are defined as an ESD protected area**.**

## 11.2 Requirements?

- *Static Dissipative Bench Mats* must be used. A three-layer mat, having one conducting layer between a top dissipative layer and a bottom non-conductive layer must be used in central workshops and is recommended for field service. Mats on which the dissipative layer is added by a surface treatment are not recommended because the layer may wear out and frequent tests of the surface resistivity are required. In the central workshops the mat must be permanently connected to ground by a cord with a resistance of between 0.9 and 5 Mohm.
- *Wrist strap* must be used. The inner surface must make permanent full contact with the wrist. The outer surface must be non-conductive. The wrist strap must be connected to the bench mat ground connector by a safety cord with a resistance of between 0.9 and 5 Mohm, when in use.
- *Verification tests of ESD equipment* must be carried out. The resistance and proper functioning of wrist straps must be checked daily. Proper ground connection of bench mats; measuring instruments and solder irons must be checked every 6 months and documented in an ESD protection logbook. Resistance and ground connection checks may be performed with a standard DVM ohmmeter, or on automatic resistivity testers with audio or light alert facilities.
- *Signs* for ESD protected area must be clearly visible to personnel.
- *All instruments* supplied by the mains must be grounded.
- *Battery operated instruments* such as TCM4 need no ground connection when dismantled in an ESD protected area. However, if a non-grounded charger is connected (the TCM4 chargers are non-grounded) the bench mat ground point must be connected to a major ground point in the instrument, e.g. by help of an alligator clip (in TCM4 the main screen plate constitutes such a major ground point).
- *Replacement PC-boards/ESD sensitive components* must not be unpacked from ESD protected bags outside a protected area.
- *Faulty/suspect PC-boards/ESD sensitive components* must be placed in ESD protected bags before they are moved from a protected area.
- *Tools*, including hand tools (tweezers, screwdrivers etc.), solder sucking devices, vacuum cleaners etc. shall, as far as is practical, be so constructed that they do not generate or hold an induced electrostatic charge.
- Discharge tools by placing them on the bench mat before use.
- *Solder irons* must be fitted with grounded tips. Solder irons, which are powered directly from the mains, must be grounded via its mains plug. Solder "stations" are normally without ground lead in its power cable and must be grounded by connecting its chassis ground connector to the bench mat ground connector.
- *Rubber (latex) gloves*, which protects against infection, may be worn in an ESD protected area.
- *Cloth/hair*. Prevent loose clothing and hair from touching the ESD sensitive part, *e.g. ties and long hair are excellent static generators and may hold a charge even if the person wears wrist strap.*
- *Low humidity* severely reduces the dissipative properties of materials and special care should be taken when handling ESD sensitive devices in case the relative humidity is below 20%.

## 11.3 Working Instructions

- Establish the ESD protection by connecting the bench mat ground connector with the instrument chassis (use safety cord with a resistance between 0.9 and 5 Mohm) and by connecting the wrist strap. Figures 1 through 3 shows how to connect the ESD equipment.
  If the workspace in the field is limited the bench mat may be folded or placed under the instrument.
- Remove ESD generating packing material such as polystyrene, foam rubber, cardboard etc. (but not the ESD protective bag/box) from instrument and PC-boards *before* they are brought into ESD protected area.
- Put-on wrist strap and connect it to the bench mat ground connector.
- Connect the instrument to a grounded power outlet by its power cable (with ground cord) ***or*** connect the instrument chassis connector to the bench mat ground connector. For details please refer to the figures 1 through 3.
  If no chassis connector is available the grounding may be established after the cabinet dismantling.
- Perform maintenance/checkout/adjustment/repair. Place faulty/suspect PC-board/ESD sensitive component on the static dissipative mat.
- Unpack the replacement PC-board/component from its ESD protected bag/box and mount in the instrument.
- Place faulty/suspect PC-board/component in the ESD protected bag/box. Close the bag/box by its static awareness label.
- Remount the instrument case.
- Disconnect the wrist strap and the instrument ground connection.

## 11.4 Inventory and Transport

Any ESD sensitive devices will be delivered from RADIOMETER in ESD protected bags or boxes and must be kept packed in those bags/boxes throughout storage and transport.

ESD sensitive devices which are to be returned to RADIOMETER must be packed (in an ESD protected area) in ESD protected bags or boxes before shipment.

- RADIOMETER will not issue credit for ESD sensitive, which are returned unprotected
- RADIOMETER will discard ESD sensitive devices, which are returned unprotected

## 11.5 Approved Equipment

Bench mats, wrist straps and cords must be in accordance with CECC 00015/1, i.e.

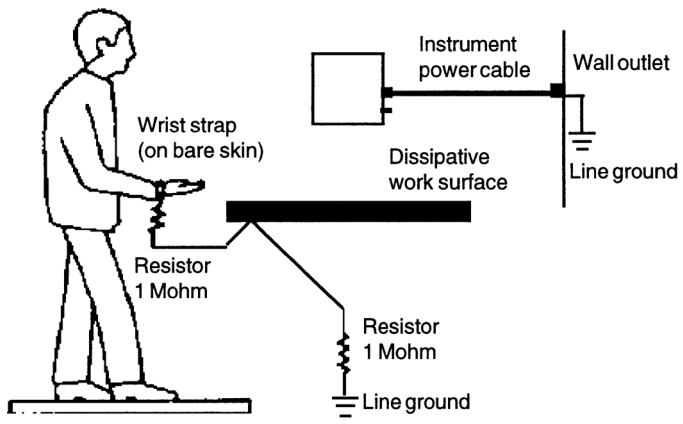
- Surface resistivity of bench mats must be between 10 kohm/sq. and 1000 Mohm/sq.
- Surface (inner, next to the skin) resistivity of wristband must be less than 10 Mohm/sq.
- Resistance of each cord used in the ESD protection system (wrist band to bench mat ground point, bench mat ground point to line ground, bench mat ground point to instrument chassis) must be between 0.9 and 5 Mohm.
- Effective resistance from bench mat ground point to ground must be between 750 kohm and 1000 Mohm.

## 11.6 References

CECC 00015/1 Protection of Electrostatic Sensitive Devices, 1991.

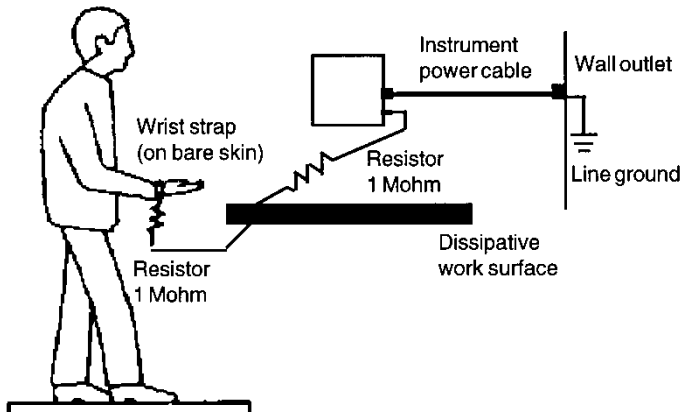
Workshop ESD Protection Instructions and Field ESD Protection Work Instructions. Radiometer LTD, 1992.

## 11.7 Figure 1 Central Workshops



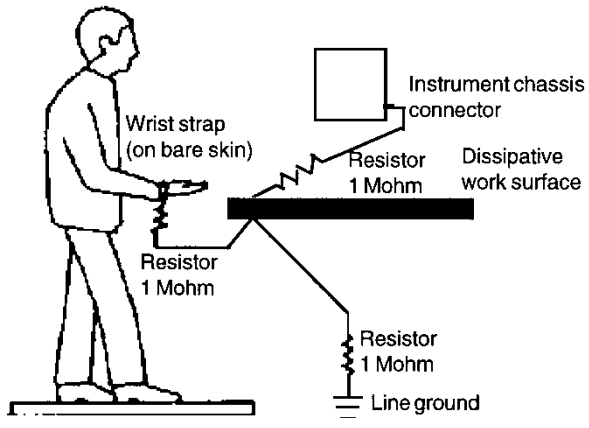

Permanent installation (central workshops). The instrument is grounded via its power cable and the bench mat is connected to line ground. ***Do not*** connect instrument chassis to bench mat ground connector ***simultaneously with*** above set up (resultant resistance to ground may then be less than required by CECC 00015/1).

## 11.8 Figure 2 Field Service




Temporary installation (field service). The instrument is grounded via its power cable and its chassis is connected to the bench mat. ***Do not*** connect the bench mat to line ground ***simultaneously with*** above set up (resultant resistance to ground may then be less than required by CECC 00015/1).

## 11.9 Figure 3 Instrument disconnected from mains




The instrument is grounded via the bench mat ground connector. This set up is an alternative to figures 1 and 2, and must be used if the instrument power cable is disconnected for safety reasons.

# 11.10 Audit ESD Protection Facilities

**Report on Audit of Electrostatic Protection Facilities**

**Subsidiary/Distributor:** **Carried out by:** **Date:**

All status fields must be filled in with “OK” or “FAIL”

**STATUS**

Identification of Electrostatic Protected Area (central workshop). Signs for ESD protected area must be clearly visible to personnel. _____

Warehouse check. Any ESD sensitive devices (PC-boards and EPROMs) must be stored in ESD protected bags or boxes (including conductive foam) and labeled ESD protected. _____

Bench mat ground connections. Check that resistance from mat ground connector to the line ground is in accordance with CECC 00015/1, i.e. between 0.9 and 5 Mohm. _____

Wrist strap cord. Check that resistance is in accordance with CECC 00015/1, i.e. between 0.9 and 5 Mohm. _____

Measuring instruments and solder irons. Check that resistance from the instrument chassis to the line ground and from the solder iron tip to the line ground is below 5 Mohm. _____

It is recommended to use automatic resistivity testers with audio or light alert facilities.

# 12 USB flash drive usage - recommended practice

## 12.1.1 Purpose

Incorrect handling of a USB flash drive has the potential to introduce malware to an analyzer. The purpose of this procedure is to state general requirements for working with USB flash drives to reduce the risk of infecting Radiometer analyzers with malware.

## 12.1.2 Role & Responsibilities

All Radiometer field staff must adhere to this procedure, when working with USB flash drives at customer sites.

## 12.1.3 Prerequisite & Tools requested

A PC with an updated anti-virus program

## 12.2 General requirements for working with USB flash drives

The following general requirements apply when working with USB flash drives:

- Clearly mark USB flash drives for easy identification of its contents and/or purpose.
- Use only USB flash drives for the specific purpose it is intended for.
- Do not use USB flash drives outside of your professional working environment (hence, not with your private PC).
- Scan USB flash drives for malware using a PC with an updated anti-virus program prior to connecting them to Radiometer analyzers.
- Re-scan USB flash drives for malware on a PC with an updated anti-virus program immediately upon disconnecting them from Radiometer analyzers.
- USB flash drives used for temporary data storage must only contain data from one analyzer. Hence, it must be empty prior to connecting it to an analyzer. Temporary data storage takes place in the following processes:
  - Back-up and restoring data and setup,
  - Storing Service dumps or data logs, and
  - Copying setup from one analyzer and load it into a second analyzer,
- Dispose of USB flash drives which have been infected by malware (even if the anti-virus program indicates that the malware has successfully been removed).
- Do not copy or in other ways re-use files from an infected USB flash drive.

## 12.2.1 Suggestions for marking USB flash drives

USB flash drives may be marked in numerous ways. What is important is that they must be marked such a way that that you will never be in doubt of their contents/purpose. The following merely serves as suggestions:

“ABL90 V3.3 MR1”, “ABL800 ServiceDump”, “RWES7, 933-372”, “Data”, “AVScan”, “933-423”, etc.

## 12.2.2 How to scan USB flash drives for malware

Most anti-virus programs do not automatically scan all files on the USB flash drive upon connection of the USB flash drive to the PC. Therefore, it is required to manually

1. initiate the scan as follows:
2. Connect the USB flash drive to a PC with an updated anti-virus program.
3. Open the explorer
4. Right-click on the USB disk, and
5. Select “Scan with <name of antivirus program>”.

## 12.2.3 How to prepare empty USB flash drives

As mentioned above this procedure applies to USB flash drives used for Back-up and restoring data and setup, producing Service dumps, and copying setup:

1. Connect the USB flash drive to a PC.
2. Open the explorer
3. Select the files to be deleted
4. Press Delete.

## 12.3 What to do if malware is found on a USB flash drive

If malware is identified on a USB flash drive which has been connected to a Radiometer analyzer, you must proceed to the procedure “Anti-Virus Scan and Mitigation of Malware” to determine if the analyzer is infected.

## 12.4 What to do with respect to the PC that identified the malware

In case malware is identified on a USB flash drive, then the following must be carried out on the PC that identified the malware:

1. Perform a full anti-virus scan on the PC that has been used to identify the malware:
    a. Disconnect your PC from the network (if connected)
    b. Open the anti-virus program on your PC
    c. Perform a full anti-virus scan on your PC (All drives)
2. For RADIOMETER subsidiary employees report the incident to Radiometer Global IT Servicedesk within 2 hours:
    a. Send an email to Servicedesk@radiometer.dk or
    b. Phone Servicedesk +45 3827 2112

Please include information about the incident, the result of anti-virus scanning of the PC and state that you are field staff.

# 13 Safe blood handling - recommended training

## 13.1.1 Purpose

Due to the fact that Radiometer instruments are dealing with Blood product, staff working with these instruments have a greater risk of exposure to biological agents and blood borne pathogens. The purpose of this procedure is to state general requirements for minimize the risk of incident when working with Radiometer analyzers

## 13.1.2 Role & Responsibilities

Local Management are responsible for training staff in safe work practice.

## 13.1.3 Prerequisite & Tools requested

Personal protective equipment (PPE)

## 13.2 General Topics:

- Common blood borne diseases.
- Nature of infection
- Safety precautions
- Recommended Personal protective equipment
- Actions to take in the case of potential exposure

## 13.3 Content - recommended information:

## 13.3.1 Biological agents

**Definition of biological agents**
All micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity.
Micro-organisms typically encompass bacteria, virus and fungus.
Human blood, animal blood and biological agents (class 2) should be handled in the same way. All types are treated with respect for health risks.

**What is blood?**
Human blood is a thick, red and sticky fluid with a light salty taste.
7% of an adult's body weight is blood.
On average a woman has 4.5 liters of blood and a man has 6 liters.

Blood function:

- Transport of O2, CO2, nutritions, hormones, control of fluid balance, metabolics and waste products
- Temperature regulation
- Defenses against infections, virus and wounds

Blood consists of blood cells (floating in plasma): Blood cells are tiny, and can only be seen in microscope. Nearly half the body's cells are blood cells.

- Red blood cells (erythrocytes): transports $O_2$. Lives approximately 120 days
- Blood platelets (thrombocytes): Hemostasis. Lives approximately. 9 days.
- White blood cells (leukocytes): Immune defends, watchmen.

## 13.3.2 Bloodborne diseases

**These diseases are transmited via blood:**
HIV, Hepatitis B and Hepatitis C

Transmission can be avoided:

- Use personal protective and other safety equipment
- Work calmly and methodological
- Work a comfortable work posture
- Avoid reassembling the syringe safety hood (or use hands-free technique)
- Avoid touching the needle (you and colleagues)
- Dispose in puncture-safe box

**HIV & AIDS:**
HIV can lead to AIDS – a potentially deadly disease that runs down the immune defence system. Immediate HIV antiretroviral treatment after exposure can reduce risks with more than 80 %. Approximately 33 million people are HIV infected world wide

The risk of contamination by needle puncture with infected needle is approximately. 0,3%. The use of protective gloves can reduce the risk.
The risk of contamination via blood contact on mucosa membranes is less than 0,1%.

**HIV - Transmission methods**
HIV (retrovirus): HIV is found in all body-fluids and is transmitted via sexual contact, via blood, blood products, tissue and organ transplant and perinatal from mother to child.
Blood transmission

- Puncture and lesions
- Cuts, wounds, rash, eczema
- Mucosa membrane
- Eyes, mouth, genitals
- Other body fluids Sex, breast-feed, pregnancy

**Hepatitis: Inflammatory liver condition**
A, B, C, D, E, F, G…..
Hepatitis B and C virus is transmitted via blood

**Hepatitis transmission methods**

- Hepatitis B and C (virus)
- Blood transmission
- Puncture and lesions
- Cuts, wounds, rash, eczema
- Mucosa membrane
- Eyes, mouth, genitals
- Other body fluids (HPV B)
- Sexual contact
- Semen and spit

Hepatitis B Incubation time: 1-5 month after transmission.
SYMPTOMS: Fever, nausea, jaundice, dark urine, light faeces

Approximately 200 million people worldwide are chronic carriers.
5-10% of cases develops to chronic liver disease
The risk of contamination by needle puncture with infected needle is up to 30%.
Use of protective gloves can reduce the risk.

Hepatitis B - Treatment and vaccination
Medical treatment:

- Long term and not always effective

Vaccination:

- Pre-Exposure Prophylaxis (preventive)
- Post-Exposure Prophylaxis (early stage treatment)
  - Intra Muscular, 3 injections
  - Protects up to 30 years
  - Side-effects: Soreness (fever)
- Contact your doctor or vaccination center

**Hepatitis C**
Incubation time: 5 - 12 weeks
SYMPTOMS: Influenza-like symptoms, tiredness, joint pain, jaundice, dark urine, light faeces.
75-80 % of cases experience no symptoms the first weeks, month or years (sneaking infection)
60-80% of cases develops chronic hepatitis, with cirrhosis and severe liver failure

Hepatitis C is transmitted primarily via blood transmission eg. Shared needles, piercing- and tattoo needles etc.
Hepatitis C – Treatment and Vaccines

- Medical treatment: Long term and only effective 2/3 cases
- Vaccine: None

**Other pathogens (Influenza, norovirus, Clostr. Difficile, MRSA, meningitis, listeria…) transmission methods**

- Hands and skin
- Surface contact
- Airways
- Saliva, nasal mucus
- Spores
- Dirt, water and food

**Diseases that are not transmitted via blood:**

- Anemia (decrease in red blood cells)
- Coagulation disorders
- Cancer (leukemia)
- Blood platelets deficiency (bruise easily)

## 13.3.3 Safe work practice

**Cleaning instruments**
Instruments and parts must be disinfected prior to shipping
Parts that are not disinfected must be sealed off (plastic container/bag) and labelled
Bio-hazardous waste from blood-areas must not be mixed with other waste types
Waste must be labelled and marked with: Date, initials, phone no.

**Behavior and PPE**
Personal Protective Equipment (PPE) in blood area

- Always gloves and lab-coat
- Use  eye-protection if risk of splashing
- Infected equipment must not be taken outside blood-area before it has been cleaned or disinfected.
- Avoid contact with blood – even if you wear gloves. Don't touch inventory while handling blood e.g. tools, cabinet doors, (door) handles, power switches etc.

**Hand hygiene**
Before and after handling blood hand wash and/or disinfect
The consequence of poor hand hygiene are increased risk of contamination to yourself, colleagues, instruments and inventory.
PLEASE NOTE: If hand wash and disinfection is not done correctly, it is not effective!

**Hand disinfection**
Hand disinfection is used when:

- Risk of contact with blood or other biological agents (pathogens)
- When working with gloves microorganisms thrive on your skin. To prevent this use hand disinfection before and after.

Evidence of inadequate hand disinfection:

- Visible dirt or blood on your hands
- Wet hands

Note:
Disinfectants only work on the surface, and do not penetrate through dirt.
Water thins the disinfectant reducing its effectiveness.

Hand disinfection procedure:

- Use disinfectant with 70-85% ethanol and glycerol.
- Leave to work at least 30 seconds

**Hand wash**
Hand wash is performed when

- We come from outdoor environment
- Before we eat
- After WC
- we wash our hands when they are visibly dirty

Wash with soap for approximately. 1 min. to be effective

**If an accident occurs**
In case of blood in eyes, mouth or open cuts

- Wash/flush immediately with water (eye flush)
- Contact doctor/ER (1813)
- Report to EHS-representative and line manager

In case of Puncture by infected needle, glass or similar:

- Press out a drop of blood
- Wash thoroughly with water + soap
- Disinfect insert/wound with wipe 2 times (ethanol, chlorhexidine or iodine 2,5%) - remember to dry in between
- Contact doctor/ER  Vaccination and blood samples
- Report to EHS-group and line-manager!
- Need for medical assistance – call doctor/ER

# 14 TCM5 repair process

## 14.1 Introduction

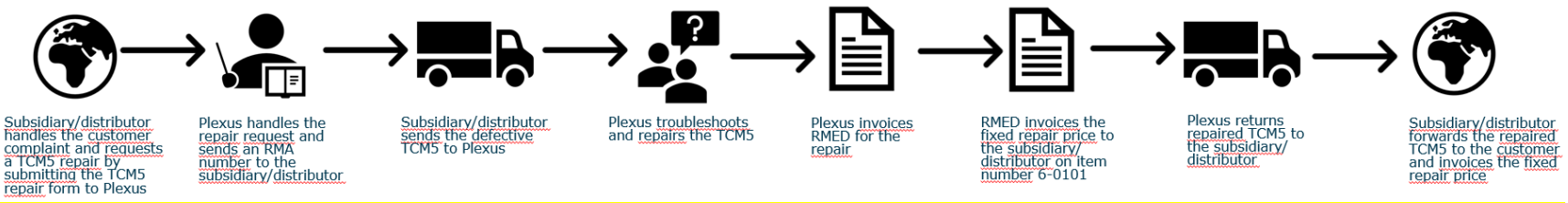
Except for the few parts that can be replaced locally, all repairs are centralized and performed by the manufacturer of the TCM5, Plexus, who is based in in Europe (Oradea in Romania).

For factory repairs of the TCM5 a “fixed repair price” business model has been chosen. This means that subsidiaries/distributors always invoice their customers a fixed price for a TCM5 repair, whatever the issue is and how it is fixed.

A TCM5 repair is initiated and handled by the subsidiaries/distributors directly. Plexus communicates only with subsidiaries/distributors (hence, not with end-users/customers) and will always return a repaired TCM5 to the subsidiary/distributor.

## 14.2 Workflow for a TCM5 repair

The repair process follows the workflow below:




## 14.3 Requesting a repair

Once the subsidiary/distributor has determined that a TCM5 issue cannot be repaired locally, a factory repair may be requested as follows:

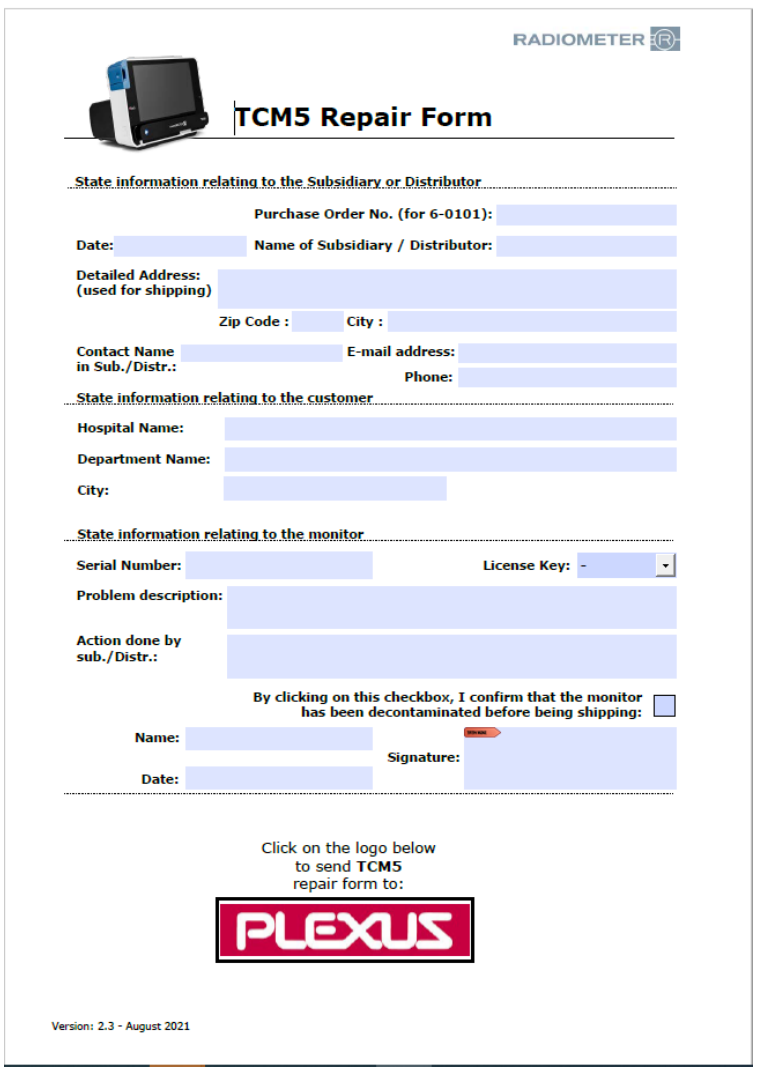
1. Place an order at RMED for a “TCM5 Monitor repair”, item number 6-0101
2. Fill in a “TCM5 repair form.pdf” (see paragraph 15.4)
3. Submit the TCM5 repair form to Plexus (by clicking the PLEXUS logo)
4. Wait for Plexus to provide a Return Material Authorization (RMA)
5. Remove the battery, the sensor, and the gas bottle from the TCM5
6. Send the defective TCM5 to Plexus:

   CRG/RMA Coordinator
   Plexus Services RO SRL
   Strada Eugeniu Carada nr. 2-4
   410610 Oradea
   Bihor, Romania
   VAT# RO25153581

## 14.4 TCM5 repair form

The TCM5 repair form can be found on the Global Services Library in TransCutaneous Monitoring/Tools & guides/TCM5 repair.
Please note that:

- All fields in the TCM5 repair form are mandatory and all text entered must be in English. Plexus may reject the form if fields are improperly filled.
- The “Contact Name” and “e-mail address” must be for a subsidiary/ distributor employee: it is used for subsequent communication with Plexus.



RADIOMETER

**TCM5 Repair Form**

State information relating to the Subsidiary or Distributor

Purchase Order No. (for 6-0101):
Date: Name of Subsidiary / Distributor:
Detailed Address: (used for shipping)
Zip Code : City :
Contact Name in Sub./Distr.: E-mail address:
Phone:

State information relating to the customer

Hospital Name:
Department Name:
City:

State information relating to the monitor

Serial Number: License Key: -
Problem description:
Action done by sub./Distr.:
By clicking on this checkbox, I confirm that the monitor has been decontaminated before being shipping:
Name:
Signature:
Date:

Click on the logo below to send **TCM5** repair form to:

PLEXUS

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# 15 PeriFlux6000 repair process

## 15.1 Introduction

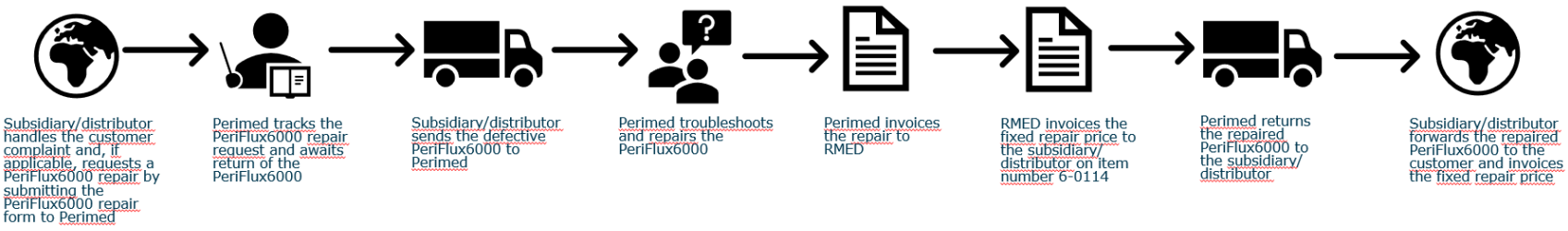
All repairs are centralized and performed by the manufacturer of the PeriFlux6000, Perimed, who is based in in Europe (Sweden).

For factory repairs of the PeriFlux6000 a “fixed repair price” business model has been chosen. This means that subsidiaries/distributors always invoice their customers a fixed price for a PeriFlux6000 repair, whatever the issue is and how it is fixed.

A PeriFlux6000 repair is initiated and handled by the subsidiaries/distributors directly. Perimed communicates only with subsidiaries/distributors (hence, not with end-users/customers) and will always return a repaired PeriFlux6000 to the subsidiary/distributor.

## 15.2 Workflow for a PeriFlux6000 repair

The repair process follows the workflow below:




## 15.3 Initial troubleshooting via an RMED support request

Prior to starting the repair workflow Perimed is to assess if the PeriFlux6000 may be repaired locally or if it should be returned for factory repair as follows:

1. Subsidiary/distributor submits a support request to RMED TPS&S as follows:
   a. CRM users: Escalate a support request in CRM
   b. Non-CRM users: Send an e-mail to product.support@radiometer.dk
2. RMED TPS&S requests Perimed to assess the PeriFlux6000 issue
3. Perimed provides instructions/conclusion to RMED TPS&S
   a. If the monitor may be repaired locally Perimed provides instructions for how to repair
   b. If the monitor must be repaired at the factory Perimed provides a “Repair reference number”
4. RMED TPS&S forwards the instructions/conclusion to the subsidiary/distributor

## 15.4 Requesting a repair

Once it has determined that a PeriFlux6000 issue cannot be repaired locally, a factory repair may be requested as follows:

7. Place an order at RMED for a “PERIMED Monitor diagnosis and repair”, item number 6-0114
8. Fill in a “PeriFlux6000 repair form.pdf” (see paragraph 16.5), including the repair reference number
9. Submit the PeriFlux6000 repair form to Perimed (by clicking the PERIMED logo)
10. Remove the battery, the sensor(s), and the gas bottle from the PeriFlux6000
11. Put the PeriFlux6000 into a shipping box and be sure to state the repair reference number on the box
12. Send the defective PeriFlux6000 to Perimed:

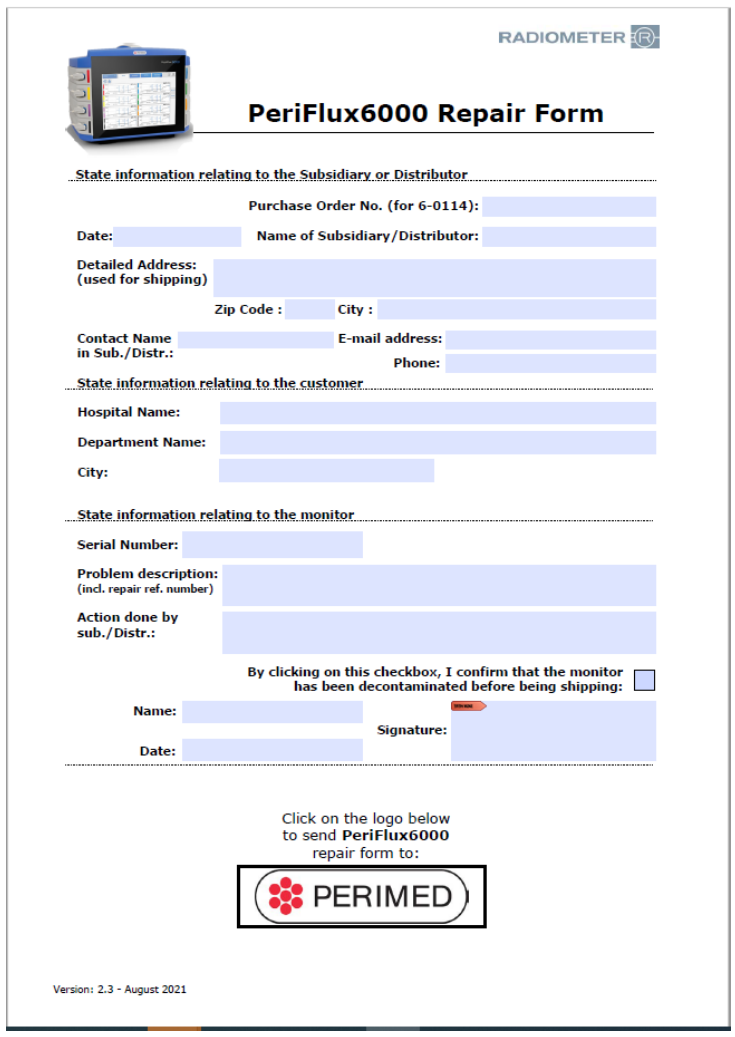
Service Department

Perimed AB
Datavägen 9 A
175 43 Järfälla
Sweden

## 15.5 PeriFlux6000 repair form

The PeriFlux6000 repair form can be found on the Global Services Library in TransCutaneous/Monitoring/Tools & guides/ PeriFlux6000 repair.
Please note that:

- All fields in the PeriFlux6000 repair form are mandatory and all text entered must be in English. Perimed may reject the form if fields are improperly filled.
- The “Contact Name” and “e-mail address” must be for a subsidiary/ distributor employee: it is used for subsequent communication with Perimed.


RADIOMETER

**PeriFlux6000 Repair Form**

State information relating to the Subsidiary or Distributor

Purchase Order No. (for 6-0114):
Date:
Name of Subsidiary/Distributor:
Detailed Address: (used for shipping)
Zip Code :
City :
Contact Name in Sub./Distr.:
E-mail address:
Phone:

State information relating to the customer

Hospital Name:
Department Name:
City:

State information relating to the monitor

Serial Number:
Problem description: (incl. repair ref. number)
Action done by sub./Distr.:
By clicking on this checkbox, I confirm that the monitor has been decontaminated before being shipping:
Name:
Signature:
Date:

Click on the logo below to send **PeriFlux6000** repair form to:

PERIMED

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