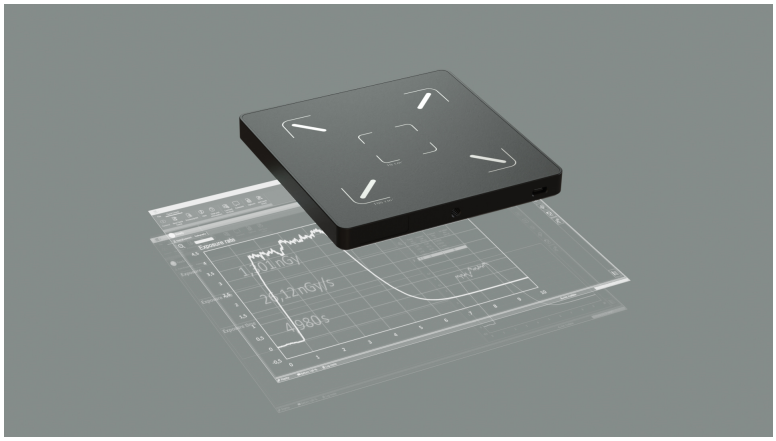
RTI Scatter Probe

Scatter & Leakage in X-ray Environment

RTI Scatter Probe User's Manual - English - Version 2021.5B



RTI document number: 4731.002128

RTI Scatter Probe

INDEPENDENT X-RAY
QUALITY ASSURANCE

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Safety Precautions and Intended Use

The RTI Scatter Probe is intended to be used for independent service and quality control, including measurements of air kerma, air kerma rate, ambient dose equivalent, mean energy, half value layer, and time, within limitations stated below.

When installed according to accompanying documents, the product is intended to be used in the area surrounding medical X-ray equipment except for:
- X-ray equipment with tube potential below 18 kV or above 160 kV.
- specific types of X-ray equipment listed in the instructions for use or in additional information from the manufacturer.

With the X-ray installation without patient present, the product is intended to be used:
- for assessing the performance of the X-ray equipment.
- for evaluation of examination techniques and procedures.
- for service and maintenance of the X-ray equipment.
- for quality control of the X-ray equipment.
- for educational purposes, authority supervision etc.

The product is intended to be used by hospital physicists, X-ray engineers, manufacturer's service teams, and other professionals with similar tasks and competencies. The operator needs training to be able to use the product as intended. This training can be achieved either by study of the manual or, on request, by a course ordered from the manufacturer.

The product is intended to be used in the area in and arround X-ray rooms ready for clinical use and can safely be left switched on and in any measuring mode in the vicinity of patients.

The product is NOT intended to be used:
- for direct control of diagnostic X-ray equipment performance during irradiation of a patient.
- so that patients or other unqualified persons can change settings of operating parameters during, immediately before, or after measurements.
- for any guidance to diagnosis of patients.

Table of Contents

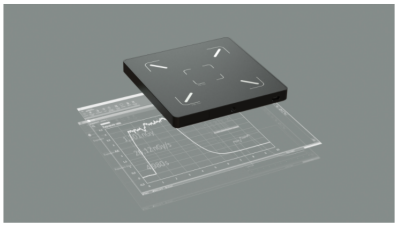
Chapter 1

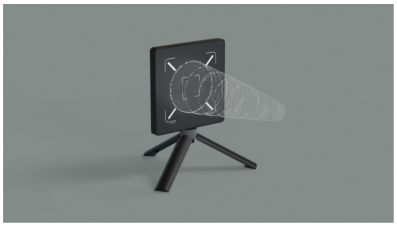
Introduction

Introduction

10 and 100 cm^2 Leakage and Scatter detector in one

The RTI Scatter Probe is a rugged, flat solid-state detector for leakage and scatter detection in x-ray environments. The unique design with two separate detector areas of 10 cm^2 and 100 cm^2 makes no trade-off in fulfilling current regulations and standards for x-ray leakage and scatter measurements.
The RTI Scatter Probe connects via USB cable to the Ocean software for reading and reporting.





Reliable Dosimetry

For barrier, leakage and scatter measurements various industry standards apply. Examples of such standards are 21 CFR 1020.30 to 21 CFR 1020.39, IEC 60601-2-3, IEC 60601-2-54, and IEC 60601-1-3. There are several more standards for various modalities. Common for all these standards is that the measurement has to be made covering an area of 10 or 100 cm^2 at a certain distance. The 10 cm^2 or the 100 cm^2 detector area of the RTI Scatter Probe ensures full compliance with these standards.
It does not matter if your scatter and leakage application requires measurements at a short distance, long distance, in a fix position or sweeping. With a click you select to use the 10 cm^2 or the 100 cm^2 area for your measurement.

Easy Positioning

Regardless if holding the probe by hand, if it stands on a table or mounting it on a tripod, the positioning is quick and simple. The included mini-tripod makes the hand-held use simple. Just flip out the feet on the mini-tripod and you have a vertical positioning. The design with anti-slip surface allows safe positioning facing upwards without sliding. With the standard camera tripod thread, the RTI Scatter Probe can be mounted to any tripod or jig.

Measurement Parameters

The RTI Scatter Probe measures following parameters.

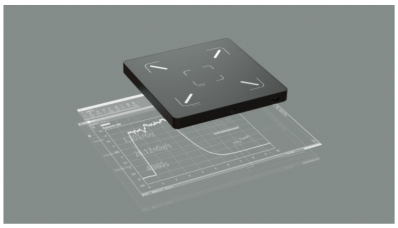
- Air Kerma
- Air Kerma Rate
- Peak Air Kerma Rate
- H*(10)
- H*(10) Rate
- Peak H*(10) Rate
- Mean Energy
- Half Value Layer
- Time

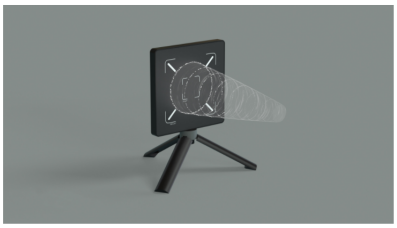
Notice: Some parameters may not be measured depending on signal level and/or radiation energy.

Chapter 2

Product Overview

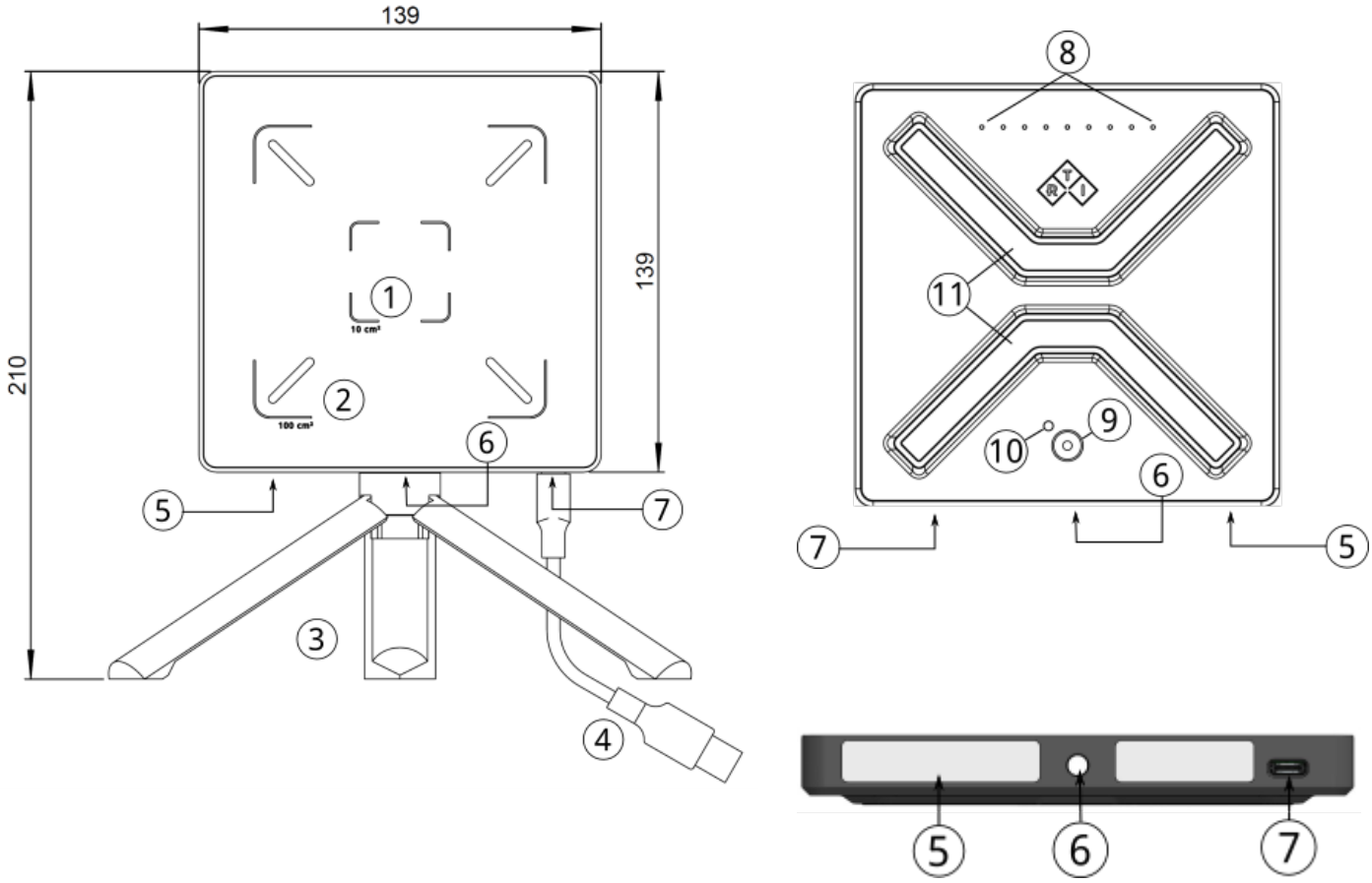
Product Overview





Indicators and parts

The images and tables below describe the indicators, connectors, and parts of the RTI Scatter Probe



Front view (left)

#	Name	Description
1	10 cm^2 detector surface	The Scatter Probe has two integrated detector areas. The center marks show the 10 cm^2 area (33.3 x 33.3 mm).
2	100 cm^2 detector surface	The outer marks show the 100 cm^2 area (100 x 100 mm).
3	Mini-tripod/handle	The Scatter Probe comes with a mini-tripod.
4	USB cable	USB A to USB C, 5 m cable (re-scaled in image).
5	Product marking	Displays detailed information about the product and model
6	Camera thread	Camera thread for mounting the Scatter Probe to the complementary mini-tripod, or any standard camera tripod.
7	USB port	USB C port for connection to display unit.

Rear view (right)

#	Name	Description
8	LED bar	A nine multi-color LED bar, serves as radiation level indicator.
9	Trig button	Button for triggering. The function of the trig button is controlled from the display device.
10	Status LED indicator	The LED (green/red) indicates the status of the Scatter Probe.
11	Rubber feet	The rubber cross on the rear of the Scatter Probe makes it safe to place the Scatter Probe on a flat surface with the detector surface facing upwards, without slipping.

The Detector surfaces (1 and 2)

The Scatter Probe has two detector areas of 10 and 100 cm^2 respectively. The area to use for a measurement is user-selectable from Ocean. The area to use depend on the application and what standard or regulation to follow.

Status indicator (10)

The Scatter Probe power on when it is connected via USB to a display unit. The status indicator turns RED when the Scatter Probe has power. During measurement with Ocean, the status indicator has various functions, see below.

GREEN	READY for radiation (in communication with Ocean).
Flashing GREEN	MEASURE. The Scatter Probe measures, either by auto-trig or manual trig.
RED	NOT ready for radiation.
Flashing RED	Pause

The LED bar (8)

The LED bar serves as radiation level indicator. The number of lit LEDs is proportional to the irradiation rate.
The sensitivity of the LED bar is user-selectable by setting the Alarm Level for air kerma rate, or for ambient dose equivalent rate. The settings are made from Ocean, see Measurement settings.

The table below describes the function of the LED indicators from left to right.

1st to 7th TURQUOISE	Irradiation rate lower than Alarm Level. Each LED corresponds to 15% of the Alarm Level. The 1st LED will light up as soon as radiation is detected.
8th Flashing ORANGE	Irradiation rate higher than Alarm Level. Range from Alarm Level to 25 mGy/h (50 mSv/h).
8th ORANGE	Irradiation rate higher than Alarm Level. Range from 25 to 50 mGy/h (50 to 100 mSv/h).
9th Flashing ORANGE	Irradiation rate higher than Alarm Level. Range from 50 to 75 mGy/h (100 mSv/h to 150 mSv/h).
9th ORANGE	Irradiation rate higher than Alarm Level. Range from 75 to 100 mGy/h (150 to 200 mSv/h).
8th and 9th Flashing RED	Detector saturation. Irradiation rate too high.

Peak Rate indication

The highest rate during the measurement is indicated on the LED bar. When highest rate during a measurement is indicated by a blue LED. The indication of the highest rate will stay lit until measurement is finished.

The trig button (9)

The trig button is controlled by Ocean. The function of the button depends on measuring mode and measuring status. The button is a pressure sensitive surface. The response of the button is indicated by the status LED (10) and a vibration.

The various functions for the trig button is described below.

Manual Mode (Free-run)	When the status LED shows constant green (ready for radiation) - Start Measure When the status LED shows flashing green  (measure) - Stop Measure
Timed Mode	When the status LED shows constant green (ready for radiation) - Start Measure
Normal Mode (Auto-trig)	The trig button is not active

Other functions

Sound

The radiation level is indicated with a crackling sound (GM-counter like sound), which is proportional to the irradiation rate. The sensitivity (changing frequency of the sound) is changed when the Alarm Level is changed, as described above. The sound can be enabled/disabled from Ocean, see Measurement settings.

Trig Mode - Post Delay

When Normal measuring mode (auto-trig) is used the radiation has to be off for 3 seconds after trig off before the Scatter Probe is ready for a new measurement. This time is called **Post Delay**. If radiation is detected before the **Post Delay** has passed, the Scatter Probe will consider the measurement not finished, and will continue to measure.

E.g:
If an interrupt between two irradiation events is < 3 s, the Scatter Probe will consider them as one event.
If an interrupt between two irradiation events is > 3 s, the Scatter Probe will consider them as separate events.

> **Notice:**
> When the irradiation rate is low and varies, and temporarily goes below the trig level for a longer period of time than the **Post Delay**, the Scatter Probe will trig off, and a new measurement may start. In such case it is advised to use Manual Mode (Free-run) or Timed Mode to avoid "false" trig off.

Chapter 3

Measure

Measure

3.1 Measuring using Ocean

The following description assumes that Ocean is installed on a computer and started. For more information about Ocean, see separate documentation.
Furthermore it assumes that measurement is performed in an X-ray environment using a diagnostic x-ray unit with open collimation.

The first measurement

Normal Mode (Auto trig)

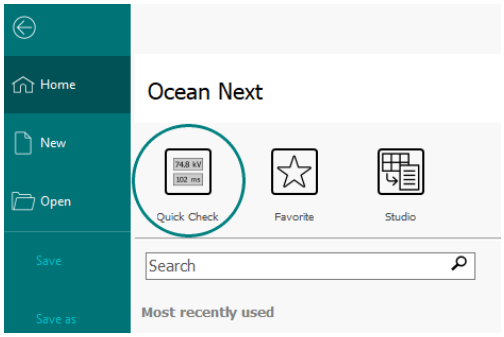
When the irradiation rate is expected to be higher than 5 µGy/h (or 10 µSv/h) during the entire measurement, Normal Mode can be used. The Scatter Probe will then auto-trig when irradiation rate is above trig level.

1. Connect the RTI Scatter Probe to the computer with an USB cable to the USB port, see Product overview.

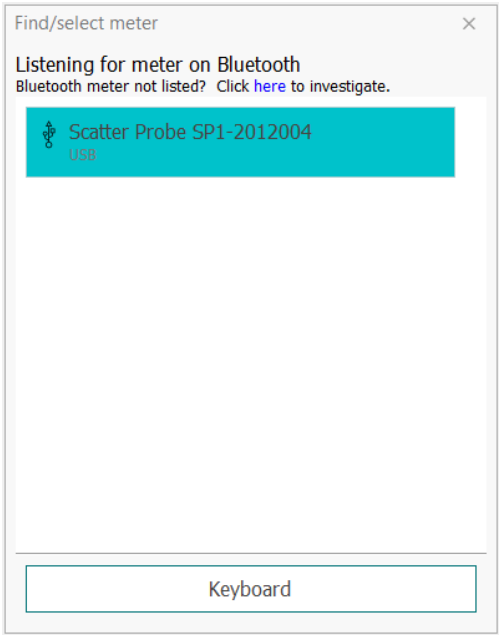
2. Start Ocean and wait for the Scatter Probe to connect.

3. Place the RTI Scatter Probe in a position about 1 m from the x-ray source with the detector surface facing the x-ray unit.

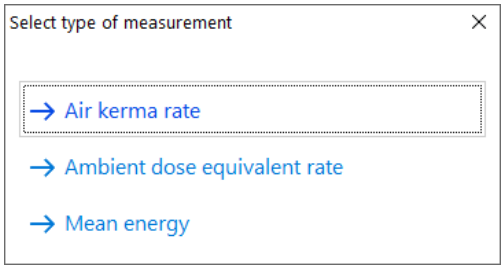
4. From the Backstage in Ocean, select Quick Check.



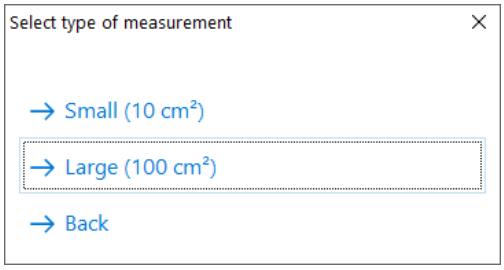
5. Select the Scatter Probe if the Find/select meter window appears.



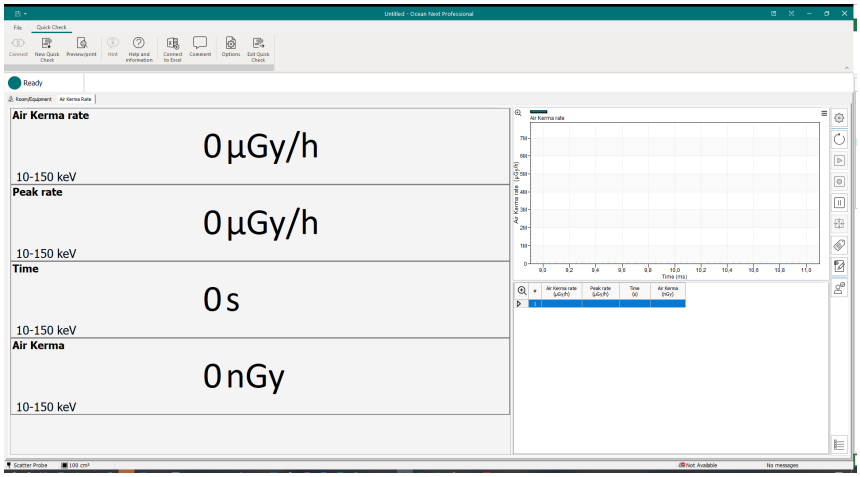
6. Select type of measurement - In this example select **Air kerma rate**



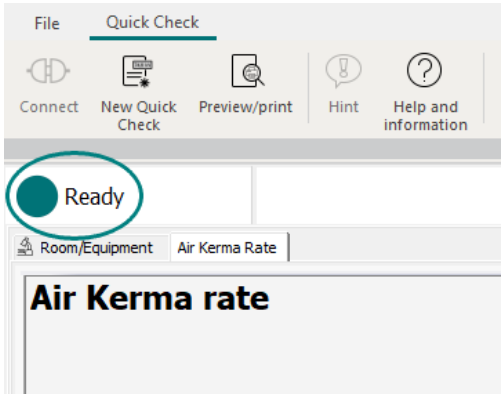
7. Select which detector area you want to use - In this example select **Large (100 cm²)**



8. The measurement screen will open.

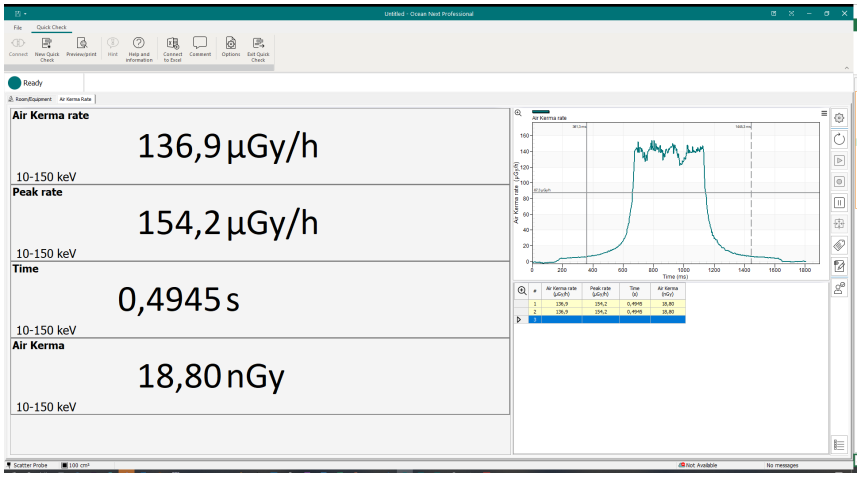


9. The Scatter Probe is ready to measure when the the Ready sign in the upper left part of the measurement screen turns green and shows Ready. The status indicator LED on the Scatter Probe will also turn green.



10. Make an exposure at an high kV, mA and time setting. E.g. on R/F system select 100 kV, 500 ms, 100 mA.

11. The display will update.



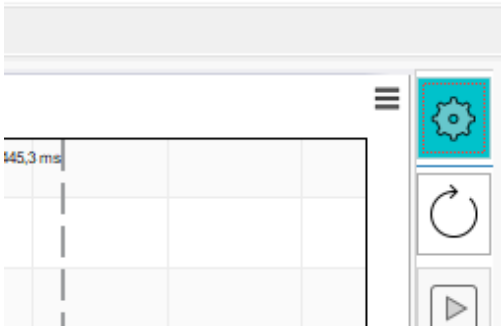
Notice:
The displayed values after end of measurement for Air Kerma (Gy) and Ambient Dose Equivalent H*(10) (Sv) represent the integrated radiation from start to stop of measurement.
The peak rate (Air Kerma rate and H*(10) rate) parameters show the highest identified value between start and stop of measurement.
The rest of the parameters (rate, mean energy, HVL) show the values from the last complete two-second period. I.e. a time frame slightly before end of measure.
If the measuring time is shorter than two seconds, all displayed values will represent the entire measurement.

Free-run (Manual trig on and off)

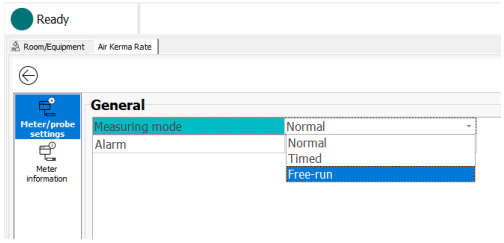
When the irradiation rate is expected to be below 5 µGy/h (or 10 µSv/h), Free-run or Timed Mode i recommended. The Scatter Probe will then be manually trigged by the user.

Assuming that the instruction for **The first measurement** above is followed until the measurement screen is open (point #8).

1. Go to Meter Settings.

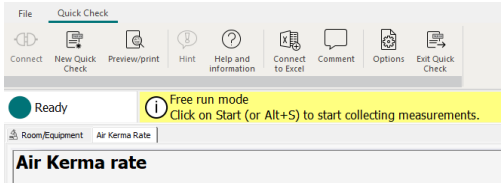


2. Select measuring mode - **Free-run**.

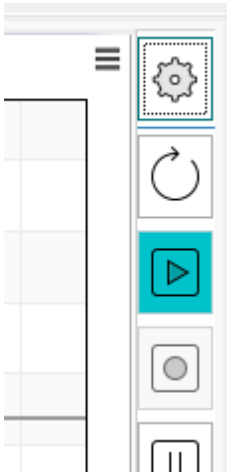


3. Press the Meter settings icon to get back to the measurement screen.

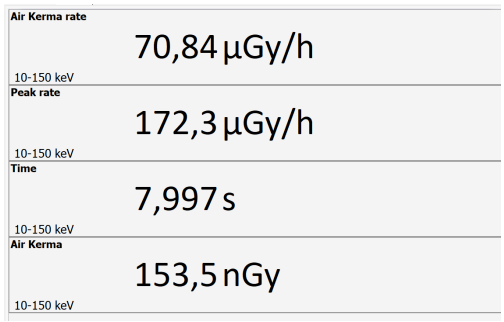
4. The Scatter Probe is ready to measure when the the Ready sign in the upper left part of the measurement screen turns green and shows Ready. The status indicator LED on the Scatter Probe will also turn green.



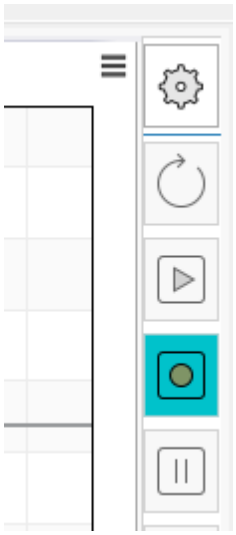
5. Start the measurement (trig on) by pressing the Start button in Ocean, or the Trig button on the Scatter Probe.



6. Measured values will update in the displays every two seconds until the measurement is stopped.



7. End measurement by pressing the Stop button in Ocean, or the Trig button on the Scatter Probe.



8. The Scatter Probe is ready for a new measurement when the Ready sign in the upper left part of the measurement screen turns green and shows Ready. The status indicator LED on the Scatter Probe will also turn green.

Notice:
The displayed values after end of measurement for Air Kerma (Gy) and Ambient Dose Equivalent H*(10) (Sv) represent the integrated radiation from start to stop of measurement.
The peak rate (Air Kerma rate and H*(10) rate) parameters show the highest identified value between start and stop of measurement.
The rest of the parameters (rate, mean energy, HVL) show the values from the last complete two-second period. I.e. a time frame slightly before end of measure.
If the measuring time is shorter than two seconds, all displayed values will represent the entire measurement.

Timed Mode (Manual trig on)

As an alternative to Free-run (see above), Timed Mode can be used. The difference is that instead of a manual stop of the measurement, a predefined measurement time is used.
Assuming that the instruction for **The first measurement** above is followed until the measurement screen is open (point #8).

1. Go to Meter Settings.

2. Select Timed Measuring Mode, and a desired measuring time window.

3. Press the Meter settings icon to get back to the measurement screen.

4. The Scatter Probe is ready to measure when the the Ready sign in the upper left part of the measurement screen turns green and shows Ready. The status indicator LED on the Scatter Probe will also turn green.

5. Start the measurement (trig on) by pressing the Start button in Ocean, or the Trig button on the Scatter Probe.

6. Measured values will update in the displays every two seconds until the measurement is finished.

7. The measurement will automatically stop after the measuring time window has elapsed.
   Alternatively the measurement can be stopped manually by pressing the Stop button in Ocean, or the Trig button on the Scatter Probe.

8. The display will update.

9. The Scatter Probe is ready for a new measurement when the Ready sign in the upper left part of the measurement screen turns green and shows Ready. The status indicator LED on the Scatter Probe will also turn green.

Notice:

The displayed values after end of measurement for Air Kerma (Gy) and Ambient Dose Equivalent H*(10) (Sv) represent the integrated radiation from start to stop of measurement.
The peak rate (Air Kerma rate and H*(10) rate) parameters show the highest identified value between start and stop of measurement.
The rest of the parameters (rate, mean energy, HVL) show the values from the last complete two-second period. I.e. a time frame slightly before end of measure.
If the measuring time is shorter than two seconds, all displayed values will represent the entire measurement.

3.2 Measurement Settings

Meter Adjust

Here general measurement settings for the RTI Scatter Probe are shown. In Quick Check these settings are found under **Meter Adjust**.

For a graphical overview of the settings, see section Waveforms and Triggers.

Measure Mode

Normal (auto trig)	The trig level of the Scatter Probe is NNN mGy/h (NNN µSv/h). When the irradiation rate is expected to be higher than the trig level for the entire measurement Normal mode is convenient to use, since no manual action is needed. After trig off the Scatter Probe and Ocean will get ready for a new measurement.
Free run (manual trig)	When Free run mode is enabled the measurement is manually started and stopped. Either from Ocean (Start/Stop) or from the trig button on the Scatter Probe.
Timed	When Timed mode is enabled the measurement is manually started. The measure time is set by the **Measuring time**. The measurement can be interrupted from Ocean (Stop). **Measuring time** is user-selectable from 1 to 300 s.

Settings

Measuring time (Timed mode)	The measurement window for a Timed measurement. Default setting is 10 s.
Measuring area	The large 100 cm^2 or the small 10 cm^2 detector area. Default setting is Large.
Activate Alarm	Yes or No Default setting is No.
Alarm-level	The Alarm-level defines the scale and signal for the LED bar as well as the crackling (GM-counter type) sound. The Alarm-level can be set in units of Gy or Sv in the range 0.01- 25 mGy/h, or 0.02 - 50 mSv/h. Default setting is 1 mGy/h.
Sound on/off	On or Off. Default setting is On.

Chapter 4

Measurement Principles & Theory

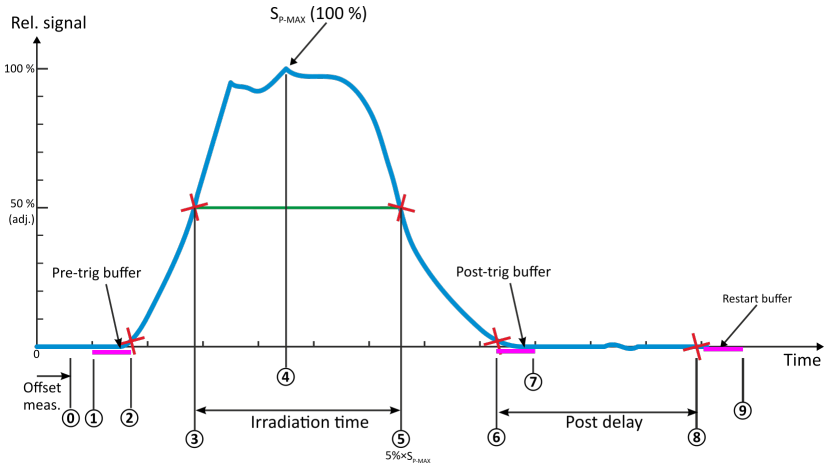
Measurement Principles & Theory

The RTI Scatter Probe has a number of measurement algorithms and applications built-in. This section describes the main measuring principles, how some values are calculated, and the basic meaning of them.

4.1 Waveforms and Triggers

Short Exposure (<2 s)

To get an understanding of how triggers, delays, and windows work, please refer to the waveform below. This illustrates a radiation measurement shorter than 2 seconds.



1. Pre-trig buffer start point. The pre-trig buffer (500 ms) is in use to avoid loosing any radiation information just before trig.
2. Trig On - The measurement starts, when irradiation rate goes over the detector's lowest trig level (or is manually started). The status LED starts flashing GREEN.
3. The signal reaches 50 % of its maximum. This is the starting point for the irradiation time calculation.
4. The signal reaches its maximum.
5. The signal goes below 50 % of its maximum. This is the end point for the Irradiation time calculation.
6. The irradiation rate goes under the detector's lowest trig level.
7. Post-trig buffer end point - A post-trig buffer (500 ms) is in use to avoid loosing any radiation information just after trig off.
8. If the signal has been below the trig level during Post delay (point 6-8, 3 sec), the exposure is considered finished. All exposure readings are calculated and displayed.
9. Restart buffer end point - During the Restart buffer the display software gets ready for a new exposure. The status LED turns RED during Restart buffer, but may not be visible due fast communication and thereby a very short Restart buffer.

Integrated signal - Air kerma and Ambient Dose Equivalent H*(10)
This is the integration of all signal which means the area below the curve above from point 1 to 7.

Irradiation time
The irradiation time is defined as the time between point 3 and 5 as described above.

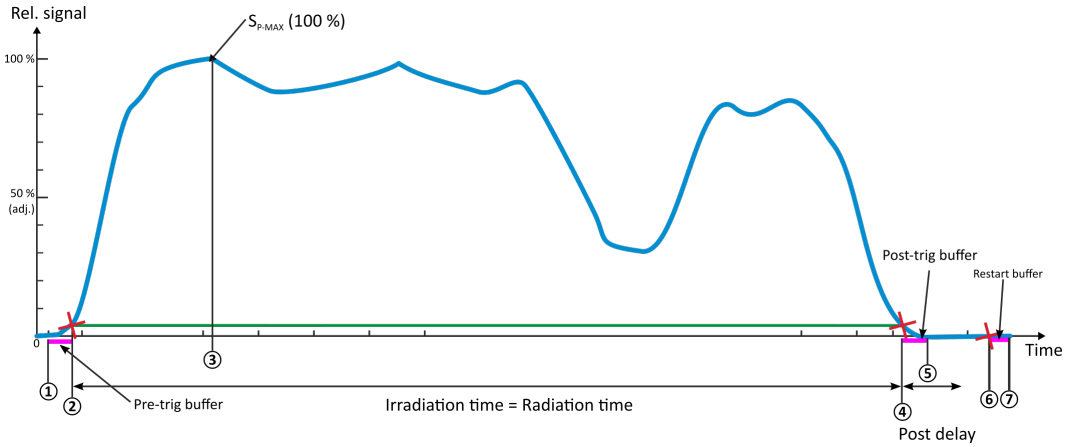
Signal rate (dose rate and H*(10) rate)
When the measurement ends, point 6 above, the average for the whole measurement is displayed. The signal rate is calculated as the integrated signal from point 1 to 7 as described above) divided by the Irradiation time (point 3 to 5).

Peak rate
The peak rate is the highest detected signal rate value during the measurement. Point 4 as described above.

HVL and Mean Energy
HVL and Mean Energy is calculated in the same window as described for Signal rate above.

Long Exposure (>2 s)

When the measurement continues for more than two seconds, the mean signal for the last two seconds is displayed every two seconds. When the measurement is over, the value from the second last update is displayed. This, to avoid trig off ramp effects in the last two seconds. See graph for long exposure below.



1. Pre-trig buffer start point. The pre-trig buffer (500 ms) is in use to avoid loosing any radiation information just before trig.
2. Trig On - The measurement starts, when irradiation rate goes over the detector's lowest trig level (or is manually started). The status LED starts flashing GREEN.
3. The signal reaches its maximum.
4. The radiation ends, i.e. it goes under the detector's lowest trig level.
5. Post-trig buffer end point.
6. If the signal has been below the trig level during Post delay (4-6), the exposure is considered finished. Final exposure readings are calculated and displayed.
7. Restart buffer end point - During the Restart buffer the display software gets ready for a new exposure. The status LED turns RED during Restart buffer, but may not be visible due to fast communication and thereby a very short Restart buffer.

Integrated signal - Air kerma and Ambient Dose Equivalent H*(10)
This is the integration of all signal which means the area below the curve above from point 1 to 5. During the measurement (exposure) the currently accumulated signal (dose, etc) is updated and displayed every two seconds.

Irradiation time
The irradiation time is defined as the time between point 2 and 4 as described above.

Signal rate (dose rate and H*(10) rate)
Every two seconds the signal rate values, representing the average rate over the last two second, is updated and displayed. When the measurement ends, point 5 above, the average values from the last complete two-second period is displayed.

Peak rate
The peak rate is the highest detected signal rate value during the entire measurement. Point 3 as described above.

HVL and Mean Energy
HVL and Mean Energy is calculated in the same window as described for Signal rate above.

4.2 Mean Energy and Ambient Dose Equivalent

Relevant parameters to be measured with the RTI Scatter Probe are Air Kerma, Ambient Dose Equivalent (H*(10)), HVL and Mean Energy. The RTI Scatter Probe algorithms are built upon a database for spectrum-specific values with the database being structured in terms of kVp and filtration.

The Air Kerma algorithm is based on reference measurements with the RTI Dose Probe and several reference ion chambers. Measurements for Air Kerma were performed at RTI's accredited calibration laboratory for radiography and mammography at RTI Headquarters in Sweden.

HVL and spectral Mean Energy are acquainted from spectrum calculations with SpekCalc and Siemens Spectrum Analyser where set values of kVp and filtration are used as input parameters for producing spectral changes in radiography and mammography, respectively.

SpekCalc is a software program for the calculation of x-ray spectra from tungsten anode x-ray tubes and is based on research articles [1] - [3]. Siemens Spectrum Analyser is a web-based service hosted by Siemens Healthcare Deutschland [4] where spectrum calculations are based on research articles [5] - [8].

Furthermore, the spectral Mean Energy is used to obtain a conversion coefficient to calculate Ambient Dose Equivalent (H*(10)) from Air Kerma by using the relationship found from [9], cf. Figure 1.

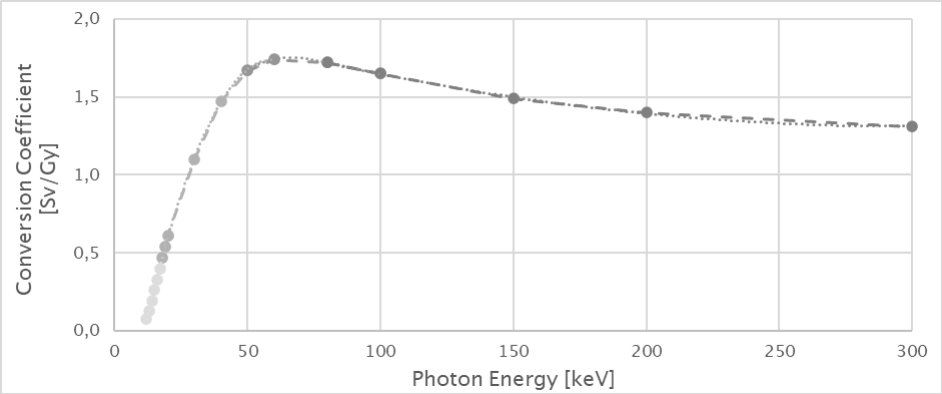


Figure 1: Conversion coefficient for calculation of Ambient Dose Equivalent, H*(10), at given photon energy.

[1] Poludniowski G, Landry G, DeBlois F, Evans PM, Verhaegen F. SpekCalc: a program to calculate photon spectra from tungsten anode x-ray tubes. Phys Med Biol. 2009 Oct 7;54(19):N433-8. doi: 10.1088/0031-9155/54/19/N01. Epub 2009 Sep 1. PMID: 19724100.
[2] Poludniowski GG, Evans PM. Calculation of x-ray spectra emerging from an x-ray tube. Part I. electron penetration characteristics in x-ray targets. Med Phys. 2007 Jun;34(6):2164-74. doi: 10.1118/1.2734725. PMID: 17654919.
[3] Poludniowski GG. Calculation of x-ray spectra emerging from an x-ray tube. Part II. X-ray production and filtration in x-ray targets. Med Phys. 2007 Jun;34(6):2175-86. doi: 10.1118/1.2734726. PMID: 17654920.
[4] health.siemens.com/booneweb/
[5] John M. Boone, Thomas R. Fewell, Robert J. Jennings: Molybdenum, rhodium, and tungsten anode spectral models using interpolating polynomials with application to mammography; Medical Physics 24(12), 1883 - 1874, 1997
[6] John M. Boone, J. Anthony Seibert: An accurate method for computer-generating tungsten anode x-ray spectra from 30 to 140 kV; Medical Physics 24(11), 1661 - 1670, 1997
[7] T.R. Fewell, R.E. Shuping: Handbook of Mammographic X-ray Spectra; HEW Publication (FDA) 79-8071; Rockville, MD (1978)
[8] T.R. Fewell, R.E. Shuping, K. Healy: Handbook of Computed Tomography X-ray Spectra; HHS Publication (FDA) 81-8162; Rockville, MD (1981)
[9] Report 57, Journal of the International Commission on Radiation Units and Measurements, Volume os29, Issue 2, 1 August 1998

Chapter 5

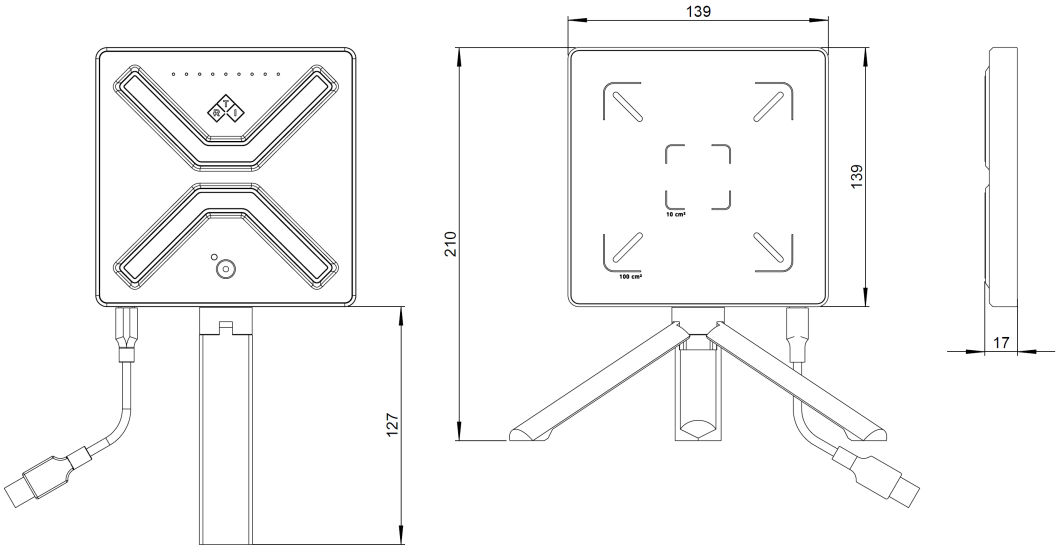
Hardware and Specifications

Hardware and Specifications

5.1 Specifications

The specifications are valid after a warm-up time of five minutes assuming reference conditions.

Dimensions



General Specifications

Connector type	USB Type C	Reference Point	5 mm below detector surface, in center of the marked detector area.
Cable	5 m, USB A to C Extendable with optional USB active extension cable.	Waveforms	Air Kerma and Ambient Dose Equivalent Max recording time 300 s
Power	5V, from display unit, via USB	Bandwidth	1 - 300 Hz
Active area	10 cm^2 and 100 cm^2	Rated Range of use	10 - 150 keV 80 - 100 kPa 10 - 40 °C 10 - 80% rel. humidity
Dimensions	139 x 139 x 17 mm		
Weight	370 g (430 g incl. handle)	Storage temperature	-10 °C to +50 °C
Trig Modes	Auto or Manual		

Measurement Specifications 100 cm^2 detector area

Parameter	Range	Expanded Uncertainty	Notice
Trig Modes	Auto or Manual		
Trig Level	5 µGy/h (0.6 mR/h) or 10 µSv/h		
Air Kerma Rate	0 - 100 mGy/h (0 - 10 R/h)	±10% or ±0.3 µGy/h (0.03 mR/h) (ISO N20-N150)	

Ambient Dose Equivalent, H*(10)	0 - 200 mSv/h	±10% or ±0.6 µSv/h (ISO N20-N150)	
Mean Energy	10 - 150 keV	±10% or 5 keV	min rate: 25 µGy/h
Half Value Layer (HVL)	0.1 - 17 mm Al	±10% or 0.05 mm Al	min rate: 25 µGy/h
Time	0-9999 s	±1% or 0.1 s	

Measurement Specifications 10 cm^2 detector area

Parameter	Range	Expanded Uncertainty	Notice
Trig Modes	Auto or Manual		
Trig Level	15 µGy/h (1.9 mR/h) or 30 µSv/h		
Air Kerma Rate	0 - 900 mGy/h (0 - 90 R/h)	±10% or ±0.9 µGy/h (0.09 mR/h) (ISO N20-N150)	
Ambient Dose Equivalent, H*(10)	0 - 1800 mSv/h	±10% or ±2 µSv/h (ISO N20-N150)	
Mean Energy	10 - 150 keV	±10% or 5 keV	min rate: 75 µGy/h
Half Value Layer (HVL)	0.1 - 17 mm Al	±10% or 0.05 mm Al	min rate: 75 µGy/h
Time	0-9999 s	±1% or 0.1 s	

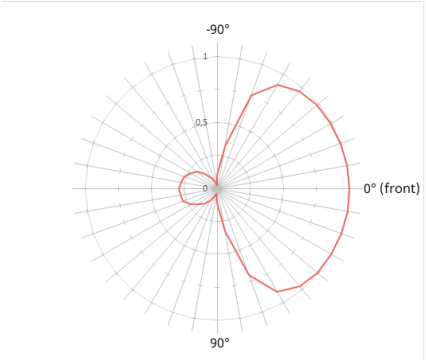
Reference conditions

Temperature:	20 °C
Pressure:	101.3 kPa
Relative humidity:	50%

Expanded Uncertainty

The expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k = 2, which for a normal distribution corresponds to a coverage probability of approximately 95%. The standard uncertainty of measurement has been determined in accordance with EAL Publication EA-4/02.

Angular Dependence



5.2 Standards and Compliances

Hereafter you can find declarations of conformity, as well as documents describing the intended use of the RTI Scatter Probe system.

5.2.1 Manufacturer's Declaration of Conformity

Declaration of Conformity

We, RTI Group AB, Flöjelbergsg. 8C, SE-431 37 MÖLNDAL, Sweden, declare under our sole responsibility that the product:

Product name:	RTI Scatter Probe
Model part number:	9631001-00
Type of equipment:	Scatter radiation detector
Intended use of this product:	According to appendix 1

is in conformity with the provisions of the following EC Directive(s):

- **2014/30/EU Electromagnetic Compatibility** (EMC) **Directive**
- **2015/863/EU Restriction of Hazardous Substances in EEE Directive** (RoHS 3)

and that the following standards and/or technical specifications referenced below have been applied:

EN 61000-4-2:2008
EN 61000-4-3:2020
EN 62368-1 + AC1:2015

CE

Mölndal, 2021-04-05

Declaration of Conformity – Appendix 1

Intended Use of the RTI Scatter Probe

The RTI Scatter Probe is intended to be used for independent service and quality control, including measurements of air kerma, air kerma rate, Ambient dose equivalent, mean energy, half value layer, and time, within limitations stated below.

When installed according to accompanying documents, the product is intended to be used in the area surrounding medical X-ray equipment except for:

- X-ray equipment with tube potential below 18 kV or above 160 kV.
- specific types of X-ray equipment listed in the instructions for use or in additional information from the manufacturer.

With the X-ray installation without patient present, the product is intended to be used:

- for assessing the performance of the X-ray equipment.
- for evaluation of examination techniques and procedures.
- for service and maintenance of the X-ray equipment.
- for quality control of the X-ray equipment.
- for educational purposes, authority supervision etc.

The product is intended to be used by hospital physicists, X-ray engineers, manufacturer's service teams, and other professionals with similar tasks and competencies. The operator needs training to be able to use the product as intended. This training can be achieved either by study of the manual or, on request, by a course ordered from the manufacturer.

The product is intended to be used in the area in and arround X-ray rooms ready for clinical use and can safely be left switched on and in any measuring mode in the vicinity of patients.

The product is NOT intended to be used:

- for direct control of diagnostic X-ray equipment performance during irradiation of a patient.
- so that patients or other unqualified persons can change settings of operating parameters
- during, immediately before, or after measurements.
- for any guidance to diagnosis of patients.

5.2.2 **FCC Certification**

Supplier's Declaration of Conformity
47 CFR § 2.1077 Compliance Information

Unique Identifier: RTI Scatter Probe, model number 9631001-00

Responsible Party – U.S. Contact Information
RTI Group North America
33 Jacksonville Road, Building 1
Towaco, NJ 07082,

USA
+1 973-439-0242
support.us@rtigroup.com

FCC Compliance Statement
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

5.2.3 **Waste Electrical and Electronic Equipment (WEEE)**

The European Union Directive 2002/96/EC on Waste from Electrical and Electronic Equipment (WEEE) places an obligation on manufacturers, distributors, and retailers to take back electronics products at the end of their useful life.
The WEEE directive covers all RTI products being sold into the European Union (EU) as of August 13, 2005. Manufacturers, distributors, and retailers are obliged to finance the cost of recovery from municipal collection points, reuse, and recycling of specified percentages per the WEEE requirements.

Instructions for disposal of WEEE by Users in the European Union

The symbol, shown left, is marked on the product, which indicates that this product must not be disposed of with other waste. Instead, it is the user's responsibility to dispose of the user's waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local distributor from whom you purchased the product.

Chapter 6

Maintenance

Maintenance

6.1 Scheduled Calibration

RTI recommends that the Scatter Probe is calibrated every 24 months. Send your Scatter Probe to your local RTI distributor, who will send it to our service department in Mölndal, Sweden, or New Jersey, USA. For contact details, please see the back of this manual or the list of local RTI distributors on the RTI website (www.rtigroup.com).

6.2 Updating the System

The system update can easily be done on any computer with support for USB memories.
Start by downloading the latest versions from www.rtigroup.com/downloads, using a web browser.

1. Unpack the downloaded RTI Scatter Probe Update zip file to a local drive.
2. Follow the installation instructions that comes with the update package. The update procedure will take a few minuets.

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