



gen2-SCA
Skin Composition Analyzer

with RiverlCon 3.2 control software

Operator Manual



gen2-SCA: 2nd generation SKIN COMPOSITION ANALYZER

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Introduction

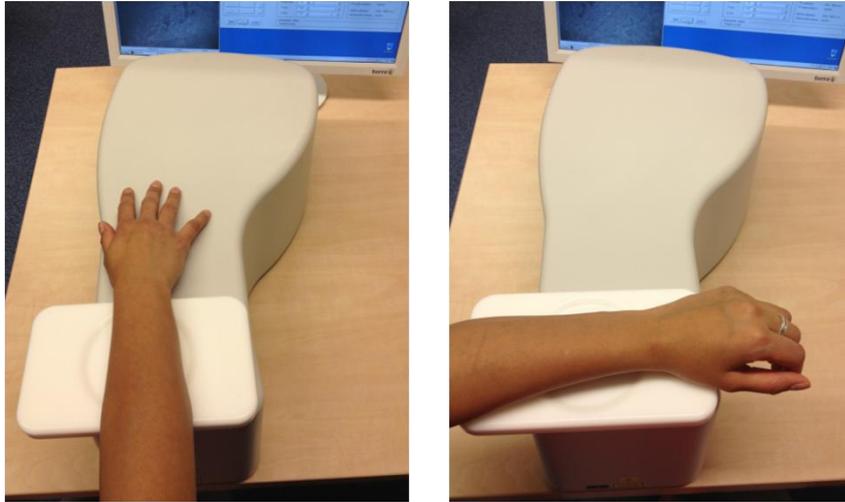
The gen2-SCA is RiverD's second generation Skin Composition Analyzer.

It is a full re-design of RiverD's successful Model 3510 SCA (introduced in 2004) and has been rigorously optimized for simple and rapid *in vivo* analysis of the molecular composition of the skin with high spatial resolution.

The re-design is based on valuable feedback from users of the Model 3510 SCA with regard to applicability to various skin areas/body locations (arm, underarm, scalp), performance (signal collection time), appearance, and user friendliness (system auto-calibration, measurement location selection).

Lasers have been integrated in the analyzer, which is connected to a power supply unit into which also various controllers have been integrated, and to a Personal Computer. Compared to the Model 3510 SCA this results in a much tidier appearance of the desk space.





The gen2-SCA is available in 3 versions which differ in system performance and capabilities:

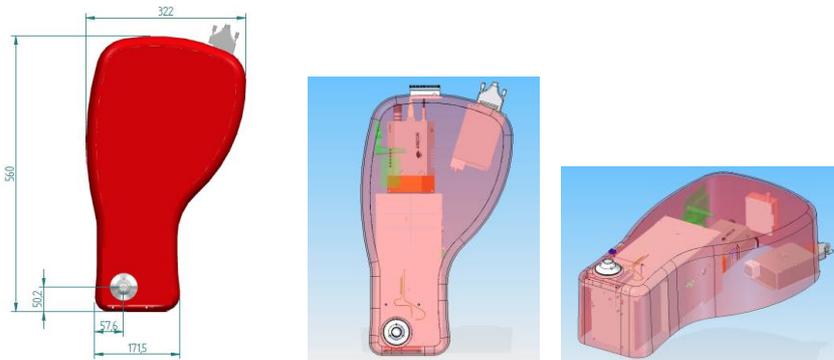
- **gen2-SCA standard:** combines the system performance features of the Model 3510 SCA with much enhanced ease-of-use and applicability to the underarm region and the scalp (by means of optional measurement supports).
- **gen2-SCA performance:** features a 4 times higher signal intensity than the gen2-SCA standard for significantly reduced signal collection time, or higher spectral quality.
- **gen2-SCA ultimate:** features the system performance features of the gen2-SCA performance + high spatial resolution mode (3 μm depth resolution), and enhanced depth range (0 ~ 500 μm).

	Model 3510 SCA	gen2-SCA standard	gen2-SCA performance	gen2-SCA ultimate
relative signal intensity	1	1	4	4
<i>laser power on skin 785nm (mW)</i>	25 (+/- 5)	12 (+/- 2)	25 (+/- 5)	25 (+/- 5)
<i>laser power 671nm (mW)</i>	18 (+/- 2)	9 (+/- 2)	18 (+/- 2)	18 (+/- 2)
depth range (μm)	0-200	0-200	0-200	0-500
depth resolution (μm)	5	5	5	3-5
system auto-calibration	✗	✓	✓	✓
measurement location selection	1D, 100 micron resolution	2D, 5 micron resolution	2D, 5 micron resolution	2D, 5 micron resolution
accessibility underarm	✗	✓	✓	✓
accessibility scalp	✗	✓	✓	✓

gen2-SCA system

The gen2-SCA system comprises

- an analyzer unit containing:
 - 2 laser sources
 - a High Performance Raman Module
 - a cooled scientific CCD-camera
 - a dedicated measurement stage for skin measurements
- a power supply unit
- a Windows 7-compatible Medical PC and user interface
- RiverIcon 3.2 analyzer control software
- SkinTools 2.0 data analysis software



*Top view and side view of the gen2-SCA system: dimensions in mm, weight: approx. 17 kg.
Note: artist impression of work in progress: final design may differ from image shown*

Lasers

- 785 nm laser source (for measurements in the 400-2400 cm^{-1} spectral region).
- 671 nm laser source (for measurements in the 2400-4000 cm^{-1} spectral region).

Note:

For optimum stability of laser coupling, laser power, and laser wavelength, the system should be operated in a normal laboratory environment ($T_{\text{room}} = 19\text{-}24^\circ \text{C}$). Rapid environmental temperature changes and mechanical shocks should be avoided.



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High Performance Raman Module (HPRM+)

The HPRM+ has been designed and rigorously optimized for highly efficient and reproducible Raman measurements of biological tissue. It delivers laser light to the analyzer measurement stage through a confocal pinhole and receives Raman scattered light back from the sample through the same confocal pinhole.

CCD-detector System

High sensitivity 1024 x 128 pixels NIR detector system, thermoelectrically cooled to approximately -65° C (no liquid coolant required).

Measurement stage

The measurement stage, is an inverted microscope stage, which has been optimized for spatially resolved, high precision, *in vivo* confocal Raman measurements of the skin. It contains a immersion microscope objective which focuses laser light in the skin through an optical window on which the skin rests. The objective also collects Raman scattered light from the skin.

The measurement stage comprises:

- a custom designed proprietary 1.2 numerical aperture NIR-Raman optimized microscope objective.
- high precision, fast and durable translation stage for the microscope objective, enabling automated acquisition of measurements at a range of distances to the skin surface enabling determination of molecular concentration profiles.
- ergonomic housing and sample platform, enabling unobstructed subject positioning.
 - the system comes with a standard detachable support. This support carries the weight of the body part on which measurements take place, while the skin area of interest is in contact with the measurement window of the analyzer.
 - the standard support can be replaced by optional dedicated supports for measurements on the scalp, the underarm area, or the arm.
- a built-in video-imaging system providing a magnified view of the skin surface that is in contact with the measurement window. The video-image can be used for selection of measurement locations to with a resolution of about 2 micron (in 2 directions).

Personal Computer,

CE certified for use in Medical Devices. Includes appropriate capabilities for use with system hardware and software. Microsoft Windows 7 based operating system.

RiverIcon vs 3.2 system operating software*:



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The instrument control software provides an easy-to-use graphical user-interface for defining measurement settings, real-time analysis of measurement results and for initiating analyzer auto-calibration.

RiverIcon 3.2 features comprise:

- Spectral data acquisition
- Depth scanning control
- CCD camera control
- Spectrum preprocessing and real-time data analysis
- System auto-calibration
- auto-preparation of data for Remote Instrument Health Monitoring purposes

Collected data can be analyzed off-line with SkinTools 2.0 data analysis software* including:

- Excel sheet based input of Raman spectra, sorted by the different experimental variables.
- plotting and browsing of spectral data, processing parameters and results.
- export of spectra in ASCII format
- automated, customizable outlier detection.
- standard RiverD International analysis methods for the generation of depth concentration profiles of water, free amino acids and other main components of untreated skin (stratum corneum).
- flexible calculation of various depth profiles based on user-definable integration of single Raman peaks.
- user definable expansion of the standard RiverD International analysis methods with components other than the endogenous skin constituents.
- various ASCII output formats for the depth concentration profiles, enabling easy interfacing to further data analysis software for statistical analysis and cross correlation to other skin measurements:

**Note:*

Non-exclusive, single-user licenses to RiverIcon 3.2 and SkinTools 2.0 are included in the sales price of the gen2-SCA.



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gen2-SCA system performance metrics

Laser power from measurement window

- 785nm:
 - 12 (+/- 2) mW (standard)
 - 25 (+/-5) mW (performance, ultimate)
- 671nm:
 - 8 (+/- 2) mW (standard)
 - 16 (+/- 4) mW (performance, ultimate)
- Depth Resolution:
 - 5 (+/- 0.5) μm (standard, performance)
 - 3 (+/- 0.5) μm
or 5 (+/- 0.5) μm (ultimate, user selectable)
- Depth Range:
 - 0-200 μm (standard, performance)
 - 0~500 μm (ultimate)
- HPRM+
 - laser suppression: > 8 O.D.
 - signal throughput*: > 70% throughout the 400-4000 cm^{-1} spectral range, independent of signal polarization.
**Note: signal throughput from HPRM entrance pinhole to CCD-detector, comprising laser suppression stage and spectrometer*
 - spectral range
 - 400 - 2500 cm^{-1} (with 785 nm laser excitation)*
** Note: spectral range shown and analyzed in real time 400-1800 cm^{-1}*
 - 2500 - 4000 cm^{-1} (with 671 nm laser excitation)
 - spectral Resolution 5 cm^{-1} or better over entire spectral range
- CCD-camera:
 - quantum efficiency up to 45% (standard)
 - quantum efficiency up to 90% (performance, ultimate)



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Other

Safety

The gen2-SCA complies with international laser safety standards. Low power laser light is employed, which makes the device eye-safe (class 2M laser device) and skin-safe.

The laser power at the sample complies with the maximum permissible exposure levels for skin (< 30mW for 785nm, and < 20mW for 671nm) defined by the international laser safety standard*.

* *EN ISO 60825-1: 2007, Safety of laser products - Part 1: Equipment classification and requirements*



CAUTION! The gen2-SCA is a Class 2M laser device. **Do not stare into the laser beam or view with magnifying optics.**

The Class 2M classification indicates that the instrument is eye safe provided the blink and aversion responses work. Do not purposely stare into the laser beam or look at it through magnifying optics such as binoculars or a magnifying glass.

EN ISO 60825-1: 2007, Safety of laser products - Part 1: Equipment classification and requirements

The gen2-SCA is CE-marked and is compliant with electrical safety standards and electromagnetic compatibility standards for medical devices.

Installation

Expert RiverD International personnel will carry out the system installation at the customer's laboratory.

Operator/Application training

One full day of instrument operator training is included and will be provided by RiverD International personnel at the time of installation at customer's laboratory.

Remote Instrument Health Monitoring

Included in the training is an instruction for RiverD International's instrument 'Remote Instrument Health Monitoring'-service. This service, which is a part of RiverD International's service & support package, is offered free of charge during the warranty period.

Telephone and email service and software support

Consultation by telephone and email on service and software problems will be provided free of charge during the warranty period.



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Available service contracts after warranty period

See document: 2014 RiverD service & support program - Skin Composition Analyzers.pdf

Documentation

All system documentation is provided in English only.

Power requirements

The system requires a single standard power outlet (100-240V).

Supplies and tools

RiverD International recommends for proper operation use of cleaning fluid (lab-grade 97% ethanol), lens tissue paper (Edmund optics lens tissue – commercial grade, www.edmundoptics.com) and a laser power meter (e.g. Thorlabs: PM100USB - USB Power and Energy Meter Interface for C-Type Sensors + S130C - Slim Photodiode Power Sensor, Si, 400 - 1100 nm, 500 mW, or PD3003W calibrated head with an Ophir Nova II Display, alternatively a PD200 head can be used, www.ophiropt.com). The laser power meter is critical for proper maintenance and instrument health monitoring of the gen2-SCA.

Environmental requirements

This instrument is intended for use in a normally clean laboratory environment. It contains precision optics that should not be exposed to airborne dust. No liquid nitrogen or other liquid coolant is required for the CCD detector. No water-cooling is required for the lasers or any other components. For stable and reliable laser operation the room temperature should normally be in the range of 19-24° C. Conditions of very high humidity should be avoided. Temperature and mechanical shocks should be avoided.

Warranty

12 months, materials and workmanship for all RiverD International manufactured equipment.

Optional items

1. Dedicated measurement supports

Ergonomic detachable support for scalp measurements (support is fixed to the analyzer)



Ergonomic detachable support for underarm measurements (support is fixed to the analyzer)



2. Comprehensive 2-day training course

gen2-SCA operation & data analysis for up to 5 people

3. 1-day system maintenance course

gen2-SCA 1-day system maintenance training course

System tree

gen2-SCA performance configuration

