

Directions for Use

REFERENCE TARGET PRODUCT FAMILY

Concentration Targets:

RCS-xxx-xxxx-QUELxx (Standard and Mini)

Depth Targets:

RDS-xxx-xxxx-QUELxx (Standard and Mini)

Resolution Targets:

RRT-xxx-xxxx-QUELxx

Radiometric Emitter Targets:

RRL-xxx-xxxx-QUELxx

Associated kits containing above products



1. Scope

- a. This document is intended to inform the customer on the normal, day-to-day use and care of this product. Please don't hesitate to contact QUEL Imaging at info@quelimaging.com if there are questions not answered here.

2. Warnings

- a. The QUEL Imaging Reference Target Product Family is intended for use in **characterizing** fluorescence imaging systems. Products should neither be used as the basis for **calibrating and adjusting** clinical imaging systems nor in clinical care.

3. Intended Use

QUEL Imaging supports the following uses for these products:

- a. Concentration Targets
 - i. Assessment of the fluorescence sensitivity of an imaging system.
 - ii. Characterization of the imaging system's range of linearity, where an increase in fluorophore concentration is matched by a proportional increase in fluorescence intensity.
 - iii. Identification of the noise floor of a fluorescence imaging system.
 - iv. Identification of the saturation point of a fluorescence imaging system.
 - v. For more technical details, please see: Directions for Use and/or Use Guide at our [Downloads and Resources Page](#)

b. Depth Targets

- i. Characterization of a fixed fluorescence signal's relationship to depth through material with specific optical properties.
- ii. For more technical details, please see: Directions for Use and/or Use Guide at our [Downloads and Resources Page](#)

c. Resolution Targets

- i. Evaluation of the fluorescence resolution capability of an imaging system.
- ii. Measurement of the depth of field (DoF) by positioning the target at varying heights while maintaining a fixed focus, thereby determining the range over which the system maintains adequate focus.
- iii. For more technical details, please see: Directions for Use and/or Use Guide at our [Downloads and Resources Page](#)

d. Radiometric Emitter Targets

- i. Optimization of fluorescence capture during the development of an imaging system by mimicking fluorescence emission without requiring laser excitation.
- ii. Detection and tracking of photobleaching of fluorescent targets and phantoms over time by providing a stable radiance reference.
- iii. Determination of the radiance level of a fluorescent signal using the characterized radiance output of the target.
- iv. Characterization the spatial light collection efficiency (relative illumination) of an imaging system by placing the target at multiple positions around the field of view.
- v. Constraint of the gain setting in longitudinal fluorescence imaging studies with systems that have an auto-gain feature.
- vi. For more technical details, please see: Directions for Use and/or Use Guide at our [Downloads and Resources Page](#)

4. Product Limitations

a. GENERAL:

- i. The QUEL Imaging Reference Target Product Family is designed for use in research, evaluation, and demonstration environments – at no time should these products be used in clinical care.
- ii. All QUEL products containing fluorophores will undergo some photo-bleaching – for details on specific fluorophore bleaching rates, please refer to the information below:
 - ICG-01: 80% of initial fluorescence intensity remaining at 3.4mWhr/cm². 50% of initial fluorescence intensity remaining at 14mWhr/cm². Contact us for more information at info@quelimaging.com

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- Q800-01: In-process. Contact us for more information at info@quelimaging.com
 - Q700-01: In-process. Contact us for more information at info@quelimaging.com
- iii. All QUEL Imaging products will experience some small change in performance over time (shelf-stability). For details of specific fluorophore shelf stability, please refer to the information below:
- ICG-01 products: Have been measured to have less than $\pm 5\%$ variation in fluorescence signal over 12 months – provided they're kept in darkness and at room temperature (20-25°C). Prolonged exposure to temperatures above 27°C should be avoided to ensure the shelf-stability of this product.
 - Q800-01 products: Have been measured to have less than $\pm 5\%$ variation over 12 months – provided they're kept in darkness and at room temperature (20-25°C). Prolonged exposure to temperatures above 27°C should be avoided to ensure the shelf-stability of this product.
 - Q700-01 products: In-progress. We anticipate similar stability to other QUEL products. Contact us for more information (info@quelimaging.com).
- b. Concentration Targets: These targets provide a fixed number of data points (i.e., concentrations) to evaluate an imaging system's fluorescence sensitivity. For this reason, analysis can only provide estimates of desired metrics. Contact QUEL Imaging to inquire about custom phantoms with specific fluorophore concentration ranges at sales@quelimaging.com
- c. Depth Targets: These targets evaluate the change in fluorescence intensity with depth; however, their specific geometry does not allow for assessing the spatial spread or blurring of fluorescence with depth or the fluorescence depth sensitivity related to in-vivo geometries. Contact QUEL Imaging to inquire about Depth Resolution Targets at sales@quelimaging.com
- d. Resolution Targets: In order to characterize the spatial resolution across the imaging system's field of view, the target may need to be imaged and analyzed in multiple locations.
5. Radiometric Emitter Targets: The radiance output of these targets may vary beyond the specified stability if imaged while being illuminated, particularly at high irradiance. This depends on the power and wavelength of the illumination source. QUEL Imaging recommends the customer perform an output stability evaluation prior to using the target in an environment where it is being illuminated at high irradiances for prolonged periods. For details, please contact us at info@quelimaging.com to inquire about the respective RET target stability testing protocol.

6. Storage

- a. Targets should be stored at room temperature (20 to 25°C) and in complete darkness to prevent photobleaching. QUEL Imaging recommends storing the targets in their original shipping packaging for storage.

7. Handling/Care

- a. All Targets: Targets should be handled with gloves to avoid getting dirt and oils on the imaging surfaces. Avoid prolonged skin contact.
- b. Concentration, Depth, and Resolution Targets: Clean imaging surfaces with isopropyl alcohol and soft lint-free material.
- c. Radiometric Emitter Targets:
 - i. Remove dust from the emitting surface using gentle air (e.g., an air bulb) – DO NOT clean surface with isopropyl alcohol or other liquids.
 - ii. There are no user-serviceable parts – DO NOT open the LED housing or the attached power supply. Warranty will be void if opened.
 - iii. We recommend annual re-characterization RET radiance output. Email sales@quelimaging.com to inquire about re-characterization services.