

Reference Target Design Change Notice:

Increasing usability + traceability & enabling ISO 13485 certification

Summary: The design of our standard fluorescence reference targets (Concentration Sensitivity, Depth Sensitivity, and Resolution) have been updated to the new "Version 3" targets. **The main design of the targets remains largely unchanged** with new changes implemented to 1) maximize the usability of the targets 2) minimize manufacturing variability 3) provide ISO 13485 compliant product traceability and 4) enable scalable manufacturing of custom targets (fluorescence properties, fluorophore concentration, optical properties, and form-factor).



Version 3 Changes: Modifications from the V2 design

The form factor of our targets remains the same:

Concentration Sensitivity - $50 \times 50 \times 20 \text{ mm}^3$ with 10 mm (\emptyset) wells at the imaging aperture Depth Sensitivity- $50 \times 50 \times 20 \text{ mm}^3$ with 10 mm (\emptyset) wells at the imaging aperture Resolution - $25 \times 25 \times 20 \text{ mm}^3$ with USAF1951 resolution test chart

The fluorescent material formulation remains the same: There are no changes to the ICG-mimicking fluorescent material such that the V3 and V2 targets share the same fluorescence excitation-emission properties as well as absorption (μ_a) and reduced scattering (μ'_s) coefficients.

Black base material change: The black base material has been changed to simultaneously provide ISO 13485 compliant traceability and enable custom-form factor manufacturing. The change in the manufacturing process of the black bases also provides tighter dimensional tolerances and enables monitoring of the manufactured material optical properties. This new material provides similar handling, optical properties, and background signal to the V2 material.

Concentration Sensitivity target change: The QD800 quantum dot well has been replaced by a 60 nM ICG-equivalent well, increasing the concentration datapoints available for determining system linearity and eliminating the manufacturing environmental hazards associated with quantum dots. The QD800 well was initially included to provide a relative method for detecting target photobleaching; our new radiometric emitter target now provides quantitative photobleaching monitoring alongside enhanced radiometric characterization of imager response.

Well #	V3	V2 (superseded)
1	1000 nM	1000 nM
2	300 nM	300 nM
3	100 nM	100 nM
4	60 nM	30 nM
5	30 nM	10 nM
6	10 nM	3 nM
7	3 nM	1 nM
8	1 nM	Control
9	Control	OD800

Depth Sensitivity target change: The non-fluorescent depth material has been changed to provide updated optical properties, integrate the new mold material manufacturing, and enable the scalable production of targets with application-specific optical properties. Furthermore, the new manufacturing process associated with the V3 design improves target-to-target variability and enables simultaneous monitoring of the manufactured material properties.

V3 standard optical properties: $\mu_a \sim 0.018 \text{ mm}^{-1} \mu_s' \sim 1.4 \text{ mm}^{-1}$ @ 800 nm V2 optical properties: $\mu_a \sim 0.010 \text{ mm}^{-1} \mu_s' \sim 1.9 \text{ mm}^{-1}$ @ 800 nm

Note: additional formulations are in development to mimic application-specific tissue optical properties (i.e. lung, muscle, fat, etc)

Resolution target change: The only change implemented in the V3 design is the new black base material.

Updated Reference Target Set







