3DQuorum® Software Health Canada Addendum

This addendum adds additional information required by Health Canada for the use of 3DQuorum on the Selenia® Dimensions® and 3Dimensions™ systems. Place this addendum with your User Guide for future reference.

3DQuorum Reader Study Information

The safety and efficacy of the 3DQuorum product image was demonstrated in a multi-reader, multi-case (MRMC) clinical validation study. Fifteen readers with a range of clinical and tomosynthesis experience participated in the study. All readers were required to be board-certified, with at least 2 years of experience reading Tomosynthesis images, MQSA-qualified, and representative of the intended users. Cases were selected for subjects who will meet the following criteria:

- Indicated for a mammography exam
- Female
- Any ethnicity

Cases excluded from the training data and validation data were based on the following exclusion criteria:

- Abnormal lesion size larger than 2 cm
- Abnormality with symptomatic and palpable lesions
- Breast Implants
- Patient with pacemakers in the mammography field of view
- Skin markers
- Motion during imaging
- Cut-off anatomy
- Prior surgery and/or presence of biopsy clips visible in imaging
- Studies with missing standard views or reports

The clinical study specifically excluded cases that would be thought to possibly bias the primary analysis of accuracy and/or are relatively rarer in the population, for example:

Women with previous breast surgery (which have a prevalence of <3% of the population) are known to have much higher recall rates than the general population; large lesions 2cm or larger are expected to be detected easily by all forms of mammography and thus are not useful to assess sensitivity impacts, especially when attempting to establish non-inferiority specifically;

Cases with cutoff and motion are generally considered to not be of diagnostic quality and thus would not be clinically accepted for primary interpretation by a physician; etc.

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3DQuorum Algorithm use of Artificial Intelligence (AI)

The 3DQuorum algorithm uses artificial intelligence to detect potentially clinically relevant features (e.g., bright spots, radiating lines, rounded dense objects) to be given additional weight in the processed 6mm SmartSlices.

While the clinical study excluded image data with certain criteria described above, the training image data for AI excluded only a subset of those criteria. Here are the criteria for exclusion for training image data:

- Abnormal lesion size larger than 5 cm
- Breast implants and pacemakers in the field of view
- Cut off anatomy

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