

LANDAUER®

June 23, 2023

Customer Communication – Please Follow the microSTAR®ii Medical Dosimetry System User Manual

Dear Customer:

LANDAUER® has received reports that some customers may not be following the instructions in the microSTAR®ii Medical Dosimetry System User Manual (User Manual). We would like to remind our customers about some important elements of the microSTAR®ii Medical Dosimetry System (microSTAR®ii system), which includes the nanoDot component, as described in its User Manual. You can access the User Manual on our website at <https://www.landauer.com/microstarii>.

The LANDAUER® microSTAR®ii Medical Dosimetry System is intended for use in measuring dose on-phantom or on-patient in medical dosimetry applications, such as radiotherapy and diagnostic radiology. When used to measure patient dose, the system is used to provide a **secondary** verification of radiation dose as a means of Quality Control for the primary dose calculation method.

Most significantly, the output of the microSTAR®ii system is not intended to be used to adjust the dose to the patient. Instead, the microSTAR®ii system User Manual states that the “system should only be employed as one of a number of tools in a program of quality assurance for the primary dose verification systems”. The User Manual state that “[i]f a discrepancy is identified, further investigation and a root cause analysis must be performed, which would include a check of the primary dosimetry system and possibly verification of the radiation emitting device output levels and calibration. Results obtained using a secondary dose verification system should never be used to direct patient care decisions.”

Additionally, the nanoDot™ component, a dosimeter that is used with the microSTAR®ii reader and software, is for single-use when used with patients. Per the User Manual, “[t]he nanoDot™ dosimeter used in the microSTAR®ii Medical Dosimetry System is manufactured as a single-use” component when used with patients: “Due to the potential for changes in dosimeter performance with accumulating life-time dose, LANDAUER® and its affiliates do not support reuse of the nanoDot dosimeter for use with patients.”

Finally, there are other instructions in the User Manual, including those related to daily quality assurance procedures performed on the microSTAR®ii system itself, that should be referenced and followed.

Please also note that this communication does not alter the voluntary ship hold implemented in April. We are working diligently to resolve issues we had discovered. We do not have an updated timeline as of now but will provide one as soon as possible.

Thank you for your patience and for being a valued customer. If you have any questions regarding this communication, please contact LANDAUER Customer Service at 1-800-323-8830 and custserv@landauer.com.

Sincerely,

Brian P. Malone

Brian Malone, Sr. Director of RA/QA