

# Medtronic

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Dear Valued Customer,

We are aware of the 2015 joint communication distributed to healthcare stakeholders related to relative humidity (RH) levels lower than 30%. ASHRAE (American Society of Heating, Refrigerating, and Air-Conditioning Engineers) revised its international standard for HVAC design parameters by expanding the minimum end of the operating room environmental RH range to 20%. The change was made to accommodate facilities where dry environmental conditions occur, such as those subject to cold weather or desert environments. However, the majority of hospitals are able to maintain 30% or already have equipment in place that maintains the 30% humidity level.

The User's Guides provided with several of our electrosurgical generators state in the section labeled "Operating Parameters" that the relative humidity should be 30% to 75% non-condensing, which was the prevalent standard when these units were designed.

To conform to the revised specification request from ASHRAE, the Valleylab™ FT10 and ForceTriad™ energy platforms have been tested at a broad set of relative humidity and temperature conditions and validated to perform under expanded parameters.

Please be advised:

- The Valleylab™ FT10 and ForceTriad™ energy platforms now have revised specifications in the United States to support operation between 15% and 85% relative humidity. The testing was performed with a temperature range of 10° C to 40°C.
- The Sonicision™ cordless ultrasonic dissection devices state a relative humidity of 10%-85% non-condensing on the packaging and in the IFU. The testing was performed with a temperature range of 10° C to 30°C.
- Our reusable LigaSure™ handpieces, LigaSure™ Dolphin Tip, and LigaSure Atlas™ state a relative humidity of 0%-75% non-condensing on the packaging. The testing was performed with a temperature range of -34° C to 65°C.
- As some of our newer LigaSure™ devices have labeling that indicates different recommended levels than the ASHRAE standards, it should be noted that the intended use condition limits considered are 10° C to 40° C at 10% relative humidity to 95% relative humidity.

This letter was created to address concerns related to the expanded ASHRAE guidelines, and to provide customers with guidance to support the use of certain Valleylab™ electrosurgical generators under a broader range of operating conditions.