May 7, 2020

Re: Emergency Use of Aperio WebViewer and Aperio GT 450 Next Generation Scanner

Dear valued customer,

Your continued safety is very important to us at Leica Biosystems. We are pleased to make you aware that we have received notification from the FDA about its intention to exercise enforcement discretion when the Aperio WebViewer, our web-based viewing software within the Aperio eSlide Manager software platform, is used for remote diagnosis with images acquired on Aperio GT450, Aperio AT2 or Aperio AT2 DX digital pathology scanners. This is in response to the COVID-19 pandemic. This application will allow Pathologists maximum flexibility to safely view and diagnose Pathology cases from remote locations using readily available consumer monitors at home.

The enforcement discretion for remote diagnosis is in line with recent guidance from Centers for Medicare and Medicaid Services (CMS), which announced on March 26, 2020 that pathologists may review slides remotely if certain defined conditions are met. For additional details see: <a href="https://www.cms.gov/files/document/gso-20-21-clia.pdf-0">https://www.cms.gov/files/document/gso-20-21-clia.pdf-0</a>

You may use the Aperio WebViewer web-based viewing software at remote locations via a secure VPN. You may also provide your own PC and monitor as long as they meet the minimum specifications provided by Leica Biosystems. Please see <u>Aperio WebViewer</u> remote use specifications, which include minimum specifications for monitors and PCs, as well as recommended brand name monitors. If you would like to order the Dell monitor (Dell model MR2416) that comes with our Aperio Viewing Station directly from Leica Biosystems, please contact your sales representative and reference part number 2316365.

We care for your safety and we hope that remote use of the Aperio WebViewer will allow you to perform your important healthcare services from an alternate location during the COVID-19 pandemic. As the COVID-19 response is changing rapidly, we are evaluating additional ways to support customers during this time.

For Aperio WebViewer specifications, business and product updates related to COVID-19 please visit the Leica Biosystems website: <a href="https://www.leicabiosystems.com/covid-19-update/">https://www.leicabiosystems.com/covid-19-update/</a>

For further information, please use the following contact information:

Aperio Technical Support at 1-844-534-2262, option 2.

Leica Biosystems sales representative information at 1-760-539-1154.

Sincerely,

Lance Mikus, MBA | Product Management Leader - Scanners and Clinical Systems

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