

LEICA BIOSYSTEMS COMMUNICATION

April 3, 2020

Re: FDA's Enforcement Discretion Allowing Use of ImageScope DX Viewing Software for Remote Diagnosis During COVID-19 Emergency

Dear valued customer,

Your safety is very important to us at Leica Biosystems. We are pleased to inform you that Aperio ImageScope DX with images acquired on Aperio AT2 DX scanners can be used for remote diagnosis. In response to the COVID-19 pandemic, Leica Biosystems has received notification from the U.S. Food & Drug Administration (FDA) that our AT2 DX System can be used for remote diagnosis under emergency use. Emergency use will allow Pathologists to diagnose cases from remote locations in response to the COVID-19 pandemic. The emergency use of 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: <https://www.cms.gov/files/document/qso-20-21-clia.pdf-0>.

You may use your existing Aperio AT2 DX viewing station at remote locations via a secure VPN. Please see Aperio ImageScope DX remote use specification. If you would like additional Aperio AT2 DX viewing stations (Part Number 23DX-VWS), please contact your sales representative.

We care for your safety and we hope that remote use of ImageScope DX 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 business and product updates related to COVID-19 please visit the Leica Biosystems website: <https://www.leicabiosystems.com/covid-19-update/>

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For further details, please use the following contact information:

Aperio Technical Support at 1-844-534-2262 or contact your
Leica Biosystems sales representative at 1-760-539-1154.

Sincerely,

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

Advanced Staining & Imaging Solutions | **Leica Biosystems**

1360 Park Center Drive | Vista, CA 92081, USA

T: +1.760.655.3809

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