

Monitors cleared by FDA

For use with Sectra Digital Pathology Module for primary diagnosis (USA only)

1. About this document

This document lists monitors cleared by FDA for use with Sectra Digital Pathology Module for primary diagnosis (USA only).

2. Document change history

Version	Date	Changes
4.0	9 June 2022	Baseline version
6.0	April 2024	Added monitor Dell U3223QE for images from Aperio GT 450 DX for Sectra Digital Pathology Module (3.3) – DPAT (3.3)
7.0	May 2024	Included information on monitors Dell MR2416 and Barco MDPC-8127 from document version 4.0.

3. Monitor model

The technical summary in the table below is only included for a quick overview.
Please consult the technical specification provided by the monitor vendor for details.

Monitor model	DPAT (version ¹)	Scanner model		Technical summary				FDA reference	Required settings – sRGB color mode
		Aperio AT2 DX	Aperio GT 450 DX	Size	Resolution	Refresh rate	Built in QC sensor		
Dell MR2416	DPAT (2.3)	x		24"	2 MP (1920 x 1200)	60 Hz	No	K193054 ²	Use with sRGB icc profile, see 5 <ul style="list-style-type: none"> • Mode: Standard • Brightness: 75 • Contrast: 75
Barco MDPC-8127	DPAT (2.3)	x		27"	8 MP (3840 x 2160)	120 Hz	Yes	K203364 ³	Use with sRGB icc profile, see 5 <ul style="list-style-type: none"> • Mode: sRGB
Dell U3223QE	DPAT (3.3)		x	31.5"	8 MP (3840 x 2160)	60Hz		K232208 ⁴	For monitor IVD labels, see 6 Brightness set to 90 Use with sRGB icc profile, see 5 <ul style="list-style-type: none"> • Mode: sRGB

¹ Sectra Digital Pathology Module (DPAT) where the version numbering refers to the release in which the Indications for Use was introduced.

² https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193054.pdf

³ https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203364.pdf

⁴ https://www.accessdata.fda.gov/cdrh_docs/reviews/K232208.pdf

4. Additional instructions

Each monitor must be installed, configured, and calibrated in accordance with the instructions from the monitor vendor.

If there are additional instructions required for use together with Sectra Digital Pathology Module, this is noted in the table above and described further in the section below.

5. sRGB ICC profile for monitor output

For monitors that require an sRGB icc profile the recommendation is to use the default ICC profile included in Windows 10 (sRGB IEC61966-2.1).

To see which profiles are available on the system, use the following procedure:

1. Open “Display settings” (e.g. by right clicking the Windows Desktop).
2. Click “Advanced display settings”.
3. Click “Display adapter properties for <Display>”.
4. “Color Management” tab → “Color Management...”

In this view it is possible to add and remove color profiles to the system, as well as set which profile should be used as default. If there are multiple color profiles available, it is possible to select which one to use from the “Display settings” menu.

6. Monitor IVD label from Leica

For Dell U3223QE, Leica takes responsibility for recalls, since the specified Dell monitors are not FDA Cleared Displays under product code PZZ.

Leica Biosystems Field Service Engineers will provide customers with labels to affix to qualified monitors. This label indicates “for IVD Use” and includes the Leica Biosystems contact information. Leica Biosystems Field Service Engineers will affix the label during installation if the monitor is available at that time.

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