

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

3. Monitor models

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	Technical summary				FDA reference	Required settings – sRGB color mode
	Size	Resolution	Refresh rate	Built in QC sensor		
Dell MR2416	24"	2 MP (1920 x 1200)	60 Hz	No	K193054 ¹	Use with sRGB icc profile, see 5 <ul style="list-style-type: none"> Mode: Standard Brightness: 75 Contrast: 75
Barco MDPC-8127	27"	8 MP (3840 x 2160)	120 Hz	Yes	K203364 ²	Use with sRGB icc profile, see 5 <ul style="list-style-type: none"> Mode: sRGB

¹ https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193054.pdf

² https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203364.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.

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