IQ/OQ Test Procedure for Integrated Barcode Scanners
GEX Doc# 100-278

1.0 PURPOSE

1.1 Provides instructions for installation qualification of the Integrated Barcode Scanner. The Integrated Barcode Scanner attached to the dosimeter holder baseplate inside the sample compartment of the Evolution 220 Spectrophotometer, the Evolution One Plus Spectrophotometer or the GENESYS 30 Spectrophotometer; the integrated barcode scanner is used to scan the unique ID of each dosimeter using the printed barcode. The scanner can scan 1D barcode (DoseStix) and 2D barcode (GEX B3).

2.0 SCOPE

2.1 The procedure is specifically for the Integrated Barcode Scanner used with the Evolution Series dosimeter holder system or the GENESYS 30 dosimeter holder system to scan the DoseStix dosimeter or the GEX B3 dosimeter barcodes.

3.0 FREQUENCY

- As needed for IQ and OQ of the barcode scanner as part of the DoseControl Dosimetry System.

- As needed for re-qualification after removal of the integrated barcode scanner from the instrument.

4.0 MATERIALS

4.1 Installed DoseControl dosimetry system hardware for the Evolution-DoseControl or GENESYS 30-DoseControl Dosimetry System including:

- Integrated Barcode Scanner – make/model: Datalogic Matrix 120 (GEX P/N: P4390)

- Evolution Spectrophotometer (GEX P/N: P4300)
    - Dosimeter holder baseplate for Evolution (GEX P/N: P4330)
    - If using DoseStix type dosimeters:
        - DoseStix Scanner mounting bracket and Datalogic Matrix 120 Barcode for Evolution (GEX P/N: P4390)
        - DoseStix dosimeters holder for Evolution (GEX P/N: P4332)
    - If using GB3 type dosimeters
        - GEX B3 Scanner mounting bracket for Evolution (GEX P/N: P4339)
        - GEX B3 dosimeters holder for Evolution (GEX P/N: P4345)

- GENESYS 30 Spectrophotometer (GEX P/N: P4400)
    - Dosimeter holder baseplate for GENESYS 30 (GEX P/N: P4405)
    - If using DoseStix type dosimeters
        - DoseStix Scanner mounting bracket and Datalogic Matrix 120 Barcode for GENESYS 30 (GEX P/N: P4450)
        - DoseStix dosimeters holder for GENESYS 30 (GEX P/N: P4410)
    - If using GB3 type dosimeters

- ▪ GEX B3 Scanner mounting bracket and Datalogic Matrix 120 Barcode for GENESYS 30 (GEX P/N: P4452)

- ▪ GEX B3 dosimeters holder for GENESYS 30 (GEX P/N: P4430)

- Three (3) dosimeter samples of each dosimeter type to be used for dosimetry.

- Datalogic DL.CODE Software (recommended, but optional)

- PC Workstation running Windows 10/11

5.0 PREREQUISITES

- The scanner has been installed in accordance with *GEX Doc #100-132 P4390 / P4450 Datalogic Matrix 120 Barcode Scanner – Product Specification and Usage (PSU)*. The scanner's serial number is printed on the back of the scanner.

- The user has downloaded and installed the Datalogic DL.CODE software on to the workstation, as instructed in *GEX Doc #100-132, P4390 / P4450 Datalogic Matrix 120 Barcode Scanner – Product Specification and Usage (PSU).* Alternately, GEX DoseControl software must be installed and operational on the user's PC.

6.0 PROCEDURE

Use *GEX Doc# 100-279 Integrated Barcode Scanner IQ/OQ Test Form* to record the results of each test case.

6.1 Confirm the Integrated Barcode Scanner is installed and operating correctly.

6.1.1   Plug the scanner into one of the computer's USB ports.

6.1.2   Wait approximately 20 seconds for the scanner to initialize. The scanner will be ready to operate once the steady green Run LED appears on the hardware. (See example in *Figure 1* below).
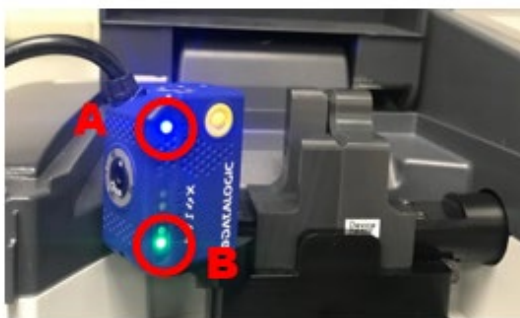

Figure 1

6.2 Enter actual results for the following in GEX Doc #100-279, TEST 1: After the scanner initializes, confirm the scanner device displays:

A.   Power indicator - The blue power LED light is on and steady.

B.   Ready indicator - The green status indicator LED light is on and steady.

6.3 Confirm the Integrated Barcode Scanner communicates correctly with the computer.

6.3.1 Launch the Datalogic DL.CODE software or GEX DoseControl software. Locate the connected scanner information; confirm the information is correct including the device serial number.

6.3.2 DL.CODE should locate the scanner automatically on start-up. Click on the scanner device name in the left column to view the instrument details:
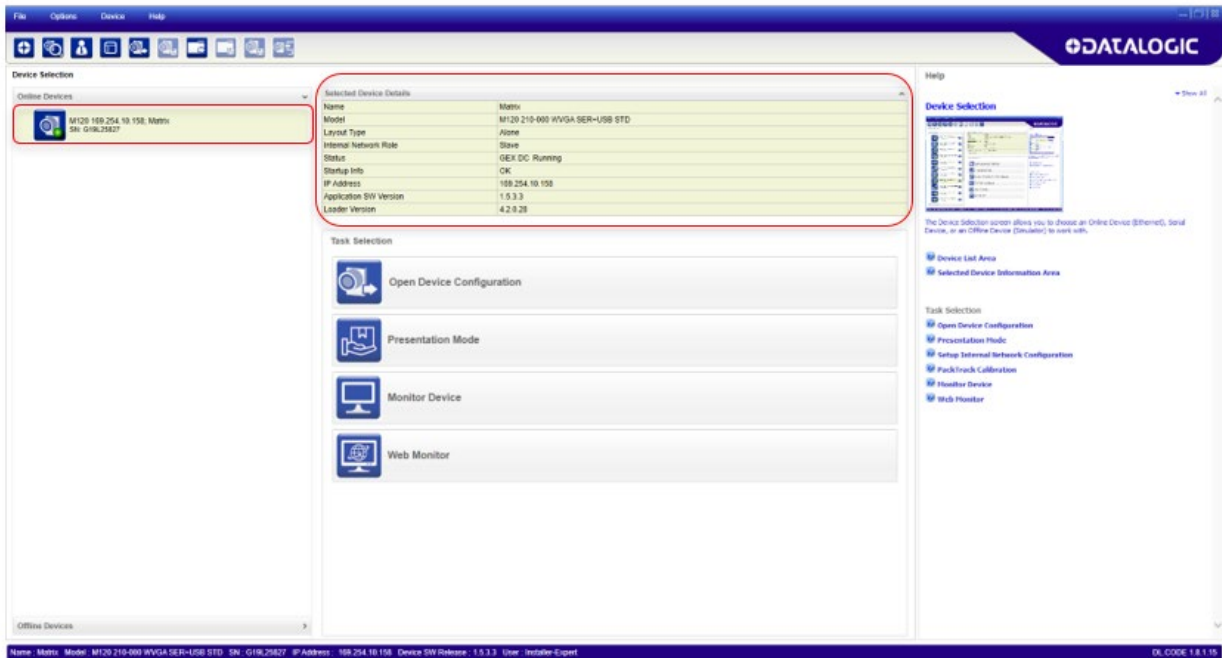
6.3.3 DoseControl will display the scanner details in the Reader configuration:
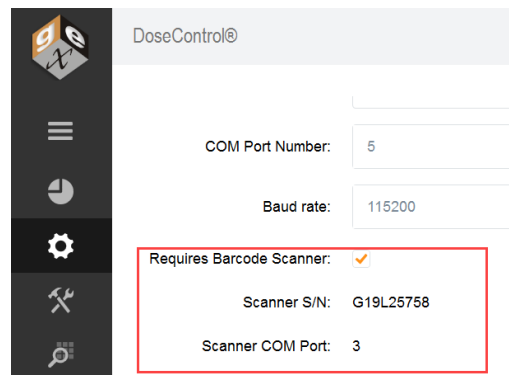
6.4 <u>**Enter actual results for the following in TEST 2:**</u> Confirm the scanner type and serial number displayed are correct. Capture a screenshot as evidence.

6.5 **Confirm the Integrated Barcode Scanner correctly and accurately scans the GEX dosimeter barcode ID.**

6.5.1 Place the dosimeter holder in the spectrophotometer.

6.5.2 The Integrated Barcode Scanner scans the GEX dosimeter barcode.

dosimetry solutions

6.5.3 <u>Use either the DL.CODE software (section 3.3.1) or DoseControl software (section 3.3.2) for this test.</u> **Enter actual results for the following in TEST 3:** Confirm the scanner correctly and accurately scans GEX dosimeter barcodes for the 3 dosimeter samples. The dosimeter ID must match the value scanned. Capture a screenshot as evidence.

6.5.4 DL.CODE instructions:

6.5.4.1 Place the first dosimeter sample in the holder, with the barcode facing the scanner.

6.5.4.2 In DL.CODE, ensure the device is connected and click on the "Open Device Configuration" screen. DL.CODE will open the Automatic Setup window for the scanner. The scanner will enter Continuous Mode, and its strobe will start to pulse.
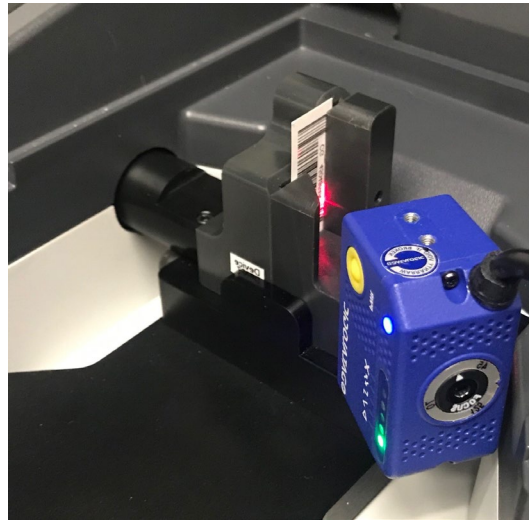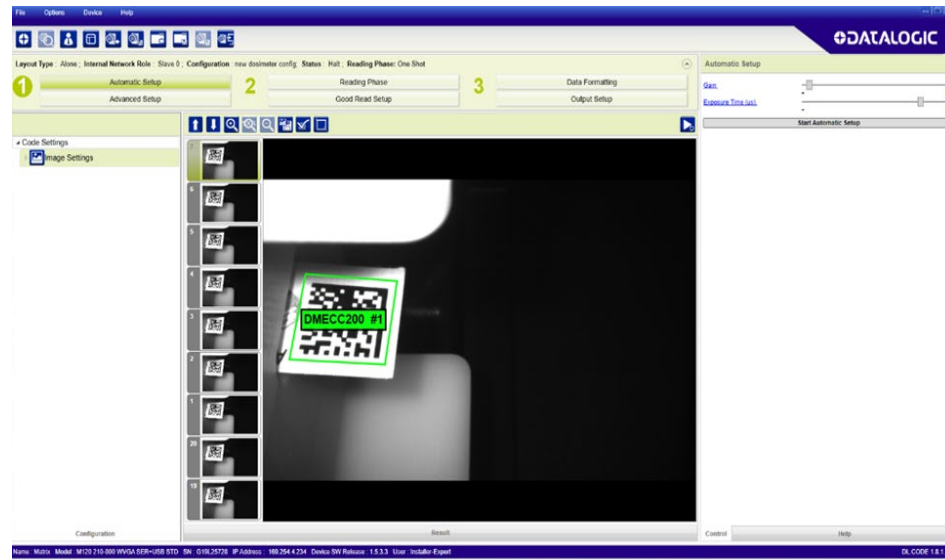

6.5.4.3 Good scans will appear with a green highlight around them in the Result window. Click the pause button. Capture a screenshot as evidence of a good scan, with the green highlight around the barcode in the Result window.

6.5.4.4   Repeat the above instructions two more times for a total of three (3) barcoded dosimeters. Take a screenshot of each scan and ensure the scan capture matches the dosimeter barcode sample for each test.

6.5.5   DoseControl software instructions:

6.5.5.1   Create a new dosimetry report in DoseControl. Allow the spectrophotometer to zero, and then place the first DoseStix dosimeter sample in the holder with the barcode facing the scanner.

6.5.5.2   Click the "Measure" button. The dosimeter barcode ID is captured in DoseControl and displays in the dosimeter list on the screen.

6.5.5.3   Repeat these instructions two more times for a total of three (3) GEX dosimeters. Take a screenshot of the dosimeter list in DoseControl.

6.6 Acceptance Criteria and Disposition of IQ/OQ Testing

6.6.1   If one or more tests fails, then the complete test case fails.

6.6.2   Disposition the entire results test as "Pass" or "Fail" on the results form GEX Doc# 100-279. Sign and date the form.

6.6.3   Have a qualified person review this procedure and the results. The reviewer must sign and date the form.

6.7 Procedure in Event of Failure

6.7.1   If there is any failure, it is likely that there is an issue with the focus setting of the scanner. Alter the focus setting on the scanner and view scan results in the DL.CODE Automatic Setup window. Review the installation steps.

6.7.2   Repeat the entire procedure. Always retain any failed test results.

6.7.3 If you experience repeated failure, contact GEX Customer Service for technical support at support@gexcorp.com.

6.8 IQ/OQ of the Internal Barcode Scanner is complete.

6.8.1 The integration of the barcode Scanner with the DoseControl software is verified as during DoseControl software OQ (see *GEX Doc# 100-280, DoseControl IQ/OQ Protocol for DoseControl Dosimetry System*).

RELATED DOCUMENTS

- GEX Doc #100-132, P4390/P4450 Matrix 120 Barcode Scanner – Product Specification and Usage (PSU).

- GEX Doc# 100-156, P4300 Evolution 220 Spectrophotometer – Product Specifications and Usage (PSU)

- GEX Doc# 100-159, Evolution 220 Dosimeter Holder System – Product Specifications and Usage (PSU)

- GEX Doc #100-167, P4400 GENESYS 30 Spectrophotometer – Product Specifications and Usage (PSU)

- GEX Doc #100-168, GENESYS 30 Dosimeter Holder System – Product Specifications and Usage (PSU)

- GEX Doc# 100-279, Integrated Barcode Scanner IQOQ Test Form

- GEX Doc# 100-280, DoseControl IQ/OQ Protocol for DoseControl Dosimetry System

REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
04/28/2021	Initial release. ECO 70571	A
07/07/2021	• Prerequisites and Procedure sections changed to include the use of GEX DoseControl software in addition to DL.CODE in the test case. • Procedure and Test Form test case steps simplified to improve usability. ECO 70579	B
08/29/2023	• Added section numbers throughout document. • Replaced reference of Evo220 with 'Evolution' throughout document. • 4.0 added reference to GB3 type dosimeters and GEX P/N P4339, P4345, P4452, P4430). Added 'PC workstation running Window 10/11'. • 6.0 replaced reference of Matrix 120 with 'integrated barcode scanner'. • Added information about the GEX B3 vs DoseStix mounts for the Matrix in both the Evolution and GENESYS 30 sections. • Added scanning 2D barcodes on the new GEX B3 dosimeter. ECO 70641.	C