

IQ/OQ Test Procedure for Integrated Barcode Scanners

GEX Doc# 100-275

1.0 PURPOSE

To provide instructions for installation qualification of the MS-2 Barcode Scanner, as part of the Evolution 220 dosimeter holder system. The MS-2 Barcode Scanner is integrated into the sample compartment of the Evolution 220 Spectrophotometer, and used to scan the unique ID of each DoseStix dosimeter using the printed barcode.

2.0 SCOPE

The procedure is specifically for the MS-2 Barcode Scanner used with the Evolution 220 dosimeter holder system supplied by GEX.

3.0 FREQUENCY

- 3.1 As needed for IQ and OQ of the barcode scanner as part of the DoseControl Dosimetry System.
- 3.2 As needed for re-qualification after removal of the scanner from the instrument.

4.0 MATERIALS

- 4.1 Installed DoseControl dosimetry system hardware including:
 - 4.1.1 Evolution 220 Spectrophotometer (P4300)
 - 4.1.2 Dosimeter holder baseplate (P4330)
 - 4.1.3 Scanner mounting bracket and MS-2 Barcode Scanner (P4360)
 - 4.1.4 DoseStix dosimeters holder (P4332)
- 4.2 DoseStix dosimeter samples
- 4.3 Microscan ESP Software (see below)

5.0 PREREQUISITES

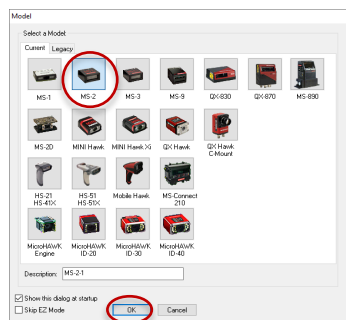
- 5.1 The scanner has been installed in accordance with the procedure in *GEX Doc #100-166, P4360 MS-2 Integrated Barcode Scanner – Product Specification and Usage (PSU)*.
- 5.2 The user has downloaded and installed the latest version of Microscan ESP Software: <https://www.microscan.com/en-us/products/barcode-software-and-connectivity/esp-easy-setup-program-software>. (Refer to the *Microscan MS-2 CCD Reader User Manual* for details).

6.0 PROCEDURE

- 6.1 Open the Microscan ESP software by double-clicking the icon.



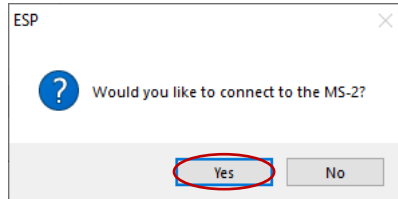
- 6.2 Select the MS-2 model and press "OK" (see image below).



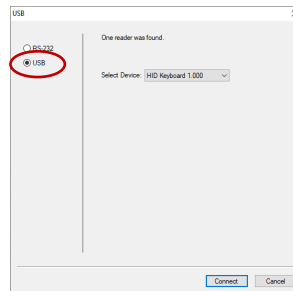
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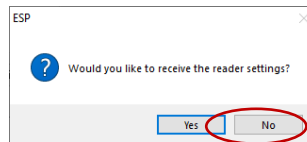
6.3 A dialog box appears asking if you would like to connect to the MS-2 (see image below). Select “Yes”.



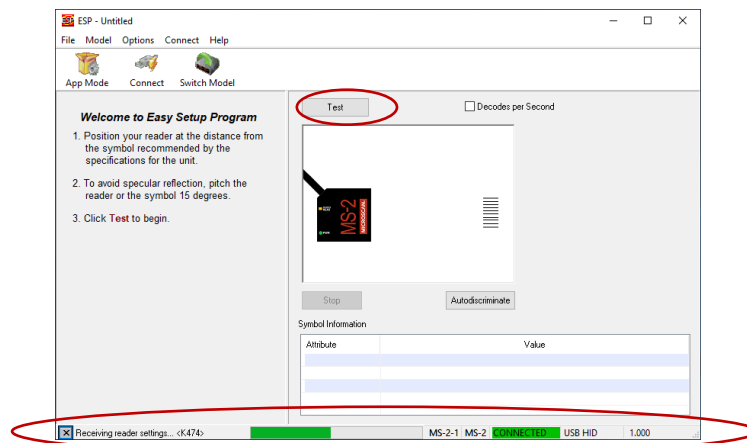
6.4 Select the “USB” radio button the window that opens (see image below).



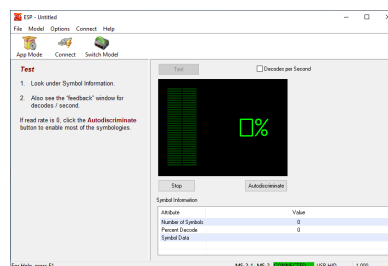
6.5 A dialog box appears asking if you would like to receive the scanner settings (see image below). Select “Yes”.



6.6 The software receives the settings and displays “CONNECTED” at the bottom (see image below).



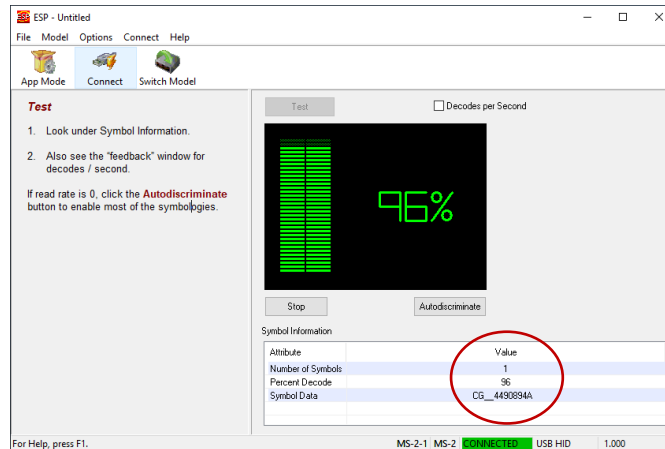
6.7 Select the “Test” button to begin operation. The screen changes the display.



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- 6.8 Insert a DoseStix dosimeter into the DoseStix holder. The signal will register after a couple seconds. The signal may continue to fluctuate a little, let the variation settle down.



- 6.9 Take a screenshot of the result. Copy and paste it into IQ Test Result #1 box in *GEX Doc# 100-274, Integrated Barcode Scanner IQOQ Test Form*.
- 6.10 Check 'Pass' or 'Fail' for the Test Result #1.
- 6.11 Repeat the test two more times with two additional DoseStix dosimeters (use different serial numbers from the sample used in the first test).
- 6.12 **Acceptance Criteria and Disposition of IQ Testing**
- 6.12.1 The testing of all three dosimeters must result in the "symbol data" on the screen matching the serial number on the dosimeter.
- 6.12.2 If one or more tests fails, then the complete test case fails.
- 6.13 Disposition the entire test as "Pass" or "Fail" on the form. Sign and Date the form.
- 6.14 Have a qualified person review this procedure and the results. Sign and Date the form.
- 6.15 **Procedure in Event of Failure**
- 6.15.1 If there is any failure, it is likely that there is an issue with the connection or alignment of the scanner. Check all connections and alignment and test again.
- 6.15.2 Review the installation steps and repeat the test but always retain any failed test results.
- 6.15.3 If you experience repeated failure, contact GEX Customer Service for technical support at cs@gexcorp.com.
- 6.16 IQ/OQ of the barcode scanner is complete. The integration of the barcode Scanner with the DoseControl software is verified as during DoseControl software OQ (see *GEX Doc# 100-280, DoseControl Software Qualification Protocol*).

7.0 RELATED DOCUMENTS

- Microscan MS-2 CCD Reader User Manual
- GEX Doc# 100-156, Evo220 Spectrophotometer - Product Specifications and Usage (PSU)
- GEX Doc# 100-159, Evo220 Dosimeter Holder System - Product Specifications and Usage (PSU)
- GEX Doc #100-166, P4360 MS-2 Integrated Barcode Scanner – Product Specification and Usage (PSU)
- GEX Doc# 100-274, Integrated Barcode Scanner IQOQ Test Form
- GEX Doc# 100-280, DoseControl Software Qualification Protocol
- GEX Doc# 100-281, DoseControl Hardware Qualification Protocol

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8.0 REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
05/24/19	Initial release.	A