



Dexcom

PTL-903014

Rev: 005

PROTOCOL

Data Sheets

DOCUMENT OWNER: R&D

Protocol Notes Sheet

Note: This page may be copied as necessary.

Sheet # ____ of ____

Group _____

Note:

Deviations may be entered by an Executor and shall be approved by an Engineer.Test Method Losses and Anomalies shall be entered by an Executor and approved by a Quality Engineer.

Run #	Specimen #	Noted at Section #	Deviation	Anomaly	Test Method Loss	Note
1	28	10.10	<input type="checkbox"/> N/A YV 10/18/22	<input checked="" type="checkbox"/>	<input type="checkbox"/> N/A YV 10/18/22	After taking the Applicator out of the carton it was observed that the Applicator did not have a barcode.
(Sign & Date) Entered by: <i>Gladira L. Velaz Vera</i> Oct 19, 2022					(Sign & Date) Approved by: <i>Jim Harney</i> Oct 19, 2022	
1	16	10.13	<input type="checkbox"/> N/A YV 10/18/22	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	After downloading the data per section 11.9.1 of TP-90763, it was observed that the downloaded database was incomplete. The wearable did not record data for the entire duration of the test and did not contain timestamps. After manually inputting the timestamps, the specimen was used for data analysis for section 10.14.1 of PTL-903014. However, the specimen did not have enough data to verify Requirement 114568 and was considered a test methods loss for section 10.14.2 of PTL-903014. Refer to the PTL-903014 Memo.
(Sign & Date) Entered by: <i>Gladira L. Velaz Vera</i> Oct 19, 2022					(Sign & Date) Approved by: <i>Jim Harney</i> Oct 19, 2022	
1	28	10.13	<input type="checkbox"/> N/A YV 10/18/22	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	During data download per section 11.9.1 of TP-90763, the Wearable did not communicate with the PC.
(Sign & Date) Entered by: <i>Gladira L. Velaz Vera</i> Oct 19, 2022					(Sign & Date) Approved by: <i>Jim Harney</i> Oct 19, 2022	

(Print, Sign, & Date) Reviewer: _____






PTL-903014 Protocol Notes Sheet

Final Audit Report

2022-10-19

Created:	2022-10-19
By:	Yadira Velez Vera (yadira.velezvera@dexcom.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAkjClu_xxgO_hNvb7Q-sM5nyTLYJvWLrg

"PTL-903014 Protocol Notes Sheet" History

-  Document created by Yadira Velez Vera (yadira.velezvera@dexcom.com)
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-  Document e-signed by Yadira Velez Vera (yadira.velezvera@dexcom.com)
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-  Document emailed to Jim Harney (jharney@dexcom.com) for signature
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Signature Date: 2022-10-19 - 8:46:39 PM GMT - Time Source: server- IP address: 163.116.139.116
-  Agreement completed.
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