



Dexcom

CORPFT-010005

Rev: 006

Deviation Sheet

Document Owner: Operations

Deviation Sheet

(For use with PTL, PLN, PQ, IQ, OQ or Software Plans/Protocols. The completed forms must be scanned and attached to the Report.)

IDENTIFICATION INFORMATION

Deviation Number: 1

Document ID: TP-90763 Revision: 002 Section ID: 11.8.7.2

DEVIATION

Original Instructions per Test Procedure:

11.8.7.2 Enter the glucose concentration in the "YSI Average" column of each bath provided in Table 1.

3.) Lid #

Bath #	Year (yyyy)	Month (MM)	Day (dd)	Hour (24H)	Minute (mm)	YSI Average
0	0	0	0	0	0	0
0	0	0	0	0	0	0

Does Deviation affect the Test Results? ☒ Yes ☐ No

Deviation Description Summary:

During execution of PTL-903014 Rev 003, executors trained to and executed TP-90763 Rev 002. Data analysis per TP-90763 Rev 002 section 11.8.7.2 instructs to enter the theoretical glucose concentration of each bath in the "YSI Average" column of SW11500 AcetaGUI. The YSI average is used for the SW11500 AcetaGUI to calculate the MARD. Instead, data was processed per TP-90763 Rev 003 section 11.8.7.2 which states to enter the glucose concentration in the "YSI Average" column of each bath using an average of the YSI values from TP-90763 Data Sheet 1 – Bath Preparation. Data analysis was completed using TP-90763 Rev 003 since that revision was released and active at the time of data analysis. It was determined that when using actual YSI averages, it produces a more accurate representation of the MARD data given the 4% tolerance that is allowed for the glucose concentration, instead of using the theoretical concentrations.

Deviation Proposed Update:

N/A



Dexcom

CORPFT-010005

Rev: 006

Deviation Sheet

Document Owner: Operations

IMPACT ASSESSMENT

Select which items will need to be updated (include current revision):

- ☐ Software:
- ☐ User Requirement:
- ☐ Design Documentation:
- ☐ Equipment Binder/Hardware:
- ☐ Drawings:
- ☐ Plan/Protocol#:
- ☐ Other:

N/A CC 6/13/2022

TEST PLAN

Protocols that Require Execution:

IQ- _____ Revision: _____

OO- _____ Revision: _____

PQ- _____ Revision: _____

PLN/Protocol- _____ Revision: _____

Sections/steps to execute:

ACTION PLAN TO RESOLVE DEVIATION

Complete Prior to Deviation Approval:

Complete Post Deviation Approval:

DEVIATION REQUEST APPROVALS

Function	Printed Name	Signature	Date
Deviation Originator	Cristina Carabet	<i>Carabet C.</i>	Jun 13, 2022
Engineer	Lindsay Mazur	<i>Lindsay Mazur</i> <small>Lindsay Mazur (Jun 13, 2022 12:58 PDT)</small>	Jun 13, 2022
Quality Engineer	Jim Harney	<i>Jim Harney</i>	Jun 13, 2022










CORPFT-010005_Deviation Sheet

Final Audit Report

2022-06-13

Created:	2022-06-13
By:	Cristina Carabet (cristina.carabet@dexcom.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAvkNurdI86fCKz6Oxyxo2IKgEVEFC1D3m

"CORPFT-010005_Deviation Sheet" History

-  Document created by Cristina Carabet (cristina.carabet@dexcom.com)
2022-06-13 - 7:45:40 PM GMT- IP address: 163.116.132.120
-  Document e-signed by Cristina Carabet (cristina.carabet@dexcom.com)
Signature Date: 2022-06-13 - 7:48:21 PM GMT - Time Source: server- IP address: 163.116.132.120
-  Document emailed to Lindsay Mazur (lindsay.mazur@dexcom.com) for signature
2022-06-13 - 7:48:22 PM GMT
-  Email viewed by Lindsay Mazur (lindsay.mazur@dexcom.com)
2022-06-13 - 7:57:08 PM GMT- IP address: 119.13.194.139
-  Document e-signed by Lindsay Mazur (lindsay.mazur@dexcom.com)
Signature Date: 2022-06-13 - 7:58:06 PM GMT - Time Source: server- IP address: 66.85.67.20
-  Document emailed to Jim Harney (jharney@dexcom.com) for signature
2022-06-13 - 7:58:08 PM GMT
-  Email viewed by Jim Harney (jharney@dexcom.com)
2022-06-13 - 7:59:57 PM GMT- IP address: 163.116.132.117
-  Document e-signed by Jim Harney (jharney@dexcom.com)
Signature Date: 2022-06-13 - 11:28:50 PM GMT - Time Source: server- IP address: 163.116.132.117
-  Agreement completed.
2022-06-13 - 11:28:50 PM GMT



Adobe Acrobat Sign