# Purpose

## The purpose of this protocol is to verify, through accelerated and real-time aging, that the G7 GSS Transmitter will have sufficient battery life to work reliably over its specified maximum storage and operational durations.

# Scope

## This protocol is applicable to the G7 GSS Transmitter and satisfies the specifications in Table 1 and Table 2 depending on the session length of the system.

Table Requirements for a 15.5 days session G7 GSS system

|  |  |  |
| --- | --- | --- |
| **Doc ID** | **REQ ID** | **Requirement** |
| RS-00002 | 110596 | While in Distribution & Storage, the GSS shall have a shelf life of at least 18 months. |
| RS-00002 | 202364 | While In-Session and for up to 15.5 days after Deployment, the wearable shall generate Glucose Data. |
| RS-00002 | 110672 | Once the session has ended, the Wearable shall support communication with paired devices for a minimum of 24 hours. |
| HRS-900026 | 202369 | The battery capacity of the wearable shall permit the following:  a. 6 months of storage between battery insertion up to when the wearable is built into the applicator  b. 18 months of storage before use  c. 15.5 days of usage  d. 1 day of post session use. |

# Test Method Summary

## The battery accelerated aging test consist of verifying the remaining battery capacity at the end of a sensor session after accelerating the aging of batteries for an equivalent 36 months of storage. The aging acceleration is performed through a thermal acceleration, determined by the Arrhenius equation, and is followed by a constant load discharge to reproduce the loss of capacity during storage. Then, the aged batteries are built into transmitters and the exposure to manufacturing temperatures (i.e. sensor epoxy cure and sterilization) is reproduced. The devices are then placed in temperature chambers simulating temperature seen under clothing for an amount of time representing a full sensor session plus 24 hours after the session ends. The battery voltage is checked to be above 2.0V at the end of the session (guaranteeing enough battery capacity to not terminate the session) and the device is checked for its capability to communicate with a display device 24 hours after the end of the session.

# References

| **Doc Reference** | **Document Title** |
| --- | --- |
| HRS-900026 | G7 IIT Glucose Sensing System Hardware Requirements Specification |
| RS-00002 | G7 IIT Glucose Sensing System Requirement Specification |
| RA-000573 | G7 GSS Design FMEA |
| CORPPI-040900 | Sample Size Determination and Analysis for Verification Testing |
| PLN-12232 | Beta Glucose Sensing Subsystem Hardware Design Verification Plan |
| LBR-1000404 | Osprey Battery Consumption Test Lab Report |
| TDR-1000527 | G7 Osprey Monte Carlo Simulations |
| MT25025 | CR1216 Lithium Manganese Primary Coin Cell Battery with Insulated Sleeve |
| ***External Documents*** |  |
| ASTM F1980-21 | Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices |

# Definitions

| **Acronym / Abbreviation** | **Term** |
| --- | --- |
| AA | Accelerated Aging |
| AAF | Accelerated Aging Factor, a calculated ratio of the time to achieve the same level of physical property change as compared to a device stored at real time (RT) conditions |
| AAT | Accelerated Aging Time, the length of time the accelerated aging is conducted |
| ASIC | Application Specific Integrated Circuit |
| BG | Blood Glucose |
| BLE | Bluetooth Low Energy |
| CGM | Continuous Glucose Monitor |
| CM | Contract Manufacturer |
| EGV | Estimated Glucose Value |
| FRA | Fast Reconnect Advertising |
| GSS | Glucose Sensing Subsystem (consists of the Applicator, wearable and packaging) |
| PCBA | Printed Circuit Board Assembly |
| PDD | Private Data Download |
| Q10 | An aging factor that represents a 10°C increase or decrease in temperature |
| RF | Radio Frequency |
| RFID | Radio Frequency Identification |
| RT | Real-Time aging, the actual real specified storage time of a device at ambient conditions |
| RTE | Real-Time Equivalent, amount of real-time aging that is equivalent to accelerated aging conditions |
| TAA | Accelerated Aging Temperature, the temperature at which the aging will be conducted |
| TRT | Ambient Temperature, storage for real-time aging (RT) of device samples that represents storage conditions. This temperature is typically between 20 to 25°C. |
| TXID | Transmitter ID or Serial number |
| V&V | Verification and Validation |
| WIP | Work In Progress |

# Responsibility – n/a

# Materials

## Device Under Test Configuration

| **Part Number** | **Description** |
| --- | --- |
| Record in report | G7 GSS Wearables Built into Applicators with   * Pre-discharged batteries (per this protocol) for each battery manufacturer defined per the project or test plan scope. * CGM FW * RC load instead of Sensors, with Tacking Adhesive and Encapsulant * Sterilized |

Test articles should reflect the final configuration of the product. Ensure that build information is captured in the report.

## Test Consumables – N/A

# Equipment

| **Part Number** | **Equipment Name** |
| --- | --- |
| EQ-900888  Or  EB-900285 | TestEquity Temperature/Humidity Chamber Model 123HS/ 123HS-EX  Or  TENNY ENVIRONMENTAL CHAMBER MODEL# BTC  Or equivalent |
| EB-901061 | Arbin BT2000-HSP Battery Test System or equivalent battery tester capable of 0.100 mA constant current discharge |
| FX92215 | NFC/RFID Controller Breakout Board with Shield |
| SW10886 | Quasar Smart-Transmitter Communication Tool (or equivalent) |
| SW11835 | NFCCmd Tool |
| N/A | Windows PC |
| MDBT50Q-RX | Raytac Dongles (NRF52) |
| EB-900946 | Keysight N6705B DC Power Analyzer Mainframe |
| N/A | USB Cables |

# General Instructions

## This procedure needs preparation prior to starting the test. Figure 1 gives an overview of the preparation activities and their relationship with building the test units and typical estimated durations related to each task. It is recommended to review the related sections and determine resources needed to execute each of these steps. This is particularly important if some of the assumptions needs to be changed and characterization is needed to create the information needed for the calculation’s steps. The duration estimates should be reviewed with the different groups involved in these steps prior to making commitments to project leadership. See the referenced sections below and Appendix C for more guidance on who to contact to execute the preparation steps.

## Also, Appendix B captures the rationale for key parameters used in this protocol.

Figure . General activities required to prepare test prior to execution. (corresponding sections in parenthesis)

A diagram of a battery

Description automatically generated

# Procedure for Battery Accelerated Conditioning (Part 1 of 3)

## Before being built into a transmitter, every G7 battery will be stored for some amount of time representing the time from the battery manufacturer to Dexcom manufacturing sites. The battery is then stored again as it waits at these manufacturing sites to be built into transmitters. This amount of time will be taken as 12 months per MT25025. Once in manufacturing, the transmitters can be stored for 6 months. After manufacturing, the transmitters can be stored an additional 18 months, bringing the total storage time to 36 months (12 months with a bare battery and 24 months in a transmitter).

Table . Equivalent Maximum Storage Time to Reproduce for Battery Life Test.

|  |  |
| --- | --- |
| **Battery Storage Parameters** | **Time** |
| Maximum age of battery prior to manufacturing | 12 months |
| Maximum time batteries remain in WIP  (built into transmitters but waiting to become Final Goods) | 6 months |
| Time in Storage before use | 18 months |
| **TOTAL Months in Storage (for thermal aging)** | **36 months (1,095 days)** |
| **TOTAL MONTHS In Transmitters (for current discharge)** | **24 months** |

## Calculate battery accelerated aging needed and age batteries

### Because the battery will have already been stored for part of the 36 months cited in Table 3, a calculation needs to be performed to determine the remaining amount of real-time storage that will be done through accelerated aging, as explained in this section.

### Review *Attachment A - Test Calculation Assumptions tab* and ensure assumptions are valid for this test. Ensure that TAA, TRT, Q10, transmitter storage current and transmitter storage time are still correct for this test (defaults are in Table 4 and Table 5).

If modifications are needed, update *Attachment A - Test Calculation Assumptions tab* and mention these modifications in the report with justifications.

### Fill out *Attachment A - Battery Accelerated Aging Calc* tab with the following information for each batteries manufacturer and manufacturer lots:

* Battery Manufacturer,
* Battery Manufacturer lot number,
* Battery date code,
* Battery manufacturing date, which corresponds to the manufacturer date code scheme, and,
* Start of accelerated aging date.

For battery manufacturing date, if the date code only indicated month/year of manufacture assume manufacturing was done on the 15th day of that month if there is no other documentation for the manufacturing date. Attach battery documentation to the report if needed to demonstrate battery manufacturing date. Some manufacturer Certificate of Compliance reports a manufacturing date that is different than the battery date code. For example, Panasonic’s manufacturing date represents the date at which the batteries are packaged to be shipped out, which can occur 1 or 2 months after the batteries have been fabricated. In this case use the date code not the manufacturing date for the battery manufacturing date.

The *Attachment A - Battery Accelerated Aging Calc* worksheet will determine the amount of real time aging that needs to be accelerated based on the age of the battery when the accelerated aging starts per this equation:

Equation . Total battery aging to accelerate.

The worksheet will also calculate the accelerated aging time (AAT) based on the Arrhenius equation:

Equation . Arrhenius equation for Accelerated Aging Time

*Where*:

And the default parameters are:

Table . Arrhenius Equation default parameters

| **Parameter** | **Value** |
| --- | --- |
| Temperature Coefficient (Q10) [[1]](#footnote-2) | 2 |
| Accelerated Aging Temp (TAA)[[2]](#footnote-3) | 60 °C |
| Ambient Temp (TRT)b | 22 °C |

## Place all the batteries for the test inside the oven following this procedure:

### Record the temperature chamber oven information and supporting equipment to use in the oven in *Attachment B – Test Article and Equipment Log*

### Set the Oven temperature to 60º C. Place the units in the oven and allow them to soak for 20 minutes at 60º C. The accelerating aging starts after the soak is complete.

### Maintain the batteries at 60º C for the time calculated and specified in *Attachment A - Battery Accelerated Aging Calc*.

# Procedure for Battery Discharge (Part 2 of 3)

## Following the battery accelerated aging, each battery for the G7 transmitter assembly must be partially drained prior to performing the accelerated storage testing. This step is required to compensate for the difference between the partial battery capacity that will be consumed during the relatively short period of time of accelerated storage and the total battery capacity that would have been consumed if the transmitter had been stored for an entire 24-month period (6 months of storage in manufacturing + 18 months of storage after manufacturing).

## Verify *Attachment A – Battery prep Calculation - Test Calculation Assumptions* tab has the correct values for Transmitter Storage Current and Transmitter Storage time (Table 5 lists the defaults used). Characterization of the Transmitter Storage Current may need to be done if changes were made to the hardware. (see Appendix B for more details on what determines the transmitter storage current)

Table . Battery Discharge default parameters

| **Parameter** | **Value** |
| --- | --- |
| Transmitter Storage Current[[3]](#footnote-4) | 198 nA |
| Transmitter Storage Time | 730 days or 17,500 hours (2 years @ 365 days/yr) |

If a different calculation is needed for different battery manufacturer, modify the worksheet accordingly to capture the calculation and mention the modifications in the report with justifications.

The worksheet uses this equation to calculate the battery capacity to discharge:

Equation . Battery capacity consumed while transmitter is in storage

With default parameters from Table 5, the *Battery Capacity Consumed in Storage* to simulate is 3.47 mAh at a rate of 0.100 mA constant current discharge.

## Procedure to Predischarge Batteries:

### Capture the Arbin Test equipment in *Attachment B – Test Articles and Equipment Log*.

### Using the Arbin battery test equipment, set the equipment to discharge the batteries for 3.47 mAh at a constant current of 0.100 mA.

### Place batteries on the Arbin and start the test.

# Build Batteries into Transmitters and Perform Sterilization

## After the battery predischarge, the batteries are built into G7 GSS Wearables with RC instead of a sensor, and with tacking adhesive and encapsulant epoxy.

## G7 Wearables are built into applicators and in the packaging configuration and sterilized.

# Procedure for Real-Time Operating Life test (Part 3 of 3)

This section covers Part 3 of 3 the Accelerated Aging test. The Beta GSS samples will be tested at skin temperature while running in a real-time operating mode.

## Ensure calculation of equivalent test session length was performed prior to executing this section by collecting the required measurements required to fill out *Attachment D – Worksheet to Determine Equivalent Test Session Length, in accordance* with the instructions from *Appendix A – Transmitter Current Measurements and Calculations to Determine Test Session length.* The calculation describes the method to ensure the test run for a period of time equivalent to having 2 displays connected[[4]](#footnote-5) ( a receiver and mobile phone) with the transmitter.

## Record following transmitter information in *Attachment C – Test Article Log & Test Results:*

* transmitter part number,
* serial number,
* ER used to built the devices (if applicable) and
* the battery vendor used in the transmitter.

## Deploy the transmitters

## One hour after deployment, verify the transmitters are no longer in storage mode by connecting via Quasar for at least 2 connections or checking the firmware state via NFC. Log confirmation of CGM operation for each Transmitter in *Attachment C – Test Article Log & Test Results*.

### If NFC is used it will not stop fast pairing, be sure to perform 2 successful connections with Quasar afterward to stop fast pairing operation and force the device into Fast Reconnect Advertising.

## Move all the transmitters into an oven at 34°C[[5]](#footnote-6). Run the G7 transmitters for the amount of time calculated and specified in *Attachment D – Worksheet to Determine Equivalent Test Session Length*.

### In this procedure it is assumed that Fast Reconnect Advertising will occur in the chamber, therefore use the *Total Test Time* which includes:

* Fast Reconnect Advertising
* Adjusted CGM Session Test Time
* 24 hours Post-Session Time

If this is not how the protocol is executed, recalculate the times appropriately and document in the report how the test times were derived.

### At Day 10, configure the oven to 20°C[[6]](#footnote-7) by ramping down as quickly as possible. Dwell for 1 hour at 20°C. After 1 hour, ramp to 42°Cf as quickly as possible. Dwell for 1 hour at 42°C. After 1 hour, ramp back down to 34°C and continue the test until the total test time calculated and specified in *Attachment D* has elapsed.

### Execute the following tasks with the transmitters remaining in the temperature chamber[[7]](#footnote-8) at the end of the *Total Test Time* listed in Table 6.

### If the test is to verify a 10.5-day product, only perform activity A in Table 6. If the test verifies a 15.5-day product, only perform activity B in Table 6.

Table . Task to perform to verify acceptance criteria

| **#** | **Activity** | **Time Point** | **Action** |
| --- | --- | --- | --- |
| A | Verify battery voltage at  11.5-day mark equivalent | Use the Total Test Time (no Display) for the  **10.5-day product** | Connect either via Quasar to download the session database that includes EGV and Battery Voltage information.  Record result of communication in *Attachment C* for *Successful port-session display connection?* |
| A | Communicate with Display at 16.5-day mark equivalent | Use the Total Test Time (no Display) for the  **15.5-day product** | Connect either via Quasar to download the session database that includes EGV and Battery Voltage information.  Record result of communication in *Attachment C* for *Successful port-session display connection?* |

### Review the battery voltage measurements in the database and locate the battery dynamic voltage measurement for the 10.5- and 15.5-day mark which are the times named *Total Session Test Time* from the calculations in *Attachment D* (Use the first battery voltage measurement after the 10.5- and 15.5-day mark). Record results of battery voltage and communication after post-session with a display in *Attachment C*.

### Include in the report Attachment A to D used in the previous steps.

### The test has ended but if requested by R&D, optionally, leave units into the oven at 34°C for characterization purposes.

# Risk Analysis Review

Based on the G7 GSS DFMEA RA-000573 Attachment 1, “3. Wearable” Worksheet the following risk are relevant to this test

| **Risk Item** | **Hazardous Situation** | **Severity** |
| --- | --- | --- |
| 3.13 | Transmitter unexpected end-of-session | S4 - Critical |

Also, the part of the requirements where the device needs to be able to communicate 24 hours after the session ends is not related to a hazardous situation in the SHA or DFMEA which corresponds to a Negligible Severity. That extra 24 hours is to let a user communicate one last time with the transmitter to get backfill data if the user’s display was out of range for an extended period and the session ended during that time. In this use case, the user is aware their display is not available and is not using their CGM to manage their blood glucose. A user without their historical data after their CGM session ends does not result into a harm or hazardous situation.

# Sample Size Justification

This test consists of 2 acceptance criteria with different risk level. Based on CORPPI-040900 for variable data, the sampling plan is choosing a PNC > 1.0% due to the importance of this specification and no historical data available for the configuration tested.

| **#** | **Use Case / Criteria** | **Risk Level** | **Confidence** | **Reliability** | **Data Type** | **Minimum Sample size** |
| --- | --- | --- | --- | --- | --- | --- |
| #1 | Battery to have sufficient capacity to complete a session | Critical - 4 | 95% | 90% | Variable | 70 |
| #2 | Battery to have sufficient capacity to communication with display device 24 hours after session end | Negligible - 1 | 90% | 90% | Attribute | 22 |

Based on this information a minimum sample size of 70 is selected and the attribute test will be performed on all 70 units as well.

# Acceptance Criteria

There are two criteria to satisfy:

|  |  |  |
| --- | --- | --- |
| **#** | **Related REQ ID** | **Acceptance Criteria** |
| #1 | 110596, 110672, 202369 | Transmitter must successfully connect to a display 24 hours after the Total Session Test Time specified in Attachment D – Worksheet to Determine Equivalent Test Session Length with 90%/90% (conf/rel) |

# Attachments

Attachment A – Battery Preparation Calculations

Attachment B – Equipment Log

Attachment C – Test Article Log and Test Results

Attachment D – Worksheet to Determine Equivalent Test Session Length

Attachment E – G7 Transmitter Temperature Readings (US population 20240101-20240520)

Attachment F – Manufacturer communication related to AAF of batteries

# Appendices

Appendix A – Transmitter Current Measurements and Calculations to Determine Test Session length

Appendix B – Justifications for test method parameters

Appendix C – Guidance on how to build test units

Appendix A: Transmitter current measurements and calculations to determine test session length

The sequence of events for the test in section 13.0 of this protocol is represented in Figure 2.

Figure . Representation of the time to execute each step of a test session of 15.5 days + 24 hours.

A screenshot of a test

Description automatically generated

Where the *Adj CGM Session Time* is:

Equation . Adjusted CGM Session Time:

*Adj CGM Session Time = CGM Session Time – Fast Pairing Time – Fast Reconnect Time*

For example, a 15.5-day session product would be:

*Adj CGM Session Time = 15.5 days – 1 hour – 12 hours = 14.96 days*

However, because the test is not executed with display devices, some part of the test needs to be adjusted to account for lower battery capacity consumption when no display devices are connected to the transmitter. Table 7 describes the events that needs to be considered in the adjusted of the test time and describes which event will be present or not when no display is connected to the transmitter.

In Figure 2, the portion related to Fast Pairing Time (event #1, in Table 7), which also includes Cybersecurity (event #2, in Table 7) will not be adjusted as they are part of the test setup but is counted as 1 hour of session time as seen in Equation 4.

Fast Reconnect Time (event #3, in Table 7) battery consumption is slightly higher than when 2 displays are connected to the transmitter and therefore that portion of the test execution will not be adjusted as it represents a possible use case of having FRA run for 12 hours (FRA represents about 158.7mAh for 12 hours and 2 display connected for 12 hours is about 143mAh).

Finally, the 24 hours Post Session Time (event #13) is already meant to be executed with no display to represent the use case of the display device being out of range of the transmitter and will not be adjusted.

Therefore, only the portion called *Adjusted CGM Session Time* (with display device) needs to be adjusted when no display device is used during that portion of the test. Events #4 to #12 from Table 7 needs to be considered in the adjustment calculation. This adjustment is called *Adjusted Session Test Time* and is described in the next section below.

Table . Events Related to Battery Capacity

| **#** | **Events related to battery capacity consumption** | **Will event occur during the test?** | **Adjustment Needed?** |
| --- | --- | --- | --- |
| 1 | Faster Pairing beginning of session | Yes, 1 hour at start of test, during test setup | No Adjustment Needed |
| 2 | Cybersecurity | Yes, during test setup at initial pairing | No Adjustment Needed |
| 3 | Faster Reconnect Advertising (FRA) | Yes, 12 hours after fast pairing event | No Adjustment Needed, similar to 2 display connected |
| 4 | Advertising current 5 min interval | Yes, occurs without display | Yes, adjustment is done through the ratio between average current with 2 displays and average current without a display in Equation 8. |
| 5 | Sleep current of AFE & BLE | Yes, occurs without display |
| 6 | 30s sampling | Yes, occurs without display |
| 7 | RC calibration | Yes, occurs without display |
| 8 | Dynamic voltage measurements | Yes, occurs without display |
| 9 | Temperature Measurement | Yes, occurs without display |
| 10 | BLE Connection Current | No, does not occur without display |
| 11 | Private Data download  (Occurs every 2 hours,126 events for 10.5-day session, 186 events for 15.5-day session) | No, does not occur without display | Yes, considered as part of the PDD\_BG Factor in Equation 9 |
| 12 | BG Calibration measurements  (30 BG Calibrations for a 15.5-day session) | No, does not occur without display |
| 13 | 24 hours Post Session | Yes, this part of the use case is meant to be done without a display | No Adjustment Needed |

***Adjusted Session Test Time Calculation***

The calculations in this section are implemented in *Attachment D – Worksheet to Determine Equivalent Test Session Length* and requires as inputs the parameters described in the section called “Parameters to Measure to determine *Adj Session Test Time* and *Total Test Time”* below. This section explains how the calculations were derived.

The *Adjusted Session Test Time* represents the amount of time the test setup must run with no display to represent the battery consumption of a device connected to 2 displays during a session as shown in Figure 3.

Figure Representation of *Adj Session Test Time* battery consumption equivalency with *Adj CGM Session Time*

A screenshot of a computer screen

Description automatically generated

In Figure 3, the *Adjusted Session Test Time* is represented by Equation 5

Equation Calculation of Adjusted Session Test Time

Where Adj CGM Session Time is 14.96 days.

*NbDays\_OutOfSession* is found by determining the difference between the battery capacity consumed with 2 displays in session and the battery capacity consumed by no display when executing this protocol as demonstrated in Equation 6 to Equation 11

Equation Relationship between Battery Capacity Consumed with displays versus no display

Where:

From Equation 6 the *NbDays\_OutOfSession* is determined by Equation 7.

Equation Calculation for NbDays\_OutOfSession

Where the following terms are:

| **Term** | **Definition** | **Equation / Calculation** |
| --- | --- | --- |
|  | The number of days needed to extent the test past the end of session with 0 display so the test unit consume an equivalent battery capacity than if the test was ran with 2 displays | Equation 7 |
|  | The average battery capacity consumed by event #4 to #10 from Table 7 while In-Session with 2 displays for 14.96 days | Equation 8 |
|  | The average battery capacity consumed by events #11 and #12 from Table 7 for 15.5 days | Equation 9 |
|  | The average battery capacity consumed by event #4 to #9 from Table 7 while In-Session with no display for 14.96 days. | Equation 10 |
|  | The average battery capacity consumed by event #4 to #9 from Table 7 while Out-Of-Session with no display for 1 day. | Equation 11 |

Equation Calculation of Average Capacity Consumed during the communication interval for 2 displays for 14.96 days

For example:

Equation Calculation of Average Capacity Consumed by PDD and BG Cals events for 15.5 days

Where:

For example:

Equation Calculation of Average Capacity Consumed during the communication interval for no display connected display for 14.96 days

For example:

Equation Calculation of Average Capacity Consumed during the communication interval for no display connected display for 14.96 days

For example:

With the examples from Equation 8 to Equation 11, the from Equation 7 would equate to:

And the Adj Session Test Time from Equation 5 would be:

**Parameters to Measure to determine *Adj Session Test Time* and *Total Test Time.***

The measurements for the parameters listed below should use the test setup captured in Attachment D of LBR-1000404 and be done on at least 5 PCBA. If past data is used, the test engineer should confirm the parameters still corresponds to the design being tested in this protocol.

If the measurements are added as part of the report, add the information related to the equipment used in *Attachment B – Equipment Log* and ensure the data for the measurements are included and summarized in the report or one of its attachments.

Table Parameters used as inputs for *Attachment D – Worksheet to Determine Equivalent Test Session Length*

| **Parameters to Measure** | **Measurement Method** |
| --- | --- |
|  | * Measure the average battery capacity consumed over 3 communication intervals with 2 displays while **In-Session**. |
|  | * Measure the average battery capacity consumed over 3 communication intervals with **no** display while **In-Session**. |
|  | * Measure the average battery capacity consumed over 3 communication intervals with **no** display while **Out-Of-Session**. |
|  | * Measure the average battery capacity consumed by 1 PDD event |
|  | * Measure the average battery capacity consumed by 1 BG Cal event |

Once *Adj Session Test Time* is determined, the *Total Test Time* to have the units with no display in the temperature chamber is determined with Equation 12:

Equation . Total Test Time in a temperature chamber

The source for these parameters / measurements should be either referenced in the report or the measurements added to the test report as attachment and explained as part of the discussion of the report as needed.

Appendix B - Justification for test method parameters

This section explains the decisions behind the selection of the following parameters of the test method:

1. Transmitter Storage Current to use in battery capacity depletion
2. Accelerated Aging temperature
3. TRT Selection
4. Arrhenius Accelerated Aging Factor
5. Operating / Body temperature
6. Verification of final battery voltage at body temperature
7. Use of 20C and 42C for temperature extremes exposure
8. Number of Displays to Use to Calculation *Adj Session Session Test Time*

***Transmitter Storage Current to Use for Battery Capacity Depletion***

For this protocol, the average transmitter storage current (nA) will be used to calculate the battery capacity to deplete from the batteries. The average current is used to avoid stacking multiple worst cases for this test. The battery capacity calculation uses the worst-case storage time with the transmitter current and using worst-case for both parameters is not representative of the use case.

The transmitter storage current (from manufacturing inventory up to deployment) comes from the current drawn by the TMR (magnet detection) chip and the AFE. Other components, such as the BLE chip, are turned off. The transmitter storage current is the same across all versions of circuits boards as the components involved in drawing this current are the same and used in the same conditions while in storage.

Table . uBTS data for G7 device transmitter storage current:

|  |  |  |  |
| --- | --- | --- | --- |
| **Transmitter Configuration** | **Sample Size** | **Average Transmitter Storage Current** | **STD DEV** |
| Nordic V3 | >> 1000 | 198 nA | 23.6 nA |
| Silabs | >> 1000 | 198 nA | 21.6 nA |

***Accelerated Aging temperature***

The accelerated aging temperature was chosen to avoid unrealistic failure conditions and is based on the absolute maximum rating of the batteries of 60°C per manufacturer specifications.

***TRT Selection***

For this protocol, 22°C is chosen as the storage temperature as the rounded down mid-point between 20°C and 25°C.

***Arrhenius Accelerated Aging Factor***

The accelerated aging factor used by Dexcom is more aggressive than the recommendation from the battery manufacturers and is based on ASTM F1980-21.

To use a different accelerated aging factor than the default from this protocol, a justification is needed for **all** the batteries used in the test. **Do not assume** that an acceleration factor for one manufacturer applies to all manufacturers of batteries.

The justification may be composed of manufacturer information or experiments done by Dexcom to determine the acceleration factor to use.

When information to support the justification is obtained, update the information in Table 9 and add the reference to the information / data supporting the new acceleration factor.

Table . Acceleration factor used by battery manufacturers

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Battery Vendor** | **TRT** | **TAA** | **AAF** | **Comment from Manufacturer** |
| Maxell | 20°C | 60°C | 18.25 | 20 days @ 60°C corresponds to 1 year of aging (see Attachment F for reference) |

***Operating / Body temperature***

Data from approximately 1.68 million real transmitter sessions (Attachment E) over a period of 5 months from January 1, 2024 to May 20, 2024 were used to derived a non-parametric one-sided upper tolerance interval at 95%/90% (conf/rel) for the average temperature during a session.

Table . Temperature chamber temperature selection

|  |  |  |  |
| --- | --- | --- | --- |
| **Temperature** | **One-sided Upper Tolerance Interval** | **Temperature selected** | **Rationale** |
| Average Body temperature | 33.5°C | 34°C | See below and rounded up to nearest degree |

The selection of 34C also corresponds to the average steady state of skin temperature in *Sullivan, P & Mekjavic, Igor. (1992). Temperature and humidity within the clothing microenvironment. Aviation, space, and environmental medicine. 63. 186-92* which gives an average skin temperature from 33.81°C to 34.73°C depending on various type of clothing.

Figure . Distribution of average temperatures from field data

***A screenshot of a computer

Description automatically generated***

***Verification of final battery voltage at body temperature***.

This protocol verifies two events related to battery life:

1. Battery voltage at the end of the sensor session (at 10.5 or 15.5 days depending on the product)
2. Ability to communicate with the CGM device 24 hours after the end of the sensor session.

The 24 hours after the session ends is meant to represent the use case where a user is away from their display device and the sensor session ends during that time. These 24 hours extra of battery life is to give the user one last chance to connect their display to their CGM device and gather historical data up to their end of session. In this scenario it is expected the user keeps their CGM device on body during that extra 24 hours of time.

Therefore, the testing of end of session battery voltage and communication with display device 24 hours after end of session should be done with a simulated body temperature. When devices are brought to ambient temperature there is typically a drop of 10-15C degrees which affects the battery dynamic voltage values negatively and could give false negative to this test.

***Use of 20C and 42C for temperature extremes exposure***

The original temperature extremes evaluated were in line with the operating range of 10C to 42C.

However, the G7 product is a body worn device and the temperature extremes seen at the device while it is worn are different than the ambient temperature due to the proximity to the body and being mostly worn under clothing.

Data from approximately 1.68 million real transmitter sessions over a period of 5 months from January 1, 2024 to May 20, 2024 were used to derived a non-parametric one-sided tolerance interval (95% Confidence and 98% Reliability) for maximum and minimum temperatures seen by the transmitters in the table below.

Table . Minimum and Maximum temperature selection for temperature swings at Day 10 of the protocol

|  |  |  |  |
| --- | --- | --- | --- |
| **Temperature** | **One-sided Interval** | **Temperature selected** | **Rouding method** |
| Minimum Temperature | 20.9°C | 20°C | Rounded down to nearest degree |
| Maximum Temperature | 41.8°C | 42°C | Rounded up to nearest degree |

The rounding method chosen is to ensure the value from the one-sided interval would be included in the temperature range. Therefore, the minimum temperature is rounded down.

Figure . Distribution of minimum and maximum temperatures from field data

A screenshot of a computer

Description automatically generated

***Number of Displays to Use to Calculation Adj Session Test Time***

Two displays (A receiver and mobile phone) are used to determine the *Total Session Test Time* as it is considered the worst-case situation in terms of battery consumption even if 3 displays can be used with the transmitter.

The 7 second advertising is one of the most energy consuming event. In the use case where 3 displays are used the 7 seconds advertising will stop before the 7 seconds is over, while in a 2 displays situation, the 7 seconds advertising will continue until the 7 seconds is over.

Evaluation of current consumption between 1, 2, and 3 displays (see Figure 6) shows that 2 displays is the worst case for current consumption during a communication interval.

Figure Evaluation of capacity consumption between 1, 2, and 3 displays

A screenshot of a computer

Description automatically generated

**Appendix C – Guidance on Building Units**

Building test units requires coordination between multiple teams. DO NOT UNDERESTIMATE THE EFFORT AND COORDINATION NEEDED FOR THESE STEPS. Plan in advance, do not assume timelines commitments, follow up continuously with the various team members related to each step and over communicate during the whole build process with the various team to ensure successful test articles builds.

This section describes guidance to reduce learning curve on how Dexcom processes work to get these parts built. This guidance reflects the current state of the processes when rev002 of this document was released. The responsible engineer for the execution of this test should reach out to the various teams in advance as these processes may have changed.

Figure 6 lists all the steps required to build the test articles. Steps related to Accelerate Aging of batteries and Discharge Batteries are described in the section referenced in parentheses.

A diagram of a battery

Description automatically generated

Figure Steps to prepare and built test units from Figure 1

For the following other steps described below, the responsible engineer should reach out and prepare the documentation required to have these steps executed.

Team members in the table below can help fill out the Jira tickets, but filling out the information is the responsibility of the test engineer who also needs to confirm the information is correct for the test.

| **Steps** | **Team To Contact** | **Documentation to Provide** | **Comments** |
| --- | --- | --- | --- |
| **Procure batteries**  (Order the batteries to use for this test) | R&D Planning | PO or request from inventory | Please keep the PO information or source of procurement for the report.  Also work with planners to estimate the number of batteries needed to account for the manufacturing yield loss. |
| **Built Transmitters**  (Installs the depleted batteries into transmitters) | R&D Planning,  R&D Process Development | Create Jira Ticket in RDBP  &  Statement of Work to provide to contract manufacturer (see SOW example below) | Confirm with R&D Process Development if the configuration selected matches the needs of the protocol.  Provide the depleted batteries to the planner packaged properly and identified.  A SOW will need to specify the following:   * Appropriate tooling to use * Appropriate Patch to use * Cleanroom to use * FW # to use for test * Reference Document * PCBA version to use * Special instructions for builds and tests results such as not reject device for low battery results.   There may be other aspects to cover, please work in advance with the R&D Planners and the Process Development Team. |
| **Install RC**  (Install a Resistor and Capacitor instead of the Sensor to provide a constant signal during a session) | Engineering Services Techs | Request Jira Ticket in EELABS project and Create ER (See example of how to create an ER for RC install below) | Coordinate with the Tech team in advance to reserve time and figure out documentation needed to proceed. |
| **Build into Ax and Pkg**  (Prepares the transmitters to be sterilized and account for manufacturing temperature exposures) | R&D Planning | Ensure Jira Ticket in RDBP above specifies the type of Build | Pilot Line Builds may only happen during certain days of the week or the year. |
| **Sterilize Ax** | R&D Planning | Ensure Jira Ticket in RDBP above specifies the type of sterilization and sterilization supplier | DVT generally request worst case sterilization for this protocol unless justified. |
| **Execute Test** | Engineering Services | Reserve test chambers with the team. | There may be a limited amount of equipment. Plan this step early.  The execution of the test is the responsibility of the test engineer and if a technician is requested to assist, the technician may require to be trained to the execution of the test. |

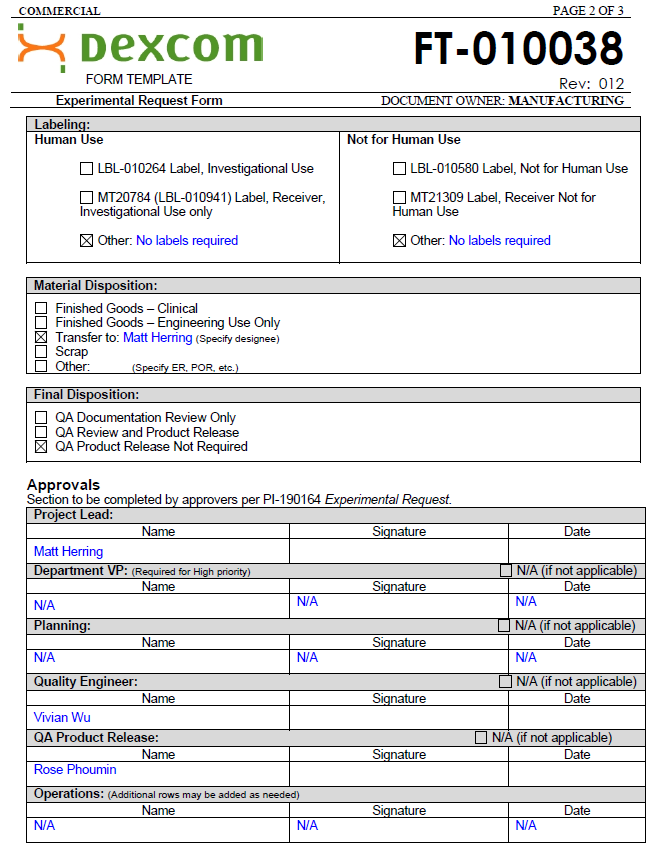
**Example of Statement of Work to build Batteries into transmitters:**

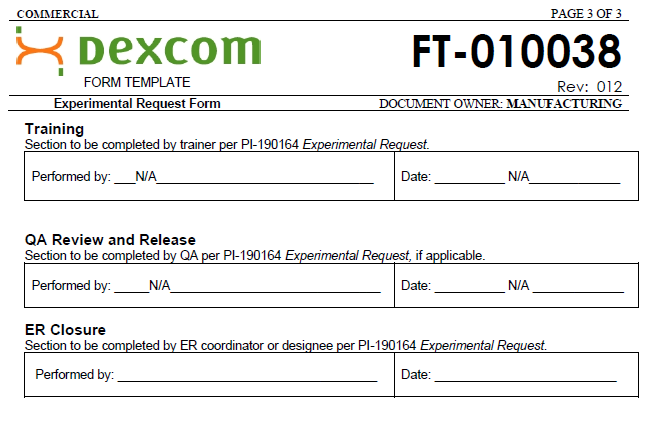
|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **DEXCOM** | | | | | | |
| *Statement of Work* | | | | | | |
| **Project Name:** | | Osprey DVT | **SOW #:** | | MH-090424-03-CVT | |
| **Project Code:** | | PRJ\_01359: G7 Extensions | **SOW Rev:** | | 002 | |
| **Complexity:**  **Standard** is normal feasibility build complexity.  **High** is very complex build requiring Dexcom engineering support on site at the CM. | | | | | Standard  High | |
| **Dept. Code:** | | 51043:  DVT - San Diego | **Charge Dept:** | | 51043:  DVT - San Diego | |
| **Platform:** | | G7 | **Build Type:** | | Functional | |
| **MT#:** | | MT-26023-72  Beta Transmitter (Osprey 15.5-day, INTG-1 R&D) | **Rev:** | | 001 | |
| **MT Description:** | | Beta Molded Transmitter with pre-conditioned Maxell battery cells. | | | | |
| **Purpose:** | | Molded Transmitters with pre-conditioned Maxell battery cells in support of PTL-903900 for Osprey DVT. | | | | |
| **Need by Date:** | | [Need by Date] | **Tagging:**  *(SOWs are for feasibility only, not DVT or V&V)* | | Blue  None | |
| **Engineering Contact** | | | | | | |
| **Name:** | |  | **Title:** | | Test Engineer | |
| **Email:** | |  | **Phone:** | |  | |
| **LPM CM Only** | | | | | | |
| **Tool Number:** | | Arburg 8 Cavity (no Energy Directors, with 0.1 mm increased thickness | | | | |
| **Patch (POR / AR):** | | | AR | | | |
| **Cleanroom:** 1  2  **Tape & Reel:** Y  N | | | **Island 0 Testing:** Y  N  **FW # for Testing:** SW14531 Version 57.192.109.36 | | | |
| **Reference Documents** | | | | | | |
| **Ref.** | **Document** | | | | | |
| 1 | DWG-26023-HR | | | | | |
| 2 |  | | | | | |
| 3 |  | | | | | |
| **Deliverables** | | | | | | |
| QTY 200 MT-26023-72 Rev 001 | | | | | | |
| **Materials** (CFM= Customer [Dexcom] Furnished Materials) | | | | | | |
| **Ref.** | **Part Description** | | | **Part Number** | **Quantity** | **CFM Y/N** |
| 1 | Beta Transmitter PCBA | | | MT-25668-72 | 200 | Y  N |
| 2 | Pre-conditioned Maxell Coin Cell Battery (provided by Dexcom). | | | MT25025 | 200 | Y  N |
| 3 |  | | |  |  | Y  N |
| 4 |  | | |  |  | Y  N |
| **Instructions for Failures** *Specify if you would like failures to be shipped back (shipped and labeled separately)* | | | | | | |
| Yes. | | | | | | |
| **CM Labeling and Documents** | | | | | | |
| Note for CM: Please label all shipping documents (packing slip & C of C, etc.) and boxes with the SOW # and MT# for identification. Do not combine these SOW units with others in the queue. | | | | | | |
| **General Instructions** | | | | | | |
| Engineering notes:  Cavist to produce MT-26023-72 Beta Molded Transmitters (Beta No ED Molded Transmitter (Osprey 15-Day INTG-1 R&D)) in the following configuration:   * Parts to be built inside Cleanroom 2 to accommodate testing. * Only build parts using the pre-conditioned Maxell batteries provided by Dexcom.  **DO NOT USE** Maxell batteries from Cavist inventory for this build. * **CLEARLY LABEL** each unit based on the battery used on the TX. * Battery Insertion and Overmold tests to be run on test stations with special configuration (see special instructions for additional information) * Molding configuration per DWG-26023-HR   + Arburg 8 Cavity, no ED, and thicker mold (+0.1 mm) * PA-673 LPM * Ship good and scrap units separately with scrap separately binned and marked. * Perform Incoming and Outgoing Testing per agreement with Dexcom. * All shipping documents and boxes to be labeled with the SOW#.  Do not combine these SOW units with others in the queue.   Special instructions: The preconditioned Maxell battery samples are expected to have lower voltage characteristics than standard CR1216 coin cells from Cavist inventory. Therefore, the following accommodations will apply at the test stations.   * Battery Insertion test station   + Do not reject units for low voltage. Process low voltage failures as if they had passed. * Overmold test station   + Do not reject units for low voltage. Process low voltage failures as if they had passed.   Received units need to be Blue Tagged for traceability. | | | | | | |

**Example of an ER to install RC into transmitters:**

A close-up of a form

Description automatically generated





1. Selected based on ASTM F1980, see Appendix B to justify another acceleration factor to use. [↑](#footnote-ref-2)
2. See Appendix B for AA temperature and TRT section [↑](#footnote-ref-3)
3. See Appendix B for justification for selection of transmitter storage current to use [↑](#footnote-ref-4)
4. See Appendix B for the choice of number of displays [↑](#footnote-ref-5)
5. See Appendix B for justification for selection of operating and body temperature [↑](#footnote-ref-6)
6. See Appendix B for justification for temperature extreme exposures [↑](#footnote-ref-7)
7. See Appendix B for justification for final battery voltage measurement at body temperature [↑](#footnote-ref-8)