# PURPOSE

Purpose should be based on the protocol or test procedure used for this test. The purpose should match the protocol but be adapted for a report that executed the protocol and reference the protocol or test procedure used for this report.

# SCOPE

The scope should define the boundaries for which this document applies for example the product part number, equipment being qualified or production line location. If a protocol exists, the scope should match the protocol scope.

The scope should include a table that includes, the Requirement Document Number, the Requirement ID being verified and the requirement text when applicable.

| **Doc. #** | **REQ ID** | **Requirement** |
| --- | --- | --- |
|  |  |  |
|  |  |  |

# REFERENCES

Reference in this section the any documents that are referenced in the body of this report. Reference the relevant revision of the document for this report, normally the latest revision but can be an earlier released revision if appropriate for the content of this report.

Typically, at minimum the protocol or test procedure used for the report should be referenced here.

| **Document No.** | **Description** | **Rev** |
| --- | --- | --- |
|  |  |  |
|  |  |  |

# ACRONYMS & DEFINITIONS

## Acronyms

List in this section all acronyms referenced in this document.

| **Acronym** | **Definitions** |
| --- | --- |
|  |  |
|  |  |

## Definitions

List all relevant definitions for terms that have a specific meaning for the purpose of this document.

| **Term** | **Definitions** |
| --- | --- |
|  |  |
|  |  |

# Test Procedure Summary

Give a brief description of the test procedure in 1 or 2 paragraph. The summary should be written so that a technical (engineer or scientist) can visualize generally the test procedure without having to pull out the protocol. This summary should include a brief statement of: how the specification is measured, which type of equipment are involved, how the device under test is monitored during the test and if the method is manually operated or automated.

# Material & Equipment

## Device Under Test Configuration

List here the total test articles used for this test, the test article part number, the build ER number or Lot Number. Describe the configuration of test articles. For example, wearable with or without a sensor, Logging FW or CGM FW. Describe if units were sterilized and the sterilization cycle used.

If a Test Log worksheet is provided, only provide the test article configurations in this section

### Test article configurations

| **Part Number** | **rev** | **ER Numbers / Lot Numbers** | **Description / Configuration** |
| --- | --- | --- | --- |
| MT252525 | 001 | ER25-999 | Molded transmitter with RC and logging FW SW46464 rev 001  Sterilized using Steris Cycle 2 |
| MT252524 | 001 | ER25-988 | Molded transmitter with RC and CGM FW SW27635 rev 001  Sterilized using Steris Cycle 2 |

### Test article traceability information

If a Test Log worksheet is provided, this section should only refer to the attachment instead of having a table here.

| **Specimen Number** | **Serial Number** | **Lot Number** | **ER Number** |
| --- | --- | --- | --- |
| 1 | 446366463623 | 983488934 | ER25-999 |
| 2 | 646323459234 | 965789990 | ER25-988 |

## Consumable Material, Equipment, Fixture and Software Used

When consumable materials with expiration date are used, provide a list of the material part number, lot number or serial number or ER number, and expiration date (ex. Buffer solution, deployment substrate).

Provide a table with a list of all equipment used including Equipment Number (or serial number if Dexcom equipment number not available), Equipment Description (include manufacturer and model number if equipment number is not available) and Calibration due date if applicable. Ensure that equipment that should be calibrated were calibrated prior to the start of the test and state here that all equipment was calibrated at the start of the test.

Provide all fixture used in a table including fixture number, fixture description and calibration due date if applicable.

Provide supporting software used for the collection of data and analysis of data if applicable.

If worksheets are used to capture the information of this section, the worksheets should be referenced here and provided as attachment to this report.

Below are examples of tables, adapt the columns to fit the needs of the test report.

### Equipment Used

| **EQ Number** | **Description** | **Calibration Due Date** |
| --- | --- | --- |
|  |  |  |
|  |  |  |

### Fixtures

| **FX Number** | **Description** | **Calibration Due Date** |
| --- | --- | --- |
|  |  |  |
|  |  |  |

### Supporting SW

| **SW Number** | **Rev** | **Description** |
| --- | --- | --- |
|  |  |  |
|  |  |  |

### Material

| **Part Number** | **ER Number** | **Expiration date** | **Descripion** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

# TEST RESULTS

## Test Result Summary

Provide a table that list each requirement verified and that includes at minimum:

* Reference the requirement ID and acceptance criteria
* Number test articles used, number of defective units and test method losses.
* The confidence and reliability required for the analysis in accordance with the protocol
* If test data is analyzed as attribute data, the confidence achieved for the reliability specified for the test
* If test data is analyzed as variable data, the tolerance interval for the confidence and reliability specified for the test
* A PASS or FAIL statement depending on if the acceptance criteria was met or not.

Table 1. Summary of Test Results (Attribute Data)

| **REQ ID** | **Acceptance Criteria** | **Confidence / Reliability** | **Initial Sample Size** | **Test Method Losses** | **Actual Sample Size** | **Defective Units** | **Actual Confidence/ Reliability** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 123950 | After the cap is removed, the inner housing is retained within the applicator. | 95% / 90% | 29 | 0 | 29 | 0 | 95.3% / 90% |

Table 2. Summary of Test Results (Variable Data)

| **REQ ID** | **Acceptance Criteria** | **Initial Sample Size** | **Test Method Losses** | **Actual Sample Size** | **Defective Units** | **Tolerance Interval** | **Confidence / Reliability** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 123950 | The measured length of the sensor is between 4.95 mm and 6.45 mm | 29 | 0 | 29 | 0 | [5.13, 6.34] mm | 95% / 90% |

## Test results details

### Test Execution Chronology

Provide test execution start and end dates and relevant conditioning dates if the conditioning was NOT part of the build instructions. For example, sterilization is normally part of the build instructions and do not need to be added here, while distribution simulation is usually not part of the build instructions and should be added here.

|  |  |  |  |
| --- | --- | --- | --- |
| **Step** | **Start Date** | **End date** | **Location** |
| Distribution Simulation | 06/01/2024 | 06/01/2025 | Westpak |
| Test Execution | 06/02/2025 | 06/17/2025 | Dexcom San Diego |

### Test Result Analysis

Provide in this section any discussion, graphs or pictures of the data collected that is relevant to the interpretation of the test results.

For example, use this section to present the statistical analysis of the test result that determined the tolerance interval against the acceptance criteria.

# PROTOCOL DEVIATIONS

List in this section each deviation to the protocol. See CORPPI-1000046 for the definition of a *deviation* and only mention events that fits this definition in this section.

Correction of typos or references in a protocol is not a deviation and should be discussed in the observations section.

If there are no deviations, mention “No deviations.” for this section.

## DEVIATION #1

Provide a summary of the deviation, how the deviation impacts the test results or how it was determined the deviation does not impact test results. Provide also if the protocol or test procedure was updated to address this deviation or the investigation ticket/number that will resolve the implementation of the deviation.

# DEFECTIVE UNIT INVESTIGATIONS

See CORPPI-1000046 for the definition of a *defective unit* and only mention events that fits this definition in this section.

Create a subsection for each defective unit investigation with the format explained in the example below. If there are more than 1 defective unit investigation, create an introduction that includes the total number of defective units, which specifications were not met and the number of defective units for each specification that was not met.

If there are no defective unit mention “No defective unit in the execution of this test” in this section.

## DEFECTIVE UNIT INVESTIGATION #1 [Place here investigation ticket / number]

For each Defective Unit Investigation provide a summary that includes:

* Which specification was not met by the defective unit(s)
* The number of defective units related to this specification
* The serial number of the defective units.
* Statement that execution of test method was reviewed and the defective units was not caused by the test method not being followed.
* Summary of the root cause investigation of the failed unit(s) or a statement to refer to the investigation for further information.

# TEST METHOD LOSS INVESTIGATIONS

See CORPPI-1000046 for the definition of a *test method loss* and only mention events that fits this definition in this section.

Create a subsection for each test method investigation with the format explained in the example below.

If there are more than 1 test method investigation, create an introduction that includes the total number of test method losses, if test unit replacement were done and the total replacement and, if the minimum sample size was still met.

If there are no test method loss, mention “No test method loss occurred in the execution of this test” in this section.

## TEST METHOD LOSS INVESTIGATION #1 [Place here investigation ticket / number, if appropriate]

For each Test Method Loss Investigation provide a summary that includes:

* Description of the events that lead to disposition test article(s) as test method loss(es).
* The number of units flagged as test method loss and the serial numbers of each test articles flagged as test method losses
* The number of units replaced and their serial numbers.
* Statement if the minimum sample size was still met for this test.

# OBSERVATIONS

This section provides a place for context worth documenting in the report but that do not fit in any of the other sections. Separate each observation under its own subsection.

# CONCLUSION

Provide a conclusion that includes:

* A statement that the overall test units passed or failed to meet the acceptance criteria.
* Total units passing the specification over the total of units tested (excluding test method losses) in the following format ([# units meeting specification / # units tested excluding test method losses)
* If data from the test is analyzed as attribute data, include the confidence achieved for the reliability requested by the acceptance criteria.
* If data from the test is analyzed as variable data, include the tolerance interval per the required confidence and reliability from the acceptance criteria.
* The parameter measured for the acceptance criteria and the required confidence and reliability needed.

If more the test verifies more than 1 acceptance criteria, create 1 separate conclusion for each acceptance criteria.

# ATTACHMENTS

Provide in this section the list of attachments provided as separate documents from this report. Typically Test Procedure or protocol will reference forms or provide forms to collect the data to be attached to the report. Typical attachments are:

* Data sheets
* Equipment log used with calibration due date
* Test Article Traceability Log with part number, serial number
* Raw data files
* Test executor log

Below an example of the Attachment List. The name of the attachment should follow the same convention as the file name of the attachment.

Attachment 1 – Raw Data

Attachment 2 – Equipment Log

Attachment 3 – Test Article Log

Attachment 4 – Evidence of Test Article Conditioning