Document Version History

Version	Date	By	Description
1.0	14/01/2019	Gil Leibiker	First version
2.0	26/02/2020	Asaf Yona / Nir Amrany	• Added Document Version History section • Software rename from WatchM to Pointer IoT • Changed POINTER IoT version from 1.8 to 1.9.0 • Updating the Test Summary Report according to the IQ/OQ/PQ revision 2.0 protocol

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POINTER

1. General

1.1 Document Purpose

The purpose of this Validation Summary Report (VSR) is to summarize the activities executed for 'Pointer IoT' software version 1.9.0 as a part of its validation effort in Pointer Telocation. The purpose of this document is:

- To summarize all the validation activities executed for Pointer IoT as part of software update from version 1.8 to version 1.9.0 (see Change Control #Feature 23895).
- To verify that validation deliverables were executed according to the validation plan.
- To assure that all tests were executed successfully or properly justified for their failure(s).
- To release and approve that Pointer IoT version 1.9.0 is ready to use.

1.2 Scope

The scope of the VSR refers to all validation activities executed for Pointer IoT software version 1.9.0 in Pointer Telocation.

2. Definitions and Abbreviations

The following is a list of abbreviations which are used in this document:

#	Acronym	Acronym Description
1.	cGMP	Current Good Manufacturing Practice
2.	GAMP5	Good Automated Manufacturing Practice 5
3.	GxP	Refers collectively to Good Practices where 'x' refers to Clinical (GCP), Laboratory (GLP) and Manufacturing (GMP) and Distribution (GDP).
4.	CE	Conformity European
5.	CFR	Code of Federal Regulations
6.	FDA	Food and Drug Administration
7.	QA	Quality Assurance
8.	IT	Information Technology

#	Acronym	Acronym Description
9.	MOH	Ministry of Health
10.	SOP	Standard Operating Procedure
11.	URS	User Requirements Specifications
12.	VSR	Validation Summary Report

3. References

#	Document /SOP ID	Document / SOP Title
[1]	GAMP5	Good Automated Manufacturing Practice 5
[2]	21 CFR Part 11	Electronic Records & Electronic Signature Validations
[3]	EU Annex 11	European Union Annex 11 for computerized system
[4]	נוהל 126 של משרד הבריאות	תנאי אחסון והובלה של תכשירים של MOH
[5]	PI_ENG_VAL_f01 (Revision 2)	Validation Plan for Pointer IoT Software Application Version 1.9.0
[6]	PI_ENG_VAL_f02 (Revision 2)	User Requirements Specifications for Pointer IoT Software Application Version 1.9.0
[7]	PI_ENG_VAL_f03 (Revision 2)	Installation, Operation and Performance Qualification Protocol for Pointer IoT Software Application Version 1.9.0
[8]	PI_ENG_04	בקרת שינויים בתוכנה Pointer IoT Software change control
[9]	PI_ENG_02	נוהל אבטחת מידע לוגי ופיזי Procedure for securing logical information
[10]	PI_ENG_01	Backup and Recovery procedure

4. Validation Summary

Pointer IoT validation process uses GAMP5 guideline lifecycle approach and recommendations. This validation process complies with FDA 21CFR Part 11 regulation, and with Pointer Telocation policies and procedures. The validation has included a set of deliverables (as described in the following section 4.1) that has matched with the V-Model phases.

4.1 Summary of Validation Deliverables

The following table summarizes the validation activities and their related deliverables for Pointer IoT.

Document ID	Document name	Final Approval Date	Notes
PI_ENG_VAL_f01 (Revision 2)	Validation Plan for Pointer IoT Software Application Version 1.9.0	13/02/2020	N/A
PI_ENG_VAL_f02 (Revision 2)	User Requirements Specifications for Pointer IoT Software Application Version 1.9.0	13/02/2020	N/A
PI_ENG_VAL_f03 (Revision 2)	Installation, Operation and Performance Qualification Protocol for Pointer IoT Software Application Version 1.9.0	16/02/2020	N/A
PI_ENG_VAL_f04 (Revision 2)	Validation Summary Report for Pointer IoT Software Application Version 1.9.0	26/02/2020	N/A

5. Execution

5.1 Initiation

The validation project for Pointer IoT (Previously known as WatchM) software version 1.8 was initiated on August 2018. The validation project for Pointer IoT version 1.9.0 which was updated during September 2019- January 2020 according to Change Control #Feature 23895 was initiated on January 2020. The Validation Plan (VP) summarized project activities, scope and resources.

5.2 Specifications

Following the approval of the VP, User Requirements Specification document was created and specified.

5.3 Testing

Pointer IoT version 1.9.0 testing was executed in the Installation, Operation and Performance Qualification Protocol (PI_ENG_VAL_f03 Revision 02). The test description included test instruction and all the tests scripts required for execution. All the test scripts were performed by a tester and were later reviewed by a reviewer. IQOQPQ tests were successfully executed on the 17/02/2020 and 18/02/2020.

6. Test Result Summary

This section summarizes test results, test failures and test failures assessments for the various test cases of Pointer IoT.

6.1 Test Results Summary

Test Script ID	Test Name	Results	Comment
TC010	Notifications Setup	Pass	N/A
TC011	Alerts	Pass	N/A
TC012	Polygon	Pass	N/A
TC013	Graphs and Charts	Pass	N/A
TC014	Reports	Pass	N/A
TC015	Device Reports	Pass	N/A

6.2 Deviations and Failure list

There weren't deviations found during the validation execution.

7. Maintenance of the validated state

Changes to the validated state will be executed according to Pointer Telocation change control procedure SOP ID: PI_ENG_04.

8. Deliverable Archive and Retrieval

The Validation documents will be stored in Pointer Telocation in secured Documentation Center.

9. Validation Conclusions

- The required validation activities, as specified in the VP, under the limitation that is defined in the scope of this document, have been completed successfully.
- The validation met the acceptance criteria which was defined in system VP document
- The related required deliverables, as specified in the VP, have been delivered, reviewed and approved.
- All the tests have been completed successfully, has detailed in the test execution report.
- The Pointer IoT Software version 1.9.0 is ready for use and authorized for work according to its intended use in Pointer Telocation.
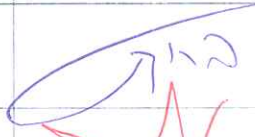- When this VSR is approved, it serves as the certificate to the validated status of the validated system.
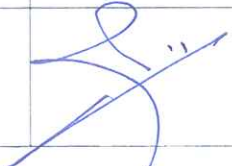
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Validation Summary Report for Pointer IoT Software Application Version 1.9.0

APPROVAL

This Validation Plan has been reviewed and approved by the following:

Title	Name	Signature	Date
Written by \ Validation	Asaf Yona / Nir Amrany		26/02/2020
VP Marketing and Business Development	Yaniv Baruch		27/2/2020
Technical Owner	Oded Busme		27/2/2020
CEO	Ilan Goldshtein		27/2/2020