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Approvals

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Revision History for CARTO® 3 System V7 Top Level Validation

DAP	Rev.	Description
DAP012786	1.1	New Document
DAP012937	1.2	Added MC Catheter support to Phase 1 Moved 'Image convert to FAM' from Phase 2 to Phase 1 Detailed the base improvements for Phase 1 Added power noise reject filter in WS to Phase1 Removed V&V strategy for content which was moved to Phase 2 Changed unit test to POD for Parallel Mapping and LAT hybrid
DAP014284	1.4	Update System Configurations and Combability Update V&V method for some of the features Update Phase1 content Remove support for: • nMARQ™ Multi Channel RF generator • Qdot • SIA
DAP014658	1.6	Updates for Phase 1 V&V cycle 2 Remove Octaray from Phase 1
DAP015102	2.0	Updates for Phase 1 V&V cycle 3 Remove HP Z440 WS Remove W530, W540\1 laptops from Phase 1 Update GE Vivid™ iq Remove upgrade functionality from Phase 1 Remove support for SURPOINT™ module enabling key
DAP015435	2.1	Update Top Level Validation Plans revision Add new WS Dell 7820 Add list of declaration of compatibility documents Update Phase 2 content and Phase 3 content (as TBD)
DAP015556	2.3	Remove WS Dell 7820 Update REP numbers for the V&V documents

DAP	Rev.	Description
		Fix typos: • Pre-clinical validation for power noise filter (Yes->No) • Section 6.1.3 title (Phase2->Phase3) • PIU configurations (ACLRx->LocRx)

CARTO® 3 SYSTEM V7 TOP LEVEL VALIDATION

1. PURPOSE

The purpose of this document is to layout the tests that will be done for verification and validation of CARTO® 3 system Version 7.

2. SCOPE

This verification and validation plan contains tests for CARTO® 3 System V7 and all its modules and interfaces.

This plan includes integration tests that will be detailed in POD plans, SW\Alg. tests and pre-clinical trial plan.

The CARTO® 3 System V7 project is developed in 2 phases (see REF2). See the overview in section 6.1.

The scope of this document is the validation required for phase 1.

3. REFERENCES

REF #	Document Title	Rep#/ Document ID
REF1	Design Verification and System Validation	PD-511-730
REF2	CARTO® 3 V7 Project Plan	REP9725
REF3	CARTO® 3 V7 Essential Requirements	REP9625
REF4	CARTO® 3 V7 Top Level FRS	REP9722
REF5	CARTO® 3 V7 Top Level Pre-Clinical Trial Plan	REP9718

REF6	List of Compatible Catheters	REP6185
REF7	Impact analysis for PIU HW configurations	REP8149

4. DEFINITIONS AND ACRONYMS

AFIB – **A**trial **Fib**rillation

AFL – **A**trial **Fl**utter

ARA – **A**dvanced **R**eference **A**nnotation

BS – **B**ody **S**urface

CL – **C**ycle **L**ength

CS – **C**oronary **S**inus

DX – **D**iagnostic

ECG – **E**lectro**c**ardio**g**ram

FAM – **F**ast **A**natomical **M**apping

HW – **H**ard**w**are

IC – **I**ntra **C**ardiac

MC – **M**ulti **C**onnector

MEM – **M**ulti-**E**lectrode **M**apping

LAT – **L**ocal **A**ctivation **T**ime

NSR – **N**ormal **S**inus **R**hythm

PbP – **P**oint **b**y **P**oint

PIU – **P**atient **I**nterface **U**nit

PVC – **P**remature **V**entricular **C**ontraction

RMT – **R**emote **M**agnetic **T**echnology

ROI – **R**egion **o**f **I**nterest

SIA – **S**hort **I**nterval **A**blation

SQA- **S**oftware **Q**uality **A**ssurance

SW – **S**oft**w**are

TPI – **T**issue **P**roximity **I**ndication

VT – **V**entricle **T**achycardia

5. RESPONSIBILITY

The system engineer who is the technical lead of V7 project is responsible for ensuring that the tests listed in this plan provide full coverage of the project content.

It is the responsibility of the system integration engineers to provide POD plans for the tests in this plan, execute the tests and issue reports for the results.

It is the responsibility of the Clinical team to provide pre-clinical plan for the product items in this document, execute it and issue a report.

It is the responsibility of the SQA team to provide functional test plans, detailed test items, tests execution, test results and report.

The usability expert is responsible for all verification and validation activities that are related to the human factors and usability aspects of the system.

It is the responsibility of the Project Manager to verify that the needed resources, for the execution of this plan are available, and fit the timelines of the project.

6. OVERVIEW

6.1 V7 Main Features

6.1.1 V7 main system functionalities in phase1:

1. Base – improvements for ease of use, streamlined workflow and User Satisfaction, including the following improvements:
    - New design for catheter setup screen
    - HD propagation style and point visualization improvements for legacy coloring
    - Increase the limit for number of points in map and study
    - Visualization setup updates
2. Base – power noise reject filter – applying the concept of the CARTOFINDER power noise reject filter to all the channels in the WS instead of the legacy filter in the PIU.
3. Base – feature removal:
    - Vessel feature
    - Freeze\Accept mode
    - RMT support
    - VisiTag Impedance Drop filter
4. Advanced Reference Annotation (ARA) – algorithm aims to provide a reliable and consistent reference annotation.
5. Parallel Mapping – The Parallel Mapping feature enables to create multiple maps simultaneously with different set of continuous acquisition filters (prospectively and retrospectively).
6. COHERENT Mapping – mapping which improves the representation of the electric wave propagation over the heart chamber by means of coloring and direction vector.
7. CARTOFINDER™ – algorithm which is dedicated to identifying activation patterns in persistent AFIB patients with supported MEM catheters.

8. LAT Hybrid – feature which combines signals from the PVC and anatomical position at Sinus rhythm.

6.1.2 V7 main system functionalities in phase2:

1. Base – improvements for ease of use, streamlined workflow and User Satisfaction, including the following improvements:
    - Frequency detection
    - Previous beat overlay
    - LAT histogram
    - Ongoing LAT consistency
    - Increase number of points per map and study.
    - Improve density of points
    - Media export
    - VisiTag ODP values
    - TPI - Catheter setup: proximity parameters selection shall be saved in template
    - Service improvements - Error reporting tool update
    - Color bar improvement (System shall save the color bar mode (Auto, Manual, Custom) and limits per each coloring type, per each viewer)
2. Phas1 features improvements (ARA, Parallel Mapping, COHERENT Mapping, CARTOFINDER™)
3. HELIOSTAR
4. QMODE+

6.1.3 V7 main system functionalities in phase 3:

TBD

6.2 System Requirements

The system requirements for V7 are detailed in the top-level FRS REF4.

6.3 V&V Methodology

Verification and validation of V7 will be done using the following methods:

- Usability Test – The purpose of those tests is to verify that the design and implementation meet the product's usability requirements. The tests will be performed by the usability expert.
- Functional Test – will be performed by the SQA team following the functional requirements defined in the various features' FRSs. Those tests are out of scope of this plan.
- Unit Test – the purpose of this test is to verify the design implementation in CARTO®3 V7 software is compatible to the design. The test will be performed by the SW team.
- Proof of Design (POD) – The purpose of those tests is to verify that the system design meets the specifications. The tests will be planned, performed and analyzed by the SE\SI team.
- Pre-clinical Validation – An experiment performed on a test animal model which is a required essential step for a product/feature development and validation. Two types of pre-clinical trials can be performed - Workflow Trial and/or Validation trial, according to feature/module scope. The tests will be performed by the clinical development team. See REF5.

7. PHASE 1 VERSION

7.1 Version Content

The version content is CARTO®3 V6 phase 6 with the addition CARTO®3 V7 phase 1 features as detailed in section 6.1.1.

7.2 Top Level Validation Plans

Top Level Validation Plan	REP#, Revision
CARTO 3 V7 - Power Reject Validation Plan	REP10029 Rev. 1.2
CARTO 3 V7 - Parallel Mapping Top Level Validation and Verification	REP10021 Rev.1.5
CARTO 3 V7 Cartofinder Top Level Validation	REP9945 Rev. 1.6
CARTO 3 V7 Coherent TL Validation Plan	REP9816 Rev. 2.0
ARA - Top Level Validation Plan	REP9938 Rev. 1.1

7.2.1 Verification and Validation Strategy

Test Plans for each feature in Phase 1:

V&V Method / Feature		Usability Test	Functional Test	Unit test	POD	Pre-clinical Validation
Phase 1						
Base	Improvements for ease of use, streamlined workflow and User Satisfaction	Yes Plan: REP9939, REP10392 Results: REP10152, REP10640	Yes Plan: REP9707 Results: REP9709	No	No	No

Feature \ V&V Method		Usability Test	Functional Test	Unit test	POD	Pre-clinical Validation
	Power noise reject filter in WS	No	Yes Plan: REP9707 Results: REP9709	Yes Plan: REP9557 Results: REP9928	Yes Plan: REP10179 Results: REP10756	No
	Feature removal	No	Yes Plan: REP9707 Results: REP9709	No	No	No
	Basic functionality – Map coloring	No	No	No	Yes Plan: REP10603 Results: REP10987	No
ARA		Yes Plan: REP9939, REP10392 Results: REP10152, REP10640	Yes Plan: REP9707 Results: REP9709	Yes Plan: REP10438, REP9616 Results: REP10439, REP10486	Yes Plan: REP9753 Results: REP10631	Yes Plan: REP10487 Results: REP10669
Parallel Mapping		Yes Plan: REP9939, REP10392 Results: REP10152, REP10640	Yes Plan: REP9707 Results: REP9709	Yes Plan: REP8796, REP10443 Results: REP10977, REP10662	No	Yes Plan: REP10473 Results: REP10670
COHERENT Mapping		Yes Plan: REP9939, REP10392 Results: REP10152, REP10640	Yes Plan: REP9707 Results: REP9709	Yes Plan: REP10247, REP10256, REP10249 Results: REP10248, REP10800, REP10250	Yes Plan: REP9999 Results: REP10318	Yes Plan: REP10251 Results: REP10252
CARTOFINDER™		Yes Plan: REP9939, REP10392	Yes Plan: REP9707 Results: REP9709	Yes Plan: REP10428, 10399	Yes Plan: REP10181 Results: REP10744	Yes Plan: REP10502, REP10450

V&V Method / Feature	Usability Test	Functional Test	Unit test	POD	Pre-clinical Validation
	Results: REP10152, REP10640		Results: REP10691, REP10690		Results: REP10668, REP10666
LAT Hybrid	Yes Plan: REP9939, REP10392 Results: REP10152, REP10640	Yes Plan: REP9707 Results: REP9709	Yes Plan: REP8796, REP10443 Results: REP10977, REP10662	No	Yes Plan: REP10473 Results: REP10670

7.3 System Configurations and Compatibility

7.3.1 PIU Configurations

According to document REF7 the configurations below cover the span of all configurations in the field and therefore provide a full coverage

Cards/Modules vs Configurations	*DC/DC*	*ECG*	*ACLTx*	*LocRx*	*MAGTx module*	*Main Module*	*Supported Yes/No*
1	EA-5401-12	EA-5401-16	EA-5401-26	EA-5401-29	EM-5401-15	EM-5401-20	No
2	EA-5401-12	EA-5401-16	EA-5401-26	EA-5401-29	EM-5401-151	EM-5401-201	No
3	EA-5401-121	EA-5401-162	EA-5401-26	EA-5401-29	EM-5401-151	EM-5401-201	No
4	EA-5401-121	EA-5401-162	EA-5401-263F	EA-5401-29	EM-5401-151	EM-5401-201	yes
5	EA-5401-121	EA-5401-16	EA-5401-263F	EA-5401-29	EM-5401-15	EM-5401-201	yes
6	EA-5401-121	EA-5401-16	EA-5401-263F	EA-5401-291	EM-5401-151	EM-5401-201	No
7	EA-5401-121	EA-5401-162	EA-5401-26	EA-5401-29	EM-5401-151	EM-5401-20	No

- According to REF7:
  - EM-5401-201 and EM-5401-201F are equivalent
  - EM-5401-15 Rev:02B or higher is fully compatible to EM-5401-151

7.3.2 Workstation

#	Model	Frame Grabber	Graphics Card
1	Dell 5810	Solios	GTX980
2	Dell 5810	Solios	GTX1080
3	Dell 5810	None	GTX980
4	Dell 5810	None	GTX1080

- HP Z440 was removed at this version.
  All workstation HW version were tested to be qualified to the SW requirement (including HP Z440), so it's removal doesn't impact the prior tests performed on this workstation.

7.3.3 Monitor

Monitor	Resolutions
Dell	1,600 pixels × 1,200 1,920 pixels × 1,200 1,920 pixels × 1,080 2,560 pixels × 1,440

7.3.4 Compatible equipment that will be tested during the V&V cycles

System	Model	Versions	Vendor	*Supported Yes/No*
RF Generator for Qdot Catheter	nMARQ™ Multi Channel RF generator.	SW version 3.0.1.59	Biosense	No

System	Model	Versions	Vendor	*Supported Yes/No*
	Note: nMARQ™ catheters (produced by Biosense) are not supported by this version of nMARQ™ and therefore are not part of the validation for this version			
RF Generator for Legacy Catheter	Stockert GmbH SMARTABLATE System RF Generator	1.2, 1.7	Stockert	Yes
RF Generator for Legacy Catheter	Stockert GmbH EP Shuttle System RF Generator	1.037,1.036,1.035	Stockert	Yes
Micro-Qdot Catheter	Clinical workflow study Version by BWIUS	NA	Biosense	No
Micro-Qdot Extension cable	Clinical workflow study Version by BWIUS	NA	Biosense	No
Micro-Qdot dongle	Biosense Webster Tx eco Cable	P27	Biosense	No
EPU	VISITAG SURPOINT™ External Processing	Unit-Version # 1.0.0.1	Biosense	Yes
Vizigo Sheath	Clinical workflow study Version by BWIUS	NA	Biosense	Yes
Recording System	Siemens AXIOM Sensis XP EP Recording System	VC12B	Siemens	Yes
Recording System	GE Marquette CardioLab® EP Recording System	V6.9.5	GE	Yes
Recording System	Bard System PRO EP Recording System	V2.6.0.19	Bard	Yes
Fluoro System	Siemens Artis_Zee_Floor	VC21C	Siemens	Yes
UltraSound System	SIEMENS Acuson X700™	VB20E-2.0.04(0041)	Siemens	Yes
UltraSound System	SIEMENS Acuson SC2000™	VB20C	Siemens	Yes
UltraSound System	SIEMENS Sequoia™	12.221	Siemens	Yes
UltraSound System	SIEMENS Acuson X300™	7.5.06 (3748)	Siemens	Yes
UltraSound System	SIEMENS Acuson P500™	VB10C(2.0.10)	Siemens	Yes
UltraSound System	GE Vivid™ i\q	Application version: 12.2 System Version: 8.1.2	GE	Yes
UltraSound System	GE Vivid™ iq	Version 1.0.5 revision 4942	GE	Yes
Ultrasound System	GE Vivid S70	202 Rev. 34.3	GE	Yes

- CARTO® 3 V7 is compatible with the equipment supported by the previously released CARTO® V6 version as detailed in the following declaration of compatibility documents:
    - DC-5400-044 CARTO 3 Decl. of compatibility with Toshiba
    - DC-5400-046 CARTO 3 Decl. of compatibility with Philips.
    - DC-5400-047 CARTO 3 Decl. of compatibility with GE.
    - DC-5400-048 CARTO 3 Decl. of compatibility with Siemens.
    - DC-5400-049 CARTO 3 Decl. of compatibility with Stockert.
    - DC-5400-051 CARTO 3 Decl. of compatibility with Bard
    - DC-5400-058 CARTO 3 Decl. of compatibility with ITD Cart

7.3.5 Catheters

See REF6 for catheter compatibility.

7.3.6 Service JIG Utility

Version	Compatibility
2.1	V4 LMR and above

7.3.7 AFC Utility – not supported in Phase 1

Version	Compatibility
Not supported	N\A

7.3.8 CARTOUNIVU™ Module Service CD

Version	Compatibility
V1.18	V4 LMR and above

7.3.9 CARTO® VisiTag™ Module Analysis Tool – not supported in Phase 1

Version	Compatibility
Not supported	N\A

7.3.10 Laptops

Laptop	Model
Lenovo	Phase 1 - P50 Phase 2 - W530, W540\1, P50

7.3.11 Upgrade

CARTO3 V7 Phase 1 does not support upgrade from previous versions.

CARTO3 V7 Phase 2 supports upgrade from:

- V6 Phase 4 (6.0.45.171 and 6.0.45.169)
- V6 Phase 5 (6.0.54.133)
- V6 Phase 6 (6.0.60.70)
- V6 Phase 7 (6.0.70.70)

7.3.12 V6 Modules keys compatibility

CARTO3 V7 Phase 1 does not support V6 module enabling keys:

- CARTO VISITAG SURPOINT™ with EPU (obsolete)
- CARTO VISITAG SURPOINT™ without EPU (obsolete)
- Qdot
- SIA (with Qdot)