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DAP013683	5.9	See the Revision History table on the next page	15 Nov 2017
DAP013353	5.4	See the Revision History table on the next page	12 Sep 2017
DAP013170	5.3	See the Revision History table on the next page	06 Aug 2017
DAP013057	5.1	See the Revision History table on the next page	20 Jul 2017
DAP012881	4.9	See the Revision History table on the next page	23 May 2017
DAP012578	4.8	See the Revision History table on the next page	06 Apr 2017
DAP012501	4.2	See the Revision History table on the next page	22 Feb 2017
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DAP011704	3.2	See the Revision History table on the next page	16 Aug 2016
DAP011637	2.9	See the Revision History table on the next page	03 Aug 2016
DAP011361	2.8	See the Revision History table on the next page	09 Jun 2016
DAP011251	2.4	See the Revision History table on the next page	15 May 2016
DAP010550	2.1	See the Revision History table on the next page	08 Jan 2016
DAP009864	1.6	See the Revision History table on the next page	21 Jun 2015
DAP009682	1.4	See the Revision History table on the next page	21 May 2015
DAP009331	1.0	See the Revision History table on the next page	17 Feb 2015

Approvals

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Document Title: **CARTO® 3 System V6 Top Level Validation**
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Revision History for CARTO® 3 System V6 Top Level Validation

DAP	Rev.	Description
DAP009331	1.0	New Document
DAP009682	1.4	Version for Phase 1
DAP009864	1.6	Additional WS configuration support for Phase 1 nMarq protocol 2.5.1.4 support Typo and document number updates
DAP010550	2.1	Version for Phase 2.5 nMarq protocol 2.5.1.7 support
DAP011251	2.4	Version for Phase 3.0
DAP011361	2.8	Expanding the contenet of phase 3 (See section 6.1.4) Moving Qdot validation to REP8961 CARTO® 3 SYSTEM QDOT VALIDATION PLAN
DAP011637	2.9	Removing Dell 3600. Removing Old main configurations. Removing Ablation Index from phase 3.
DAP011704	3.2	Adding Ablation Index from phase 3. Documents number updates
DAP011823	3.4	Update of reports name for phase 3 Changing the document name to: “CARTO® 3 System V6 Top Level Validation” Changing nMarq version to 2.5.1.14
DAP011995	4.0	Phase 4
DAP012501	4.2	Update to include recent changes
DAP012578	4.8	Phase 5
DAP012881	4.9	Phase 4 - Compatibility Phase 4 and Phase 5 updated
DAP013057	5.1	Phase 4 – Compatibility with Vivid IQ and P500 Ultrasound machine for phase 4. Phase 5 – Remove SIEMENS Acuson SC2000™ VB10C
DAP013170	5.3	Design change before cycle 2 of phase 5

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DAP	Rev.	Description
DAP013353	5.4	Design change before cycle 3 of phase 5 Phase 4 – NOT Compatible with Vivid IQ and P500 Ultrasound machines (see 4.9).
DAP013683	5.9	Design change before cycle 6 of phase 5 with SQA comments integrated
DAP013797	6.0	CARTO3 V6 phase5 Design change related to WAVEFRONT annotation change (No LAT)
DAP013918	6.4	CARTO3 V6 phase 6 including integrated comments including compatibility updates
DAP014730	7.0	CARTO3 V6SP (phase 7) cycle 2

CARTO® 3 SYSTEM V6 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 6.

2. SCOPE

This verification and validation plan contains tests for CARTO® 3 System V6 and all its modules and interfaces.

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

The CARTO® 3 System V6 project is developed in 7 phases (see REF2). See the overview in section 6.1 below.

The scope of this document is updated, to include the validation required for V6SP (phase 7).

3. REFERENCES

REF1: CARTO® 3 V6 Top Level FRS, REP7896.

REF2: CARTO® 3 V6 Project Plan, REP7252.

REF3: CARTO® 3 V6 Pre-Clinical Plan, REP7925.

REF4: Impact analysis for PIU HW configurations, REP8149.

REF5: Impact Analysis of Qdot Dongle HW Configuration, REP8125.

REF6: Design Verification and System Validation, PD-511-730.

REF7: List of Compatible Catheters, REP6185.

REF8: WS HP Z440 Assembled by CFI Config., CP-0440-00F.

REF9: WS T3610 as in CFI Version, CP-3610-00F.

REF10: CARTO® 3 V6 Usability Engineering File, REP7326.

4. DEFINITIONS AND ACRONYMS

ACL – **Advanced C**atheter **L**ocation.

CFI – **Custom Factory Integration**

FRS – **F**unctional **R**equirements **S**pecification

GE – **G**eneral **E**lectric

HD – **H**igh **D**efinition

HW – **H**ardware

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

POD – **P**roof **O**f **D**esign

SDA – **S**hort **D**uration **A**blation

SIA - **S**hort **I**nterval **A**blation (also known as HPA/TGA)

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

TGA – **T**emperature **G**uided **A**blation

SW – **S**oft**w**are.

Qdot – Name of catheter and module.

5. RESPONSIBILITY

The system engineer who is the technical lead of V6 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

This section outlines the main features of V6 and the phases of the development. The features content of each phase is shown in Section 6.3 below.

6.1 V6 Versions

The versions for V6 are the following (See REF2):

6.1.1 Phase 1

Qdot only version.

This version is going to be released for a limited number of internal users per specific use of bench testing, thigh prep experiments and animal study.

The tested features are:

1. Connectivity of the catheter
2. Accuracy of the temperature
3. Ablation

All other features are tested briefly as there is ***no patient involved***.

The intended workflow for the system in phase 1:

1. Connect a dongle and catheter.
2. Balance the catheter on the tissue (bench tests or thigh prep) with a given load.
3. Ablate at various powers and durations.
4. Log the temperature readings of the system.

The verification content for this version is covered in section 7.1 below.

The tested configurations for this version are covered in section8.1 below.

Due to the above, there is no requirement for pre-clinical trials (See REF3).

6.1.2 Phase 2

Cancelled due to the introduction of micro electrodes to the Qdot catheter.

6.1.3 Phase 2.5

Micro-Qdot only version

Version for Micro-Qdot catheter safety studies.

Out of V6 the following will be used:

1. Qdot temperature and micro electrodes feature

2. Temperature drop filter in VisiTag™

Features which are going to be available on the current version are:

Feature	Comment
Base including Qdot and micro electrodes	None
VisiTag™	Temperature drop

The tested features are:

1. Connectivity of the catheter
2. Accuracy of the temperature
3. Ablation
4. Signal quality of micro electrodes during ablation
5. Temperature drop filter in visiTag.

All other features are tested briefly as there is ***no patient involved***.

The intended workflow for the system in phase 2.5:

1. Connect a dongle and catheter.
2. Balance the catheter on the tissue (bench tests or thigh prep) with a given load.
3. Ablate at various powers and durations.
4. Log the temperature readings of the system.
5. Log the intracardiac signal of microelectrodes.
6. Observe the formation of a visiTag according to the temperature drop filter.

The verification content for this version is covered in section 7.3 below.

The tested configurations for this version are covered in section 8.3 below.

No Pre-Clinical validation is required for this version.

Micro-Qdot dongle related errors are going to be tested as part of this phase.

Micro-Qdot application related errors (system errors reported by CARTO® 3) are not going to be tested as part of this phase.

Micro-Qdot catheter is not part of this validation plan and the design freeze version of the catheter by BWIUS team is specified in section 8.3 below.

The Micro-Qdot extension cable connecting between the catheter and the dongle is not part of this validation plan and the design freeze version of the cable by BWIUS team is specified in section 8.3 below.

6.1.4 Phase 3

Version for Micro-Qdot workflow study and V6 EE.

Out of V6 the following new features will be used:

1. Micro Qdot full features
2. VisiTag™
3. CARTOUNIVU™

Base version:

- ❑ Open modules in the Phase 3: Qdot, SMARTOUCH™, CARTOUNIVU™, VisiTag™, ConfiDENSE™, Ripple Mapping, CartoSeg™, Dual Monitor & PASO™ Ablation Index
- ❑ Close Modules in the Phase 3: CartoMerge™, RMT, CARTOSOUND, CARTOREPLAY™, FAM Dx, CFAE.

The verification content for this version is covered in section 7.4 below.

The tested configurations for this version are covered in section 8.4 below.

Requirement for pre-clinical trials in REF3.

Features which are in table 1, section 6.3 (see below)

6.1.5 Phase 4

Version for Micro-Qdot workflow study and V6 EE.

The version will include VIZIGO support

All Base and previously developed features (up to CARTO® 3 System V4) will be supported

Base version:

- ❑ Open modules in the Phase 4: Qdot, SMARTOUCH™, CARTOUNIVU™, VisiTag™, ConfiDENSE™, Ripple Mapping, CartoSeg™, Dual Monitor & PASO™ Ablation Index, CartoMerge™, RMT, CARTOSOUND, CARTOREPLAY™ , FAM Dx , CFAE .
- ❑ Close Modules in the Phase 4: NA

The verification content for this version is covered in section 7.5 below.

The tested configurations for this version are covered in section 8.5 below.

Requirement for pre-clinical trials in REF3.

Features which are in table 1, section 6.3 (see below)

6.1.6 Phase 5

Version for Micro-Qdot workflow study (part 2) and launch version.

The version will include SIA compatibility, SurPoint compatibility support and HD coloring

All Base will be supported

Base version:

- ❑ Open modules in the Phase 5: Qdot, SMARTOUCH™, CARTOUNIVU™, VisiTag™, ConfiDENSE™, Ripple Mapping, CartoSeg™, Dual Monitor & PASO™ Ablation Index, CartoMerge™, RMT, CARTOSOUND, CARTOREPLAY™ , FAM Dx , CFAE, VIZIGO.
- ❑ Close Modules in the Phase 5: NA

The verification content for this version is covered in section 7.6 below.

The tested configurations for this version are covered in section 8.6 below.

Requirement for pre-clinical trials in REF3.

Features which are in table 1, section 6.3 (see below)

6.1.7 Phase 6

Update on launch version (see phase 5), to include continuous Tag index coloring, and eliminating the manual setting, when working with EPU, (while maintaining existing functionality for none-EPU use).

Updating security patches and Adobe build elements.

The verification content for this version is covered in section 7.7 below.

The tested configurations for this version are covered in section 8.7 below.

No preclinical trials required.

6.1.8 Phase 7

Update on launch version (see phase 5), to include VIZIGO visualization, Security update, encryption of exported data, Clone recording removal, HD license removal HD coloring updated parameters ,HP Z440 removal, adding DECANAV as FAM Dx enabler, and defect fixes.

Updating security patches and Adobe build elements.

The verification content for this version is covered in section 7.8 below.

The tested configurations for this version are covered in section 8.8 below.

6.2 V6 Main Features

6.2.1 BASE

Multiple enhancements to the CARTO® experience, including user experience improvements that simplify workflows, reduce visual overload and add required functionality.

6.2.2 QDOT MICRO™ MODULE

The QDOT MICRO™ Catheter (currently in development, not approved for commercial use) is an open irrigated ablation catheter with force-sensing capability, microelectrodes and enhanced tip temperature measurements and tip orientation to tissue display. CARTO® 3 System Version 6 will support the QDOT MICRO™ Catheter by integrating multi temperature readings and microelectrode signal information from the catheter and providing real-time display of temperature across the catheter tip.

6.2.3 CARTO VISITAG SURPOINT™

The CARTO VISITAG ™ Module is a commercially approved software module that allows physicians to track their ablation strategy. In CARTO® 3 System Version 6 there will be several enhancements to the CARTO VISITAG™ Module. The feature currently referred to as Ablation Index will be renamed CARTO VISITAG SURPOINT™ Module. The system will be compatible with the external processing unit (EPU) which will have the ability to calculate tag index values in real time.

6.2.4 CARTO VIZIGO™ Sheath Compatibility

The CARTO VIZIGO™ software will allow physicians to visualize the CARTO VIZIGO™ Sheath on the CARTO® 3 System. The CARTO VIZIGO™ Sheath assembly includes electrodes that enable visualization by the CARTO® 3 System.

6.2.5 CONFIDENSE™ MODULE

The CONFIDENSE™ II Module includes pattern matching and complex point identification features that will help physicians to more efficiently diagnose patients with complex arrhythmias. Pattern matching will help reduce the need for manual exclusion of irrelevant ectopic ventricular activations. Complex point identification will help physicians detect signals/areas of interest on the substrate.
Complex point will be password protected.

6.2.6 CARTOSEG™ CT Segmentation Module

CARTOSEG™ CT Segmentation Module automates the CT segmentation process providing detailed anatomic 3D image integration highlighting discrete anatomic structures.

6.2.7 CARTOSEG™ MR Segmentation Module

CARTOSEG™ MR Segmentation Module allows physicians to differentiate between different cardiac tissue/substrate by scanning characteristics. It provides tools to segment the cardiac tissue/substrate into 3D images which can be imported into CARTO® 3.

6.2.8 High Definition Mapping

HD Mapping is a new interpolation method for identifying the physical quantity across the CARTO® 3 maps on location which are different than the locations where actual points were taken.

6.2.9 Short Interval Ablation

Short Interval Ablation is a new mode of the ablation generator, which produces ablation in a short duration and high power. CARTO® 3 V6 will be compatible with this mode and will display the ablations created in this mode with a new specific tag.

6.3 Version New Features Content for Each Phase

The content of each phase is shown in the table below (v – included in the phase version. x – not included in the phase version):

Table 1: V6 features and the implemented phase.

	Base	Qdot	VisiTag	CONFIDENSE Improvements	VIZIGO	HD Mapping	CARTOSEG CT/MR	SIA	CARTOUNIVU™	SurPoint
Phase 1	x	v	X	x	x	x	x	x	x	x
Phase 2.5	x	v	v-Qdot only temperature	x	x	x	x	x	x	x
Phase 3	v	v	v	v	x	x	v	x	x	x
Phase 4	v	v	No Change fromV4, SP1	v	v	x	v	x	v	x
Phase 5	v	v	V	v	v	v	v	v	v	v
Phase 6	v	v	v+	v	v	v	v	v	v	v
Phase 7	v++	v	v+	v	v++	v	v	v	v	v

Comment: (+) See section 6.1.7

(++) Updated VIZIGO visualization

7. SYSTEM VERIFICATION PLAN

7.1 Version 6 Phase 1

A limited release version of CARTO® 3 system V6. The use of the system is in animal study, thigh prep setup and bench testing on a tissue.

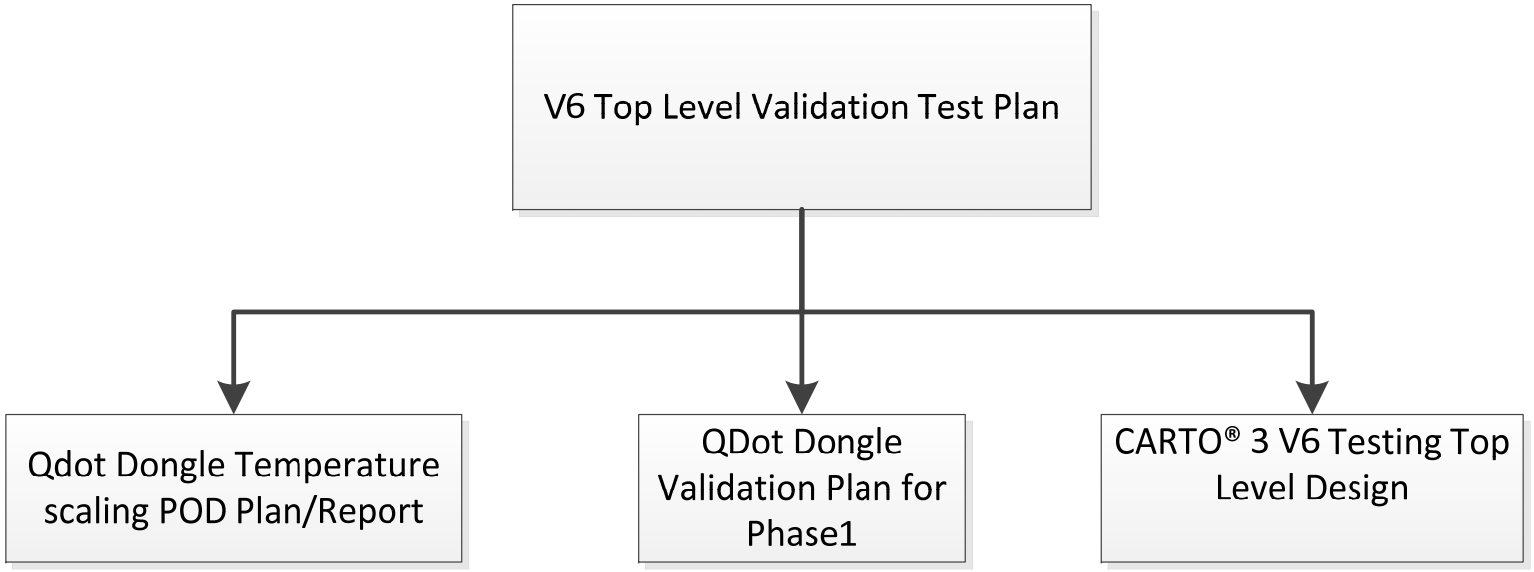

Figure 1 phase 1 validation coverage block diagram

7.1.1 Qdot Dongle and Catheter

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
Temperature scaling in Qdot dongle	Qdot Dongle Temperature Scaling POD Plan/Report	SE/SI	REP7988	SE/SI	REP8121	6.0 Phase 1	ational: Determining the scaling introduced to the Qdot dongle. Details: Qdot dongle calculates the interface temperature on the tip surface. The POD shows the accuracy and the parameters which are used for the scaling of the measured temperature within the dongle. Correctness of the temperature calculation is shown in REP8126 - Qdot Dongle POD report for phase 1.
Qdot Dongle System level test	Qdot Dongle Validation Plan/Report for Phase 1	SI	REP8003	SI	REP8126	V6.0 Phase 1	ationale: System level tests for Qdot catheter and the attached dongle. Details: Functionality of Qdot catheter shall be tested. The test plan and report cover all the required system level tests for phase 1. Covered tests are: Temperature calculations (given the parameters tested in REP7988) and correctness during ablation. PODs will be performed for phase 2.5 as the use for this version is in animal study and bench tests. Unsupported tests are: Force Accuracy ECG signal quality ACL accuracy Magnetic location accuracy Rationale: Accuracy of these tests is not required for the intended use of the system on phase 1 which is bench testing and animal studies.

7.1.2 Qdot Module

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
Functional tests of Qdot module	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 1	Rationale: Functional test of the new feature. Details: Functional tests of the Qdot module.

7.2 Version 6 Phase 2

Canceled

7.3 Version 6 Phase 2.5

A limited release version of CARTO® 3 system V6. The use of the system is in thigh prep setup and bench testing on a tissue only.

The system block diagram is shown on the figure 2 below. Each block which is modified in V6 phase 2.5 is indicated by a number and the corresponding tests for the block will be elaborated in tables at sections 7.3.1 – 7.3.3 (Purple numbered circles).

Tests:

1. Qdot Catheter and is not going to be tested on a system level (POD) in this version. The validation assumes a design version freeze for the catheter.
2. Qdot extension cable are not going to be tested on a system level (POD) in this version. The validation assumes a design version freeze for the cable.
3. Calibration POD is not going to take place as the catheter is not in the final form but in a design freeze (see 1 and 2 above)

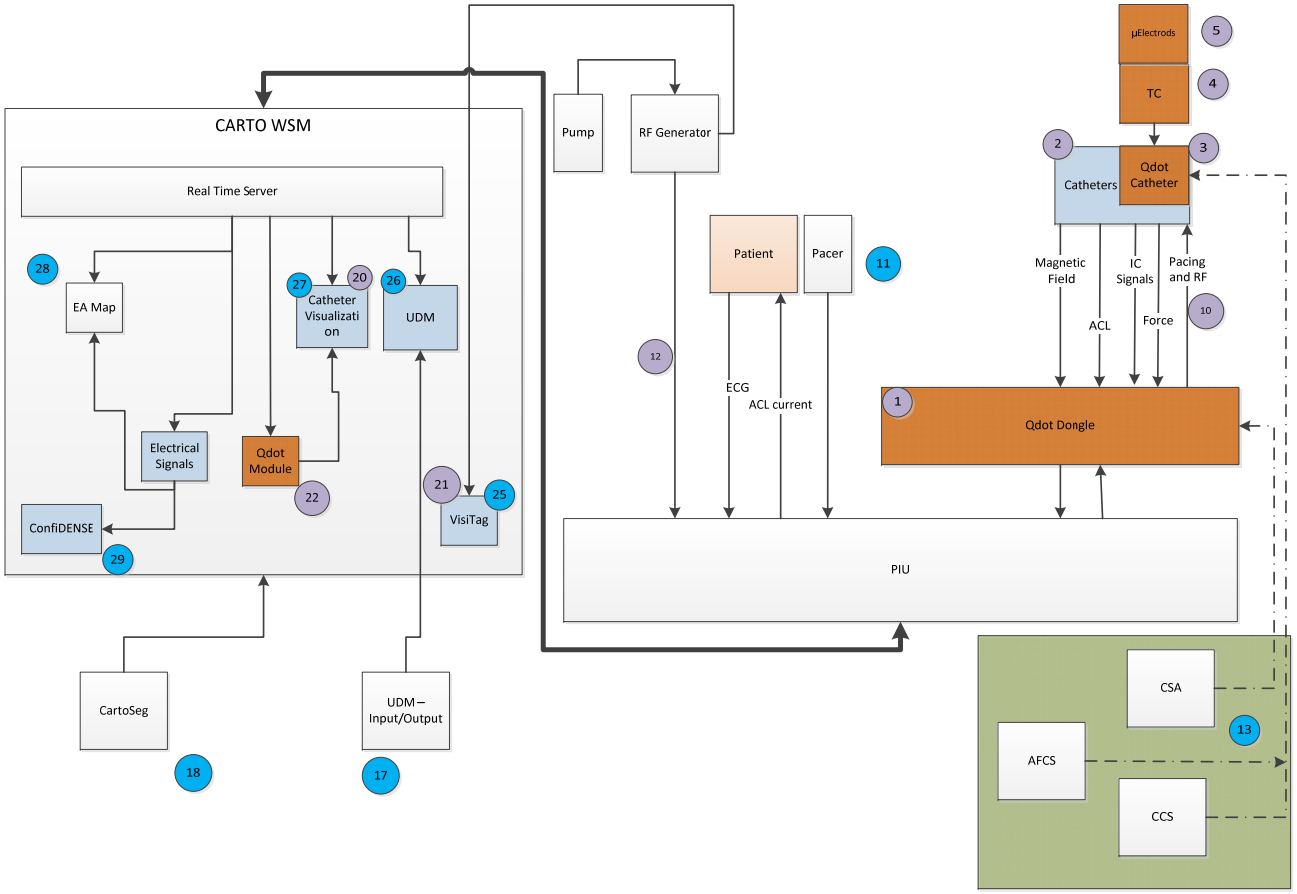

Figure 2: system block diagram for phase 2.5 purple circles are tested in version 2.5 (Micro-Qdot related). Blue circles are tested in future phases

A validation plan document tree is shown below.

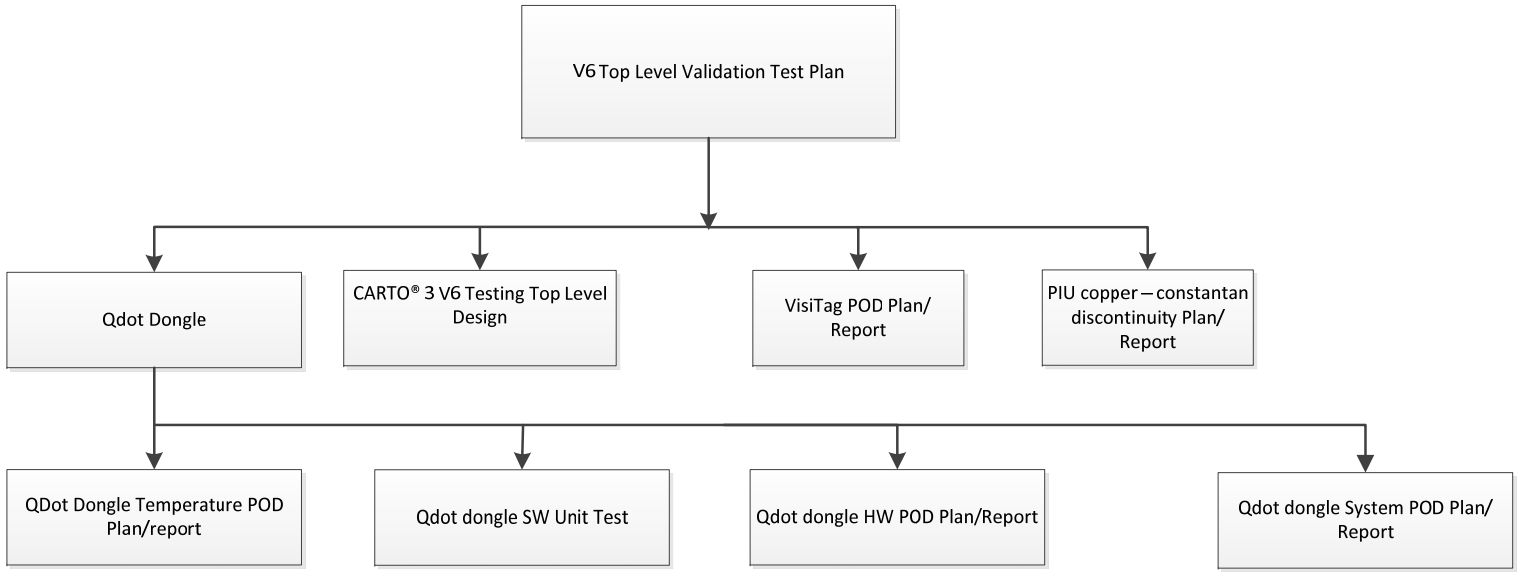

Figure 3: System top level validation plan document diagram for phase 2.5

7.3.1 Qdot dongle

In brackets on each **Subject** entry is the block number of the diagram in figure 2

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(1) Temperature measurement in Qdot dongle	Qdot Dongle Temperature POD	SE/SI	REP8298	SE/SI	REP8894	6.0 Phase 2.5	Rational: Determining correctness of temperature measurement in the dongle. Details: Qdot dongle calculates the interface temperature on the tip surface. The POD shows the accuracy and the parameters which are used for the scaling of the measured temperature within the dongle. Accuracy of TC measurement is evaluated in this document
(1) Qdot dongle HW POD	Qdot dongle HW POD	HW	REP7390	HW	REP8921	V6.0 Phase 2.5	Rational: Hardware design of the dongle is tested in this POD Details: POD covers ACL, ECG, microelectrodes, Force and Magnetics features.
(1) Qdot dongle SW Unit Test	Qdot dongle SW Unit test	SW	REP8057	SW	See Details	V6.0 Phase 2.5	SW Unit Test. Covered in Phase 3 in REP9145
(4) Microelectrodes Signals	Qdot dongle POD System level tests of the microelectrodes	SE/SI	REP8043	SE/SI	REP8845	V6.0 Phase 2.5	Testing the noise level of the micro electrode signals during run time and ablation. Out of the POD only the part which has to do with ECG is going to be tested. The system is intended for bench testing and animal study and therefore the functionality of ACL, Force and Magnetic location is not required.

7.3.2 Qdot module

In brackets on each **Subject** are the block number of the diagram in figure 2

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(22,20) Functional tests of Qdot module	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 2.5	Rationale: Functional test of the new feature. Details: Functional tests of the Qdot module.
(22,12) Data Constancy of Qdot module	Qdot Dongle Temperature POD	SE	REP8298	SE	REP8894	V6.0 Phase 2.5	Testing the data arriving from PIU and the RF ablator.
(12) PIU temp accuracy	Thermocouple path discontinuity in PIU	HW	REP8510	HW	See Details	V6.0 Phase 2.5	Testing of the thermocouples path in the PIU. The PIU holds a discontinuity of the copper constantan pair and the effect is tested in this report Covered in phase 3 REP8921

7.3.3 Visitag (Qdot related)

In brackets on each **Subject** are the block number of the diagram in figure 2

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(21) Functional tests of Visitag	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 2.5	Rationale: Functional test of the new feature and tests for the new features of visiTag. Details: Functional tests of the Qdot module.
(21) Visitag POD for Qdot	POD for visiTag + Qdot inputs	SE	REP8183	SE	REP8816	V6.0 Phase 2.5	Rationale: Functional test of the new feature. Details: Functional tests of the visiTag features in respect to the addition of temperature output from the Qdot catheter. The temperature drop filter will be tested.

7.4 Version 6 Phase 3

A limited release version of CARTO® 3 system V6. The use of the system is for the Qdot workflow study.

The system block diagram is shown on the figure 4 below. Each block which is modified in V6 phase 3 is indicated by a number and the corresponding tests for the block will be elaborated in tables at sections 7.3.1 – 7.3.3 (Purple numbered circles).

Tests:

1. Qdot Catheter is not going to be tested on a system level (POD) in this version. The validation assumes a final design of the catheter for the workflow study.
2. Qdot Extension Cable is not going to be tested on a system level (POD) in this version. The validation assumes a final design of the catheter for the workflow study.

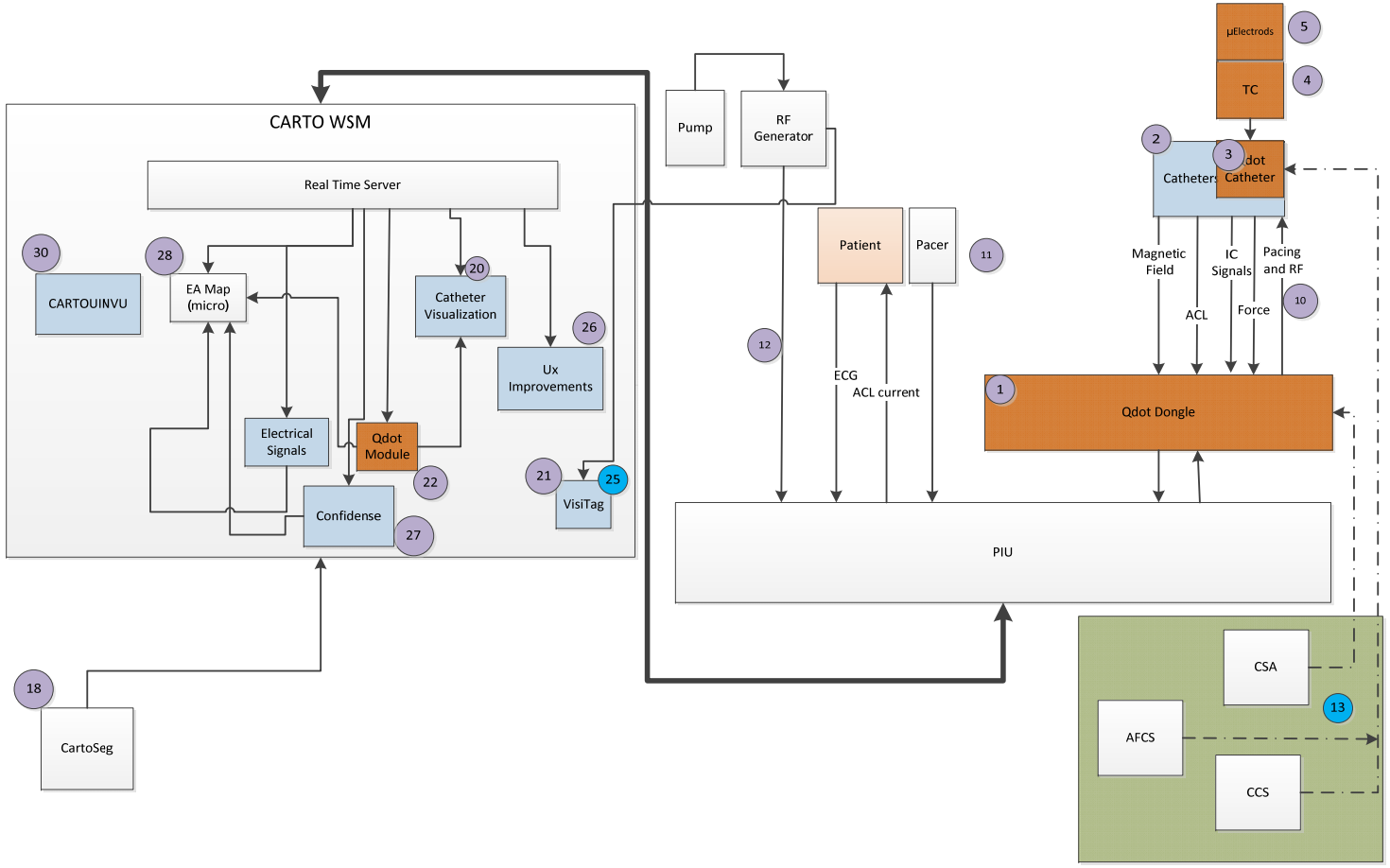

Figure 4: system block diagram for phase 3.0 purple circles are tested in version 3.0. Blue circles are tested in future phases

A validation plan document tree is shown below.

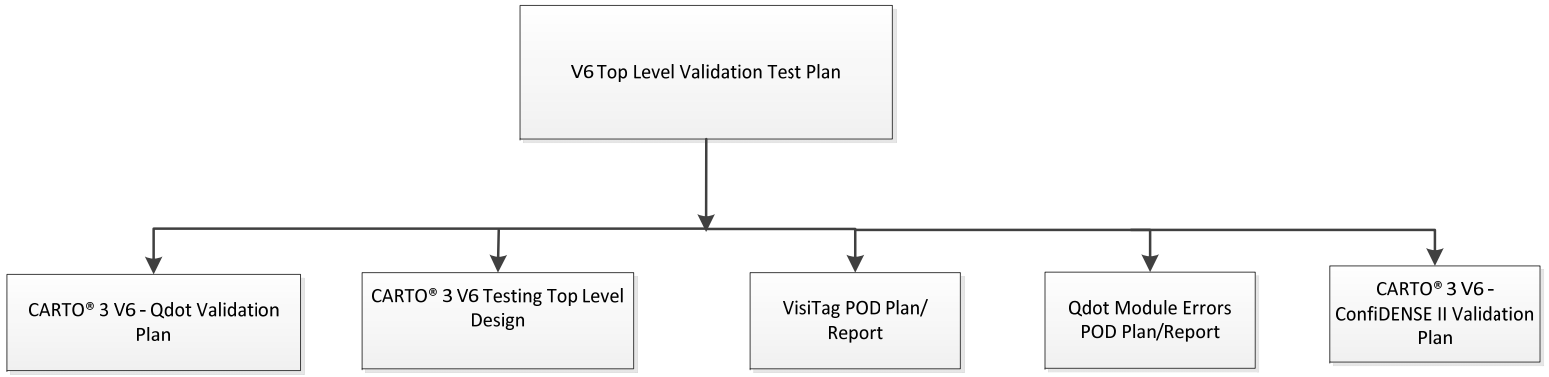

Figure 5: System top level validation

7.4.1 Qdot

In brackets on each **Subject** are the block number of the diagram in figure 4

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(3,4,5,1,22,31) Qdot	CARTO 3 System Qdot Validation	SE/SI	REP8961	SE/SI	NA	V6.0 Phase 3.0	Rationale: Competablitiy tests of Confidense. Details: See complete validation of the module in the validation plan.

7.4.2 Visitag

In brackets on each **Subject** are the block number of the diagram in figure 4

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(21) Functional tests of Visitag	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 3.0	Rationale: Functional test of the new feature and tests for the new features of visiTag. Details: Functional tests of the Qdot module.
(21) Visitag POD	POD for visiTag + Ablation Index	SE	REP8183	SE	REP8816	V6.0 Phase 3.0	Rationale: Functional test of the new feature in visiTag. Details: Functional tests of the visiTag features in respect to the addition of temperature output from the Qdot catheter. Testing of ablation index

7.4.3 Base Version

In brackets on each **Subject** are the block number of the diagram in figure 4

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(21,28,20) Functional tests of Visitag	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 3.0	Rationale: Functional test of the new feature and tests for the new features of visiTag. Details: Functional tests of the Qdot module.
(21) Error POD	System level errors are tested	SE/SI	REP8896	SE/SI	REP9127	V6.0 Phase 3	Rational: System level errors are tested Details: Testing on the functional level are tested at this point by creating the conditions which will elicit the error on the WS machine
(26) Ux Improvements	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 3.0	Rationale: Functional test of the new feature. Details: Functional tests of the Ux improvements.
(22) Qdot	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 3.0	Rationale: Functional test of the new feature. Details: Functional tests of the Qdot improvements. Changes have been made from phase 2.5 and the tests shall cover them as well.

7.4.4 Contact Force (Qdot related)

In brackets on each **Subject** are the block number of the diagram in figure 4

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(21) Functional tests of Contact Force	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 3.0	Rationale: Functional test of the contact force. Details: Functional tests of the contact force after changes in catheter connection and incorporation of CARTO® 3 V4 SP1 code. In addition, temepratrue sensing of dongle is changed and functional tests are required.

7.4.5 Ablation Index

In brackets on each **Subject** are the block number of the diagram in figure 4

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(21) Functional tests of ablation Index	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 3.0	Rationale: Functional test of ablation Index. Details: Functional tests of ablation Index implementation. Functional test of ablation index formula installer.

7.4.6 CARTOUNIVU™

In brackets on each **Subject** are the block number of the diagram in figure 4

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(30) Functional tests of CARTOUNIVU ™	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 3.0	Rationale: Functional test of CARTOUNIVU™. Details: Compatibility tests of CARTOUNIVU™ with fluro machines. Only regression tests are going to be evaluated as part of the STD with the Siemense Fluro machine.

7.4.7 Confidense II

In brackets on each **Subject** are the block number of the diagram in figure 4

Subject	**Test name**	**Plan Written by**	**Rep #**	**Performed by (and documented)**	**Rep #**	**Tested in Version**	**Rationale / Details**
(27) ConfiDENSE II	CARTO® 3 V6 - ConfiDENSE II Top Level Validation and Verification	SE/SI	REP7422	SE/SI	NA	V6.0 Phase 3.0	Rationale: Compatibility tests of Confidense. Details: See complete validation of the module in the validation plan. The document does not have a validation report as this is a validation plan.

7.5 Phase 4

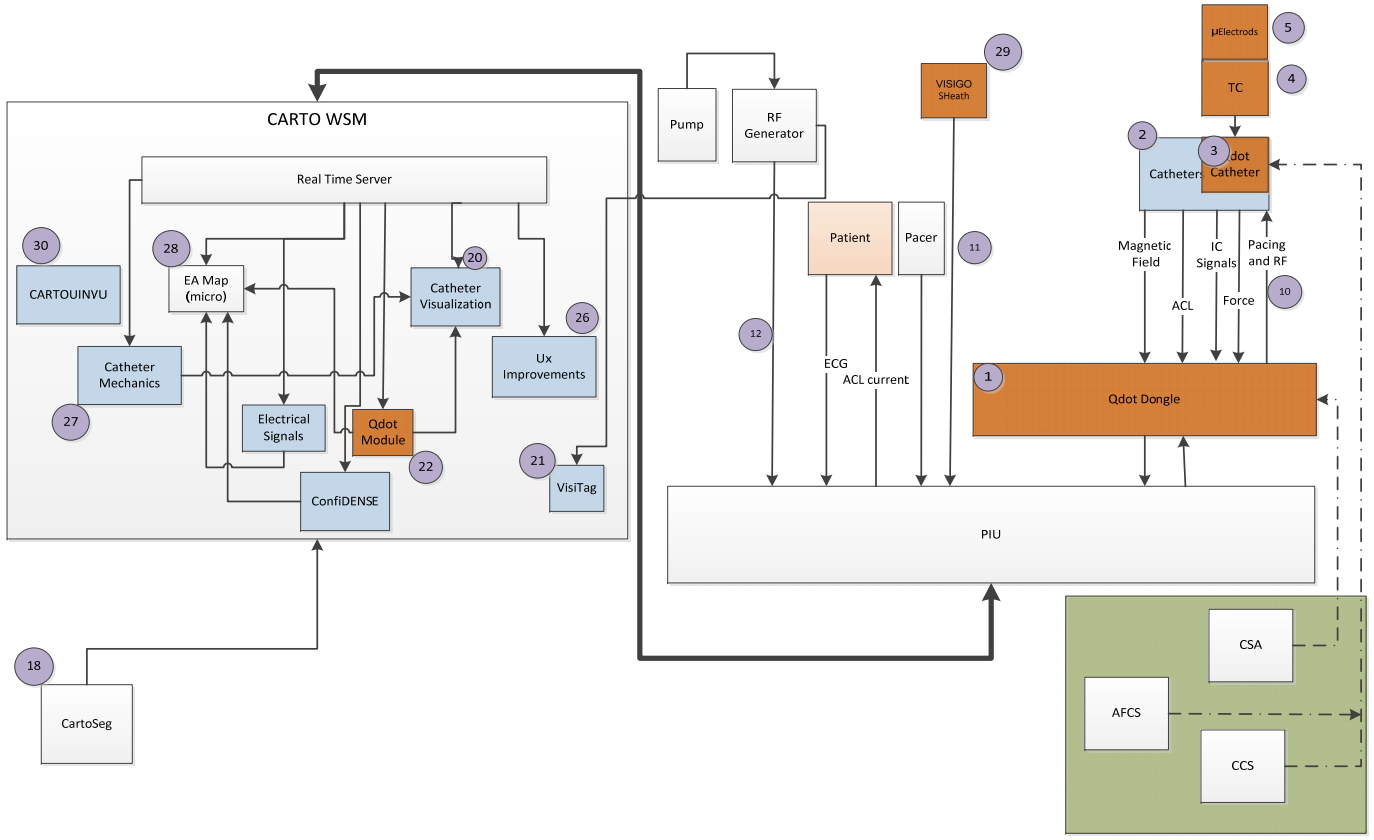

Figure 5: system block diagram for phase 4.0 purple circles are tested in version 4.0.

7.5.1 Base

In brackets on each **Subject** are the block numbers of the diagram in figure 7

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(1-30) Functional tests of Base Version	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 4.0	Rationale: Testing of Base features. Details: Testing of the Base features of CARTO® including all supported features from previous versions

Comment: Error Messages POD test was performed only on phase3, validation has passed to functional testing.

7.5.2 Qdot

In brackets on each **Subject** are the block numbers of the diagram in figure 5

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(3,4,5,1,22,31) Qdot	CARTO 3 System Qdot Validation	SE/SI	REP8961	SE/SI	NA	V6.0 Phase 3.0	ationale: Compatibility tests of Qdot. Details: See complete validation of the module in the validation plan.

7.5.3 VIZIGO

In brackets on each **Subject** are the block numbers of the diagram in figure 5

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(27,20,27) Functional tests of VIZIGO™	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 4.0	ationale: Functional test of VIZIGO™. Details: Functional test of VIZIGO™.
(27,20) POD Visualization	POD	SE	REP8531	SE	REP9267	V6.0 Phase 4.0	ationale: testing the visualization of the sheath within the CARTO system. Details: Testing that the mechanical module, as visualized on CARTO, is reliable.
(29) POD Sheath effect on the CARTO® 3 System POD	POD	SE	REP8335	SE	REP9268	V6.0 Phase 4.0	ationale: Testing the compatibility of CARTO and represented catheters functionality while using the VIZIGO sheath. Details: Testing that the mechanical module, as visualized on CARTO, is reliable.
(27) Catheter Mechanics Core Unit Test	Unit Test	SW	REP9269	SW	REP9270	V6.0 Phase 4.0	ationale: Testing the correctness of the catheter mechanics functionality after the introduction of the new VIZIGO functionality. Details: Introduction of VIZIGO sheath into the catheter mechanics software requires the testing of the previous functionality in regard to use of catheter without a sheath.

7.5.4 CARTOUNIVU™

In brackets on each **Subject** are the block numbers of the diagram in figure 5

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(30) Functional tests of CARTOUNIVU™	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 4.0	ationale: Functional test of CARTOUNIVU™. Details: Completability tests of CARTOUNIVU™ with Fluro machines.
(30) POD of CARTOUNIVU™	Fluoro integration accuracy POD For Philips systems	SE	REP7177	SE	Rep8913	V6.0 Phase 4.0	ationale: System level tests for Philips Fluro machine. Details: NA
(30) POD of CARTOUNIVU™	Fluoro integration accuracy POD For Toshiba systems	SE	REP7177	SE	Rep8912	V6.0 Phase 4.0	ationale: System level tests for Toshiba Fluro machine. Details: NA
(30) POD of CARTOUNIVU™	Fluoro integration accuracy POD For GE systems	SE	REP7177	SE	Rep9067	V6.0 Phase 4.0	ationale: System level tests for GE Fluro machine. Details: NA
(30) POD of CARTOUNIVU™	Fluoro integration accuracy POD For Siemens systems	SE	REP7177	SE	Rep9302	V6.0 Phase 4.0	ationale: System level tests for Siemens Fluro machine. Details: There was a change in the Fluoro integration accuracy spec., regarding limited translation of the C-arm up to 25 mm. In order to verify there is no impact on the accuracy, the accuracy POD plan should be performed

7.5.5 CartoSeg

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(18) Functional tests of CARTOSEG™	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 4.0	ationale: Functional test of CARTOSEG ™. Details: NA
(18) CARTOSEG	CARTO®3 System V6 Top Level Validation	SE/SI	REP6512	NA	NA	V6.0 Phase 4.0	ationale: Compatibility tests of CARTOSEG. Details: See complete validation of the module in the validation plan. The document does not have a validation report as this is a validation plan.

7.6 Phase 5

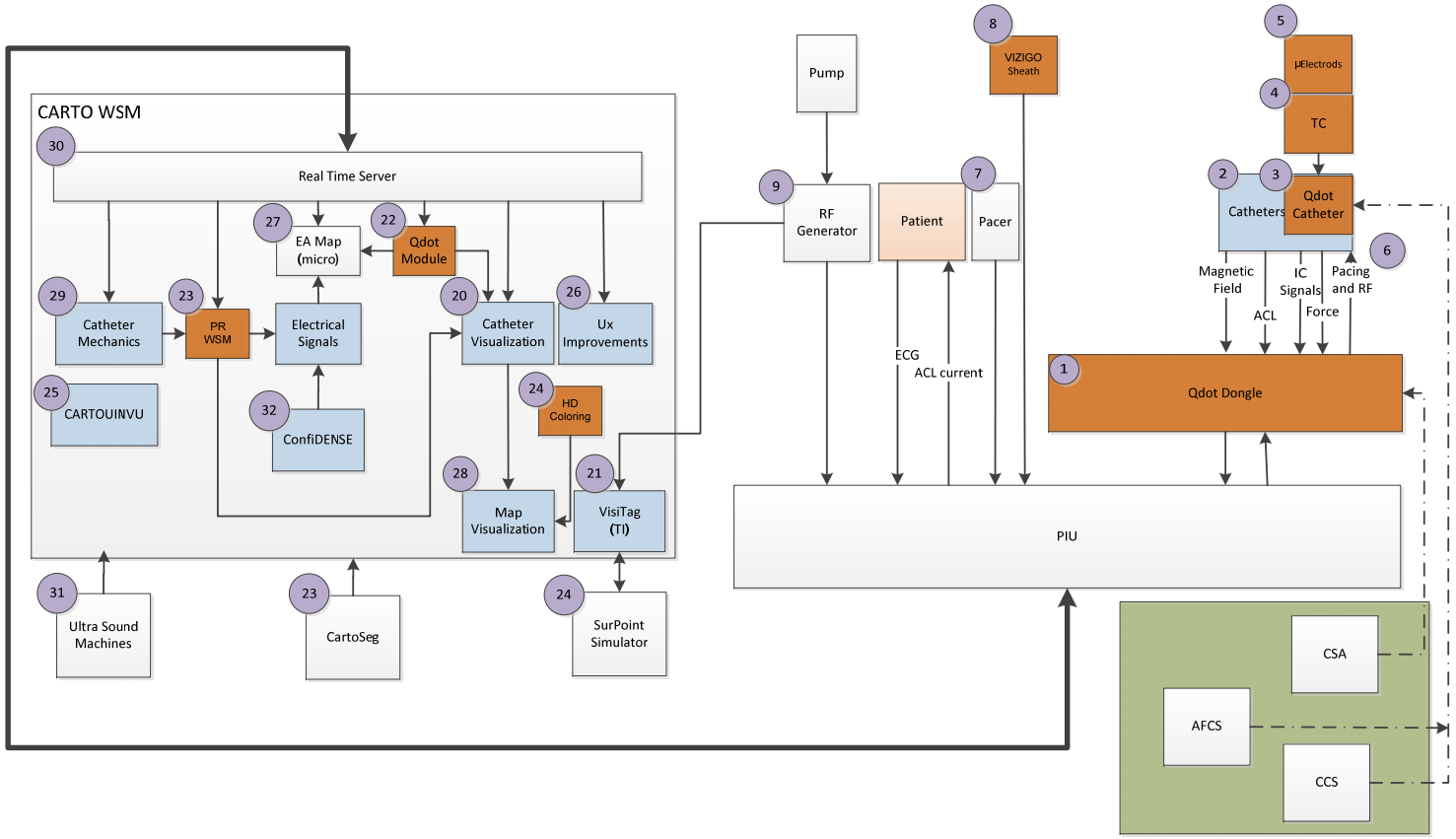

Figure 7: system block diagram for phase 5.0, purple circles are tested in version 5.0.

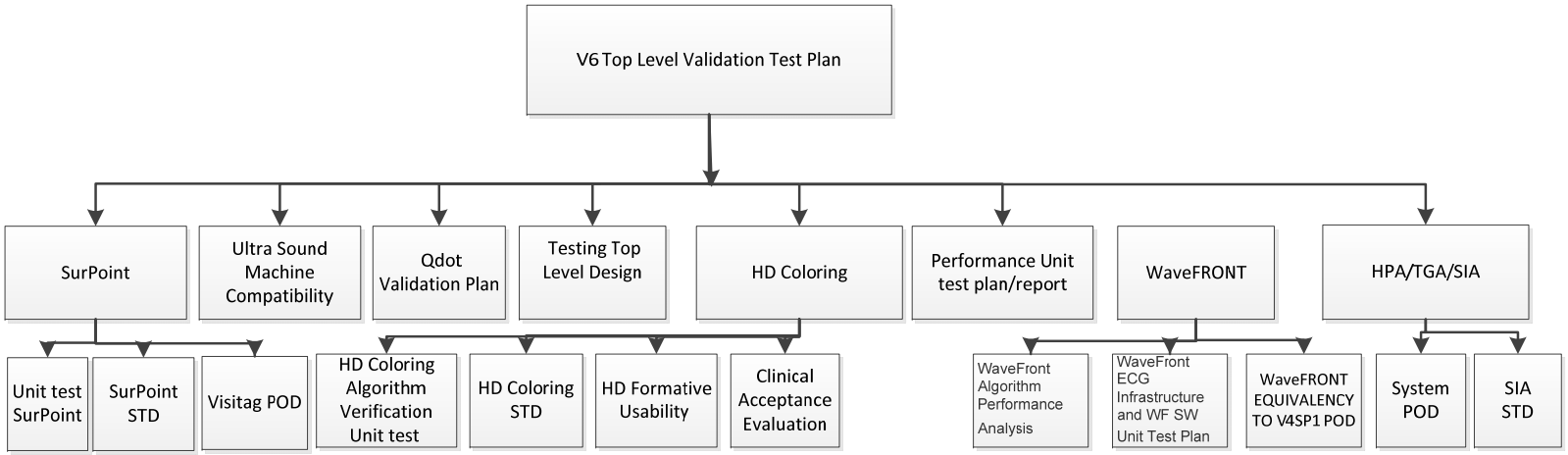

Figure 8: System top level validation

7.6.1 Base

In brackets on each **Subject** are the block numbers of the diagram in figure 7

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(1-30) Functional tests of Base Version	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 5.0	Rationale: Testing of Base features. Details: Testing of the Base features of CARTO® including all supported features from previous versions
(9) Com reliability with Stockert POD	Communication reliability with Stockert ablator	SE/SI	REP9496	SE/SI	REP9497	V6.0 Phase 4.0	Rationale: Assuring the proper implementation of the requirements which verify valid com with Stockert ablators. Details: NA
(30) CARTO® 3 Performance tests	nit Test Plan for CARTO®3 Performance Logs	SW	REP9616	SW	REP9656	V6.0 Phase 5.0	Rationale: Testing the performance of CARTO®. Details: Testing the latency and update rate of magnetic and force visualization.
(31) Ultrasound	POD for new ultrasound machine	SE	REP9374	SE	REP9969	V6.0 Phase 5.0	POD of the new GE S70 ultrasound machine. Part of the validation work is to find the delay between the ultrasound system and CARTO® REP9581 for GE and Vivid IQ Siemens Acuson P500™ Ultrasound Support was linked to CARTO3 V4 SP1.1 project

7.6.2 Qdot

In brackets on each **Subject** are the block numbers of the diagram in figure 7

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(3,4,5,1,22,31, 23) Qdot	CARTO 3 System Qdot Validation	SE/SI	REP8961	SE/SI	NA	V6.0 Phase 5.0	Rationale: Testing of Qdot new features for phase 5.0. Details: The following will be tested in the Qdot validation: WS power reject Dongle 1.1 performance Connectivity (removing the MC)

7.6.3 HD

In brackets on each **Subject** are the block numbers of the diagram in figure 7

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(24) Unit test HD Coloring	HD Coloring Algorithm Verification Unit test	SW	REP9505	SW	REP9539	V6.0 Phase 5.0	Rationale: Algorithm verification of the HD coloring. Details: NA
(24,28) Functional Testing of HD Coloring	HD Coloring STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 5.0	Rationale: Application level verification of the HD coloring. Testing the functionality of HD together with the legacy functionality of the maps on CARTO. Details: NA
(24) Usability	CARTO® 3 V6 Phase 5 Formative Usability	UX	REP9523	UX	REP9525	V6.0 Phase 5.0	Rationale: HD Coloring introduces visual differences in 3D maps visualization. The purpose of the study is to evaluate the usability of the HD coloring: that is evaluate users' ability to perceive the new visualizations and the acceptance of these new visualizations Details: NA
(24) Clinical Acceptance Evaluation	CARTO® 3 System V6 HD coloring Module: User Acceptance Evaluation Protocol	Clinical	REP9506	Clinical	REP9629	V6.0 Phase 5.0	Rationale: validate the clinical acceptance of HD coloring visual representation of the map's electro anatomical data Details: NA

7.6.4 SIA

In brackets on each **Subject** are the block numbers of the diagram in figure 7

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
Compatibility of Dongle to SIA	µQdot Dongle System POD Plan/Report for High Power Ablations	SI/SE	REP9450	SI/SE	REP9451	V6.0 Phase 5.0	Rationale: Compatibility of Dongle to High power ablations since wasn't validated on high powers or high temperatures. Details: NA
Functional Testing of SIA	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 5.0	Rationale: Application level verification of the SIA. Testing the functionality of SIA Details: NA

7.6.5 SurPoint

In brackets on each **Subject** are the block numbers of the diagram in figure 7

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(24) Unit test SurPoint	SW Unit Test Plan – CARTO® V6 Compatibility with SURPOINT™ external processing unit	SW	REP9433	SW	REP9434	V6.0 Phase 5.0	Rationale: SurPoint logic and communication protocol verification of the SurPoint module. Details: NA
(24,28) Functional Testing of SurPoint	VisiTag STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 5.0	Rationale: Application level verification of the Surpoint module coloring. Testing the functionality of the module at both internal and EPU configurations. Details: NA
(21) VisiTag POD	CARTO® 3 System V6 VisiTag™ POD	SE/SI	REP8183	SE/SI	REP9611	V6.0 Phase 5.0	Rationale: Assuring the validity of the TI formula as part of the SurPoint module. Testing at both internal and EPU configurations. Details: NA

7.6.1 ConfiDENSE II

In brackets on each **Subject** are the block number of the diagram in figure 7

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(32) Algorithm Performance Analysis	WaveFront Algorithm Performance Analysis	Core Team	REP8296	Core Team	NA	V6.0 Phase 5.0	Rationale: WaveFront algorithm analysis in terms of sensitivity, specificity expected performance. Details: Adding to the analysis option of selecting parameter in which the WaveFront annotation performs with fuzzy logic threshold set zero to perform as in V4 SP1.
(32) Unit Test	ECG Infrastructure and WF SW Unit Test Plan	SW	REP8775	SW	REP8777	V6.0 Phase 5.0	Rationale: Unit test comparing implementation of V6 with parameter change vs. Mathematica implementation. Details: NA
(32) WaveFront Equivalency to V4 SP1 POD	CARTO® 3 V6 PHASE5 WAVEFRONT EQUIVALENCY TO V4SP1 POD Plan	SE	REP10240	SE	REP10241	V6.0 Phase 5.0	Rationale: Equivalency tests of WaveFront V6 to V4 SP1. Details: Review details in the POD plan.

Comment: Whole ConfiDENSE Validation is handled under **REP7422** (CARTO® 3 V6 – ConfiDENSE II Top Level Validation and Verification), as Phase 5 contained a limited changed related to WaveFront (which is a part of ConfiDENSE), it was decided to limit the update to this document.

7.7 Phase 6

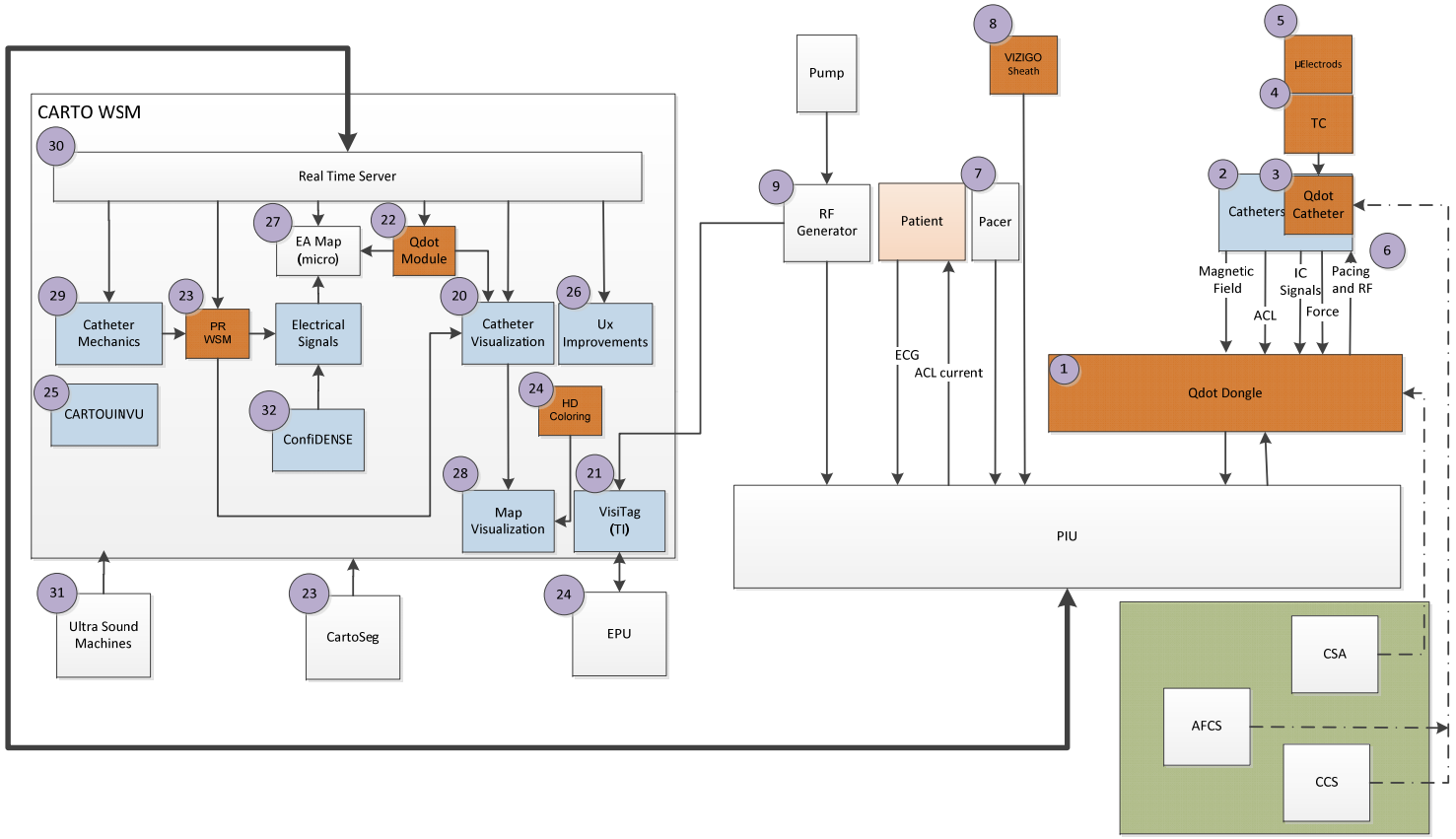

Figure 9 - Phase 6 system block diagram

7.7.1 Base

In brackets on each **Subject** are the block numbers of the diagram in figure 7

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(1-30) Functional tests of Base Version	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 6.0	Rationale: Testing of Base features with security patches. Details: Testing of the Base features of CARTO® including all supported features from previous versions And tools with emphasis on the ones who are designated by the security impact

7.7.2 SurPoint

In brackets on each **Subject** are the block numbers of the diagram in figure 7

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(24,28) Functional Testing of SurPoint	VisiTag STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 6.0	Rationale: Application level verification of the SurPoint module coloring. Testing the functionality of the module at both internal and EPU configurations. Details: NA

7.8 Phase 7

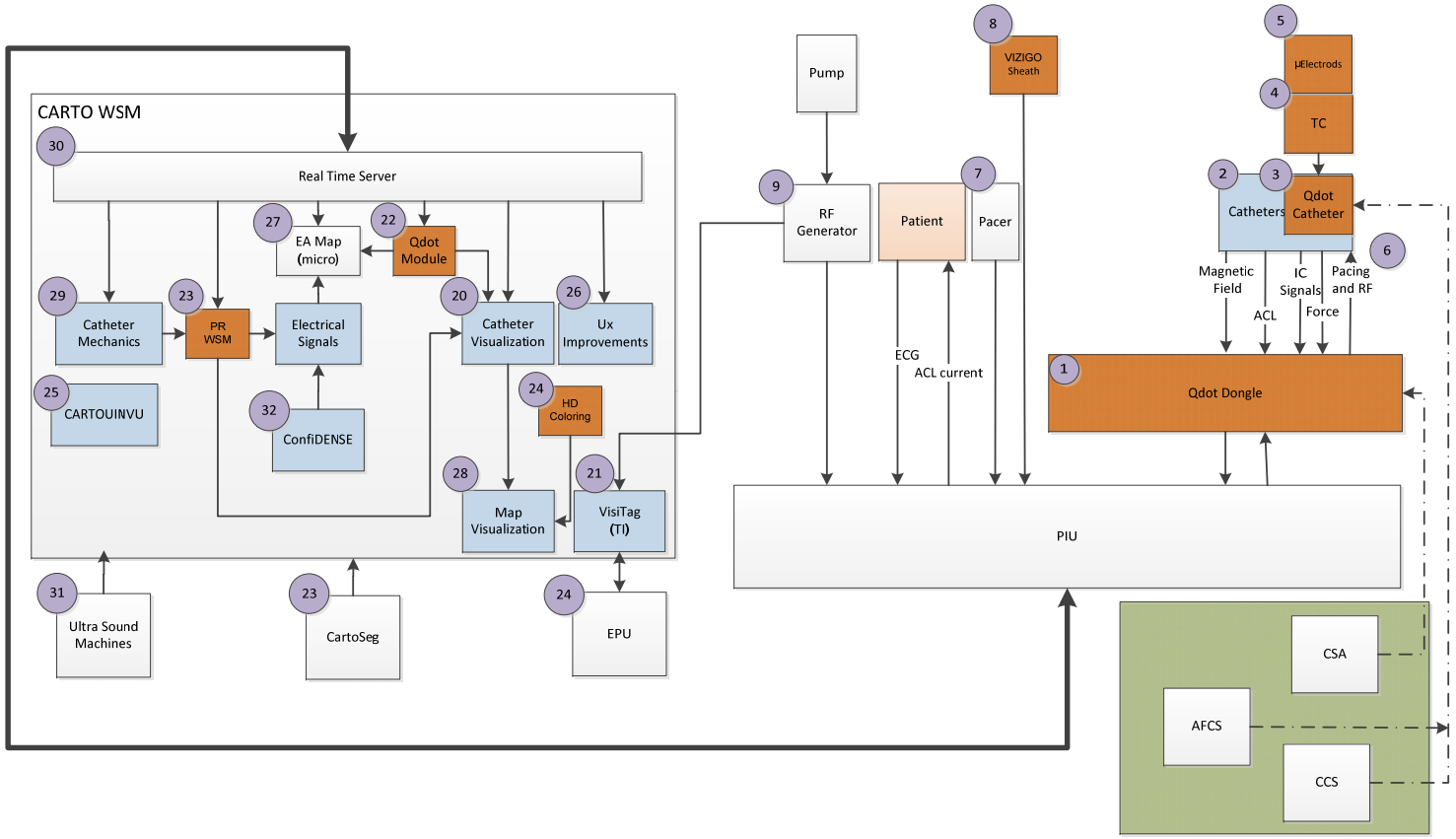

Figure 9 - Phase 7 system block diagram

7.8.1 Base

In brackets on each **Subject** are the block numbers of the diagram in figure 7

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(1-30) Functional tests of Base Version	STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 7.0	Rationale: Testing of Base features indicated by impact analysis. Details: Testing of the Base features indicated by impact analysis Including: new Data Encryption capability, HD coloring, license removal and EML parameters change, Glass window change, security updates, FAM Dx update (adding DECANAV as enabler) and related tools

7.8.2 VIZIGO

In brackets on each **Subject** are the block numbers of the diagram in figure 7

Subject	Test name	Plan Written by	Rep #	Performed by (and documented)	Rep #	Tested in Version	Rationale / Details
(20) Functional test of VIZIGO	VIZIGO STD	SQA	REP7373	SQA	REP7376	V6.0 Phase 7.0	Rationale: Application level verification of the VIZIGO visualization. Details: Pair/unpair, visualization in case of "black electrodes"
(8,29,30) POD Visualization	POD	SE	REP8531	SE	REP9267	V6.0 Phase 7.0	Rationale: testing sheath's visualization within the CARTO system after feature's update. Details: Testing that the mechanical module, as visualized on CARTO, is reliable.

8. COMPATIBILITY

8.1 Compatibility Phase 1

8.1.1 PIU Configurations

Component	Configuration 1	Configuration 2
Back plane	EA-5401-27	EA-5401-271
ECG	EA-5401-16	EA-5401-162
ACL TX (new)	EA-5401-26	EA-5401-26
DC/DC	EA-5401-121	EA-5401-121
Main	EA-5401-201	EM-5401-201

8.1.2 Work station

Model	Frame Grabber
Dell 3600	None
Dell 3610	None
Dell 3500	None

8.1.3 Monitor

Monitor	Size	Resolutions	Models
Dell, HF	24”	1,600 pixels × 1,200 1,920 pixels × 1,200 1,920 pixels × 1,080	Model 2408WFP Model P2411H Model U2410F

8.1.4 Components

System	Model	Versions	Vendor
RF Generator	Stockert EP-Shuttle RF Generator Ablation System	V1.036, V1.037	Stockert
RF Generator	Stockert GmbH SMARTABLATE™ System RF Generator	V1.2	Stockert
RF Generator	nMARQ™ Multi Channel RF generator	V0.7, SW version 2.3	Biosense
RF Generator	nMARQ™ Multi Channel RF generator	V0.7, SW version 2.5.1.4	Biosense

8.2 Compatibility Phase 2

Canceled

8.3 Compatibility Phase 2.5

8.3.1 PIU Configurations

According to document REF4 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*	*ACLRx*	*MAGTx module*	*Main Module*	*Supported in phase 2.5*
1	EA-5401-12	EA-5401-16	EA-5401-26	EA-5401-29	EM-5401-15	EM-5401-20	yes
2	EA-5401-12	EA-5401-16	EA-5401-26	EA-5401-29	EM-5401-151	EM-5401-201	yes
3	EA-5401-121	EA-5401-162	EA-5401-26	EA-5401-29	EM-5401-151	EM-5401-201	yes
4	EA-5401-121	EA-5401-162	EA-5401-263	EA-5401-29	EM-5401-151	EM-5401-201	yes

5	EA-5401-121	EA-5401-16	EA-5401-263	EA-5401-29	EM-5401-15	EM-5401-201	yes
6	EA-5401-121	EA-5401-16	EA-5401-263	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	yes

According to document in REF5 any configuration in the above table is adequate for testing the dongle as it is not affected by the actual HW of the PIU.

8.3.2 Work station

Model	Frame Grabber
Dell 3610	None
Dell 3600	None
Dell 3500	None

8.3.3 Monitor

Monitor	Size	Resolutions	Models
Dell, HP	24”	1,600 pixels × 1,200 1,920 pixels × 1,200 1,920 pixels × 1,080	Model 2408WFP Model P2411H Model U2410F

8.3.4 Components

System	Model	Versions	Vendor
RF Generator	nMARQ™ Multi Channel RF generator	SW version 2.5.1.7	Biosense
RF Generator	SmartAblate	SW version 1.5 (701.705)	Biosense
Micro-Qdot Catheter	Design freeze for phase 2.5	NA	Biosense
Micro-Qdot Extension cable	Design freeze for phase 2.5	NA	Biosense

8.4 Compatibility Phase 3

8.4.1 PIU Configurations

According to document REF4 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*	*ACLRx*	*MAGTx module*	*Main Module*	*Supported in phase 3*
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	yes
3	EA-5401-121	EA-5401-162	EA-5401-26	EA-5401-29	EM-5401-151	EM-5401-201	yes
4	EA-5401-121	EA-5401-162	EA-5401-263	EA-5401-29	EM-5401-151	EM-5401-201	yes
5	EA-5401-121	EA-5401-16	EA-5401-263	EA-5401-29	EM-5401-15	EM-5401-201	yes
6	EA-5401-121	EA-5401-16	EA-5401-263	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 document in REF5 any configuration in the above table is adequate for testing the dongle as it is not affected by the actual HW of the PIU.

8.4.2 Work station

Model	Frame Grabber
Dell 5810	None
Dell 3610	None

8.4.3 Monitor

Monitor	Size	Resolutions	Models
Dell, HP	24”	1,600 pixels × 1,200 1,920 pixels × 1,200 1,920 pixels × 1,080	2407WFPB U2412Mc U2412Mb U2711b U2410F ZR2440w (HP)

8.4.4 Components

System	Model	Versions	Vendor
RF Generator for Qdot Catheter	nMARQ™ Multi Channel RF generator	SW version 2.5.1.14	Biosense
RF Generator for Legacy Catheter	Stockert GmbH SMARTABLATE System RF Generator	1.2	Stockert
RF Generator for Legacy Catheter	Stockert GmbH EP Shuttle System RF Generator	1.037,1.036,1.035	Stockert
Micro-Qdot Catheter	Clinical workflow study Version by BWIUS	NA	Biosense
Micro-Qdot Extension cable	Clinical workflow study Version by BWIUS	NA	Biosense
Recording System	Siemens AXIOM Sensis XP EP Recording System	VC11B	Siemens
Recording System	GE Marquette CardioLab® EP Recording System	V6.9.5	GE
Recording System	Bard System PRO EP Recording System	V2.6.0.19	Bard
Fluoro System	Siemens Artis_Zee_Floor	VC14J131115	Siemens

8.4.5 Catheters

See REF7 for catheter compatibility for phase 3.

8.4.6 Service JIG Utility

Version	Compatibility
2.1	V4 LMR and above

8.4.7 CARTOUNIVU™ Module Service CD

Version	Compatibility
V1.14	V4 LMR and above

8.4.8 Ablation Index Formula Installer CD

Version	Compatibility
SM-5400-1499	V4 SP 1 and above

8.5 Compatibility Phase 4

8.5.1 PIU Configurations

According to document REF4 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*	*ACLRx*	*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	yes
3	EA-5401-121	EA-5401-162	EA-5401-26	EA-5401-29	EM-5401-151	EM-5401-201	yes
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 document in REF5 any configuration in the above table is adequate for testing the dongle as it is not affected by the actual HW of the PIU.

8.5.2 Work station

#	Model	Frame Grabber
1	Dell 5810	Solios
2	Dell 3610	Solios
3	Dell 5810	None
4	Dell 3610	None

8.5.3 Monitor

Monitor	Size	Resolutions
Dell	24”	1,600 pixels × 1,200 1,920 pixels × 1,200 1,920 pixels × 1,080 2,560 pixels x1,440

8.5.4 Components

System	Model	Versions	Vendor
RF Generator for Qdot Catheter	nMARQ™ Multi Channel RF generator	SW version 2.5.1.14	Biosense
RF Generator for Legacy Catheter	Stockert GmbH SMARTABLATE System RF Generator	1.2	Stockert
RF Generator for Legacy Catheter	Stockert GmbH EP Shuttle System RF Generator	1.037,1.036,1.035	Stockert
Micro-Qdot Catheter	Clinical workflow study Version by BWIUS	NA	Biosense
Micro-Qdot Extension cable	Clinical workflow study Version by BWIUS	NA	Biosense
Vizigo Sheath	Clinical workflow study Version by BWIUS	NA	Biosense
Recording System	Siemens AXIOM Sensis XP EP Recording System	VC11B	Siemens
Recording System	GE Marquette CardioLab® EP Recording System	V6.9.5	GE
Recording System	Bard System PRO EP Recording System	V2.6.0.19	Bard
Fluoro System	Siemens Artis_Zee_Floor	VC21B,VC21C	Siemens
UltraSound System	SIEMENS Cypress ™	14, 20	Siemens
UltraSound System	SIEMENS Acuson X700™	VB20D-2.0.03(0036)	Siemens
UltraSound System	SIEMENS Acuson SC2000™	VB10C,VB10D	Siemens

System	Model	Versions	Vendor
UltraSound System	SIEMENS Sequoia™	12.221	Siemens
UltraSound System	SIEMENS Acuson X300™	7.5.06 (3748)	Siemens
UltraSound System	GE Vivid™	Application version: 12.2 and System Version: 8.1.2	GE
Navigant System	Stereotaxis	5.0.2.12, 3.2.5, 4.6.5.6	Stereotaxis

8.5.5 Catheters

See REF7 for catheter compatibility.

8.5.6 Service JIG Utility

Version	Compatibility
2.1	V4 LMR and above

8.5.7 CARTOUNIVU™ Module Service CD

Version	Compatibility
V1.18	V4 LMR and above

8.5.8 Ablation Index Formula Installer CD

Version	Compatibility
SM-5400-1499	V4 SP 1 and above

8.5.9 Monitor Setup tool

Version	Compatibility
2.2	V6

8.5.10 Upgrade

Version	Compatibility
CARTO® 3 system V4 SP1 (4.3.5.68)	V6

8.5.11 Laptop

Laptop	Model
Lenovo	W530, W540, P50

8.6 Compatibility Phase 5

8.6.1 PIU Configurations

According to document REF4 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*	*ACLRx*	*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	yes
3	EA-5401-121	EA-5401-162	EA-5401-26	EA-5401-29	EM-5401-151	EM-5401-201	yes
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 document in REF5 any configuration in the above table is adequate for testing the dongle as it is not affected by the actual HW of the PIU.
- According to REF4 EM-5401-201 and EM-5401-201F are equivalent

8.6.2 Work station

#	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
5	Dell 3610	Solios	As defined in CFI (REF9)

#	Model	Frame Grabber	Graphics Card
6	Dell 3610	None	As defined in CFI (REF9)
7	HP Z440	None	As defined in CFI (REF8)
8	HP Z440	Solios	As defined in CFI (REF8)

8.6.3 Monitor

Monitor	Resolutions
Dell	1,600 pixels × 1,200 1,920 pixels × 1,200 1,920 pixels × 1,080 2,560 pixels x1,440

8.6.4 Components

System	Model	Versions	Vendor	*Supported Yes/No*
RF Generator for Qdot Catheter	nMARQ™ Multi Channel RF generator. 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	SW version 3.0	Biosense	Yes
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	Yes
Micro-Qdot Extension cable	Clinical workflow study Version by BWIUS	NA	Biosense	Yes
Vizigo Sheath	Clinical workflow study Version by BWIUS	NA	Biosense	Yes

System	Model	Versions	Vendor	*Supported Yes/No*
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 Cypress ™	20	Siemens	Yes
UltraSound System	SIEMENS Acuson X700™	VB20D-2.0.03(0036)	Siemens	Yes
UltraSound System	SIEMENS Acuson SC2000™	VB10D, VB10E, 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™	VB10A(2.0.7), VB10B(2.0.9)	Siemens	Yes
UltraSound System	GE Vivid™	Application ver. 12.2 System Ver. 8.1.2	GE	Yes
UltraSound System	GE Vivid IQ™	1.0.5 Rev.4898	GE	Yes
UltraSound System	GE Vivid S70	202 Revision 30.1	GE	Yes
Navigant System	Stereotaxis	5.0.2.12, 3.2.5, 4.6.5.6	Stereotaxis	Yes

8.6.5 Catheters

See REF7 for catheter compatibility.

8.6.6 Service JIG Utility

Version	Compatibility
2.1	V4 LMR and above

8.6.7 CARTOUNIVU™ Module Service CD

Version	Compatibility
V1.18	V4 LMR and above

8.6.8 Laptop

Laptop	Model
Lenovo	W530, W540, P50

8.6.9 Upgrade From

- V4 SP1 (4.3.5.68)
- V4 SP1.1 (4.3.5.68+ SP1.1)
- V6 Phase 4 (6.0.45.171 and 6.0.45.169)

8.7 Compatibility Phase 6

8.7.1 PIU Configurations

According to document REF4 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*	*ACLRx*	*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	yes
3	EA-5401-121	EA-5401-162	EA-5401-26	EA-5401-29	EM-5401-151	EM-5401-201	yes
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 document in REF5 any configuration in the above table is adequate for testing the dongle as it is not affected by the actual HW of the PIU.
- According to REF4 EM-5401-201 and EM-5401-201F are equivalent

8.7.2 Work station

#	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

#	Model	Frame Grabber	Graphics Card
5	Dell 3610	Solios	As defined in CFI (REF9)
6	Dell 3610	None	As defined in CFI (REF9)
7	HP Z440	None	As defined in CFI (REF8)
8	HP Z440	Solios	As defined in CFI (REF8)

8.7.3 Monitor

Monitor	Resolutions
Dell	1,600 pixels × 1,200 1,920 pixels × 1,200 1,920 pixels × 1,080 2,560 pixels x1,440

8.7.4 Components

System	Model	Versions	Vendor	*Supported Yes/No*
RF Generator for Qdot Catheter	nMARQ™ Multi Channel RF generator. 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	SW version 3.0	Biosense	Yes
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

System	Model	Versions	Vendor	*Supported Yes/No*
Micro-Qdot Catheter	Clinical workflow study Version by BWIUS	NA	Biosense	Yes
Micro-Qdot Extension cable	Clinical workflow study Version by BWIUS	NA	Biosense	Yes
Micro-Qdot dongle	Biosense Webster Tx eco Cable	P27	Biosense	Yes
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 Cypress ™	20	Siemens	Yes
UltraSound System	SIEMENS Acuson X700™	VB20D-2.0.03(0036)	Siemens	Yes
UltraSound System	SIEMENS Acuson SC2000™	VB10D, VB10E, VB20C	Siemens	Yes

System	Model	Versions	Vendor	*Supported Yes/No*
UltraSound System	SIEMENS Sequoia™	12.221	Siemens	Yes
UltraSound System	SIEMENS Acuson X300™	7.5.06 (3748)	Siemens	Yes
UltraSound System	SIEMENS Acuson P500™	VB10A(2.0.7), VB10B(2.0.9)	Siemens	Yes
UltraSound System	GE Vivid™	Application version: 12.2 System Version: 8.1.2	GE	Yes
UltraSound System	GE Vivid IQ™	1.0.5 Rev.4898	GE	Yes
UltraSound System	GE Vivid S70	202 Revision 30.1	GE	Yes
Navigant System	Stereotaxis	5.0.2.12, 3.2.5, 4.6.5.6	Stereotaxis	Yes

8.7.5 Catheters

See REF7 for catheter compatibility.

8.7.6 Service JIG Utility

Version	Compatibility
2.1	V4 LMR and above

8.7.7 CARTOUNIVU™ Module Service CD

Version	Compatibility
V1.18	V4 LMR and above

8.7.8 Laptops

Laptop	Model
Lenovo	W530, W540, P50

8.7.9 Upgrade From

- V4 SP1 (4.3.5.68)
- V4 SP1.1 (4.3.5.68+ SP1.1)
- V4 new GTX (4.3.5.91)
- V6 Phase 4 (6.0.45.171 and 6.0.45.169)
- V6 phase 5 (6.0.54.133)

8.7.10 Modules keys compatibility

CARTO® 3 V6 Phase 6 shall be compatible to CARTO® 3 V6 Phase 5 module enabling keys (version 6.0.54.133):

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

Comment: No need to test module keys build under phase 6, (As phase 6 is designed to be delivered with phase 5 keys).

8.8 Compatibility Phase 7

8.8.1 PIU Configurations

According to document REF4 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*	*ACLRx*	*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	yes
3	EA-5401-121	EA-5401-162	EA-5401-26	EA-5401-29	EM-5401-151	EM-5401-201	yes
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 document in REF5 any configuration in the above table is adequate for testing the dongle as it is not affected by the actual HW of the PIU.
- According to REF4 EM-5401-201 and EM-5401-201F are equivalent

8.8.2 Work station

#	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

#	Model	Frame Grabber	Graphics Card
5	Dell 3610	Solios	As defined in CFI (REF9)
6	Dell 3610	None	As defined in CFI (REF9)

Comment: 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.

8.8.3 Monitor

Monitor	Resolutions
Dell	1,600 pixels × 1,200 1,920 pixels × 1,200 1,920 pixels × 1,080 2,560 pixels x1,440

8.8.4 Components

System	Model	Versions	Vendor	*Supported Yes/No*
RF Generator for Qdot Catheter	nMARQ™ Multi Channel RF generator. 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	SW version 3.0	Biosense	Yes
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

System	Model	Versions	Vendor	*Supported Yes/No*
Micro-Qdot Catheter	Clinical workflow study Version by BWIUS	NA	Biosense	Yes
Micro-Qdot Extension cable	Clinical workflow study Version by BWIUS	NA	Biosense	Yes
Micro-Qdot dongle	Biosense Webster Tx eco Cable	P27	Biosense	Yes
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 Cypress ™	V20	Siemens	Yes
Ultrasound System	SIEMENS Acuson X700™	VB20E-2.0.04	Siemens	Yes
Ultrasound System	SIEMENS Acuson SC2000™	VB10E, VB20C, VB21A	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™	VB10	Siemens	Yes
Ultrasound System	GE Vivid™	Application version: 12.2 System Version: 8.1.2	GE	Yes

System	Model	Versions	Vendor	*Supported Yes/No*
Ultrasound System	GE Vivid IQ™	1.0.5 Rev.4898	GE	Yes
Ultrasound System	GE Vivid S70	202 Revision 34 203 Revision 16.0	GE	Yes
Navigant System	Stereotaxis	5.0.2.12, 3.2.5, 4.6.5.6	Stereotaxis	Yes

Comment: GE DL_PathFinder tested version shall be decided upon availability

8.8.5 Catheters

See REF7 for catheter compatibility.

8.8.6 Service JIG Utility

Version	Compatibility
2.1	V4 LMR and above

8.8.7 CARTOUNIVU™ Module Service CD

Version	Compatibility
V1.18	V4 LMR and above

8.8.8 Laptops

Laptop	Model
Lenovo	W530, W540/541*, P50

Comment (*): It is sufficient to check either W540 or W541 as difference between versions is negligible.

8.8.9 Upgrade From

- V4 SP1 (4.3.5.68)
- V4 SP1.1 (4.3.5.68+ SP1.1)
- V4 new GTX (4.3.5.91)
- V6 Phase 4 (6.0.45.171 and 6.0.45.169)
- V6 phase 6 (6.0.60.70)

Comment: Phase 5 is not needed as it wasn't entered to the market.

8.8.10 Modules keys compatibility

CARTO®3 V6 Phase 7 shall be compatible to CARTO 3 V6 Phase 5 module enabling keys (version 6.0.54.133):

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

Comment: No need to test module keys created in phase 7 build.