



PULSAR Clinical Study Summary

Globe® Pulsed Field System

© 2025 Kardium Inc. All rights reserved.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.



Kardium®

CONTENTS

1.	Study Objective	3
2.	Study Design	3
2.1.	Clinical Inclusion and Exclusion Criteria	4
2.2.	Follow-Up Schedule.....	6
2.3.	Clinical Endpoints.....	9
2.3.1.	Primary Safety Endpoint.....	9
2.3.2.	Primary Effectiveness Endpoint.....	10
2.3.3.	Secondary Endpoints.....	10
3.	Accountability of PMA Cohort.....	12
4.	Study Population Demographics and Baseline Parameters	13
5.	Safety and Effectiveness Results	18
5.1.	Primary Analysis.....	19
5.1.1.	Primary Safety Endpoint.....	19
5.1.2.	Primary Effectiveness Endpoint.....	19
5.2.	Secondary Analyses	22
5.2.1.	Adverse Effects that Occurred in the Clinical Study	22
5.2.2.	Secondary Effectiveness Endpoints	23
5.2.3.	Other Clinically Relevant endpoints	23
5.3.	PV-Stenosis Sub-Study	27
5.4.	Subgroup Analyses.....	28
6.	Study Conclusion	29

Study Title	A Prospective, Multicenter Clinical Study to Evaluate the Safety and Effectiveness of the Globe® Pulsed Field System for Treating Patients with Symptomatic Paroxysmal or Persistent Atrial Fibrillation (PULSAR)
Number of Centers	12 Sites in the US, EU, and Canada
Number of Subjects	183 enrollments, including 19 lead-in subjects

1. STUDY OBJECTIVE

The purpose of the PULSAR study is to demonstrate the safety and 12-month effectiveness of the Globe PF System for the treatment of drug refractory, recurrent, symptomatic Paroxysmal (PAF) or Persistent Atrial Fibrillation (PsAF). The study protocol calls for an interim analysis of effectiveness data after 50% and 75% of subjects have completed their 12-month visit. This summary is based on PAF effectiveness results, all safety results of the PAF cohort, and associated study design.

2. STUDY DESIGN

The PULSAR study was a prospective, multicohort, multicenter, non-randomized, open-label, single-arm clinical study. No active control group was used in the PULSAR study. Performance goals for the primary safety and effectiveness endpoints were defined based on an international consensus statement and state-of-the-art data available at the time of protocol creation. Results for the PAF cohort are presented below.

Patients were treated between 10-MAR-2023 and 21-MAR-2024. The database for this clinical trial included 183 enrolled patients, with 164 patients included in the Open Enrollment population of the PAF cohort while 19 were included in the Lead-In population of the same cohort. One Lead-In subject was allowed per operator as their first patient to gain clinical experience. There were 12 investigational sites.

All study transtelephonic monitoring (TTM) reports, 12-lead and Holter monitor electrocardiogram (ECG) recordings were securely transmitted to a designated ECG core lab. The ECG core lab reviewed and analyzed all TTM and Holter recordings as well as all 12-lead ECGs taken at the 3-, 6- and 12-month follow-up visits to determine if there were any episodes of atrial fibrillation/atrial flutter/atrial tachycardia (AF/AFL/AT) that met the primary effectiveness endpoint defined in the PULSAR study.

An imaging core lab was used during the PULSAR study to evaluate computed tomography (CT) and magnetic resonance imaging (MRI) images collected as part of the pulmonary vein (PV) stenosis sub-study. The imaging core lab was responsible for reviewing the baseline and 6-month CT and MRI images to characterize any potential occurrences of PV stenosis.

The PULSAR study received oversight from an independent Data Safety Monitoring Board (DSMB) which periodically conducted an independent review of the safety data to defined study termination criteria.

The PULSAR study included an independent Clinical Events Committee (CEC). CEC members provided unbiased adjudication of primary safety events. The CEC also reviewed all initial episodes of atrial fibrillation recurrence which met the study definition of a treatment failure reported by the ECG core lab to confirm the presence or absence of a primary effectiveness endpoint event.

Interim effectiveness analyses using a Fleming group-sequential design with two interim looks were to be conducted after 50% and 75%¹ of subjects have completed 12 months of follow-up within each cohort.

2.1. CLINICAL INCLUSION AND EXCLUSION CRITERIA

Enrollment in the PAF cohort of the PULSAR study was limited to patients who met the following inclusion criteria:

- Age 18-80
- A diagnosis of recurrent symptomatic PAF defined as Atrial Fibrillation (AF) that terminates spontaneously or with intervention within seven days of onset, documented by either of the following:
 - At least one documented PAF episode within twelve months prior to enrollment and a physician's note indicating at least two symptomatic PAF episodes occurring within six months prior to enrollment
 - or
 - At least two documented PAF episodes within six months prior to enrollment, and a documented physician's note indicating symptoms consistent with PAF

Documentation of an AF episode must include a recording such as electrocardiogram (ECG), transtelephonic monitoring (TTM), Holter monitor, telemetry strip, or recording from a personal wearable device approved by the relevant regulatory authority

- Failure or intolerance of at least one Antiarrhythmic Drug (AAD) Class I or III, including inability to take antiarrhythmic drug therapy due to the strong potential for adverse consequences (e.g., a patient with resting significant bradycardia).
- Signed Patient Informed Consent Form (ICF)

¹ The 75% interim analysis was not completed as the prespecified study success criteria were met during the 50% analysis.

- Able and willing to comply with all pre-, post-, and follow-up testing and requirements

Patients were not permitted to enroll in the PAF cohort of the PULSAR study if they met any of the following exclusion criteria:

- Atrial fibrillation secondary to a reversible cause or of non-cardiac origin, including but not limited to uncontrolled hyperthyroidism, untreated obstructive sleep apnea, acute alcohol toxicity
- Active fever or systemic infection, including but not limited to sepsis
- Any condition contraindicating acute or chronic anticoagulation
- Known allergies or hypersensitivities to anesthesia or contrast media that cannot be controlled with pre-treatment
- Severe mitral valve regurgitation (i.e., +3 or +4) or stenosis
- Uncontrolled heart failure or New York Heart Association (NYHA) function class III or IV
- Unstable angina
- History of pre-existing hemidiaphragmatic paralysis
- Severe bleeding disorder history
- Presence of any pre-existing pulmonary vein stenosis
- Rheumatic heart disease
- Untreated severe obstructive sleep apnea with apnea hypopnea index (AHI) > 30
- Myocardial infarction (MI)/percutaneous coronary intervention (PCI) within the last three months
- History of thromboembolic events including cerebral ischemic events (stroke or transient ischemic attacks (TIAs)) within the past six months
- Evidence of intracardiac thrombus at the time of the procedure
- Prior left atrial ablation or surgical procedure (including left atrial appendage (LAA) closures)
- Planned left atrial surgical procedure (including LAA closure) for any time during the follow-up period
- Any cardiac surgery within the previous six months
- Body mass index (BMI) > 40 kg/m²
- Presence of any pulmonary vein stents

- Mitral valve prosthesis
- Hypertrophic cardiomyopathy
- Primary pulmonary hypertension (right ventricular systolic pressure [RVSP] on echocardiogram >50 mmHg)
- Chronic kidney disease (class III or IV)
- Chronic liver disease or Child Pugh class B or C liver disease
- Presence of an implanted cardiac device, including implantable cardioverter defibrillator or pacemaker, implantable loop recorder, insertable cardiac monitor
- Planned LAA closure or implant of a cardiac device, including implantable cardioverter defibrillator or pacemaker, implantable loop recorder, insertable cardiac monitor, for any time during the follow-up period
- Known implants, conditions or anatomical abnormality that may interfere with the device delivery or positioning (e.g., myxoma, tumor, calcification, venous access path narrowing or tortuosity, atrial septal defect closure device)
- Left ventricular ejection fraction (LVEF) <35%
- Anterior-posterior LA diameter >55 mm
- Person of childbearing potential who is pregnant (as evidenced by pregnancy test if premenopausal)
- Known active drug or alcohol dependency
- Life expectancy < 12 months
- Current enrollment in any investigational study of a medical device, biologic, or drug not pre-approved by Kardium.

2.2. FOLLOW-UP SCHEDULE

All patients were scheduled to return for follow-up examinations at 7 days, 1 month, 2 months, 3 months, 6 months, and 12 months post-ablation. Table 1 below provides the schedule of events for the study. Adverse events and complications were recorded at all visits. Week-1, month-1 and month-2 visits were conducted remotely. Certain month-6 and month 12-visits were also conducted remotely.

Table 1. Schedule of Study Events

Procedure	Screening/ Baseline (Day -30 to 0)	Treatment (Day 1)	Discharge	Week 1 (Day 8 ± 3 days)	Month 1 (Day 31 ± 14 days)	Month 2 (Day 60 ± 14 days)	Month 3 (Day 91 ± 21 days)	Month 6 (Day 181 ± 28 days)	Month 12 (Day 366 ± 45 days)	Repeat ablation ¹⁰	Unscheduled visit ¹⁰
Visit Number	1	2	3	4	5	6	7	8	9		
	in person	in person	in person	remote	remote	remote	in person	in person ¹²	in person ¹²	in person	
Informed consent	✓										
Demographics	✓										
Medical history	✓										
Inclusion / Exclusion	✓										
Physical exam	✓		✓								
Pregnancy test ¹	✓										
12-lead ECG	✓		✓				✓	✓	✓		✓
Concomitant cardiac medications ²	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
TTE	✓ ³		✓ ⁴								
Chest CT or MRI	✓ ³										
TEE or ICE ⁵	✓									✓	
Ablation Procedure ⁶		✓								✓	
AFEQT	✓							✓	✓		
NIHSS	✓		✓ ¹¹							✓	
TTM							Weekly and symptomatic ⁷				
24-hour Holter monitoring ⁸								✓	✓		
Review/History of Repeat Ablations, DC Cardioversion/ Hospitalization				✓	✓		✓	✓	✓	✓	✓
Review of Arrhythmia Recurrence (AF/AFL/AT)				✓	✓		✓	✓	✓	✓	✓
Adverse events ⁹		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Device deficiencies		✓								✓	

Notes:

1. Pregnancy test performed on pre-menopausal persons of childbearing potential only, within 48 hours prior to the procedure.
2. Concomitant Antiarrhythmic Drugs (AAD) and other relevant cardiovascular medications.
3. Pre-procedure TTE imaging to determine atrial size, and CT/MRI to assess adequacy of anatomy, are required only if not performed within the last 6 months before the Screening visit. Additional imaging required for subjects enrolled in the PV Stenosis Substudy if chest CT or MRI not performed within 30 days pre-procedure.
4. Post-procedure for pericardial effusion screening if required, at the Investigator's discretion.
5. For atrial thrombus screening.
6. Index ablation procedure performed within 30 days of consent.
7. TTM supplied to subject, with transmissions weekly and symptomatic sent to core lab.
8. Subjects instructed to perform Holter monitoring during the time window allotted for the visit.
9. AEs collected from Visit 2 (Day 1) treatment.
10. If the subject has undergone any unscheduled visit or re-ablation procedure visit within the time window for a planned follow-up visit, the assessments planned for that follow-up visit were performed at the unscheduled/re-ablation visit.
11. Neurology consult performed as needed.
12. 6- and 12-month visits may be conducted remotely. 6-month visit conducted in person if participated in PV Stenosis Substudy

2.3. CLINICAL ENDPOINTS

2.3.1. PRIMARY SAFETY ENDPOINT

Rate of subjects presenting with one or more primary safety events up to and including 7 days (or otherwise indicated) after the index ablation procedure. Primary safety events comprise:

- Death
- Cardiac tamponade/perforation
- Heart block
- Major vascular access complication
- Major bleeding
- Myocardial infarction (MI)
- Pericarditis requiring intervention
- Pulmonary edema
- Stroke/cerebrovascular accident (CVA)
- Thromboembolism
- Transient ischemic attack (TIA)
- Vagal nerve injury resulting in gastroparesis
- Atrio-esophageal fistula (within 2 months of ablation procedure)
- Diaphragmatic paralysis/phrenic nerve injury (unresolved at 6 months)
- Severe PV stenosis (within 6 months of ablation procedure)
- Any Globe PF System-related or PF procedure-related cardiovascular and/or pulmonary adverse event within 7 days that prolongs or requires hospitalization for more than 48 hours (excluding recurrent AF/AFL/AT)

2.3.2. PRIMARY EFFECTIVENESS ENDPOINT

The primary effectiveness endpoint is the rate of 12-month treatment success. Treatment success is defined as freedom from treatment failure. Treatment failure includes:

- Documented recurrence of atrial fibrillation, atrial flutter[†], atrial tachycardia (AF/AFL/AT) as evidenced by episodes ≥ 30 seconds on transtelephonic monitoring (TTM), Holter monitoring, or continuously recorded on the standard 12-lead ECG during the effectiveness evaluation period (i.e., after the 90-day blanking period through to 12 months)
- Acute procedural failure, defined as:
 - Inability to isolate all accessible targeted pulmonary veins (PV) (minimally assessed for entrance block and/or exit block) during the index procedure
 - Ablation using a non-study device in the left atrium (LA)
- Direct Current (DC) cardioversion for AF/AFL/AT during the effectiveness evaluation period
- Redo ablation failure, defined as:
 - Any LA repeat ablation procedure for recurrent AF/AFL/AT at any time after the index procedure
- Antiarrhythmic Drugs (AADs) failure, defined as:
 - Administering during the effectiveness evaluation period a previously failed Class I or III AAD at a dose greater than the highest ineffective historical dose
 - Starting a new Class I or III AAD for AF during the effectiveness evaluation period
 - Use of amiodarone after the ablation procedure
- Surgical treatment for AF/AFL/AT after the index procedure

2.3.3. SECONDARY ENDPOINTS

The secondary effectiveness endpoints of this study are:

- Change in score from AF Effect on Quality-of-life (AFEQT) questionnaire from baseline
- Proportion of subjects that experienced symptomatic AF/AFL/AT (episodes ≥ 30 seconds) during the effectiveness evaluation period

Other clinically important endpoints of this study included:

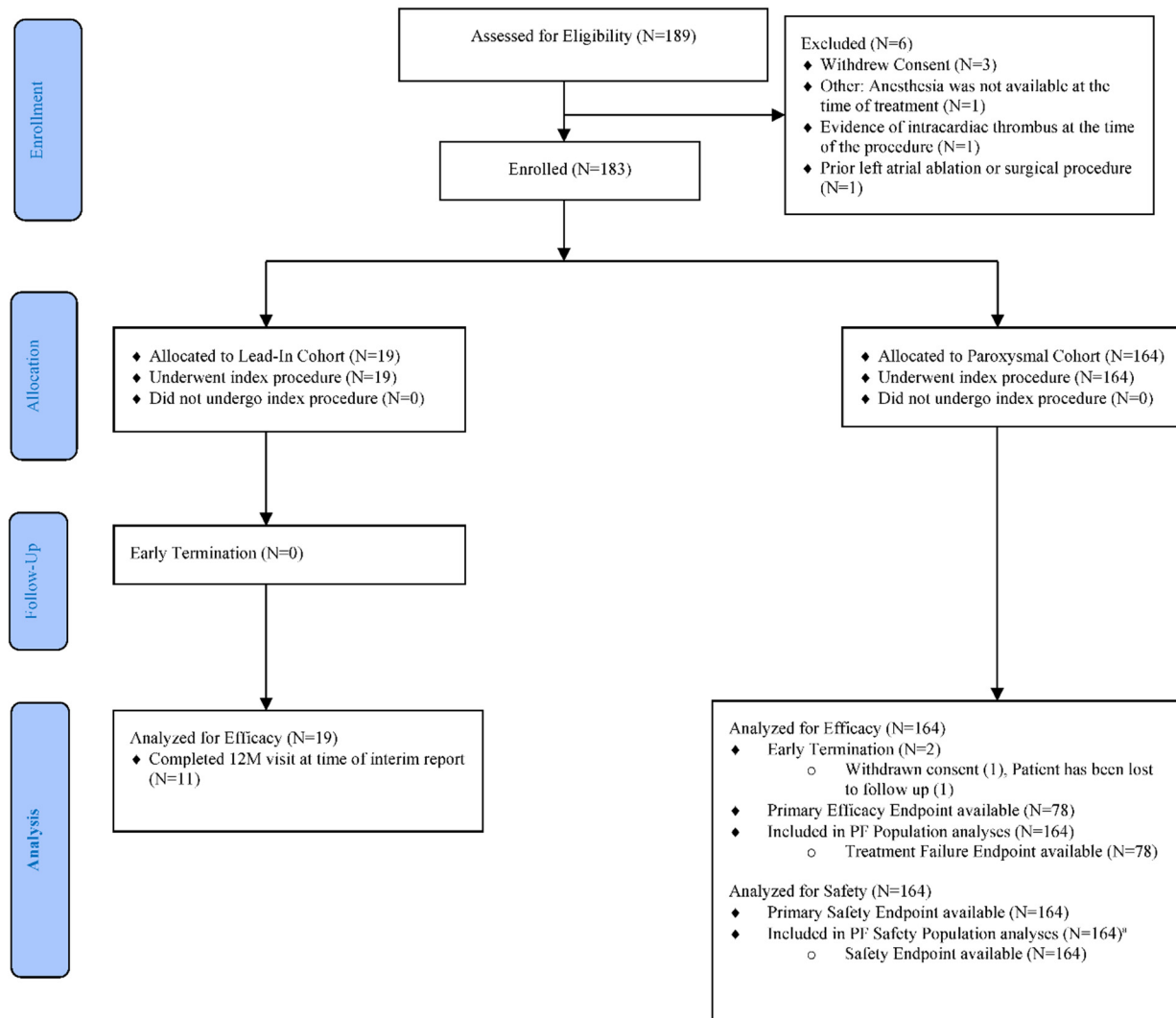
[†] Occurrence and/or ablation of cavotricuspid isthmus (CTI)-dependent AFL, as confirmed by entrainment maneuvers during EP testing at any time during this study is not a primary effectiveness failure because it is not considered an iatrogenic arrhythmia following a left atrial ablation procedure for AF.

- Rate of single-shot acute pulmonary vein isolation (PVI)
- Repeat ablation rate
- Duration of mapping
- Time from first PF energy application to last PF energy application
- Number of PF applications to achieve PVI
- Number of radiofrequency applications
- Overall procedure time
- Catheter left atrial dwell time
- Fluoroscopy time and radiation dose area product
- Occurrence of peri-procedural (up to 30 days after ablation) device-related and procedure-related other serious adverse events (SAEs)
- Occurrence of late onset (>30 days after ablation) device-related and procedure-related SAEs
- Treatment efficacy in the Lead-In Population – Treatment success as defined in the primary effectiveness endpoint
- Safety in the Lead-In Population – Rate of Lead-In subjects presenting with one or more primary safety events up to and including 7 days (or otherwise indicated in the Primary Safety Endpoint) after the index ablation procedure
- Safety in the All Enrolled Population – Rate of All Enrolled subjects presenting with one or more primary safety events up to and including 7 days (or otherwise indicated in the Primary Safety Endpoint) after the index ablation procedure
- PF-Only Effectiveness – Treatment success for the Open Enrollment Population as defined in the primary effectiveness endpoint for subjects treated with only PF
- PF-Only Safety – Rate of subjects presenting in the Safety Population treated with only PF, with one or more primary safety events up to and including 7 days (or otherwise indicated in the Primary Safety Endpoint) after the index ablation procedure

3. ACCOUNTABILITY OF PMA COHORT

One-hundred-eighty-three (183) subjects were enrolled in the study. Of the enrolled subjects, 19 were lead-in and 164 were Open Enrollment. All 164 subjects were included in the primary safety analysis and 78 subjects were included in the first primary effectiveness interim analysis that declared early study success (see Figure 1). The Lead-In subjects were included in separate safety and treatment effectiveness analyses as secondary endpoints.

Figure 1. Subject Accountability



^a Subjects who terminated the study between Day 91 and Day 181 visits are included in the Safety population for the primary safety endpoint. If patients in this situation had a safety event at one of the previously completed visits, this is counted as an event for the patient. If they did not, they are assumed to be event-free in the 6-month window despite no 6-month visit since most of these events happen early, particularly before 90 days.

The analysis populations include:

Lead-in Population	All subjects enrolled and intending to undergo the index procedure during the lead-in stage.
Open Enrollment Population	All subjects enrolled and intending to undergo the index procedure during the open enrollment stage.
Safety Population	All Open Enrollment Population subjects who have had any Globe components inserted into their vasculature
Interim Population	All Open Enrollment Population subjects who are evaluable for a 50% interim analysis of the primary effectiveness endpoint (per the Statistical Analysis Plan).
All Enrolled Population	All subjects enrolled and intending to undergo the index procedure.

NOTE: Since all subjects who had any Globe PF System component introduced into their vasculature were treated with the investigational device, the Open Enrollment and Safety Populations are identical.

4. STUDY POPULATION DEMOGRAPHICS AND BASELINE PARAMETERS

The demographics of the study population are typical for a paroxysmal atrial fibrillation ablation treatment study performed in the US. Table 2 and Table 3 present a summary of baseline and demographic characteristics for the Lead-In, Open Enrollment, Interim and All Enrolled populations. Table 4 presents a summary of the major medical history in the treated subjects by population.

Table 2. Summary of Baseline and Demographic Characteristics by Population

		Lead-In Population (N=19)		Interim Population (N=78)		Open Enrollment Population (N=164)		All Enrolled Population (N=183)	
Demographic Category	Characteristic	n	%	n	%	n	%	n	%
Sex at Birth	Male	11	58	53	68	98	60	109	60
	Female	8	42	25	32	66	40	74	40
Ethnicity	Not Hispanic or Latin	19	100	78	100	161	98	180	98
	Hispanic	0	0	0	0	3	2	3	2
	Not Reported	0	0	0	0	0	0	0	0
	Unknown	0	0	0	0	0	0	0	0
Race	Black	0	0	4	5	4	2	4	2
	East Asian	0	0	2	3	4	2	4	2
	Indigenous (First Nations, Inuk/Inuit, Metis, American Indian or Alaska Native)	0	0	0	0	2	1	2	1
	Latin American	0	0	0	0	1	1	1	1
	Middle Eastern	0	0	0	0	1	1	1	1
	Native Hawaiian or Pacific Islander	0	0	0	0	0	0	0	0
	South Asian	0	0	0	0	0	0	0	0
	Southeast Asian	0	0	0	0	0	0	0	0
	White	18	95	71	91	146	89	164	90
	Other	0	0	0	0	1	1	1	1
	Multi-Racial ^a	1	5	0	0	2	1	3	2
	Unknown	0	0	1	1	3	2	3	2

		Lead-In Population (N=19)		Interim Population (N=78)		Open Enrollment Population (N=164)		All Enrolled Population (N=183)	
Demographic Category	Characteristic	n	%	n	%	n	%	n	%
NYHA Class	I	3	16	4	5	14	9	17	9
	II	0	0	3	4	19	12	19	10
	III	0	0	0	0	0	0	0	0
	IV	0	0	0	0	0	0	0	0
	None (subject does not have HF)	16	84	71	91	131	80	147	80
N = Number of subjects in the indicated population. * Subjects may select more than one race but those subjects are only represented in Multi-Racial category.									

Table 3. Summary of Continuous Demographic Characteristics by Population

Variable	Statistic	Lead-In Population (N=19)	Interim Population (N=78)	Open Enrollment Population (N=164)	All Enrolled Population (N=183)
Age (years)	N	19	78	164	183
	Mean (SD)	68.7 (6.5)	63.9 (9.9)	65.0 (9.1)	65.4 (8.9)
	Median (Q1, Q3)	70.0 (65.0, 75.0)	65.5 (59.0, 71.0)	66.5 (60.5, 71.5)	67.0 (61.0, 72.0)
	Min, Max	57, 78	36, 80	36, 80	36, 80
Height (cm)	N	19	78	164	183
	Mean (SD)	171.2 (9.5)	175.1 (9.0)	174.5 (10.0)	174.1 (10.0)
	Median (Q1, Q3)	168.0 (165.0, 180.0)	175.0 (170.0, 182.0)	175.0 (168.0, 181.0)	175.0 (167.0, 180.0)
	Min, Max	157, 188	154, 193	152, 211	152, 211
Weight (kg)	N	19	78	164	183
	Mean (SD)	80.2 (16.4)	87.5 (15.8)	86.6 (17.4)	86.0 (17.4)
	Median (Q1, Q3)	80.0 (66.0, 90.0)	86.0 (78.0, 96.0)	84.5 (74.0, 97.0)	84.0 (73.0, 97.0)
	Min, Max	56, 108	51, 127	51, 134	51, 134
BMI (kg/m ²)	N	19	78	164	183
	Mean (SD)	27.36 (5.41)	28.51 (4.68)	28.39 (4.82)	28.28 (4.88)
	Median (Q1, Q3)	26.80 (22.90, 30.10)	28.35 (24.70, 31.50)	27.80 (24.60, 32.20)	27.60 (24.50, 32.20)
	Min, Max	20.2, 38.7	19.9, 40.5	19.3, 40.5	19.3, 40.5
Heart Rate (BPM)	N	19	78	164	183
	Mean (SD)	64.3 (14.0)	68.3 (19.1)	67.4 (16.7)	67.1 (16.5)
	Median (Q1, Q3)	61.0 (53.0, 76.0)	64.0 (55.0, 77.0)	65.0 (56.5, 73.5)	65.0 (55.0, 74.0)
	Min, Max	43, 90	39, 145	39, 145	39, 145
Systolic BP (mmHg)	N	19	78	164	183
	Mean (SD)	137.6 (15.6)	133.6 (17.3)	136.3 (19.2)	136.5 (18.8)
	Median (Q1, Q3)	135.0 (132.0, 149.0)	132.0 (121.0, 141.0)	133.5 (123.0, 151.0)	134.0 (123.0, 150.0)
	Min, Max	111, 168	101, 180	90, 180	90, 180

Variable	Statistic	Lead-In Population (N=19)	Interim Population (N=78)	Open Enrollment Population (N=164)	All Enrolled Population (N=183)
Diastolic BP (mmHg)	N	19	78	164	183
	Mean (SD)	76.4 (9.7)	78.8 (10.5)	79.5 (11.0)	79.2 (10.9)
	Median (Q1, Q3)	76.0 (68.0, 85.0)	80.0 (70.0, 86.0)	80.0 (73.0, 86.0)	80.0 (73.0, 86.0)
	Min, Max	56, 91	53, 100	50, 119	50, 119
LVEF (%)	N	19	78	163	182
	Mean (SD)	56.8 (6.2)	60.0 (6.3)	59.9 (6.0)	59.6 (6.1)
	Median (Q1, Q3)	58.0 (55.0, 60.0)	60.0 (57.0, 65.0)	60.0 (55.0, 65.0)	60.0 (55.0, 65.0)
	Min, Max	40, 65	39, 75	39, 75	39, 75
LA Diameter (cm)	N	19	77	157	176
	Mean (SD)	3.719 (0.632)	3.763 (0.660)	3.834 (0.636)	3.822 (0.635)
	Median (Q1, Q3)	3.800 (3.100, 4.100)	3.800 (3.400, 4.200)	3.800 (3.400, 4.200)	3.800 (3.400, 4.200)
	Min, Max	2.40, 4.60	2.20, 5.30	2.20, 5.50	2.20, 5.50
CHA2DS2- VASc	N	19	78	164	183
	Mean (SD)	2.5 (1.4)	2.0 (1.4)	2.1 (1.4)	2.1 (1.4)
	Median (Q1, Q3)	2.0 (2.0, 3.0)	2.0 (1.0, 3.0)	2.0 (1.0, 3.0)	2.0 (1.0, 3.0)
	Min, Max	0, 6	0, 5	0, 5	0, 6

N = Number of subjects in the indicated population.

Table 4. Baseline Medical History by Population

	Lead-in Population (N=19)		Interim Population (N=78)		Open Enrollment Population (N=164)		All Enrolled Population (N=183)	
Medical History Term	n	%	n	%	n	%	n	%
Comorbidities								
Any medical history	19	100	78	100	164	100	183	100
Atrial Fibrillation	19	100	78	100	164	100	183	100
Atrial Flutter	0	0	1	1	1	1	1	1
Atrial Tachycardia	0	0	1	1	1	1	1	1
Other Arrhythmias (PVC)	0	0	1	1	2	1	2	1
Hypertension	10	53	49	63	98	60	108	59
Type II Diabetes	2	11	11	14	21	13	23	13
Vascular Disease History	4	21	10	13	20	12	24	13
Previous Myocardial Infarction	3	16	5	6	8	5	11	6
Congestive Heart Failure	1	5	1	1	8	5	9	5
Stroke/TIA/Thrombo-embolism	1	5	3	4	7	4	8	4
Chronic Kidney Disease	1	5	2	3	3	2	4	2
Coronary Artery Disease	3	16	3	4	3	2	6	3
Sleep Apnea	2	11	4	5	8	5	10	5
COPD	0	0	3	4	5	3	5	3
Anticoagulants and AADs (Failed/Intolerant) at Baseline								
Anticoagulants	17	89	75	96	159	97	176	96
Class I or III AAD	19	100	78	100	164	100	183	100
Number of patients who had a Cardioversion within the year prior to the index procedure								
Cardioversion	0	0	10	13	21	13	21	11

5. SAFETY AND EFFECTIVENESS RESULTS

5.1. PRIMARY ANALYSIS

5.1.1. PRIMARY SAFETY ENDPOINT

The analysis of safety was based on the 164 patients of the Safety Population after completion of their 6-month visit. The key safety outcomes for this study are presented below in Table 5.

One subject had primary safety event reporting during follow-up (hemorrhagic stroke unrelated to the investigational device, adjudicated by the CEC[‡]), resulting in a rate of 0.6% (1/164). The null hypothesis, that the primary safety event rate was equal to or greater than the performance goal of 14%, was rejected ($p < 0.001$, against a critical p-value of 0.05), so the success criteria for the safety endpoint was met.

Table 5. Primary Safety Event Rate at 6-Months – Safety Population

Statistic	Safety Population (N = 164)
Number of subjects with one or more Primary Safety Events	1
Percent of subjects with one or more Primary Safety Events (95% CI)	0.6 (0.0, 3.4)
p-value ^a	< 0.001
N = Number of subjects in the Safety Population who have completed their Month 6 visit	
^a Based on a one-sided exact binomial test compared to the performance goal of 14%	

5.1.2. PRIMARY EFFECTIVENESS ENDPOINT

The analysis of primary effectiveness was based on the 12-month ablation treatment success in the Interim Population (n=78) who had completed their 12-month visit at the time of the first interim analysis. Key effectiveness outcomes are presented in Table 6 and Table 7.

The primary effectiveness endpoint of 12-month treatment success was 80.8% (63/78, 95% CI = 70.3%, 88.8%). The null hypothesis, that the primary effectiveness rate was less than or equal to the performance goal of 50%, was rejected ($p < 0.001$, against a critical p-value of 0.002674 for the interim analysis). The lower one-sided 99.7% confidence bound (based on the interim analysis critical p-value) was 65.6%. Consequently, the success criterion for this endpoint was met. A Kaplan-Meier plot of treatment failure-free survival for the Interim Population is shown in Figure 2, including the 95% confidence limits.

[‡] This subject subsequently presented with pulmonary embolism (PE) as a sequela of the hemorrhagic stroke: the stroke required contraindication to anticoagulation and rehabilitation stay that increased immobility.

A sensitivity analysis of the treatment failure-free rate at 12 months using Wilson's Method showed that the percent of treatment failure-free subjects (95% CI) was 80.8%, which supports the results of the primary effectiveness presented above. This confirms that the primary effectiveness endpoint was met in the Interim Population when the treatment failure rate is compared to a performance goal of 50%.

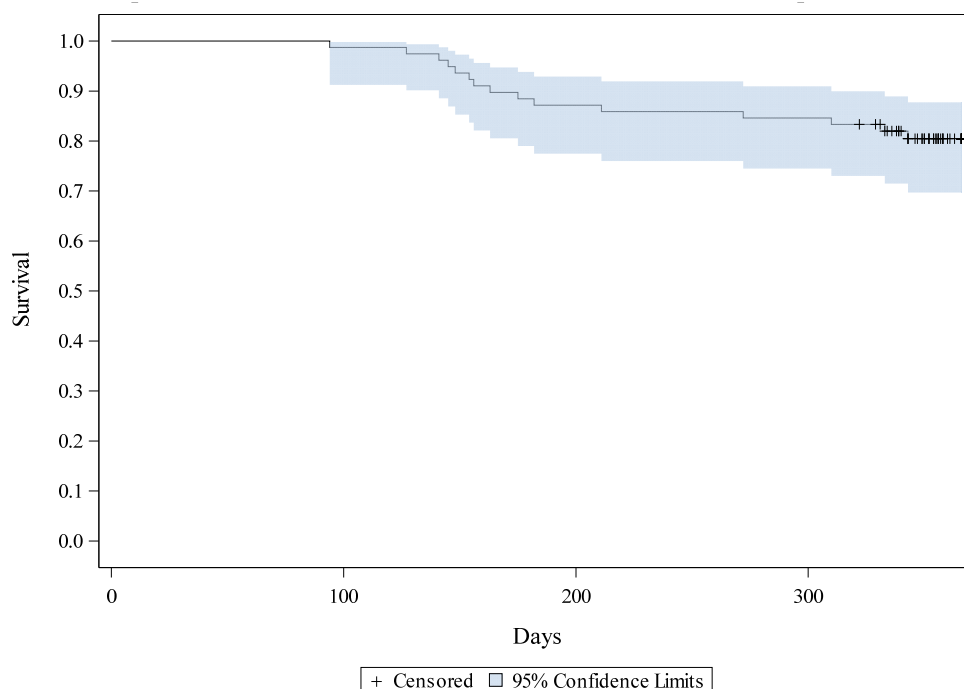
Table 6. Summary of Treatment Failure-free Rate at 12-Months – Interim Population

Statistic	Interim Population (N = 78)
Number of treatment-failure-free subjects	63
Percent of treatment-failure-free subjects (95% CI)	80.8 (70.3, 88.8)
Percent of treatment-failure-free subjects (one-sided 99.7% CI)	80.8 (65.6, 91.4)
<i>p</i> -value ^a	< 0.001
N = Number of subjects who have completed their Month 12 visit.	
^a Based on a one-sided exact binomial test compared to the performance goal of 50%.	
The significance boundary at the time of this interim analysis corresponds to a nominal p-value of 0.002674.	

Table 7. Distribution of Treatment Failure Modes at 12-Months by Population

Failure Mode	Interim Population (N = 78) n (%)	Lead-in Population (N = 11) n (%)	Interim + Lead-in Population (N = 89) n (%)
Any Failure Mode	15 (19)	4 (36)	19 (21)
Recurrence of AF/AFL/AT	14 (18)	3 (27)	17 (19)
Recurrence of AF	14 (18)	3 (27)	17 (19)
Recurrence of AFL	0 (0)	0 (0)	0 (0)
Recurrence of AT	0 (0)	0 (0)	0 (0)
Acute Procedural Failure	0 (0)	0 (0)	0 (0)
Direct Current Cardioversion	0 (0)	1 (9)	1 (1)
Redo Ablation Failure	2 (3)	0 (0)	2 (2)
AAD Failure	0 (0)	1 (9)	1 (1)
Surgical Treatment for AF/AFL/AT after Index Procedure	0 (0)	0 (0)	0 (0)
N = Number of subjects who have completed their Month 12 visit. Note: Subjects may fail via multiple modes and are counted once for each failed mode.			

Figure 2. Kaplan-Meier Plot of Treatment Failure-free Survival – Interim Population



Documentation of the primary effectiveness endpoint comprised in part transtelephonic monitoring outside of pre-specified visits. TTM compliance was defined on a per-subject basis as the ratio of observed to expected TTM measurements, based on protocol requirements. Compliance with the required TTM protocol is summarized in Table 8 for all populations.

Table 8. Summary of TTM Compliance by Population

Variable	Statistic	Interim Population (N = 78)	Lead-in Population (N = 19)	Open Enrollment Population (N = 164)	All Enrolled Population (N = 183)
TTM Compliance (%) ^a	N	78	19	164	183
	Mean (SD)	66.3 (25.6)	74.8 (23.3)	70.1 (24.9)	70.6 (24.7)
	Median (Q1, Q3)	74.7 (48.8, 87.5)	85.7 (66.7, 90.5)	76.3 (55.3, 89.3)	77.1 (56.8, 89.5)
N = Number of subjects who have reached visit 7 in the indicated population ^a TTM compliance % defined as the observed/expected number of TTM measurements per subject					

5.2. SECONDARY ANALYSES

5.2.1. ADVERSE EFFECTS THAT OCCURRED IN THE CLINICAL STUDY

A total of 165 adverse events were reported in the PAF cohort of the PULSAR study. Of those events 23 (in 20 subjects) were determined to be serious adverse events of which 5 were classified as being related or possibly related to the procedure and/or the study device, see Table 9. There were a total of 16 non-serious device-related adverse events and 39 non-serious procedure-related adverse events in the PAF cohort of the PULSAR study.

Table 9. All Procedure or Study Device Related Serious Adverse Events Summarized by Meddra Categories That Occurred in Either/Both of the Enrolled (N=183) and Safety (N=164) Populations

MedDRA System Organ Class	MedDRA Preferred Term	Procedure Related	Device Related	Population
Cardiac disorders	Atrial fibrillation	Possibly	No	Enrolled and Safety
	Dressler's syndrome with pericardial effusion	Probably	Possibly	Enrolled and Safety
Nervous system disorders	Hemorrhagic stroke	Yes	No	Enrolled and Safety
Renal and urinary disorders	Urinary retention	Yes	No	Enrolled and Safety
Respiratory, thoracic and mediastinal disorders	Aspiration	Yes	No	Enrolled and Safety

5.2.2. SECONDARY EFFECTIVENESS ENDPOINTS

Change in AF Effect on Quality-of-life (AFEQT) Questionnaire

There was a large and positive trend in the mean and median AFEQT scores between baseline and both 6-month and 12-month visits across all categories of the questionnaire. The overall mean score increased from 63.366 ± 22.017 at baseline to 94.005 ± 11.260 at 12 months after the index procedure for the Interim population. A summary of the AFEQT score by visit in the Interim Population is provided in Table 10.

Table 10. Summary of Overall AFEQT Score Through 12-Month – Interim Population

		Interim Population (N=78)			
Variable	Visit	n ^a	Mean (SD)	Median (Q1, Q3)	Min, Max
Overall Score	Baseline	78	63.366 (22.017)	66.670 (50.930, 81.480)	9.26, 99.07
	Month 6	76	92.105 (11.849)	98.150 (89.350, 100.000)	46.30, 100.00
	Month 12	78	94.005 (11.260)	99.535 (94.440, 100.000)	47.22, 100.00
N = Number of subjects in the Interim Population.					
^a Number of subjects with an AFEQT score available at the indicated visit.					

Symptomatic AF/AFL/AT

Approximately 12% (9/78) of the Interim Population patients had a recurrence of symptomatic AF/AFL/AT episodes at 12 months. A summary of the rate of patients in the Interim Population experiencing a symptomatic recurrence of AF/AFL/AT is provided in Table 11.

Table 11. Summary of Symptomatic AF/AFL/AT recurrence at 12 Months – Interim Population

Statistic	Interim Population (N = 78)
Number of Subjects with recurrent Symptomatic AF/AFL/AT	9
Percent of Subjects with Symptomatic AF/AFL/AT (95% CI) ^a	11.5 (5.4, 20.8)
N = Number of subjects who have completed their Month 12 visit	
^a Exact Clopper Pearson confidence interval	

5.2.3. OTHER CLINICALLY RELEVANT ENDPOINTS

Rate of Single-Shot Acute Pulmonary Vein Isolation (PVI)

The rate of single shot PVI was the percentage of veins that were electrically isolated in one PF energy application. Amongst the 4 superior and inferior pulmonary veins in the All Enrolled Population, the left superior and right inferior had the highest and lowest rates of single shot isolation, respectively (99% and 88%). A summary of the rate of single-shot PVI by population is presented in Table 12 below.

Table 12. Summary of Single Shot PVI by Population

	All Enrolled (N = 183)		Lead-In (N = 19)		Open Enrollment (N = 164)		Safety (N = 164)	
Vein	n/N*	%	n/N*	%	n/N*	%	n/N*	%
Right Superior	174/183	95	19/19	100	155/164	95	155/164	95
Right Inferior	161/183	88	15/19	79	146/164	89	146/164	89
Left Superior	161/163	99	17/18	94	144/145	99	144/145	99
Left Inferior	153/163	94	17/18	94	136/145	94	136/145	94
Left Common	16/20	80	0/1	0	16/19	85	16/19	84
Right Middle	10/10	100	2/2	100	8/8	100	8/8	100
Other	2/2	100	-	-	2/2	100	2/2	100
N = Number of subjects in the indicated population N* = Number of subjects in whom isolation was attempted for the indicated vein								

Repeat Ablation Rate

The rate of repeat ablation for subjects with a recurrence of AF/AFL/AT at any time after the index procedure for Interim Population patients is summarized in Table 13. A total of 2 patients in the Interim Population had a repeat ablation due to recurring AF.

Table 13. Summary of Patients Receiving a Repeat Ablation Procedure – Interim Population

Statistic	Interim Population (N = 78)
Number of subjects receiving a repeat ablation procedure	2
Percent of subjects receiving a repeat ablation procedure (95% CI) ^a	3 (0.3, 9.0)
N = Number of subjects who are available for the primary effectiveness endpoint ^a Exact Clopper-Pearson confidence interval	

Procedural Outcomes

Additional effectiveness outcomes were collected which included procedure and mapping duration, time from first to last PF application, catheter left atrial dwell time, fluoroscopy duration, radiation dose area product, and total Pulsed Field energy delivered. A summary of the results in the Open Enrollment Population is shown in Table 14. A mean of 49 seconds of PF energy was delivered and it took an average of 25.6 minutes to isolate all veins.

Table 14. Summary Overall Index Procedure Information – Open Enrollment Population

	Open Enrollment Population (N=164)		
Characteristic	n	Mean (SD)	Median (Q1, Q3)
Duration of Mapping (min)	163	9.0 (5.5)	8.0 (5.0, 11.0)
Time from first to last PF Application (min)	164	25.6 (9.8)	24.0 (19.0, 30.0)
Overall procedure time (min)	164	95.8 (20.7)	93.5 (80.5, 105.0)
Catheter Left Atrial Dwell Time (min)	164	59.9 (11.6)	58.0 (52.5, 65.0)
Fluoroscopy time (min)	164	9.169 (7.523)	7.150 (4.200, 11.650)
Radiation dose area product (mGy.cm ²)	144	49294.56 (458717.36)	4813.00 (1940.00, 11900.00)
Total PF ablation energy delivered (sec)	163	49.2 (10.2)	48.0 (42.0, 55.0)
N = Number of subjects in the Open Enrollment Population N = Number of subjects with data available for the indicated characteristic ^a General anesthesia was used in 161 subjects (98.2%) and conscious sedation in 3 subjects (1.8%)			

Peri-Procedural and Late Onset Device and Procedure Related Serious Adverse Events

The rate of peri-procedural SAEs was defined as the occurrence of device-related and procedure-related SAEs up to 30 days following ablation. A total of 4 subjects in the Safety Population had peri-procedural SAEs that were device or procedure related, which encompassed aspiration in the bronchial system, Dressler's syndrome, urinary retention, and a hemorrhagic stroke. A summary of peri-procedural SAEs in the Lead-in, Safety, and All Enrolled populations is presented in Table 15.

Table 15: Summary of Peri-procedural SAEs by Population

Statistic	Lead-in (N = 19)	Safety (N = 164)	All Enrolled (N = 183)
Number of subjects with a peri-procedural SAE	0	4	4
Percent of subjects with a peri-procedural SAE (95% CI) ^a	0.0 (0.0, 17.6)	2.4 (0.7, 6.1)	2.2 (0.6, 5.5)
N = Number of subjects in the indicated population ^a Exact Clopper-Pearson confidence interval			

The rate of late-onset SAEs was defined as the occurrence of device-related and procedure-related SAEs beyond 30 days (> 30 days) following ablation. One subject had a late onset SAE (158 days following ablation) due to AF recurrence. The subject was admitted to the hospital, where

chemical cardioversion was performed, and the subject was observed for 13 days before discharge. The event was adjudicated as possibly procedure related, resulting in a late-onset SAE rate of 0.5%. A summary of late-onset SAEs in the Lead-in, Safety, and All Enrolled populations is presented in Table 16.

Table 16: Summary of Late Onset SAEs by Population

Statistic	Lead-in (N = 19)	Safety (N = 164)	All Enrolled (N = 183)
Number of subjects with a late-onset SAE	0	1	1
Percent of subjects with a late-onset SAE (95% CI) ^a	0.0 (0.0, 17.7)	0.6 (0.0, 3.4)	0.5 (0.0, 3.0)
N = Number of subjects in the indicated population ^a Exact Clopper-Pearson confidence interval			

Safety in the Lead-In and All Enrolled Populations

A Kaplan-Meier estimate of the 6-month safety rate was calculated for the Lead-in, Safety, and All Enrolled Populations to assess the impact of censoring and intercurrent event timing on the primary safety outcome. Confidence intervals based on Kaplan-Meier analysis of the 12-month safety event-free survival in the Safety and All Enrolled Populations corroborate the results of the primary analysis ($p < 0.001$). The results of this analysis are presented in Table 17.

Table 17. Summary of Primary Safety Event-free Rate at 6-Months

Statistic	Lead-In Population (N = 19)	Safety Population (N = 164)	All Enrolled Population (N = 183)
Number of primary safety event-free subjects at 6 months	19	163	182
Primary safety event-free survival rate (95% CI)	100 (-)	99.4 (95.8, 99.9)	99.4 (96.2, 99.9)
p-value ^a	-	< 0.001	< 0.001
N = Number of subjects in the indicated population ^a Based on a one-sided test of the Kaplan-Meier rate at 6 months using the Greenwood estimate of the variance compared to the performance goal of 14%			

PF-Only Effectiveness and Safety

Only PF ablation was performed in the paroxysmal cohort of the PULSAR study, therefore the safety and effectiveness data presented is identical to the “PF Only” analysis.

5.3. PV-STENOSIS SUB-STUDY

The results of diameter changes in the treated pulmonary veins are shown in Table 18. There was no mild (30% to <50%), moderate (50% to 70%) or severe (>70%) stenosis in any pulmonary vein at 6 months following ablation. When including all veins, the aggregate mean reduction in pulmonary vein diameter at 6 months post procedure was 2.2%. These results suggest that treatment of PAF using the Globe PF System is not associated with a risk of moderate or severe stenosis at 6 months following ablation.

Table 18. PV Average Diameter Summary Statistics – Open Enrollment Population

Pulmonary Vein	Baseline (N^a=33)	6 months (N^a=33)	Change from baseline (N^b=33)	Relative change from baseline (%) (N^b=33)
Left Superior Pulmonary Vein (mm)				
Mean ± SD (N)	16.5 ± 2.9 (31)	16.2 ± 2.6 (31)	-0.3 ± 1.2 (31)	-1.3 ± 6.9 (31)
Left Inferior Pulmonary Vein (mm)				
Mean ± SD (N)	14.3 ± 2.1 (33)	13.9 ± 2.2 (33)	-0.4 ± 1.3 (33)	-2.9 ± 9.5 (33)
Left Pulmonary Vein (Common) (mm)				
Mean ± SD (N)	22.6 ± 5.4 (5)	23.8 ± 5.4 (5)	1.2 ± 2.3 (5)	6.0 ± 9.2 (5)
Right Superior Pulmonary Vein (mm)				
Mean ± SD (N)	18.2 ± 3.1 (33)	17.8 ± 2.8 (33)	-0.4 ± 1.9 (33)	-1.5 ± 9.9 (33)
Right Middle Pulmonary Vein (mm)				
Mean ± SD (N)	8.4 ± 1.4 (3)	7.6 ± 0.7 (3)	-0.7 ± 1.8 (3)	-7.0 ± 19.4 (3)
Right Inferior Pulmonary Vein (mm)				
Mean ± SD (N)	16.9 ± 2.7 (33)	16.3 ± 3.2 (33)	-0.6 ± 1.6 (33)	-3.9 ± 9.5 (33)
All veins combined (mm)				
Mean ± SD (N)	16.5 ± 3.5 (138)	16.2 ± 3.6 (138)	-0.4 ± 1.6 (138)	-2.2 ± 9.3 (138)
Abbreviations: SD=Standard Deviation, IQR=Interquartile Range, mm=millimeters				
^a The number of subjects with an evaluable result at the particular timepoint.				
^b The number of subjects with paired evaluable results.				

5.4. SUBGROUP ANALYSES

No subgroup analyses were performed for sex, gender, age, race, ethnicity, or any other relevant characteristic-specific subgroups. A poolability analysis was conducted for the primary safety and primary effectiveness endpoints across sites, regions, and sex at birth. The results are presented in Table 19 and Table 20. Both the primary safety and primary effectiveness endpoint results were poolable across study sites, regions and sex at birth.

Table 19. Poolability Analysis of Primary Safety Event at 6 Months for the Safety Population

		Safety Population (N = 164)	
Variable	Category	Subjects Experiencing Primary Safety Event (n)	p-value ^a
Site	Site 1	0	0.220
	Site 2	0	
	Site 3	0	
	Site 4	0	
	Site 5	0	
	Site 6	0	
	Site 7	0	
	Site 8	0	
	Site 9	0	
	Site 10	0	
	Site 11	1/14	
	Site 12	0	
Region	US	1/83	>0.999
	Non-US	0/81	
Sex at Birth	Female	0/66	>0.999
	Male	1/98	

N = Number of subjects in the Safety Population who have completed their 6-month visit

^a Based on a Fisher’s Exact test

Table 20. Poolability Analysis of Treatment Failure-Free Rate at 12 Months for the Interim Population

		Interim Population (N = 78)	
Variable	Category	Treatment Failure-Free Subjects (n)	p-value ^a
Site	Site 1	2/2	0.870
	Site 2	0	
	Site 3	8/9	
	Site 4	0	
	Site 5	14/16	
	Site 6	13/17	
	Site 7	0	
	Site 8	0	
	Site 9	0	
	Site 10	19/24	
	Site 11	0	
	Site 12	7/10	
Region	US	39/51	0.237
	Non-US	24/27	
Sex at Birth	Female	20/25	>0.999
	Male	43/53	

N = Number of subjects in the Interim Population who have completed their 12-month visit
^a Based on a Fisher’s Exact test

6. STUDY CONCLUSION

The results of the PULSAR study demonstrated the safety and effectiveness of the Globe Catheter for the treatment of symptomatic drug refractory paroxysmal AF, when used in conjunction with the Globe Pulsed Field System.

Kardium Inc.

155 - 8518 Glenlyon Parkway
Burnaby, BC V5J 0B6
Canada

kardium.com

info@kardium.com

Kardium®

407-00019-EN-USA REV-B
2025-09-18



Globe Introducer and Globe Catheter

Part Numbers 601-01001 and 601-01000

Instructions for Use



Kardium®

© 2024 Kardium Inc. All rights reserved.

Kardium® and Globe® are registered trademarks in the United States and Europe and are owned by Kardium Inc. GPS™ is a trademark of Kardium Inc. All other trademarks are the property of their respective owners.

The Globe® Pulsed Field System and associated technology are protected by one or more patents listed at <https://kardium.com/patents>.

NOTE: Any serious incident that has occurred due to or during the use of the Globe Pulsed Field System should be reported to Kardium and to the applicable regulatory authority in which the user and/or patient is established in accordance with jurisdictional requirements.

NOTE: Before a procedure, ensure that you have the latest version of this document downloaded by visiting <https://manuals.kardium.com> or emailing manuals@kardium.com. To get a printed copy of this document, email manuals@kardium.com.

KARDIUM DISCLAIMER OF WARRANTY AND LIMITATION OF LIABILITY

For device warranty information, visit <https://kardium.com/warranty>.

Contents

1 Prescription and safety information	6
1.1 Intended use	6
1.2 Indications for use	6
1.3 Contraindications	6
1.4 Warnings	6
1.5 Adverse events	9
1.6 Clinical data	10
1.7 Related instructions for use	10
2 Globe Introducer description	11
2.1 Contents of introducer package	11
2.2 Introducer components	11
3 Globe Catheter description	15
3.1 Contents of catheter package	15
3.2 Catheter components	16
4 Equipment requirements	21
4.1 Lab setup	21
4.2 Required items provided by the facility	22
4.3 Required equipment	23
5 Patient preparation and safety	25
5.1 Prepare the patient and accessories	25
5.2 Monitor the patient	26
5.3 Use of defibrillation equipment	27

5.4 Recommendations for anticoagulation treatment	27
5.5 Recommendations for procedure length	27
6 Directions for use	28
6.1 Unpack and inspect the introducer	28
6.2 Prepare the introducer	28
6.3 Unpack the catheter	29
6.4 Prepare the catheter	29
6.5 Insert the sheath	32
6.6 Insert the catheter	34
6.7 Cover the catheter cable	35
6.8 Connect the catheter cable	36
6.9 Mapping and ablation	36
6.10 Remove the catheter at the end of the procedure	37
6.11 Remove the sheath	38
7 Cleaning	39
8 Disposal	40
9 Troubleshooting	41
9.1 Undeploy array deployed during device preparation	41
9.2 Untangle lines in the loader during device preparation	43
9.3 Clear air bubbles in the loader during catheter insertion	45
9.4 Workaround for damaged or non-sterile vacuum pump	45
9.5 Retract stuck array into the sheath	48
9.6 Replace the catheter	51

10 Technical support	52
11 Product specifications	53
12 Environmental conditions	54
13 Symbols	55

1 Prescription and safety information

This section contains prescription and safety information.

1.1 Intended use

The Globe® Catheter is intended for cardiac anatomical and electrophysiological mapping, ablation energy delivery, and stimulation.

1.2 Indications for use

The Globe Catheter is indicated for anatomical and electrophysiological mapping and stimulation of cardiac tissue, and for the delivery of ablation energy for the treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation, when used in conjunction with the Globe Pulsed Field System.

1.3 Contraindications

The Globe PF System is contraindicated for:

- Pediatric patients
- Patients with material in or around the atrium that could become dislodged during the procedure, such as intracardiac thrombus, myxoma, or tumor
- Patients suffering from active systemic infection (sepsis)
- Patient with intolerance to anticoagulation medications

1.4 Warnings

Note the following warnings. A warning indicates a potentially hazardous situation that, if not avoided, could cause serious injury or death.

Anticoagulation therapy. To reduce the risk of thrombosis, administer appropriate levels of anticoagulation therapy and closely monitor activated clotting time levels throughout the procedure.

Array deployment. Before deploying the array, use medical imaging to confirm that the array has cleared the sheath tip and that the rib tips will not touch the sheath tip when the array is deployed. Otherwise, the sheath tip may be damaged, which may lead to trauma of the vessel wall or access site during sheath removal and to release of embolic material into the patient's circulation.

Array size. Screen patients based on atrial size and shape using a CT cardiac scan. During deployment, evaluate the size and shape of the array relative to the atrium using a combination of medical imaging, flow mapping, and impedance mapping as needed. If the array seems too large for the atrium, remove the

catheter to avoid damaging cardiac structures. If the array seems small, use caution near the entrance of the pulmonary veins to avoid ablating too deep in the pulmonary veins.

Aseptic technique. To reduce the risk of patient contamination and infection, use aseptic technique when opening the packaging and passing components into the sterile field. Maintain sterility of the sterile components throughout the procedure. Keep items that have been removed from the patient in the sterile field in case they need to be reinserted.

Cardiopulmonary arrest. Delivery of ablation energy can cause ventricular tachycardia leading to cardiopulmonary arrest. Have external defibrillation equipment available in the event of cardiopulmonary arrest.

Catheter cable support. Make sure to adequately support and stabilize the catheter cable while it is connected to the catheter. Movement of the cable can inadvertently move the catheter, leading to patient injury.

Device compatibility. Use the dilator supplied with the Globe Introducer only with the sheath supplied with the Globe Introducer. Do not use the dilator with another sheath, and do not use the sheath with another dilator. The compatibility and safety of the use of the dilator and the sheath supplied with the Globe Introducer with any other sheath or dilator respectively have not been established. Using incompatible components may damage the sheath or dilator and may result in patient injury or death.

Device compatibility. The compatibility and safety of the use of the Globe Introducer with catheters other than the Globe Catheter have not been established. Using the Globe Introducer with any other catheter may damage the sheath or the catheter and could result in patient injury or death.

Device compatibility. Using the Globe Catheter with any introducer other than the compatible Globe Introducer specified in this document can lead to patient injury.

Device compatibility. Use the Globe Catheter only with the compatible Globe Catheter Cable, Globe Controller, and Globe PF Generator as specified in this document. Using any other catheter, catheter cable, controller, or generator can impair system performance and can create a risk of burns and electrical shock for the patient or user.

Device inspection. To minimize the risk of patient injury or illness, inspect the device components before use and do not use if you suspect damage in any way. Return damaged products to Kardium.

Device modification. To avoid equipment damage that can lead to a hazardous situation for patients and users, do not modify the catheter or its accessories in any way, such as by attempting to manually bend the shaft or otherwise reshape the catheter.

Device modification. To avoid equipment damage, such as damaging the sheath coating, that can lead to a hazardous situation for patients, do not modify the introducer or its accessories.

Do not touch the circuit board. To reduce the risk of electrostatic discharge that may lead to catheter malfunction, do not touch the circuit board that is enclosed in the catheter handle. Keep the gray round splash guard in place on the handle when the catheter cable is not connected to the catheter.

Electrically conductive implants. Electrically conductive implants may concentrate or redirect high-frequency (HF) currents from the catheter and harm the patient. If in doubt, seek qualified advice.

Embolic events. To minimize the potential for embolic events, always retract the dilator and the catheter slowly, and flush the catheter shaft, catheter array, sheath, and dilator according to the instructions for use.

Expiration date. Do not use the Globe Introducer or the Globe Catheter after the expiration date (use-by date) printed on the packaging label.

Keep the catheter cable connection dry. Liquids can damage the internal electronics of the catheter handle and the catheter cable, leading to adverse performance. Whenever the catheter handle is not connected to the catheter cable:

- Ensure the round gray splash guard remains in place on the catheter handle to keep the circuit board dry.
- Ensure the clear catheter cable cap remains in place on the end of the catheter cable to keep the connection dry.

Left atrial appendage. Before the procedure, review the left atrium imaging (MR or CT), and note the position of the left atrial appendage. When inserting the catheter, position and orient the sheath tip so that the rib tips will not enter the left atrial appendage.

Limit catheter insertions. To minimize wear on the sheath and array, avoid more than two full catheter insertions through the same sheath. A full catheter insertion is defined as insertion of the array out of the sheath, starting with the array in the catheter loader.

Lubricious coating. The outer surface of the sheath contains a lubricious coating. The safety and effectiveness of the coated device have not been established, or are unknown, in vascular regions other than those specifically indicated. Follow the directions in the instructions for use. Do not wipe the sheath, do not leave the sheath soaking in the tray for longer than required, and do not use any chemicals. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

Magnetic resonance imaging. The components of the Globe Catheter are not compatible with magnetic resonance imaging (MRI). The use of MRI while the catheter is inserted in the body of the patient may cause serious injury.

Mitral valve. Use caution when moving the array near the mitral valve to avoid damaging or interfering with the mitral valve. Mitral valve interference can cause entanglement and acute or chronic reduction in cardiac function. To detect mitral valve interference, continuously monitor vital signs and echocardiograms.

Pacemakers and implantable cardioverter defibrillators (ICDs). While the Globe PF System has not been evaluated in the presence of cardiac pacemakers, ICDs and other active implants, some high-frequency (HF) surgical equipment can produce enough interference to adversely affect the operation of these types of active implanted devices or damage device components. Use extreme caution when delivering ablation energy near active implants and leads, and assess device interactions by monitoring electrocardiograms (ECGs), intracardiac electrograms, and vital signs. Have external temporary pacing and defibrillation equipment available. If in doubt, seek qualified advice.

Phrenic nerves. Use caution when ablating tissue near the phrenic nerves to avoid excessive lesion depth that can result in phrenic nerve injury.

Pinch points. To maintain the sterile integrity of gloves and avoid minor user injury, keep fingers clear of pinch points on the sheath handle sliders, the dilator loader, the catheter handle, and the catheter loader.

Qualified users only. Use of the Globe PF System is intended for physicians who have completed the Kardium training program on catheter mapping and ablation procedures with the Globe PF System, and who have been trained in the techniques of vascular access, transseptal access, percutaneous catheter delivery, and intracardiac electrophysiology studies. Device preparation of the Globe PF System should only be performed by electrophysiology lab staff who have completed the Kardium training program on device preparation.

Read product documentation. Before using this device, carefully read all instructions, warnings, and cautions in this document and all other system documentation. In addition, carefully read the instructions and safety information for all ancillary devices or products that are used for the procedure before use.

Serious adverse events. If a serious adverse event is observed, immediately remove the introducer or catheter and take appropriate patient recovery measures.

Sheath damage. To protect the sheath coating from damage, do not insert other devices into the same femoral vein as the introducer.

Sheath size. Improper use of the sheath can result in vascular or access site complications. Venous injury including dissection, thrombosis, occlusion, pseudoaneurysm, or venous fistula at the site of femoral access or at other sites along the vessels may cause hemorrhage, hematoma, or ischemic injury to an extremity or organ. Use access and closure techniques appropriate for the sheath size.

Simultaneous catheter use. Do not simultaneously use other catheters in the same cardiac chamber as the Globe Catheter array.

Single use only. The contents of the Globe Introducer and Globe Catheter packages are single use only. To avoid component damage and reduce the risk of patient contamination and infection, do not resterilize, reprocess, or reuse any of the package contents.

Sterile packaging inspection. The contents of the device package were sterilized using ethylene oxide gas before shipment and are supplied in sterile packaging to allow direct introduction into the sterile field. Keep the device in the shelf box until ready for use. At the time of use, inspect the inner and outer packaging for any signs of damage. To minimize the risk of patient infection, do not use a product if the packaging shows any signs of damage or if you suspect contamination for any reason. Return the device to Kardium.

Unintended movement. To prevent atrial trauma, avoid situations that would cause excessive or unintended movements of the catheter and sheath. Use slow, controlled movements to reduce the risk of damaging tissue and cardiac structures. Keep the catheter handle steady when connecting and disconnecting the catheter cable and use slow controlled movements when moving, retracting, and removing the catheter and sheath.

Vagal response during ablation. Delivery of ablation energy can cause a vagal response that leads to a reduced heart rate and asystole. Have external temporary pacing equipment available in the event of a vagal response.

1.5 Adverse events

The following potential adverse events are associated with using this device:

- Access site complications
- Dyspnea
- Paralysis

- Acute kidney injury
- Allergic reaction
- Anemia
- Arrhythmias
- Arterio-venous fistula
- Atrioesophageal fistula
- Cardiac tamponade
- Cardiac and/or pulmonary arrest
- Cardiovascular perforation
- Chest pain/discomfort
- Congestive heart failure
- Coronary artery occlusion
- Cough/hemoptysis
- Death
- Deep vein thrombosis
- Device entrapment necessitating conversion to surgery
- Dislodgement of or damage to ICD or pacemaker
- Electric shock
- Embolism
- Endocardial fibrosis
- Esophageal lesions/ulcerations
- Fever
- Fluid retention causing swelling, or edema in legs, pleural cavity, peritoneal cavity, lungs
- Gastrointestinal event (diverticulosis, reflux, nausea, etc.)
- Headache
- Heart block
- Heart inflammation
- Hemorrhage
- Hemothorax/hemoperitoneum
- Hypo/hypertension
- Iatrogenic atrial septal defect
- Infection
- Myocardial infarction
- Nerve injury or spasms
- Pericardial effusion
- Pneumonia
- Pneumothorax
- Pulmonary vein stenosis
- Seizure
- Sinus node dysfunction
- Skin burn
- Stroke
- Syncope
- Thrombocytopenia
- Transient ischemic attack
- Valvular damage
- Vasospasms (e.g., coronary artery spasm)
- Vasovagal reaction
- Vessel wall injury including dissection
- Visual blurring

1.6 Clinical data

Information regarding clinical studies that are applicable to the Globe Pulsed Field System is available on the Kardium Manuals website: manuals.kardium.com.

If you do not have web access, you can order printed copies of the clinical study summaries from your Kardium representative.

1.7 Related instructions for use

For complete instructions on how to use the Globe PF System, see also:

407-00003 Instructions for Use: Globe Controller, Globe PF Generator, and Globe Workstation

2 Globe Introducer description

The Globe Introducer is a component of the Globe PF System used to introduce the Globe Catheter into the heart.

2.1 Contents of introducer package

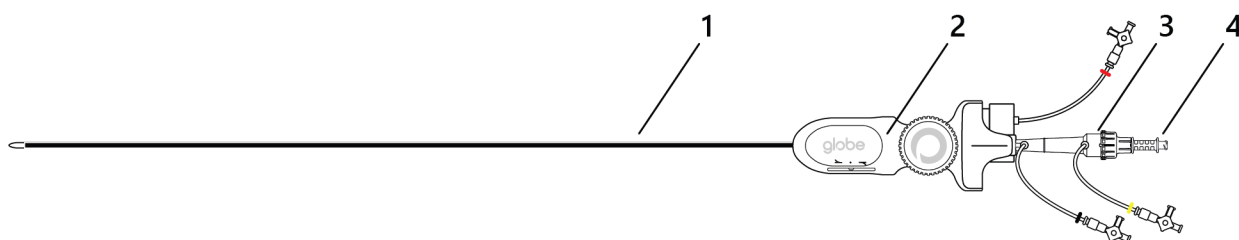
The packaging of the Globe Introducer contains the following items:

- Sheath
- Dilator
- Dilator loader
- Catheter cable cover

2.2 Introducer components

The Globe Introducer includes a sheath, a dilator, and a dilator loader.

Figure 1: Introducer components

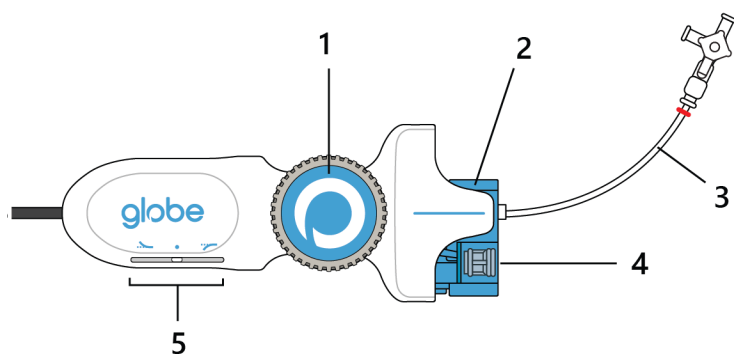


- 1 Sheath
- 2 Sheath handle
- 3 Dilator loader
- 4 Dilator

2.2.1 Sheath

The sheath includes a steerable tube connected to a handle. The tube has a hydrophilic coating on its outer surface. The sheath handle includes a steering knob, a steering indicator, and a blue slider. The slider has a line for flushing during catheter connection. The slider line can be identified by the red band. The slider has a port for connecting the dilator loader and catheter loader, used to facilitate the insertion and removal of the dilator and catheter through the sheath.

Figure 2: Sheath handle

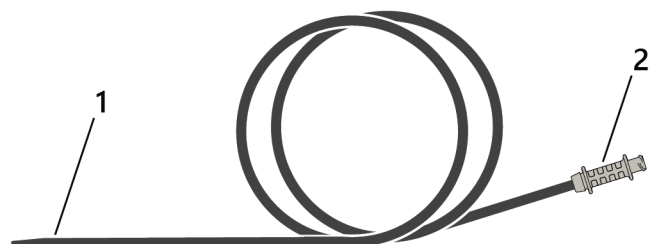


- 1 Steering knob
- 2 Slider (blue)
- 3 Slider line (red)
- 4 Loader connection port
- 5 Steering indicator

2.2.2 Dilator

The dilator is used to dilate the transseptal access site to facilitate the insertion of the sheath. The dilator conforms to the inner diameter of the sheath and accommodates a compatible guidewire. When the dilator is fully inserted in the sheath, the dilator hub connects with the clip on the dilator loader.

Figure 3: Dilator



- 1 Tip
- 2 Dilator hub

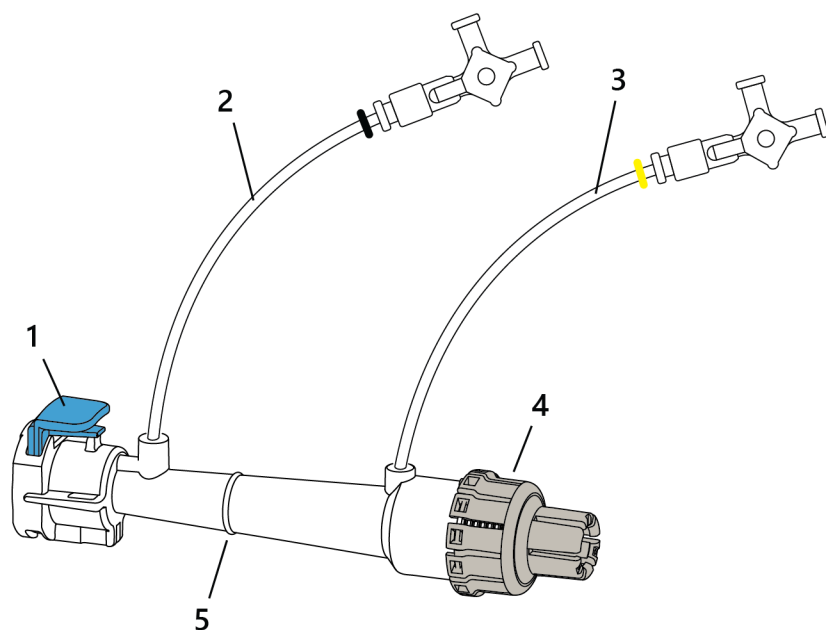
2.2.3 Dilator loader

The dilator loader is used to insert the dilator into the sheath during device preparation and to remove the dilator after sheath placement. The loader contains:

- Lines for flushing and air removal
- A latch for connecting to the sheath slider
- A clip for connecting to the dilator hub
- A hemostatic seal for holding an inserted dilator in place

The distal and proximal loader lines are identified by the black and yellow bands, respectively.

Figure 4: Dilator loader



- 1 Dilator loader latch (blue)
- 2 Distal loader line (black)
- 3 Proximal loader line (yellow)
- 4 Dilator clip
- 5 Loader band

3 Globe Catheter description

The Globe® Catheter is a component of the Globe® PF System. It is a mapping and ablation catheter designed to be used with the Globe® Introducer, the Globe® Catheter Cable, the Globe® Controller, and the Globe® PF Generator.

3.1 Contents of catheter package

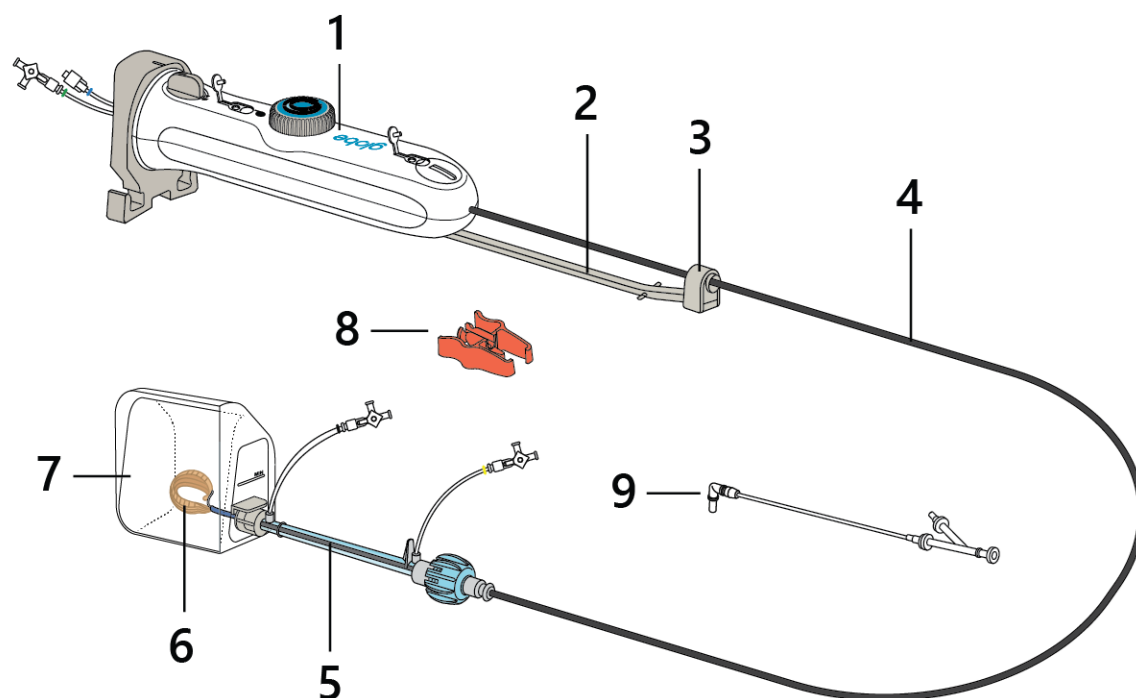
The packaging of the Globe Catheter contains the following items:

- Catheter
- Flushing chamber
- Vacuum pump
- Catheter cable cover
- Insertion guide tool

3.2 Catheter components

The Globe Catheter includes the multi-electrode array, the catheter loader, the shaft, and the catheter handle.

Figure 5: Globe Catheter

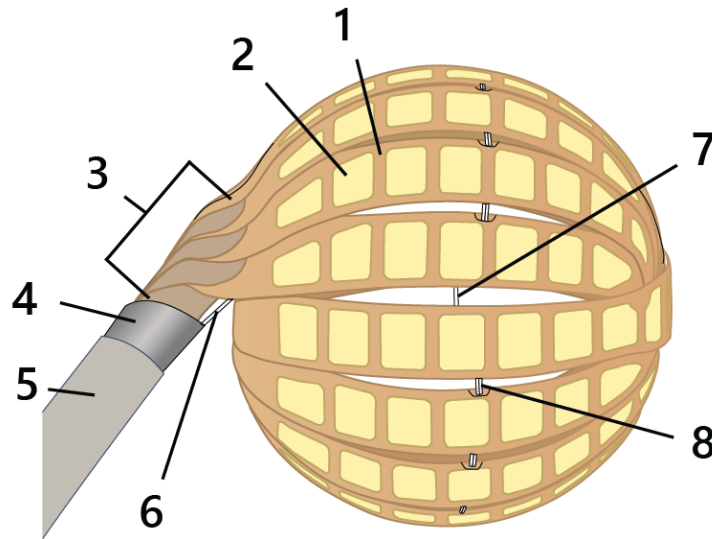


- 1 Handle
- 2 Insertion guide
- 3 Loader dock
- 4 Shaft
- 5 Catheter loader
- 6 Array
- 7 Flushing chamber
- 8 Insertion guide tool (orange)
- 9 Vacuum pump

3.2.1 Array

The array has a heparin coating and contains 122 gold-plated electrodes, each of which can measure temperature, voltage and intracardiac electrograms, deliver therapeutic energy, and apply stimulation pulses. The electrodes are part of a laminate that includes a flexible circuit and a thin, rounded stainless steel rib. The ribs are connected with lines to form a sphere when the array is fully deployed. The array is packaged inside a flushing chamber, which is used during device preparation.

Figure 6: Catheter array (deployed)

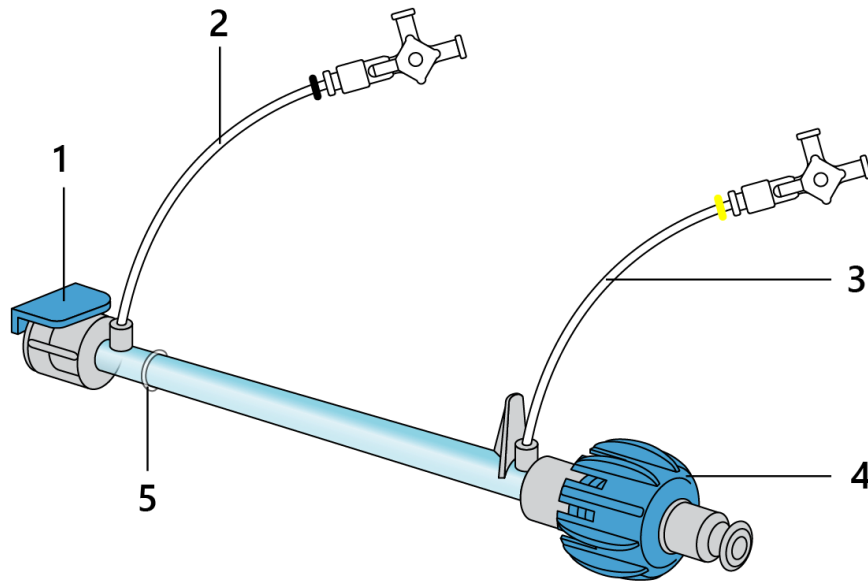


- 1 Rib
- 2 Electrode
- 3 Array base
- 4 Catheter shaft
- 5 Introducer sheath
- 6 Rib tip deployment line
- 7 Fanning deployment line
- 8 Tie line

3.2.2 Catheter loader

During device preparation, the array is retracted in a straight, stacked configuration into the catheter loader. The catheter loader connects to the slider of the introducer for insertion of the array into the left atrium. The loader contains lines for aspiration and flushing during device preparation and insertion procedures and a hemostatic seal for holding the array in place. The distal and proximal loader lines are identified by the black and yellow bands, respectively.

Figure 7: Catheter loader



- 1 Catheter loader latch (blue)
- 2 Distal loader line (black)
- 3 Proximal loader line (yellow)
- 4 Hemostatic seal
- 5 Loader band

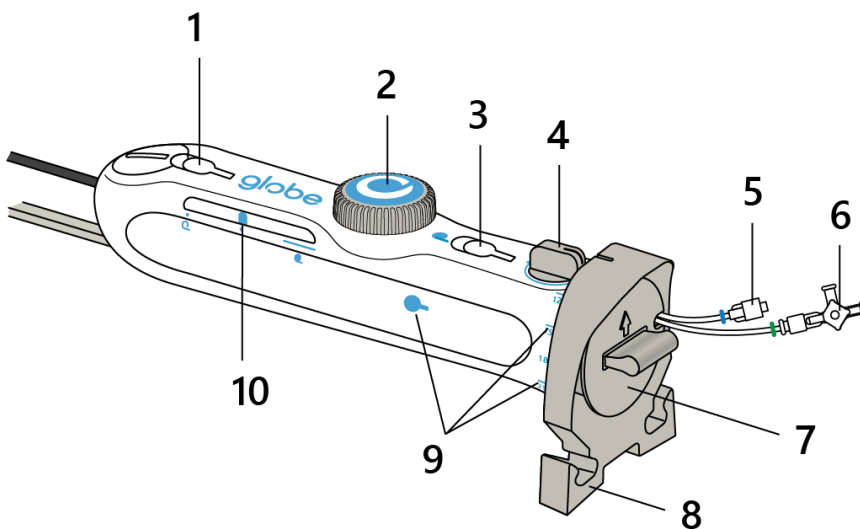
3.2.3 Shaft

The shaft is a long, flexible tube that connects the catheter handle to the array. The shaft houses the deployment lines and the electrical conductors that connect the circuitry of the catheter handle to the electrodes of the array. The handle has an insertion guide with a loader dock that connects to the proximal end of the catheter loader to guide the shaft into the introducer sheath. The insertion guide tool can be used to move the insertion guide when the insertion guide is not connected to the catheter loader or the dilator loader.

3.2.4 Catheter handle

The catheter handle contains vents and lines for flushing the catheter during device preparation. The flush lines also flush the catheter and array continuously during the procedure. The short and long flush lines are identified by the blue and green bands, respectively. The handle has a deployment knob and indicator for deploying the array. Indicators show the orientation of the catheter and array. The splash guard protects the enclosed circuit board that connects to the Globe Catheter Cable. The catheter cable is secured to the catheter handle with the cable lock.

Figure 8: Catheter handle



- 1 Distal vent
- 2 Deployment knob
- 3 Proximal vent
- 4 Cable lock
- 5 Short flush line (blue)
- 6 Long flush line (green)
- 7 Splash guard
- 8 Handle stand
- 9 Orientation indicators
- 10 Deployment indicator

4 Equipment requirements

4.1 Lab setup

Perform electrophysiology (EP) studies and cardiac ablation procedures only in a fully equipped EP lab. The following lab equipment is required for diagnostic and ablation procedures with the Globe PF System:

- Medical imaging systems (e.g., fluoroscopy and intracardiac echocardiography [ICE])
- Defibrillator
- Pacing equipment
- Activated clotting time (ACT) machine
- EP recording system that conforms to IEC 60601-2-27

4.2 Required items provided by the facility

The facility must provide the following additional items:

- Device preparation table. A stable table at least 200 cm × 60 cm (length × width) that can hold all the sterile supplies and accommodate the catheter and the introducer during the device preparation procedures
- Sterile cover for the Globe Platform
- Support pillows for the Globe Platform
- Standard supplies for gaining left atrial access
- Guidewire for placing the Globe Introducer:
 - J-tip or pigtail
 - Super stiff
 - Maximum diameter: 0.89 mm (0.035 in)
 - Recommended diameter: 0.89 mm (0.035 in)
 - Minimum length: 230 cm
 - Recommended guidewires (meeting above specifications):
 - Boston Scientific™ Amplatz Super Stiff™ J-Tip Guidewire (46-502)
 - Boston Scientific™ Baylis™ VersaCross™ RF guidewires
- Calibrated volumetric infusion pump system with two channels and compatible IV sets (with a Luer lock connection):
 - Either a single pump with two channels or two single-channel pumps
 - Each channel capable of meeting a flow rate of 90–110 mL/h (100 mL/h nominal)
- 10-mL syringes with a Luer lock connection
- 60-mL syringes with a Luer lock connection (use 50-mL syringes if 60-mL syringes are not available)
- 60-mL vacuum locking syringe with a Luer lock connection
- Sterile heparinized saline (5000 IU/L)

4.3 Required equipment

The Globe® Introducer 601-01001 and Globe® Catheter 601-01000 (defibrillation-proof type CF applied part) must be used with the following Kardium and third-party devices and accessories.

The following Globe PF System products are required for the procedure.

Table 1: Compatible Kardium devices and accessories

Device or accessory	Kardium part number
Globe® PF Generator	601-00060
Globe® Controller	601-00048
Globe® Workstation	601-00064
Globe® Catheter Cable	601-00046
Globe® Catheter Cable Support	601-00067
Globe® Platform	601-00066
Globe® GPS Cable	601-00036 Failure to use the designated cable can result in unexpected and potentially hazardous behavior during defibrillation.
Globe® GPS Electrodes (via GPS Cable)**	601-00037

**Defibrillation-proof type BF applied part

Table 2: Compatible third-party accessories

Accessory	Compatible product
ECG cable*	Cable
	IEC 60601-2-27 Color Code
	Unimed Medical Supplies E10R/30-GL-P/I Code 1 (usually European)
	Unimed Medical Supplies E10R/30-GL-P Code 2 (usually American)
	Failure to use a designated cable can result in unexpected and potentially hazardous behavior during defibrillation.

Accessory	Compatible product
Neutral electrode*	3M™ Series 9100 Universal Electrosurgical Pads (model 9165) Failure to use a compatible neutral electrode can lead to patient injury.
ECG electrodes*	3M™ Red Dot™ snap style monitoring electrodes (model 2570 or 2670)
Temperature calibration probe* with compatible temperature probe interface cable (optional)	- Smiths Medical General Purpose Probe ER400-9 (9 Fr) or ER400-12 (12 Fr) with Smiths Medical Temperature Monitoring Reusable Cable 400 series C400-10 - Smiths Medical Esophageal Stethoscope Temperature Sensors ES400-9 (9 Fr), ES400-12 (12 Fr), ES400-18 (18 Fr), or ES400-24 (24 Fr) with Smiths Medical Temperature Monitoring Reusable Cable 400 series C400-10 - Truer General Purpose Probe, GP 14400 (14 Fr) with Truer Temperature Monitor Interface Cable 400 series 70321
Reference catheter* and optional diagnostic catheter*	Standard 10-pole electrophysiology catheters can be connected to the auxiliary catheter inputs of the Globe Controller using a compatible catheter cable and the Unimed Medical Supplies 10-Pin Catheter Adapter. A reference catheter is required for the GPS. An additional optional diagnostic catheter may also be used.
10-pin catheter adapter	Unimed Medical Supplies 10-pin Catheter Adapter (part number: AD-KAR-210148) The 10-pin catheter adapter is connected to the Globe Controller by making the following connections: Standard 10-pole electrophysiology catheter → Third-party cable for standard 10-pole electrophysiology catheter → 10-pin catheter adapter → Globe Controller.
*Defibrillation-proof type CF applied part	

5 Patient preparation and safety

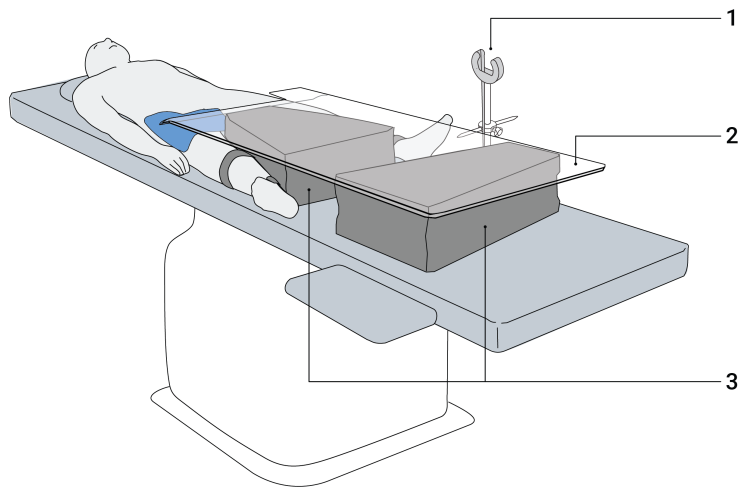
Read this section for requirements and recommendations for preparing the patient and patient safety.

5.1 Prepare the patient and accessories

The section contains instructions for Globe Catheter setup and patient preparation. The introducer and catheter are flushed with 5000 IU/L heparinized saline throughout the procedure. Prepare a flushing system using a calibrated volumetric infusion pump system with two channels, each channel capable of meeting a nominal flow rate of 100 mL/h. For information about patient preparation with Globe Controller accessories (Globe Catheter Cable, GPS Cable, GPS Electrodes, neutral electrode, ECG electrodes, and temperature calibration probe), see *Instructions for Use: Globe Controller, Globe PF Generator, and Globe Workstation*.

1. **Sedate the patient.** Use deep sedation or general anesthesia to ensure that the patient does not move during the procedure. Avoid conscious sedation.
2. **Prepare the catheter cable support.** Fasten the Globe Catheter Cable Support to the rail of the patient table. The Globe Catheter Cable Support is intended to provide a resting support for the Globe Catheter Cable.
3. **Prepare the platform for the catheter handle.** Place two support pillows next to the patient's legs. Place the Globe Platform on the pillows and cover with a sterile drape. The Globe Platform is intended to create a flat surface over the patient to facilitate positioning of the Globe Catheter near the patient. Use enough cushioning under the Globe Platform to provide support and stability for the catheter handle and to prevent placing undue pressure on the patient's body.
4. **Prepare the access site.** Be aware of possible vascular or access site complications.

Figure 9: Positioning for support accessories



- 1 Globe Catheter Cable Support
- 2 Globe Platform
- 3 Support pillows

5.2 Monitor the patient

Note the following key points when monitoring the patient:

- If a serious adverse event is observed at any time during the procedure, take appropriate patient recovery measures (which may include removing the catheter).
- Monitor sedation or anesthesia throughout the procedure.
- Monitor the patient's vital signs (heart rate, blood pressure, electrocardiogram [ECG], patient temperature, respiration, blood oxygen saturation) throughout the procedure.
- Try to maintain systolic pressure above 80 mm Hg (10.7 kPa) to minimize the risk of focal ischemia due to prolonged array pressure.
- Because the temperature measurements displayed on the Globe Workstation (electrode temperature sensors and optional temperature probe) may not accurately represent the patient's core temperature, do not use them to monitor core temperature at any time during the procedure.

- Do not rely on the ECG signals displayed on the Globe Workstation to make clinical decisions other than decisions directly related to array deployment and ablation; use the lab's ECG monitoring system instead.

5.3 Use of defibrillation equipment

Before using an external defibrillator (cardioverting) while the array is inside the atrium, move the array away from the atrial walls and stop the delivery of ablation energy and stimulation energy. The use of a defibrillator may cause a temporary (less than 5 seconds) discontinuity in the intracardiac electrograms and surface ECGs. The use of a defibrillator may also disrupt the GPS. Correct operation can be restored within 20 seconds by following the instructions on the workstation.

5.4 Recommendations for anticoagulation treatment

Throughout the procedure, the catheter shaft is flushed with heparinized saline. Heparin should be administered before or immediately after transseptal puncture and adjusted to achieve and maintain an activated clotting time (ACT) of 300 to 400 seconds. ACT levels should be monitored every 15 to 30 minutes throughout the procedure.

Performance of atrial fibrillation (AF) ablation in a patient systemically anticoagulated with warfarin does not replace the need for intravenous heparin to maintain a therapeutic ACT during the procedure. For at least two months after the AF ablation procedure, consider systemic anticoagulation with warfarin or a direct thrombin or Factor Xa inhibitor. In patients who are not therapeutically anticoagulated with warfarin at the time of AF ablation, low molecular weight heparin or intravenous heparin should be used as a bridge until systemic anticoagulation is effective following AF ablation.

5.5 Recommendations for procedure length

Avoid excessively long procedures. The probability of complications increases with procedure duration. A procedure time of less than three hours is recommended.

6 Directions for use

Read this section carefully for recommended directions for use related to the introducer and catheter. For directions for use for other components not covered in this document, refer to the instructions for use for that component.

6.1 Unpack and inspect the introducer

Use aseptic technique to open the introducer packaging and deliver the tray to the sterile preparation table. Keeping the contents in the tray, inspect for any visible damage.

6.2 Prepare the introducer

The introducer components must be flushed with 5000 IU/L heparinized saline to remove air before insertion into the left atrium. The introducer tray is used as a saline reservoir for this procedure.

6.2.1 Before you begin

1. Remove the catheter cable cover from the tray and set it aside in the sterile field where it will stay dry. To access the cable cover, you may need to unclip the dilator tip from the tray.
2. Fill the tray with heparinized saline to the **MIN** fill line, making sure that the sheath tip is fully submerged and clipped into the tray.

6.2.2 Flush the sheath

1. Leaving the sheath in place, unclip the slider line (red) from the tray.
2. Slowly aspirate the slider line (red) until the line is free of air.

6.2.3 Connect and prepare the dilator loader



WARNING

Move the blue slider by pushing directly on the slider to maintain seal integrity between the loader and the slider. Do not try to move the blue slider by pushing or pulling on the clear loader.

1. Remove the dilator loader from the tray and connect it to the blue slider.
2. Move the slider to the delivery position.

3. Aspirate the distal loader line (black) until the line is free of air.
4. Aspirate the proximal loader line (yellow) until both the loader and line are free of air.

6.2.4 Flush the dilator

1. Unclip and remove the dilator from the tray.
2. Using a 10-mL syringe, flush the dilator hub with heparinized saline until saline exits the dilator tip, then leave the syringe attached to the dilator.

6.2.5 Insert the dilator through the sheath



WARNING

Insert the dilator with wet gauze and in short increments to avoid kinking the dilator.

1. Insert the dilator tip into the dilator loader to the loader band.
2. Move the dilator tip back and forth several times in the dilator loader, finishing with a forward motion.
3. Aspirate as needed on the proximal loader line (yellow) to remove air from the loader and line.
4. Using wet gauze, insert the dilator in short increments through the sheath until the dilator hub clips into the loader.
5. When the sheath is ready for insertion, unclip it from the tray and move it to the patient table.
6. Leave the introducer tray in the sterile field, in case it is needed for future use.

6.3 Unpack the catheter

1. From outside the sterile field, open the box vertically at the top along the flap.
2. Using the handle, lift the inner box up to the crease, and fold the inner box flap over the outer box to access the pouch.
3. Open the pouch to expose the sterile tray, and use aseptic technique to deliver the tray to the sterile preparation table.

6.4 Prepare the catheter

The catheter components must be flushed with 5000 IU/L heparinized saline to remove air before connection to the introducer and insertion into the left atrium.

6.4.1 Before you begin

1. Remove the lid from the tray and inspect the contents for any visible damage.
2. Remove the catheter cable cover from the tray and set it aside in the sterile field where it will stay dry.
3. Remove the insertion guide tool from the insertion guide and set it aside in the sterile field.
4. Remove the vacuum pump from the tray and set it aside in the sterile field.
5. Unclip and remove the catheter from the sterile tray and place it on the sterile preparation table.
6. Rotate the handle stand to elevate the proximal end of the handle.

6.4.2 Fill the flushing chamber

1. Lay the flushing chamber horizontally and fill it with heparinized saline to the lip of the chamber opening.
2. Rotate the flushing chamber to its vertical position. Make sure that the chamber is filled with saline above the **MIN** fill line.

6.4.3 Fill the distal chamber of the handle

1. Attach the vacuum pump to the distal vent of the catheter handle and attach a vacuum locking syringe to the pump.
2. Pump the vacuum syringe five times (five full aspirations) and lock it in the aspirated position.
3. Fill a 60-mL syringe with heparinized saline and connect it to the short flush line (blue).
4. Allow the vacuum to pull saline through the short flush line (blue) until saline enters the vacuum syringe.
5. Release the lock on the vacuum syringe.
6. Remove the vacuum pump and plug the distal vent.

6.4.4 Fill the proximal chamber of the handle

1. Attach the vacuum syringe and vacuum pump to the proximal vent.
2. Pump the vacuum syringe 10 times and lock it in the aspirated position.
3. Fill a 60-mL syringe with heparinized saline and connect it to the long flush line (green).
4. Open the valve on the long flush line (green) to pull saline through the line.
5. When the supply syringe is empty, close the valve on the long flush line (green).
6. Refill and reconnect the supply syringe, and reopen the valve.

7. Repeat steps 5-6 until saline enters the vacuum syringe.
8. Release the lock on the vacuum syringe, then refill and reconnect the supply syringe as needed until saline stops flowing from the supply syringe.
9. Close the valve on the long flush line (green).
10. Remove the vacuum pump and plug the proximal vent.

6.4.5 Move the array into the loader



WARNINGS

- When retracting the array into the loader, check that the array lines do not cross over the electrodes to avoid line tension that could bend and damage the ribs. After retraction, inspect the ribs for damage and for any line tangling which could damage the array upon deployment.
- Confirm that the level of saline in the flushing chamber is at least at the **MIN** fill line, adding saline through the distal loader line (black) to fill the chamber as needed.



NOTE

Do not leave the array in the loader for longer than 45 minutes. If necessary, reinsert the array into the flushing chamber and repeat the remaining steps.

1. Rapidly move the array back and forth in the flushing chamber to remove air bubbles that may have formed on the array surface. Inspect for bubbles and repeat as needed.
2. Aspirate and flush the distal loader line (black) to remove air from the distal loader line.
3. Aspirate and flush the proximal loader line (yellow) to remove air from the catheter loader and the proximal loader line.
4. Retract the array, using a back and forth motion, into the catheter loader until the rib tips reach the loader band.
5. Tighten the hemostatic seal (rotate clockwise).
6. Aspirate and flush the proximal loader line (yellow). Repeat as needed.
7. Inspect the array in the catheter loader to confirm that the rib tips are not damaged, large air bubbles are not present, and the array lines are not tangled or crossing over the electrodes. If line tangling is

observed, see *Untangle lines in the loader during device preparation* on page 43.

8. When ready for insertion into the patient, return the flushing chamber to its horizontal position.
9. Disconnect the catheter loader from the flushing chamber. Point the opening of the loader upward to prevent air ingress and loss of saline.
10. Attach the loader to the catheter handle stand, if desired, and move the catheter to the patient table.

6.5 Insert the sheath



WARNINGS

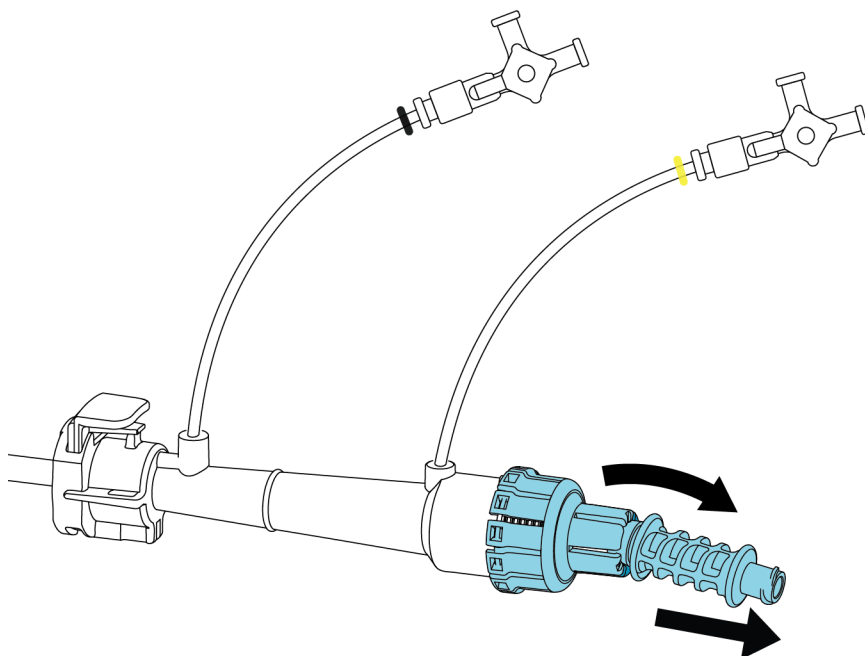
- Use medical imaging whenever inserting, moving, or retracting system components, and monitor sheath tip and array position.
- Do not use excessive force if you encounter resistance. Determine and correct the source of the resistance if possible.
- Keep the sheath relaxed while it is in the venous system.
- Keep the tips of the dilator and sheath away from the atrial walls.
- If the sheath tip slips into the right atrium, reinsert the guidewire through the prepared dilator and reintroduce the guidewire into the left atrium. Then follow the dilator and sheath over the guidewire back into the left atrium.
- Maintain the flow of saline throughout the procedure to make sure that flushing is never significantly interrupted. Significant interruption may lead to arterial thromboembolism.

6.5.1 Insert the sheath into the left atrium

1. Using a standard transseptal access technique, place an access sheath into the left atrium.
2. If not already in place, insert a super stiff exchange-length guidewire. Remove the access sheath.
3. Using wet gauze, wet the entire introducer sheath tube.
4. Holding the guidewire in place in the left atrium, insert the sheath over the guidewire into the femoral vein.
5. Remove the attached syringe from the dilator hub when the guidewire is visible.
6. Carefully advance the sheath toward the septum, deflecting the sheath as necessary to follow the guidewire into the left atrium.

- To deflect clockwise (↻), rotate the steering knob clockwise.
 - To deflect counterclockwise (↺), rotate the knob counterclockwise.
 - Use the steering indicator to determine the direction and amount of deflection applied to the sheath.
7. Disengage the dilator hub from the loader by tilting it and pulling it gently.

Figure 10: Disengage the dilator hub from the loader



8. Holding the dilator in place, advance the sheath to the center of the left atrium.

6.5.2 Retract the guidewire and the dilator

1. Deflect the sheath to ensure the sheath tip remains securely in the left atrium.
2. Holding the sheath in place, slowly retract and remove the dilator and the guidewire from the sheath.
3. Move the blue slider to the connection position.
4. Aspirate then flush at least 20 mL through the slider line (red).
5. Start a 100-mL/h heparinized saline drip on the slider line (red), then disconnect the dilator loader from the sheath.

6.6 Insert the catheter

6.6.1 Start catheter drip

1. Start a 100-mL/h heparinized saline drip on the long flush line (green) of the catheter handle.

6.6.2 Attach the catheter loader to the slider

1. Fill a 60-mL syringe with heparinized saline.
2. Connect the catheter loader to the blue slider on the introducer handle.
3. Use the prepared 60-mL syringe to flush the catheter proximal loader line (yellow) until no air is visible in the loader or the loader line.



WARNING

Do not aspirate after connecting the syringe. Flush only. Aspiration or failure to make a wet connection may result in air bubbles in the loader. If this occurs, see *Clear air bubbles in the loader during catheter insertion* on page 45.

4. Move the 100-mL/h saline drip from the slider line (red) of the sheath handle to the catheter proximal loader line (yellow).
5. Move the slider to the delivery position.



WARNING

Move the blue slider by pushing directly on the slider to maintain seal integrity between the loader and the slider. Do not try to move the blue slider by pushing or pulling on the clear loader.

6. Using the 60-mL syringe, aspirate and flush at least 20 mL through the distal loader line (black).

6.6.3 Insert the catheter and deploy the array



WARNINGS

- Use medical imaging whenever inserting, moving, or retracting system components, and monitor sheath tip and array position.
- If you have inserted the array into the left atrial appendage or the left pulmonary veins, do not try to deploy the array. Slowly and completely retract the array into the sheath, reposition the sheath, and reinsert the array.
- Do not use excessive force to insert the catheter if you encounter resistance. Determine and correct the source of the resistance if possible.

1. Loosen the hemostatic seal (rotate counterclockwise) on the catheter loader to the first click.
2. Using wet gauze, wet the catheter shaft.
3. Keeping the sheath tip centered in the left atrium, advance the array through the sheath until the loader dock engages with the catheter loader.



NOTE

When advancing, move the catheter handle as needed to straighten the catheter shaft.

4. Relax the sheath and avoid pointing it in a direction that may cause anatomical interference.
5. Holding the sheath in place, insert about half the array into the atrium.
6. Holding the catheter in place and taking care to protect the septum, retract the sheath until the array base is out of sheath.
7. Confirm the array is free to move inside the atrium and that it does not interfere with the septum and other anatomical structures.
8. Fully rotate the deployment knob clockwise to deploy the array. Listen for the click that indicates full deployment.

6.7 Cover the catheter cable

With the help of an assistant outside the sterile field, use aseptic technique to unfold the catheter cable cover over the length of the catheter cable.

1. Orient the cover so that the pull tab is up and the position of the slot on the cover is aligned with the slot on the catheter cable.
2. Ask an assistant outside the sterile field to fully insert the end of the catheter cable into the cover.
3. Using aseptic technique, extend the cover along the length of the cable.
4. Secure the catheter cable in the cable support.

6.8 Connect the catheter cable

The following steps are performed within the sterile field.

1. Holding the catheter handle in place, remove the splash guard from the back of the handle.
2. Remove the cap from the catheter cable.
3. Holding the catheter handle in place, insert the cable into the back of the handle and turn the cable lock 180° clockwise.
4. If desired, insert the splash guard into the catheter cable cap.

6.9 Mapping and ablation

Position the array in the left atrium for mapping, ablation, and stimulation. Make sure to center the array in the atrium before moving to a new location. Make sure that the sheath tip is never pushed against the array. During ablation, do not move the deployment knob or the catheter to maintain electrode contact with the atrial wall. Poor contact decreases the effectiveness of therapy. See *Instructions for Use: Globe Controller, Globe PF Generator and Globe Workstation* for additional steps and safety information.



WARNINGS

- Use medical imaging whenever inserting, moving, or retracting system components, and monitor sheath tip and array position.
- Maintaining alignment between the catheter handle and sheath handle can make navigation more intuitive.
- Take the weight off the proximal end of the handle before rotating the catheter.
- Before delivering therapeutic energy, make sure that the catheter handle is stable and resting on the handle stand.
- If the system does not respond to a request to stop ablation, disconnect the catheter cable from the catheter and turn off the controller and the PF generator.

6.10 Remove the catheter at the end of the procedure



WARNING

Use medical imaging whenever inserting, moving, or retracting system components, and monitor sheath tip and array position.

6.10.1 Disconnect the catheter cable

1. Turn the cable lock 180° counterclockwise.
2. Holding the catheter handle in place, remove the cable from the handle.
3. Place the cap on the connector end of the cable and set the cable aside within the sterile field.
4. Holding the catheter handle in place, insert the splash guard into the catheter handle.

6.10.2 Retract the array

1. Center the array in the atrium and relax the sheath.
2. Turn the deployment knob counterclockwise until the indicator on the handle reaches the far-left position to fully undeploy the array.
3. Before retracting the array, confirm that the hemostatic seal on the catheter loader is sufficiently loosened.

4. Using back and forth motion, advance the sheath over about half the array, until the array folds into the sheath.
5. Using back and forth motion, retract the array into the sheath. Ensure the rib tips are not advanced toward tissue.

6.10.3 Retract and remove the catheter

1. Retract the catheter and sheath together to bring the sheath tip into the right atrium.
2. Retract the array through the sheath and into the catheter loader, stopping when the rib tips reach the loader band.

If the catheter loader and insertion guide inadvertently separate, hold the insertion guide and catheter loader together during retraction, until the insertion guide is fully extended.

3. Move the blue slider to the connection position.
4. Stop flushing the catheter lines and disconnect the flushing lines.
5. Disconnect the catheter and loader from the sheath, and remove the catheter from the patient table.

6.11 Remove the sheath



WARNINGS

- Use medical imaging whenever inserting, moving, or retracting system components, and monitor sheath tip and array position.
- Failure to relax the sheath during removal can damage vasculature and cardiac structures. When retracting the sheath from the right atrium through the venous system, always ensure that the sheath tip is relaxed.

1. Confirm that the sheath tip is relaxed and in the right atrium. If the tip is still in the left atrium, relax the sheath and retract it into the right atrium.
2. Slowly remove the sheath from the patient.
3. Close the access site using a standard technique.

7 Cleaning

After each procedure, clean the Globe Catheter Cable Support and the Globe Platform according to standard hospital procedure.

8 Disposal

Treat used introducers and catheters as biohazardous waste. Dispose of used introducers, used catheters, used accessories, and packaging in accordance with hospital policy and local regulations. Return unused introducers and catheters to Kardia; contact your Kardia representative for shipping instructions.

9 Troubleshooting

9.1 Undeploy array deployed during device preparation

Follow this procedure if the array deploys during device preparation.

1. Undeploy the array fully by rotating the deployment knob counterclockwise until the indicator on the handle shows that the array is fully undeployed.
2. Move the insertion guide in and out:
 - 2.1. Place the sterile insertion guide tool or sterile hemostats into the loader dock to release the insertion guide. Fully insert the insertion guide into the handle.
 - 2.2. Fully extend the insertion guide from the handle until it locks in its fully extended position and remove the insertion guide tool.

Figure 11: Using the insertion guide tool to move the insertion guide

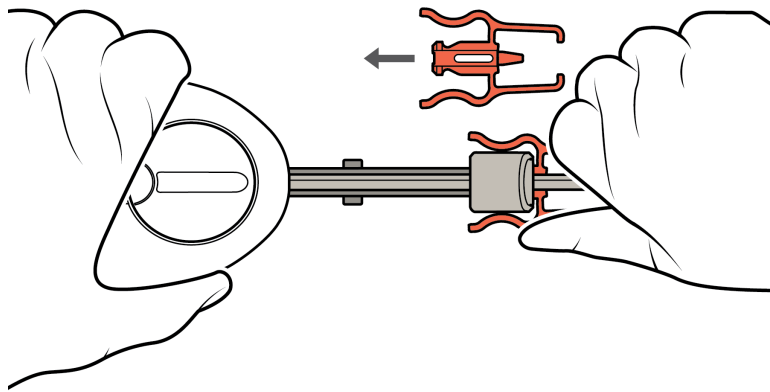
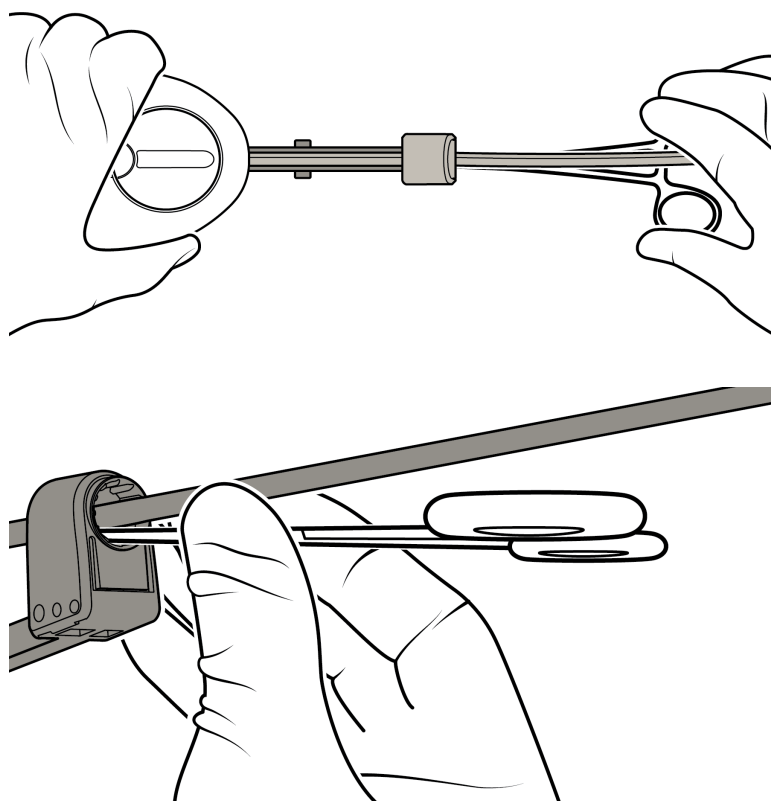


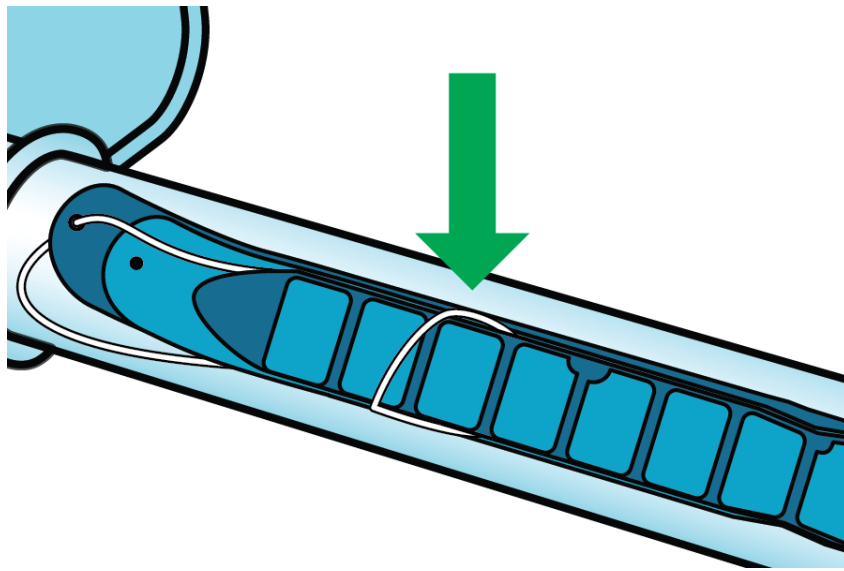
Figure 12: Using hemostats to move the insertion guide



9.2 Untangle lines in the loader during device preparation

If lines tangle when the array is in the catheter loader, follow this procedure to untangle the lines.

Figure 13: Line tangling in loader



1. Advance the array into the flushing chamber and perform the rapid back and forth movement of the array, as used in device preparation.
2. Move the array into the loader and check for line tangling.
3. If lines are tangled, move the array into the flushing chamber and deploy to remove line tangling.
4. Move the insertion guide in and out:
 - 4.1. Place the sterile insertion guide tool or sterile hemostats into the loader dock to release the insertion guide. Fully insert the insertion guide into the handle.
 - 4.2. Fully extend the insertion guide from the handle until it locks in its fully extended position and remove the insertion guide tool.

Figure 14: Using the insertion guide tool to move the insertion guide

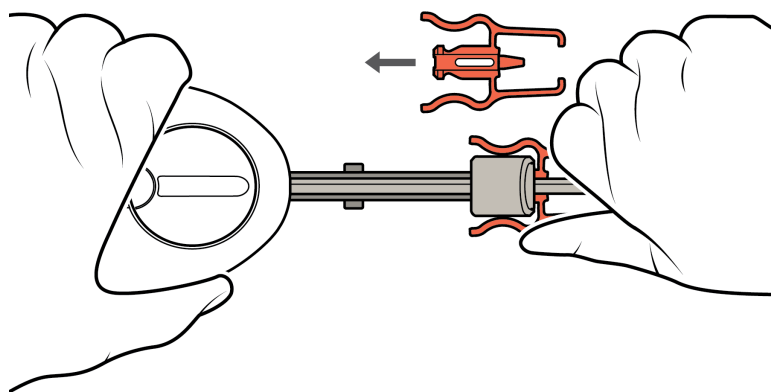
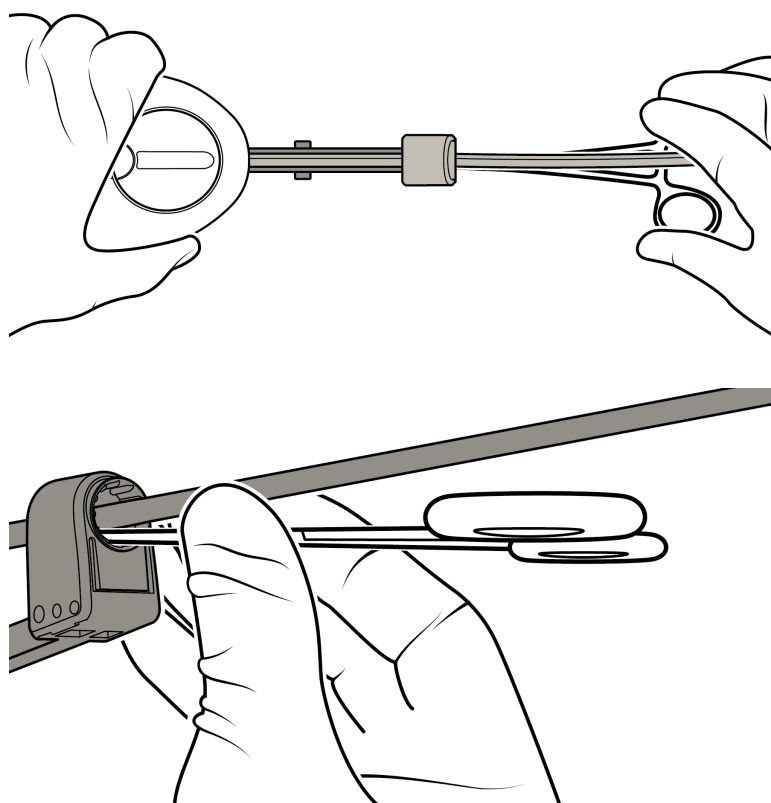


Figure 15: Using hemostats to move the insertion guide



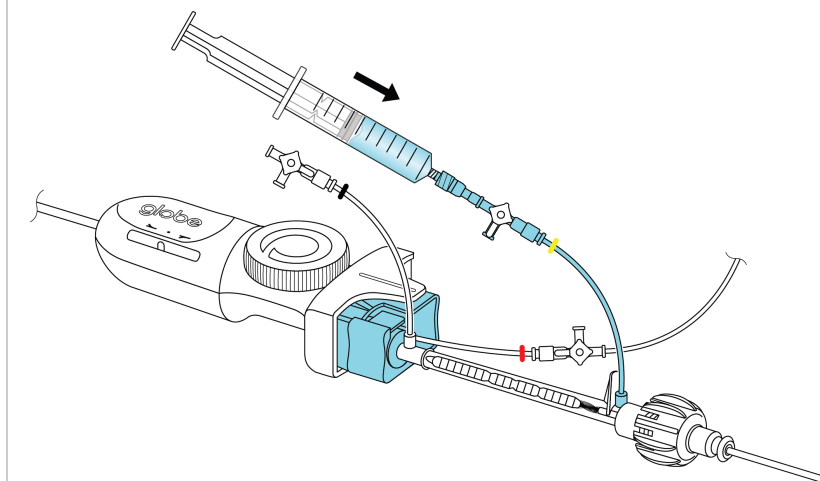
5. If the problem persists, replace the catheter.

9.3 Clear air bubbles in the loader during catheter insertion

If you introduce bubbles from aspiration or a failed wet connection, then follow these steps:

1. Flush through the catheter loader when it is connected to the blue slider, and inspect for bubbles. Continue flushing through the catheter proximal loader line (yellow) until the loader is free of air.

Figure 16: Flush through the catheter loader when it is connected to the slider



2. If bubbles are still visible:
 - 2.1. Disconnect the catheter loader from the slider.
 - 2.2. Connect the catheter loader to the flushing chamber.
 - 2.3. Repeat the device preparation steps, as described in *Prepare the catheter* on page 29.
3. Continue with the loader connection sequence, as described in *Attach the catheter loader to the slider* on page 34.

9.4 Workaround for damaged or non-sterile vacuum pump

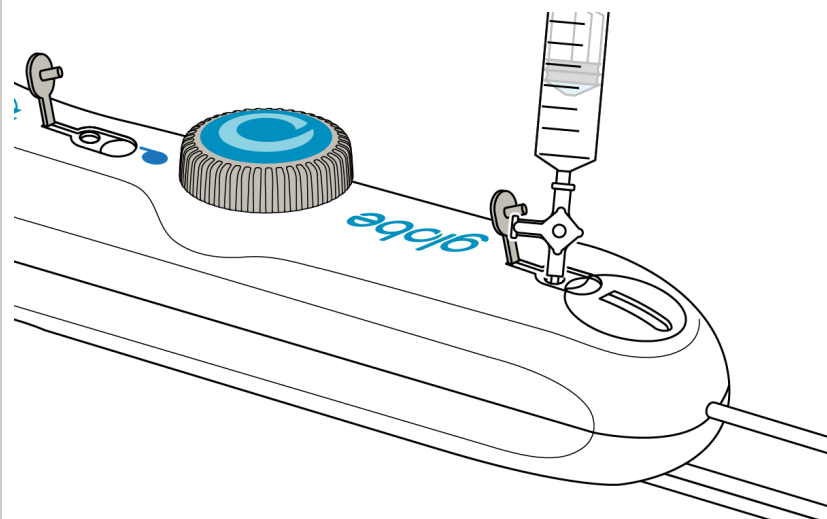
If the vacuum pump is damaged or loses sterility, obtain a replacement from a new catheter or follow the procedures below to use a 3-way slip luer (Merit Medical Slip Luer, 3-Way M3SLC) in its place.

9.4.1 Fill the distal chamber of the handle

1. Fill a 60-mL syringe with heparinized saline, and connect it to the short flush line (blue).
2. Attach the 3-way slip luer to the distal vent of the catheter handle.

3. Optionally, if extension lines are available, attach an extension line to the 3-way slip luer.
4. Attach a 60-mL vacuum locking syringe directly to the 3-way slip luer or the extension line.

Figure 17: Attach the 3-way slip luer and 60-mL vacuum locking syringe to the distal vent



5. Open the 3-way slip luer, or the extension, to the device and aspirate.
6. Close the 3-way slip luer, or the extension, to the device and flush.
7. Repeat the previous two steps four times.
8. Aspirate, and then lock the vacuum syringe in the aspirated position.
9. Allow the vacuum to pull saline through the short flush line (blue) until saline enters the vacuum syringe.



NOTE

If needed, manually flush the short flush line (blue) until saline enters the vacuum syringe.

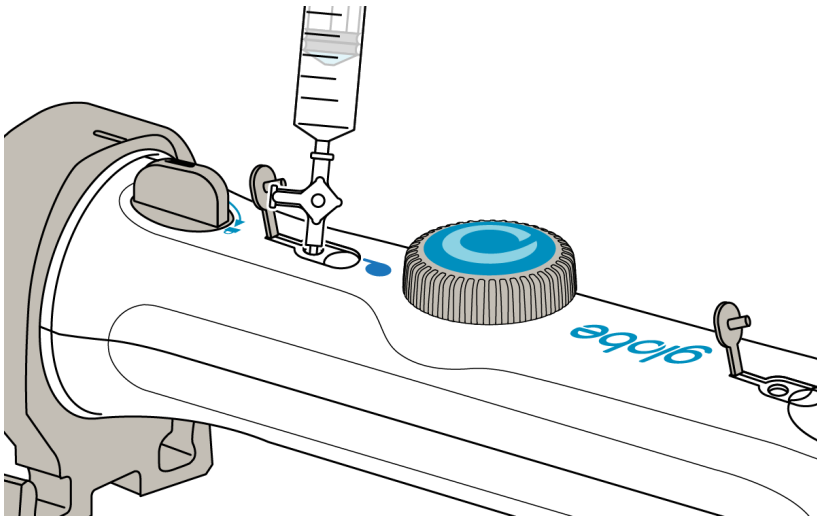
10. Release the lock on the vacuum syringe.
11. Remove the 3-way slip luer and syringe and plug the distal vent.

9.4.2 Fill the proximal chamber of the handle

1. Fill a 60-mL syringe with heparinized saline, and connect it to the long flush line.
2. Attach the 3-way slip luer to the distal vent of the catheter handle.
3. Optionally, if extension lines are available, attach an extension line to the 3-way slip luer.

4. Attach a 60-mL vacuum locking syringe directly to the 3-way slip luer or the extension line.

Figure 18: Attach the 3-way slip luer and 60-mL vacuum locking syringe to the proximal vent



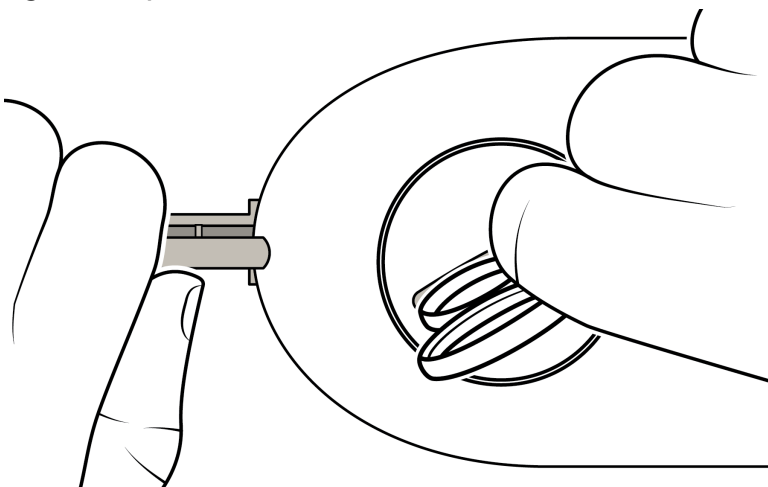
5. Open the 3-way slip luer, or the extension, to the device and aspirate.
6. Close the 3-way slip luer, or the extension, to the device and flush.
7. Repeat the previous two steps 9 times.
8. Aspirate, and then lock the vacuum syringe in the aspirated position.
9. Open the valve on the long flush line (green) to pull saline through the line.
10. When the supply syringe is empty, close the valve on the long flush line (green).
11. Refill and reconnect the supply syringe.
12. Open the valve on the long flush line (green) to pull saline through the line.
13. Repeat steps 10 to 12 until saline enters the vacuum syringe.
14. Release the lock on the vacuum syringe, and then refill and reconnect the supply syringe as needed until saline stops flowing from the supply syringe.
15. Close the valve on the long flush line (green).
16. Remove the 3-way slip luer and vacuum syringe and plug the proximal vent.

9.5 Retract stuck array into the sheath

If the array cannot be retracted into the sheath, try to determine using fluoroscopy why the device cannot be retracted. If necessary, cut the deployment lines using the following procedure.

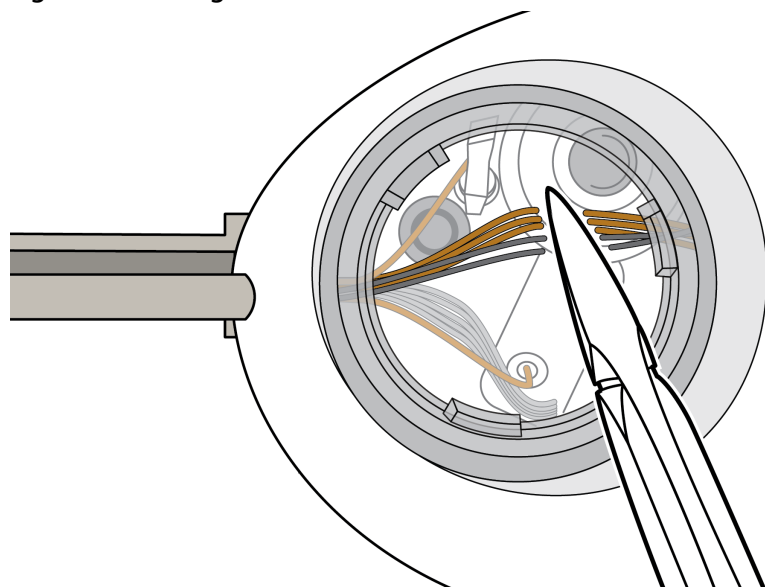
1. If possible, ensure the deployment knob is in the fully undeployed position.
2. Ensure the hemostatic seal is not overly tight.
3. Insert and center the array in the left atrium.
4. If possible, fully deploy and undeploy the array.
5. Attempt to retract the array again.
6. If the problem persists, fully insert and center the array in the left atrium.
7. Orient the catheter handle so that the access hatch is horizontal to maintain the fluid level inside the chamber when the lid is open.
8. If possible, maintain flushing on both lines.
9. Hold the catheter loader firmly to avoid movement of the catheter and sheath.
10. Remove the hatch by twisting the hatch counterclockwise using any available tool (e.g., scissors, hemostatic clamp).

Figure 19: Open hatch



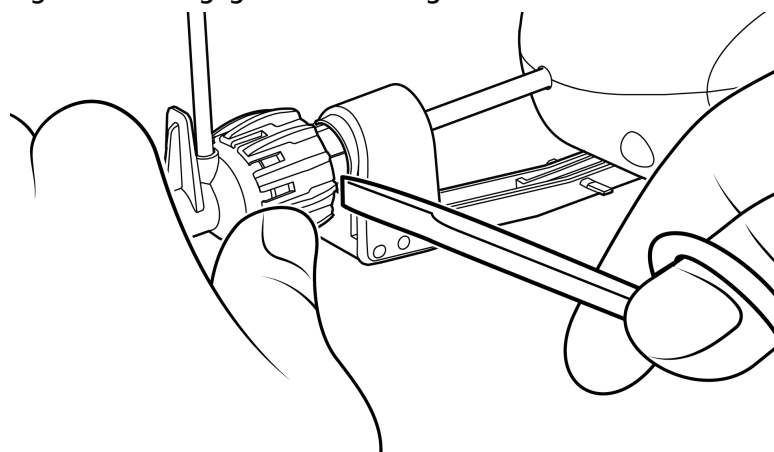
11. Cut the brown tube bundle and the two metal tubes as proximally (i.e., closest to the deployment knob) as possible. This enables additional cuts if the first cut is unsuccessful.

Figure 20: Cutting the lines



12. Disengage the insertion guide from the catheter loader by placing hemostats or another available tool between the loader and the loader dock to separate the components.

Figure 21: Disengage the insertion guide



13. Attempt to retract the array as per standard procedure.

- If the array is successfully retracted fully into sheath, immediately withdraw the sheath into the right atrium.
- If the array cannot be retracted, check for pinching of the metal tubes and repeat steps 11-12, cutting the tubes more distally (i.e., closest to the catheter shaft), as necessary.

14. If the array still cannot be retracted:

- 14.1. Fill the hatch with heparinized saline.
- 14.2. Reinstall the access hatch by twisting clockwise.
- 14.3. Maintain flushing on both lines, if possible.
- 14.4. Convert to surgical recovery procedure.

9.6 Replace the catheter



NOTE

If the procedure is not finished and you need to replace the catheter, prepare the replacement catheter before retracting and removing the existing catheter. For detailed instructions, see *Prepare the catheter* on page 29.



WARNING

Use medical imaging whenever inserting, moving, or retracting system components, and monitor sheath tip and array position.

1. Hold the sheath firmly in place in the left atrium.
2. Retract the array through the sheath and into the catheter loader; stop when the tip of the array reaches the loader band.

If the catheter loader and insertion guide inadvertently separate, hold the insertion guide and catheter loader together during retraction, until the insertion guide is fully extended.
3. Move the blue slider to the connection position.
4. Aspirate and flush at least 20 mL through the slider line (red).
5. Start a 100-mL/h drip on the slider line (red).
6. Insert the replacement catheter into the sheath by following the steps in *Insert the catheter* on page 34.

10 Technical support

For technical questions and support for your product or to coordinate product returns, contact technical support at support@kardium.com. For additional assistance, contact your local Kardium representative.

11 Product specifications

Table 3: Globe Introducer specifications

Part number	601-01001
Sheath length	71 cm
Sheath inner diameter	5.3 mm (16F)
Coating	Hydrophilic coating on entire outer surface of sheath tube
Dilator length	102 cm
Maximum guidewire diameter for dilator	0.89 mm (0.035 in)
Recommended guidewire diameter for dilator	0.89 mm (0.035 in)
Minimum guidewire length	230 cm

Table 4: Globe Catheter specifications

Part number	601-01000
Shaft length	116 cm
Shaft outer diameter	5.3 mm (16F)
Array diameter	30 mm
Coating	Heparinized coating on surface of array
Number of electrodes on array	122

12 Environmental conditions

Table 5: Globe Introducer, Globe Catheter, Globe Platform, and Globe Catheter Cable Support environmental conditions

Condition	Operating	Storage
Temperature	15–30 °C	15–30 °C
Humidity (noncondensing)	30%–70%	15%–75%
Pressure	80–106 kPa	70–106 kPa

13 Symbols

The following symbols may be used in this document and on the products and packaging.

Table 6: Symbols and definitions

Symbol	Standard	Definition
	ISO 15223-1	Catalog number
	ISO 15223-1	Serial number
	ISO 7000	Quantity of package contents
	21 CFR 801.109	For prescription use only
	ISO 15223-1	Caution
	ISO 15223-1	Consult instructions for use
	ISO 15223-1	Use-by date
	ISO 15223-1	Manufacturer
	ISO 15223-1	Date of manufacture
	ISO 15223-1	Do not use if package is damaged and consult instructions for use
	ISO 15223-1	Single use only

Symbol	Standard	Definition
	ISO 15223-1	Do not resterilize
	ISO 15223-1	Sterilized using ethylene oxide
	ISO 15223-1	Single sterile barrier system with protective packaging inside
	ISO 15223-1	Single sterile barrier system with protective packaging outside
	ISO 15223-1	Contains or incorporates a medicinal substance
	ISO 15223-1	Temperature limit
	ISO 15223-1	Humidity limitation
	ISO 15223-1	Atmospheric pressure limitation
	IEC 60417	Inner diameter
	IEC 60417	Outer diameter
	ASTM F2503-20	MR unsafe. Keep away from magnetic resonance imaging (MRI) equipment.
	ISO 15223-1	Unique device identifier
	N/A	Sheath
	N/A	Dilator

Symbol	Standard	Definition
	N/A	Maximum guidewire diameter
	N/A	Sheath steering counterclockwise
	N/A	Sheath steering clockwise
	N/A	Array orientation, anterior
	N/A	Array orientation, left
	N/A	Array orientation, posterior
	N/A	Array orientation, right
	N/A	Array deployed
	N/A	Array undeployed
	N/A	Cable lock engaged
MIN	N/A	Minimum level

21 CFR 801.109: United States Code of Federal Regulations, Title 21, Food and Drugs

ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

ISO 7000: Graphical symbols for use on equipment

IEC 60417: Graphical symbols for use on equipment

ASTM F2503-20: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Kardium Inc.
155 - 8518 Glenlyon Parkway
Burnaby, BC V5J 0B6
Canada

kardium.com
info@kardium.com

Kardium[®]

407-00010-EN-USA REV-E DRAFT
2025-06-20



Globe Controller, Globe PF Generator, and Globe Workstation

Part Numbers 601-00048, 601-00060, and 601-00064
Software Version 4.7

Instructions for Use



Kardium®

© 2025 Kardium Inc. All rights reserved.

Kardium® and Globe® are registered trademarks in the United States and Europe and are owned by Kardium Inc. WAVE™, FLOW™, CONTACT™ and GPS™ are trademarks of Kardium Inc. All other trademarks are the property of their respective owners.

The Globe® Pulsed Field System and associated technology are protected by one or more patents listed at <https://kardium.com/patents>.

NOTE: Any serious incident that has occurred due to or during use of the Globe Pulsed Field System should be reported to Kardium and to the applicable regulatory authority in which the user and/or patient is established in accordance with jurisdictional requirements.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

NOTE: Before a procedure, ensure that you have the latest version of this document downloaded by visiting <https://manuals.kardium.com> or emailing manuals@kardium.com. To get a printed copy of this document, email manuals@kardium.com.

KARDIUM DISCLAIMER OF WARRANTY AND LIMITATION OF LIABILITY

For device warranty information, visit <https://kardium.com/warranty>.

Contents

1 Prescription and safety information	8
1.1 Intended use	8
1.2 Indications for use	8
1.3 Additional prescription information	8
1.4 Warnings	8
1.5 Cautions	11
1.6 Related instructions for use	12
2 Product description	13
2.1 System	13
2.2 Globe Controller	14
2.3 Globe PF Generator	18
2.4 Globe Workstation	21
2.5 Required equipment	23
2.6 Procedure overview	25
3 Setup	26
3.1 Equipment setup	26
3.2 System startup	29
3.3 Connect the Globe Catheter Cable	30
3.4 Prepare the patient	31
3.5 Use of defibrillation equipment	32
4 Application overview	33
4.1 Screen elements	33
4.2 Screen layouts and panels	34
4.3 Global tool palette	40
4.4 Globe model	41
4.5 Orientation and navigation tools	50
4.6 Calibration temperature	53

4.7 Procedure timeline	54
4.8 New position	55
4.9 Labels	56
4.10 Procedure notes	57
5 Electrograms	59
5.1 Common commands	60
5.2 Globe Catheter electrograms	64
5.3 ECG signals	70
5.4 Signals from auxiliary catheters	71
5.5 Synchronize timeline	72
5.6 Trigger mode	72
5.7 Keyboard shortcuts for reviewing electrograms	73
5.8 Filters	75
6 Array maps	77
6.1 FLOW Map	78
6.2 Impedance Map	81
6.3 CONTACT Map	82
6.4 WAVE Map	84
6.5 Voltage Map	88
6.6 LAT Map	89
7 Globe Positioning System (GPS)	91
7.1 Enabling the GPS	91
7.2 Reference catheter	92
7.3 Globe model	93
7.4 Atrial model	95
7.5 Atrial maps	98
7.6 Selected electrogram window	102
7.7 GPS labels	103
7.8 Lesion markers	105

7.9 CT model	106
8 PF ablation	109
8.1 Select electrodes for PF ablation	109
8.2 Deliver PF energy	112
8.3 Stop PF ablation	113
9 Stimulation	115
9.1 Stimulation with the Globe Catheter	115
9.2 Stimulation with an auxiliary catheter	118
10 Procedure management	119
10.1 Start procedures	119
10.2 Stop procedures	119
10.3 Resume procedures	119
10.4 Offline review	120
11 Monitoring system	121
11.1 Troubleshooting button	121
11.2 Electrode status	121
11.3 Energy locks	123
11.4 Neutral electrode check	124
11.5 System logs	124
11.6 Alarms panel	124
11.7 Alarm messages	126
12 System shutdown	128
13 System administration	129
13.1 Archive procedure logs	129
14 Maintenance	131
14.1 Maintenance schedule	131
14.2 Clean the Globe Controller	132
14.3 Check the indicators on the Globe Controller	132
14.4 Test the audio signals on the Globe Controller	132

14.5 Clean the Globe PF Generator	133
14.6 Check the indicators on the Globe PF Generator	133
14.7 Test the audio signals on the Globe PF Generator	133
14.8 Clean the Globe Workstation	133
14.9 Clean the power cables and USB cables	133
14.10 Virus and threat protection	133
15 Disposal	135
16 Troubleshooting	136
16.1 System does not respond to request to stop ablation	136
16.2 Temperature calibration errors	136
16.3 Noisy ECG signals	136
16.4 Noisy auxiliary catheter electrograms	137
16.5 Globe Catheter Cable connection errors	137
16.6 Neutral electrode errors	137
16.7 GPS Electrodes connection errors	138
16.8 No connection between Globe Software and Globe Controller	138
17 Technical support	139
18 Product specifications	140
18.1 Globe Controller	140
18.2 Globe PF Generator	149
18.3 Globe Workstation	150
18.4 Alarm system	151
19 Environmental conditions	154
20 Essential performance	155
21 Electromagnetic compatibility compliance	156
21.1 Electromagnetic emissions	159
21.2 Electromagnetic immunity	159
22 Cybersecurity	166
22.1 Inactive interfaces	167

23 Application hotkeys	169
24 Acronyms	173
25 Symbols	177
Appendix A: Globe Positioning System Cable and Electrodes	180
Appendix B: Globe Catheter Cable	189

1 Prescription and safety information

The Globe® Controller, Globe® PF Generator, and Globe® Workstation are components of the Globe® Pulsed Field System (Globe PF System). This section contains prescriptive and safety information related to the use of these devices.

1.1 Intended use

The Globe Controller is intended for the acquisition and processing of signals for cardiac anatomical and electrophysiological mapping, transmission of ablation energy, and generation of stimulation pulses.

The Globe Workstation with Globe Software is intended to provide a Graphical User Interface (GUI) for cardiac anatomical and electrophysiological mapping, ablation energy delivery, and stimulation.

The Globe PF Generator is intended for the generation of pulsed field (PF) ablation energy.

1.2 Indications for use

The Globe PF System is indicated for catheter-based cardiac anatomical and electrophysiological mapping and stimulation of cardiac tissue.

When used for pulsed field ablation, refer to the Instructions for Use of the compatible cardiac ablation catheter for the specific indications for use.

1.3 Additional prescription information

For information on contraindications and adverse events, consult *Instructions for Use: Globe Introducer and Globe Catheter*.

1.4 Warnings

Note the following warnings for this device. A warning indicates a potentially hazardous situation that, if not avoided, could cause serious injury or death.

Accessories, transducers and cables. Use of accessories, transducers and cables other than those specified or provided by Kardiaum could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Cardiopulmonary arrest. Delivery of ablation energy can cause ventricular tachycardia leading to cardiopulmonary arrest. Have external defibrillation equipment available in the event of cardiopulmonary arrest.

Contact with metal parts. Do not allow the patient to come in contact with conductive parts or metal parts that are grounded or have an appreciable capacitance to earth (for example, operating table supports).

Continuous attendance. The Globe PF System is designed for continuous attendance. Do not leave the system unattended. An operator must be at the Globe Workstation at all times and must be able to see the indicator lights on the Globe Controller and Globe PF Generator.

Device compatibility. Defibrillator protection requires the use of accessories specified by Kardia. Only use the GPS Cable to connect the GPS Electrodes to the Globe Controller. Only connect the specified ECG cable to the Globe Controller, and use the ECG cable only with the specified monitoring electrodes. Use of any other ECG cable can create a hazardous situation for a patient connected to the Globe PF System when a defibrillator is used. Such hazardous situations include reduction of defibrillation energy delivered to the patient, equipment damage, and inaccurate ECG information. In addition, use of any other ECG cable can increase electromagnetic emissions, decrease immunity to electromagnetic disturbances, or both.

ECG signals. The ECG signals displayed on the Globe Workstation are intended solely for diagnostic purposes directly relating to the Globe procedure and are not intended for monitoring vital signs. Use two sets of ECG leads: one set connected to the Globe Controller with the ECG cable and another set connected to the lab's primary ECG monitoring system.

Electrocardiographic monitoring equipment. External ECG monitoring systems will be subjected to RF voltages typical of electrophysiology catheter ablation procedures. Only use ECG monitoring systems that conform to the IEC 60601-2-27 standard and have been evaluated for proper operation in the presence of electrosurgical equipment.

Flammable materials. The delivery of ablation energy can create fire and explosion hazards in the presence of flammable materials. Do not use the Globe Controller or the Globe PF Generator in the presence of flammable materials used for anesthetics, cleaning, disinfecting, or other purposes.

Globe Controller and Globe PF Generator connections. Connect only items that have been specified as being compatible with the Globe PF System.

GPS reference catheter position. Do not move the GPS reference catheter after it has been placed in the desired reference position. GPS accuracy may be impaired if the reference catheter is moved. The reference catheter may be fixated (for example, by using surgical tape) to prevent movement.

Grounded wall outlet. To reduce the risk of electric shock, directly connect the Globe Controller and the Globe PF Generator to fixed receptacles. Connection by other means (for example, a power bar) may create a ME SYSTEM per IEC 60601-1 and has not been evaluated for continued compliance with the requirements of IEC 60601-1.

Interference from GPS signals. The GPS signals may cause interference with other devices connected to the patient (for example, defibrillator ECG sensing). The GPS can be temporarily disabled using the Globe Software to stop the interference.

Liquid ingress. Liquid ingress can affect the performance of the Globe Controller and the Globe PF Generator. Do not allow any liquids into the Globe Controller and the Globe PF Generator. Do not spray or pour liquids onto the Globe Controller and the Globe PF Generator. Do not hang bags containing saline or other liquids above the Globe Controller and the Globe PF Generator. Keep the Globe Controller and the Globe PF Generator away from the device preparation table or any location where they could be splashed with liquids. Clean the Globe Controller and the Globe PF Generator in accordance with the instructions provided.

Lost communication during ablation. If the system does not respond to a request to stop ablation, disconnect the catheter cable from the catheter and turn off the controller and the PF generator.

Medical imaging required with the GPS. Always use medical imaging such as fluoroscopy when moving the Globe Catheter's array inside the atrium, even when using the GPS. Positioning the catheter and manipulating the array without medical imaging can result in damage to cardiac structures.

Mitral valve. Use caution when ablating tissue near the mitral valve to avoid damaging the mitral valve structure, leading to impaired function.

Monitor during stimulation. Monitor the patient's vital signs throughout stimulation with the Globe PF System. Stop immediately if adverse effects are observed.

Neuromuscular stimulation. Delivery of ablation energy to the patient may result in excessive neuromuscular stimulation.

Neutral electrode compatibility. Use of an incompatible neutral electrode may impair the ability of the system to trigger an auditory alarm during loss of safe contact between the neutral electrode and the patient. Use the specified neutral electrode and follow the instructions provided by the manufacturer.

Overheating. Position the Globe Controller and the Globe PF Generator to minimize risks of overheating. Do not block the air vents on the Globe Controller and the Globe PF Generator. Do not place the Globe Controller and the Globe PF Generator against a wall, in a confined space, near equipment that generates heat, or in an environment that exceeds the maximum allowable ambient temperature limit.

Pacemakers and implantable cardioverter defibrillators (ICDs). While the Globe PF System has not been evaluated in the presence of cardiac pacemakers, ICDs and other active implants, some high-frequency (HF) surgical equipment can produce enough interference to adversely affect the operation of these types of active implanted devices or damage device components. Use extreme caution when delivering ablation energy near active implants and leads, and assess device interactions by monitoring electrocardiograms (ECGs), intracardiac electrograms, and vital signs. Have external temporary pacing and defibrillation equipment available. If in doubt, seek qualified advice.

Phrenic nerves. Use caution when ablating tissue near the phrenic nerves to avoid excessive lesion depth that can result in phrenic nerve injury.

Placement of cables connected to the Globe Controller and Globe PF Generator. Position all cables in such a way as to minimize tripping hazards.

Placement of ECG electrodes and neutral electrode cable. Position the neutral electrode cable as far away as possible from ECG electrodes to avoid RF interference and reduce the risk of burns. Needle monitoring electrodes are not recommended.

Portable RF communications equipment. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the Globe PF System, including its cables. Otherwise, degradation of the performance of the Globe PF System could result.

Qualified users only. Use of the Globe PF System is intended for physicians who have completed the Kardia training program on catheter mapping and ablation procedures with the Globe PF System, and who have been trained in the techniques of vascular access, transseptal access, percutaneous catheter delivery, and intracardiac electrophysiology studies. Device preparation of the Globe PF System should only be performed by electrophysiology lab staff who have completed the Kardia training program on device preparation.

Read product documentation. Before using this device, carefully read all instructions, warnings, and cautions in this document and all other system documentation. In addition, carefully read the instructions and safety information for all ancillary devices or products that are used for the procedure before use.

Stacking equipment. Use of the Globe PF System equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Globe PF System equipment and the other equipment should be observed to verify that they are operating normally.

Stimulation with pacemakers and implantable cardioverters. Do not subject patients with an implanted electronic device (for example, a cardiac pacemaker) to stimulation without obtaining medical opinion from a specialist.

Stimulator. The stimulation capabilities of the Globe PF System are solely intended for purposes relating to ablation procedures with the Globe PF System and are not intended for any other purposes, including life support. A temporary external pacemaker must be available in the electrophysiology lab.

System compatibility. Use the Globe Catheter only with the compatible Globe Catheter Cable, Globe Controller, and Globe PF Generator as specified in this document. Using any other catheter, catheter cable, controller, or generator can impair system performance and can create a risk of burns and electrical shock for the patient or user.

System repairs or modifications. Do not try to modify or repair any component of the Globe PF System. Attempted modification or repair by unqualified personnel may create a hazardous situation for patients and operators, including excessive ablation energy delivery, electric shock, tissue trauma, particulate emboli, air embolism, particulate generation, and component contamination.

Unintended increase of output power or output voltage. Failure of the equipment could result in an unintended increase of output power or output voltage which may impact the safety of the patient.

Use of external stimulation with the GPS. Do not rely on the information from the GPS when using external stimulation. External stimulation may interfere with the ability of the GPS to accurately determine the location of the array.

Use of external stimulator. Simultaneous connection of the patient to the Globe Controller and an external stimulator may result in burns at the stimulator electrodes and may damage the stimulator.

Use of the GPS in the presence of implants and pacemakers. Do not rely on the information from the GPS in the presence of implants or pacemakers.

Vagal response during ablation. Delivery of ablation energy can cause a vagal response that leads to a reduced heart rate and asystole. Have external temporary pacing equipment available in the event of a vagal response.

Workstation changes and signal input/output restrictions. Do not make any changes to the Globe Workstation, including installing additional software or connecting peripheral devices or cables, connecting the workstation to a network, or using a network (Ethernet) port.

1.5 Cautions

Note the following cautions for this device. A caution indicates a hazardous situation that, if not avoided, could damage equipment or cause minor to moderate injury.

Ablation button. The Globe PF System does not require the continuous activation of a switch or button to deliver ablation energy. After the operator triggers the delivery of energy, ablation is conducted automatically. Monitor the patient's vital signs and electrode temperatures throughout ablation. End the delivery of ablation energy if conditions are deemed hazardous.

Ablation parameters. A high number of ablation pulses increases the risk of damage to adjacent tissue. Select the lowest number of pulses to achieve the desired therapy.

Apparent low power output. Apparent low power output or failure of the equipment to function correctly at the normal operating settings during RF energy delivery may indicate faulty application of the neutral electrode or poor contact in the connections. Increasing target temperature or ablation duration under these conditions can lead to patient injury. If the target temperature cannot be reached, check the neutral electrode for defects and verify that it is applied correctly before changing the ablation parameters.

Device inspection. To minimize the risk of patient injury or illness, inspect the device components before use and do not use if you suspect damage or degradation in any way. Return damaged products to Kardium.

Electrically conductive implants. Electrically conductive implants may concentrate or redirect HF currents from the Globe Catheter and harm the patient. If in doubt, seek qualified advice.

Long-term risks. The long-term effects of PF ablation have not been established. Lesions created by PF energy may have negative long-term effects on the cardiac conduction system.

Required use environment. Perform electrophysiology studies and cardiac ablation procedures only in a fully equipped electrophysiology laboratory.

Skin-to-skin contact. To reduce the potential for burns at unintended sites, position the patient to avoid skin-to-skin contact areas. Insert dry gauze at contact points, for example between the arms and the body.

1.6 Related instructions for use

For complete instructions on how to use the Globe PF System, see also:

407-00010 Instructions for Use: Globe Introducer and Globe Catheter

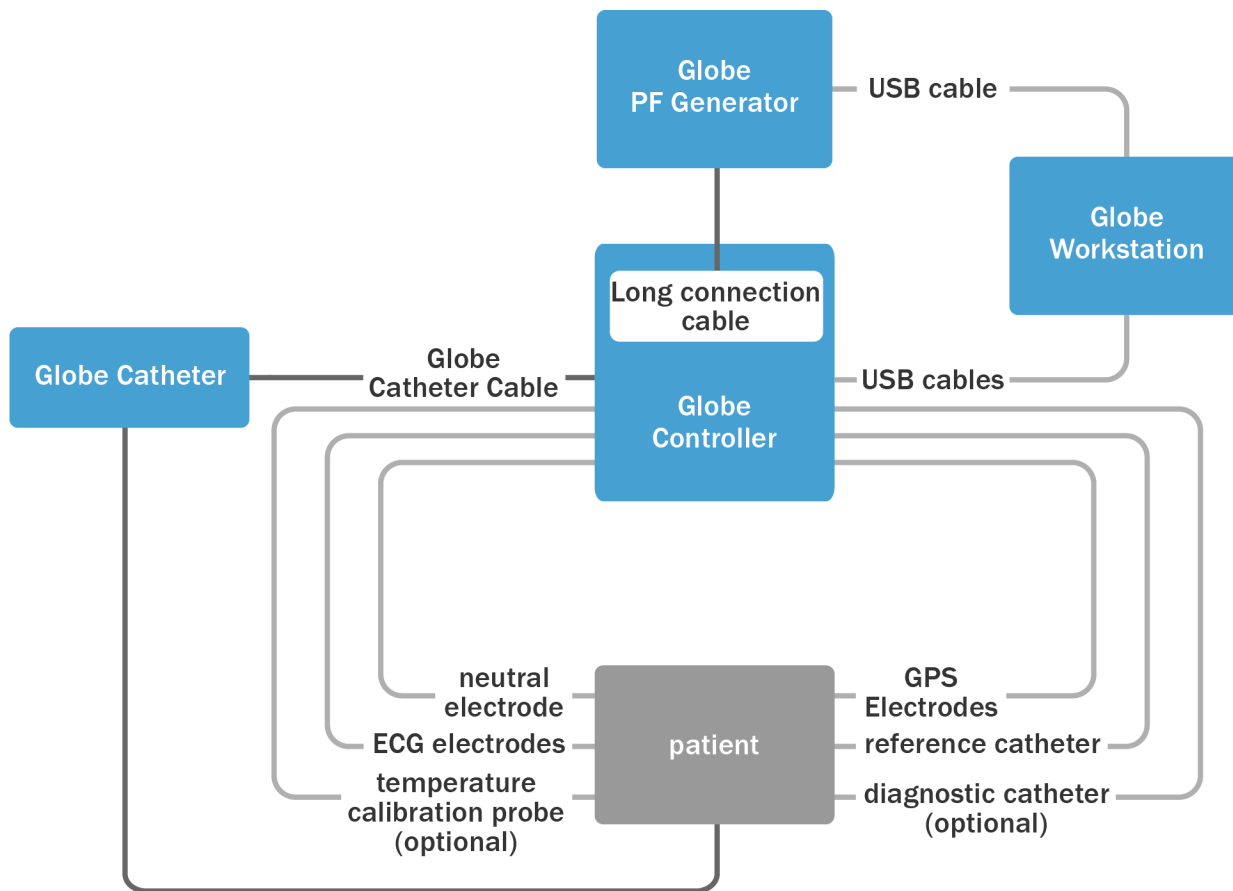
2 Product description

This section describes the functions and features of the Globe Controller, Globe PF Generator, and Globe Workstation.

2.1 System

The main components of the Globe PF System include the Globe Catheter, the Globe Controller, the Globe PF Generator, and the Globe Workstation.

Figure 1: Globe PF System diagram



The Globe Catheter is inserted into the patient to carry out energy delivery and stimulation functions generated by the Globe Controller and Globe PF Generator. The Globe Workstation provides the graphical user interface (GUI) for viewing and interacting with the Globe Software. The Globe Catheter is connected to the Globe Controller with the Globe Catheter Cable.

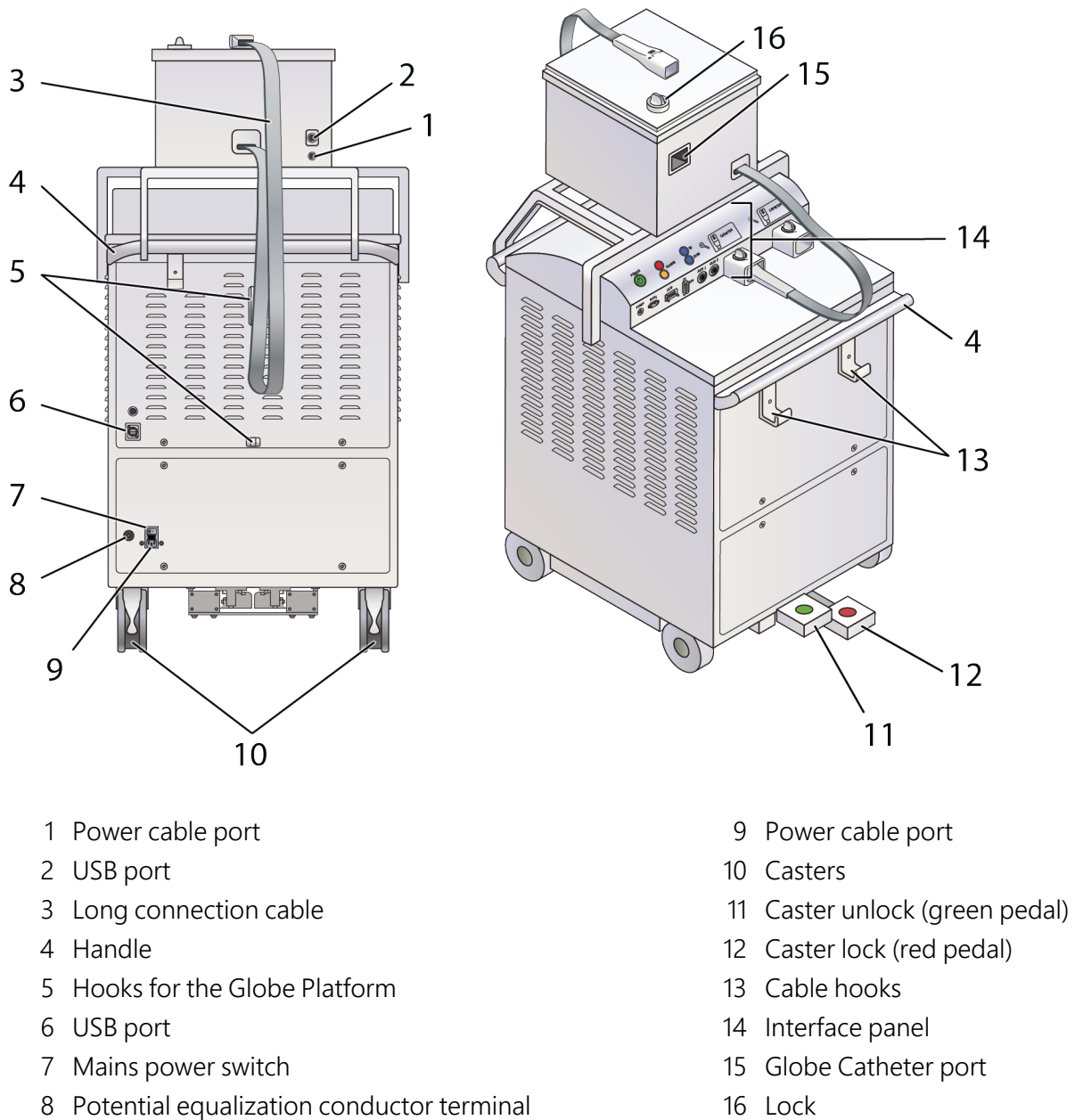
For a description of the Globe Controller, Globe PF Generator, and Globe Workstation, see below. For information about other components of the Globe PF System, refer to their respective instructions for use.

2.2 Globe Controller

The Globe Controller contains the electronics used to process sensor data from the Globe Catheter (temperature, voltage, intracardiac electrograms) and generate stimulation pulses. In addition, the Globe Controller connects to probes and electrophysiology catheters to permit sensing, measurement, and atrial anatomical and electrophysiological mapping functions.

Patient connections include the Globe Catheter, ECG monitoring electrodes, a neutral electrode, an optional temperature calibration probe, GPS Electrodes, a reference catheter (typically a coronary sinus catheter), and an optional diagnostic catheter.

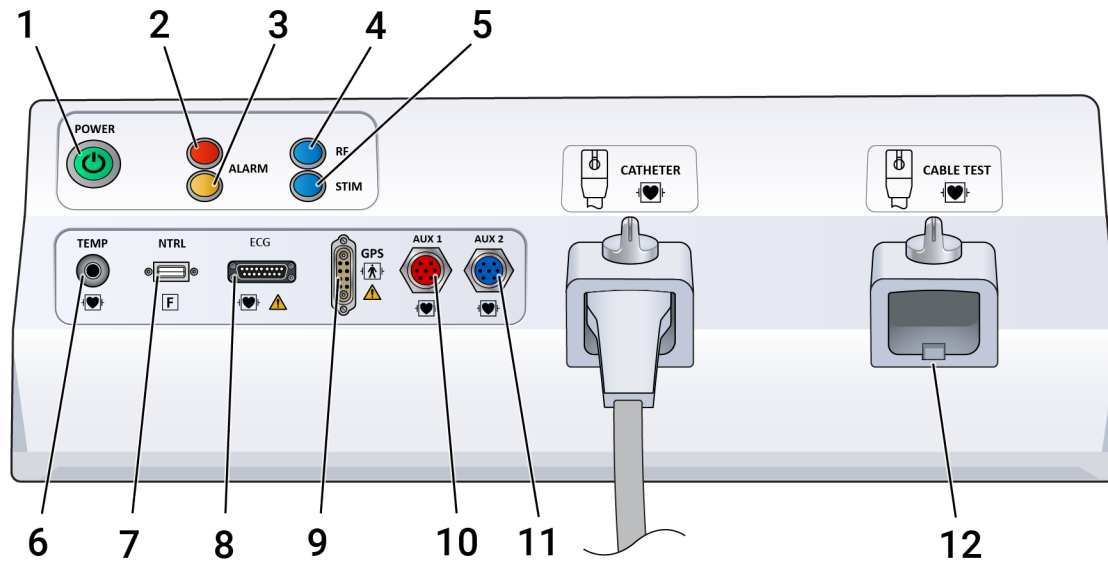
Figure 2: Globe Controller, rear (left) and front (right)



2.2.1 Controller interface panel

The interface panel of the controller contains ports for various compatible accessory cables, as well as the power button and indicator lights.

Figure 3: Interface panel of Globe Controller



- | | |
|--|---|
| 1 Power button and light | 7 Neutral electrode port |
| 2 High-priority alarm light | 8 ECG cable port |
| 3 Low-priority and medium-priority alarm light | 9 GPS Cable port |
| 4 RF energy light | 10 Reference catheter port (AUX1) |
| 5 Stimulation light | 11 Optional diagnostic catheter port (AUX2) |
| 6 Optional temperature calibration probe port | 12 Catheter cable testing port |

Table 1: Indicator lights on Globe Controller

Indicator	Illumination	Meaning
Power button	Solid green	Power is on
High-priority light	Flashing red	Active alarm is high priority
Low-priority and medium-priority light	Flashing yellow	Active alarm is medium priority
	Solid yellow	Active alarm is low priority
RF energy light	Solid blue	RF ablation or RF impedance sensing is active
Stimulation light	Solid blue	Stimulation is active

2.2.2 Controller foot pedals

Use the foot pedals on the Globe Controller to lock and unlock the casters.

Table 2: Controller caster modes

Pedal Position	Mode	Behavior
Green pedal down	Caster unlock (free swivel)	All four casters are unlocked, and all four wheels swivel and rotate freely.
Red pedal down	Caster lock (total brake)	All four casters are locked, and all four wheels do not swivel or rotate.

2.2.3 Controller functional description

The Globe Controller performs the following functions:

Flow assessment. Convective cooling measurements enable the system to infer the amount of blood flow at each electrode on the Globe Catheter's array. The rate of heat loss after applying a small amount of current to each electrode is higher where nearby blood flow is high. Electrodes in regions of high flow such as near the mitral valve or the pulmonary veins cool faster than electrodes experiencing reduced blood flow as the array is moved closer to atrial tissue. The difference in the rate of heat loss is the basis for the contrast displayed in the FLOW™ Map.

Contact assessment. Contact between the array's electrodes and the atrial wall is assessed by briefly heating electrodes using a low, non-therapeutic current and measuring the power required for each electrode to reach 40 °C . The difference in power requirement is the basis for the contrast displayed on the CONTACT™ Map.

Electrogram measurement. The electrical activity of the left atrial tissue is measured at each electrode of the array. The voltage data is also used to create the WAVE™ Map and the Voltage map.

ECG signal acquisition. Surface ECG signals acquired using the ECG cable are used by the system to synchronize the WAVE Map and the Voltage Map.

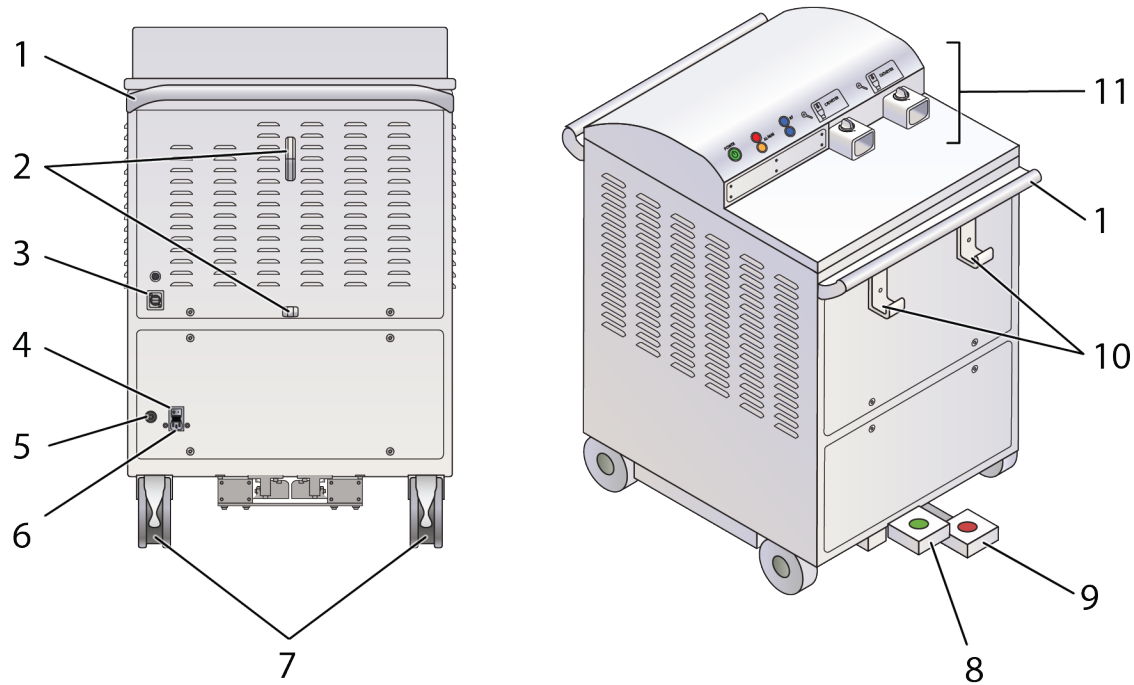
Globe Positioning System (GPS). Six surface electrodes applied to the patient's skin and a reference catheter are used to create a model of the left atrium and display the position and orientation of the array relative to the reference catheter and the patient's atrium as the array is moved inside the atrium.

Cardiac stimulation. An electrical stimulus generator emits pacing stimulation pulses that are used for diagnostic purposes.

2.3 Globe PF Generator

The Globe PF Generator contains the electronics used to deliver pulsed field energy to the Globe Catheter in the form of short high voltage pulses. The Globe PF Generator communicates with the Globe Workstation and is connected to the Globe Controller via the Globe Controller's long connection cable.

Figure 4: Globe PF Generator, rear (left) and front (right)

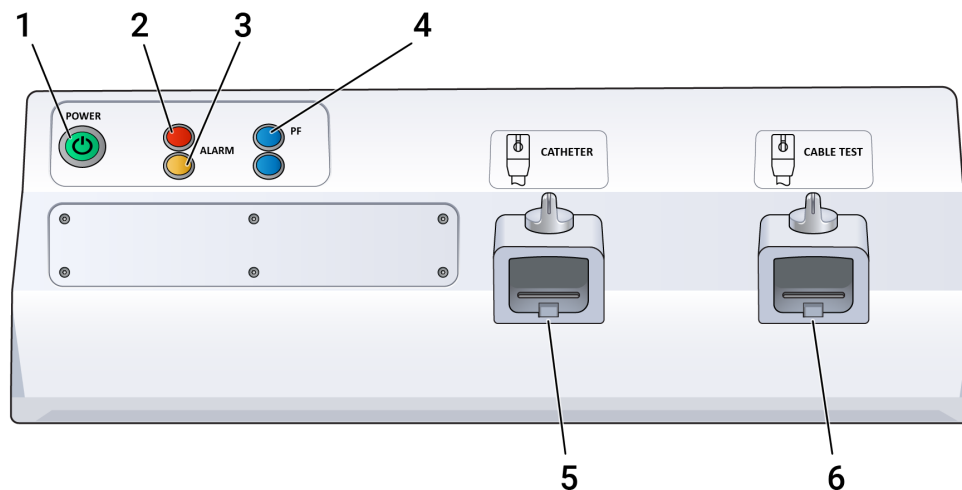


- 1 Handle
- 2 USB and power cable hooks
- 3 USB port
- 4 Mains power switch
- 5 Potential equalization conductor terminal
- 6 Power cable port
- 7 Casters
- 8 Caster unlock (green pedal)
- 9 Caster lock (red pedal)
- 10 Cable hooks
- 11 Interface panel

2.3.1 PF Generator interface panel

The interface panel of the PF generator contains ports for the Globe Controller's long connection cable and Globe Catheter Cable as well as the power button and indicator lights.

Figure 5: Interface panel of the Globe PF Generator



- 1 Power button and light
- 2 High-priority alarm light
- 3 Low-priority and medium-priority alarm light
- 4 PF energy light
- 5 Port for the Globe Controller's long connection cable
- 6 Catheter cable testing port

Table 3: Indicator lights on Globe PF Generator

Indicator	Illumination	Meaning
Power button	Solid green	Power is on
High-priority light	Flashes red	Active alarm is high priority
Low-priority and medium-priority light	Flashes yellow	Active alarm is medium priority
	Solid yellow	Active alarm is low priority
PF energy light	Solid blue	PF ablation

2.3.2 Generator foot pedals

Use the foot pedals on the Globe PF Generator to lock and unlock the casters.

Table 4: Generator caster modes

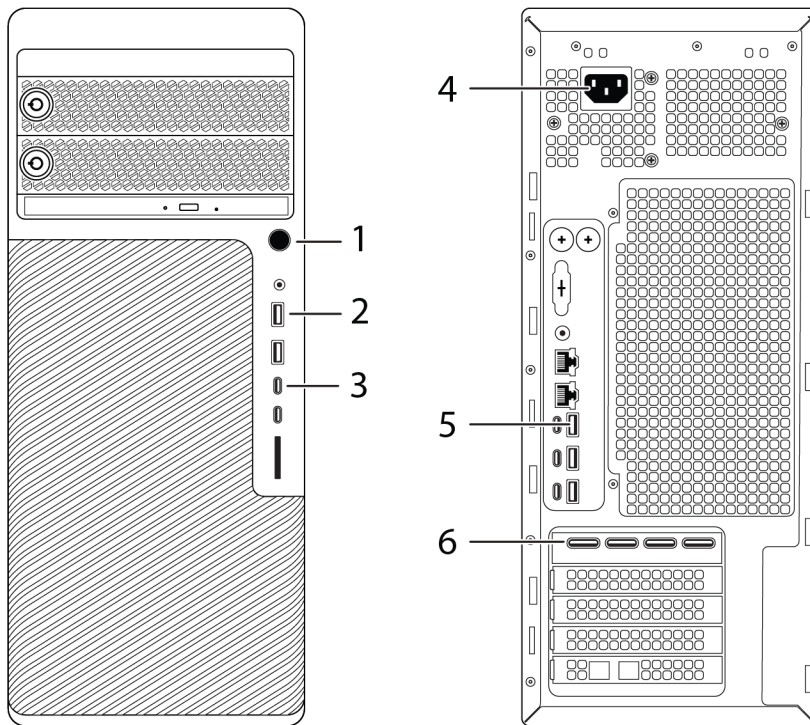
Pedal Position	Mode	Behavior
Green pedal down	Caster unlock (free swivel)	All four casters are unlocked, and all four wheels swivel and rotate freely.
Red pedal down	Caster lock (total brake)	All four casters are locked, and all four wheels do not swivel or rotate.

2.4 Globe Workstation

The Globe Workstation is a computer and associated peripherals (displays, mouse and keyboard) that runs the host software (as part of the Globe Software) as well as supporting third-party software. The physician uses the software to visualize contact between the array of the Globe Catheter and the atrium, resolve the atrial anatomy, monitor intracardiac electrograms and surface electrocardiograms, visualize the propagation of electrical signals through the atrium, identify and select suitable targets for ablation, deliver ablation energy, apply stimulation pulses for diagnostic purposes, and manage procedural data.

The Globe Workstation includes a computer tower, two displays, a mouse, and a keyboard.

Figure 6: Globe Workstation computer tower



- 1 Power button
- 2 USB-A 2.0 (black) ports for connecting the mouse and keyboard
- 3 USB-C ports for CT data transfer and connecting a password reset disc
- 4 Power connection
- 5 USB-A 3.0 (blue) ports for connecting the Globe Controller and Globe PF Generator
- 6 DisplayPort outputs for displays

2.5 Required equipment

The Globe Controller (601-00048) , Globe PF Generator (601-00060), and Globe Workstation (601-00064) must be used with the following Kardium and third-party devices and accessories.

Table 5: Compatible Kardium devices and accessories

Device or accessory	Kardium part number
Globe® Catheter* (via Globe® Catheter Cable)	601-01000
Globe® Introducer	601-01001
Globe® Catheter Cable	601-00046
Globe® Catheter Cable Support	601-00067
Globe® Platform	601-00066
Globe® GPS Cable	601-00036 Failure to use the designated cable can result in unexpected and potentially hazardous behavior during defibrillation.
Globe® GPS Electrodes (via GPS Cable)**	601-00037
*Defibrillation-proof type CF applied part	
**Defibrillation-proof type BF applied part	

Table 6: Compatible third-party accessories

Accessory	Compatible product
ECG cable*	Cable Unimed Medical Supplies E10R/30-GL-P/I Unimed Medical Supplies E10R/30-GL-P Unimed Medical Supplies 24155P-I Unimed Medical Supplies 24155P IEC 60601-2-27 Color Code Code 1 (usually European) Code 2 (usually American) Code 1 (usually European) Code 2 (usually American) Failure to use a designated cable can result in unexpected and potentially hazardous behavior during defibrillation.
Neutral electrode*	3M™ Series 9100 Universal Electrosurgical Pads (model 9165) Failure to use a compatible neutral electrode can lead to patient injury.
ECG electrodes*	3M™ Red Dot™ snap style monitoring electrodes (model 2570 or 2670)
Temperature calibration probe* with compatible temperature probe interface cable (optional)	- Smiths Medical General Purpose Probe ER400-9 (9 Fr) or ER400-12 (12 Fr) with Smiths Medical Temperature Monitoring Reusable Cable 400 series C400-10 - Smiths Medical Esophageal Stethoscope Temperature Sensors ES400-9 (9 Fr), ES400-12 (12 Fr), ES400-18 (18 Fr), or ES400-24 (24 Fr) with Smiths Medical Temperature Monitoring Reusable Cable 400 series C400-10 - Truer General Purpose Probe, GP 14400 (14 Fr) with Truer Temperature Monitor Interface Cable 400 series 70321
Reference catheter* and optional diagnostic catheter*	Standard 10-pole electrophysiology catheters can be connected to the auxiliary catheter inputs of the Globe Controller using a compatible catheter cable and the Unimed Medical Supplies 10-Pin Catheter Adapter. A reference catheter is required for the GPS. An additional optional diagnostic catheter may also be used.

Accessory	Compatible product
10-pin catheter adapter	Unimed Medical Supplies 10-Pin Catheter Adapter (part number: AD-KAR-210148) The 10-pin catheter adapter is connected to the Globe Controller by making the following connections: Standard 10-pole electrophysiology catheter → Third-party cable for standard 10-pole electrophysiology catheter → 10-pin catheter adapter → Globe Controller.
*Defibrillation-proof type CF applied part	

2.6 Procedure overview

The following section provides a general workflow for a procedure after the array has been deployed in the left atrium. Many variations are possible depending on the clinical context.

1. Enable the GPS and, optionally, create a model of the atrium.
2. Manipulate the array to the region targeted for ablation.
3. Confirm that the array has been positioned appropriately using anatomical and electrophysiological maps in combination with medical imaging such as fluoroscopy.
4. Using clinical judgment, select electrodes for pulsing. If pulsing around a feature of interest, select a two-electrode wide path.
5. Ablate.
6. Reposition the array as needed to complete a lesion set or move to a new target area.
7. Repeat all the previous steps until the procedure is completed.

3 Setup

This section contains information and instructions for setting up equipment in the electrophysiology (EP) lab, starting the system, and preparing the patient for a procedure.



NOTE

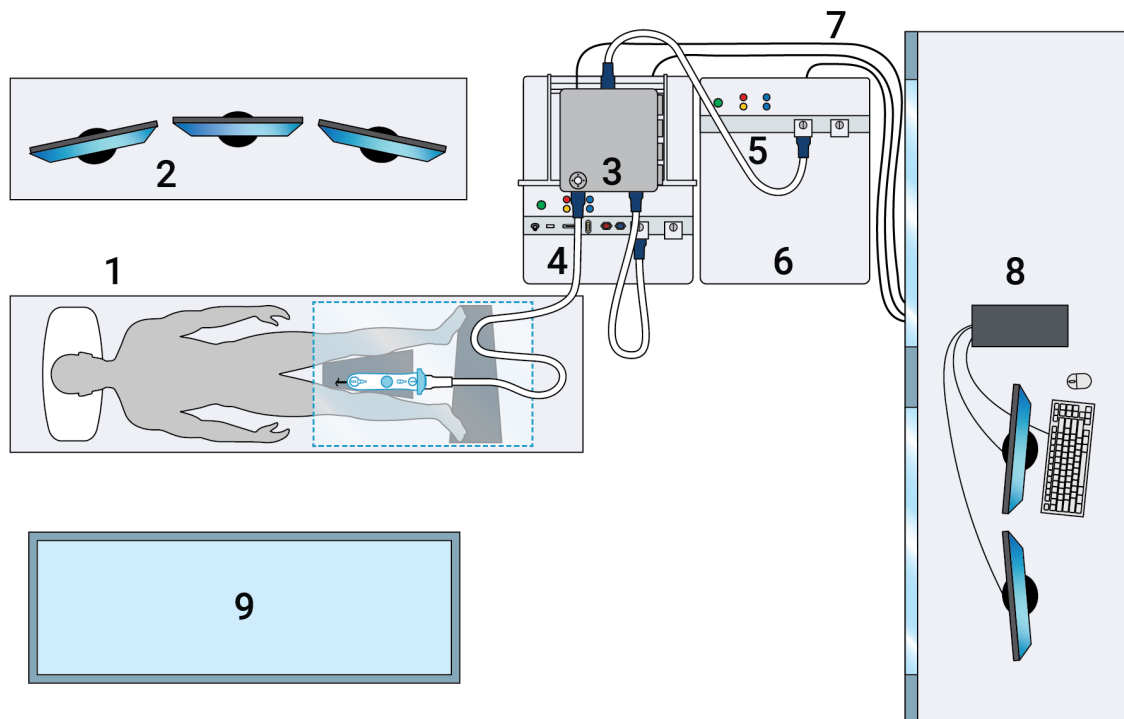
Initial installation of the Globe PF System is to be performed by Kardium qualified personnel only. For more information, contact Kardium technical support.

3.1 Equipment setup

Perform electrophysiology (EP) studies and cardiac ablation procedures only in a fully equipped EP lab. The following information contains guidelines and requirements for setting up equipment in the EP lab relative to the Globe PF System equipment. Refer to *Required equipment* on page 23 for the list of equipment and supplies related to the use of the Globe Controller and refer to *Instructions for Use: Globe Introducer and Globe Catheter* for the list of required equipment and supplies related to the use of the catheter.

Trained Kardium personnel are responsible for initial installation of the Globe PF System. If the Globe Controller and the Globe PF Generator are moved following initial installation, follow the recommendations below to set up the equipment before the next procedure.

Figure 7: Globe PF System in the EP lab



- 1 Patient table
- 2 Display system monitors
- 3 Globe Controller
- 4 Globe Catheter Cable
- 5 Globe Controller's long connection cable
- 6 Globe PF Generator
- 7 USB cables
- 8 Globe Workstation
- 9 Sterile device preparation table

Table 7: System setup requirements

Power	The power source meets power requirements. The power connection complies with site-and region-specific regulations.
Outlets	• Earthed • 100 – 120 VAC, 60 Hz or 200 – 240 VAC, 50 Hz, 600 VA • Branch current rating not exceeding 26 A • Overvoltage category II per IEC 60664-1:2020 • Compatible with plug type NEMA 5-15P
Operating conditions	See <i>Environmental conditions</i> on page 154
Workstation	The workstation can be located in the same room or a different room as the controller and PF generator. It must be positioned within 22 m of the controller and the PF generator, at least 1.83 m from the patient table, and such that the DisplayPort outputs can be connected to the EP lab's display system. The workstation user must be able to relay information at all times to the performing physician and be able to see the indicator lights on the controller and the PF generator at all times.

**Controller and
PF generator**

The controller and PF generator must be located:

- At least 50 mm from adjacent structures and equipment. Make sure that the vents are not blocked.
- Near the patient to allow patient cables to reach the patient comfortably and to avoid tripping hazards, accidental cable movement, and cable damage.

For a list of cable lengths to help in determining placement locations of the workstation and controller, see *Electromagnetic compatibility compliance* on page 156.

- Directly on a level floor (not a platform or pedestal) with the casters locked and nothing stacked on top.
- Away from device preparation table or other areas where it might get splashed.
- Away from interference-causing equipment.

The user must be able to easily access the buttons and patient lead connection on the interface panel during normal operation.

The physician must be able to see the indicator lights on the Globe Controller and Globe PF Generator at all times.

The Globe PF System is designed for continuous attendance.

Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e., IEC 60950-1 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard contained within IEC 60601-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible that the system complies with the requirements of the system standard within IEC 60601-1. If in doubt, consult your facility's technical support department.

3.2 System startup

1. Confirm that both power cables on the Globe Controller are plugged in:
 - A power cable is connected to the lower power cable port.
 - A power cable is connected to the provided power adapter, which is connected to the upper power cable port.
2. Confirm that the Globe PF Generator and Globe Workstation are plugged in.
3. Confirm that both USB cables from the Globe Controller are connected to the Globe Workstation.
4. Confirm that the USB cable from the Globe PF Generator is connected to the Globe Workstation.
5. Connect the Globe Controller's long connection cable to the Globe PF Generator.
 - 5.1. Fully insert the long connection cable into the port for the long connection cable on the Globe PF Generator.
 - 5.2. Rotate the lock 180° clockwise to lock the cable in place.

6. Flip the mains power switch at the back of the Globe Controller to the "ON" position.
7. Push the green power enable button on the interface panel of the Globe Controller.
8. Flip the mains power switch at the back of the Globe PF Generator to the "ON" position.
9. Push the green power enable button on the interface panel of the Globe PF Generator.
10. Turn on the workstation, and log on to Windows using the *operator* account.
11. Create a procedure using the Globe Software.
12. Follow the instructions provided in the Globe Software to complete the pre-procedure self-tests.

3.3 Connect the Globe Catheter Cable

The following sections provide the workflow to test the Globe Catheter Cable with the Globe Controller and the Globe PF Generator and to connect the Globe Catheter Cable to the Globe Controller for patient use.

3.3.1 Test the Globe Catheter Cable

Connect the Globe Catheter Cable to the Globe Controller or the Globe PF Generator when prompted by the Globe Software using the following steps:

1. Fully insert the catheter cable into the catheter cable testing port on the Globe Controller or Globe PF Generator, as directed by the Globe Software.
2. Rotate the lock 180° clockwise to lock the cable in place.
3. Follow the system prompts to complete any necessary tests.

3.3.2 Disconnect the Globe Catheter Cable from the Globe Controller or Globe PF Generator

If the Globe Catheter Cable needs to be disconnected from the Globe Catheter port on the Globe Controller or the Catheter cable testing port on the Globe Controller or Globe PF Generator, complete the following steps:

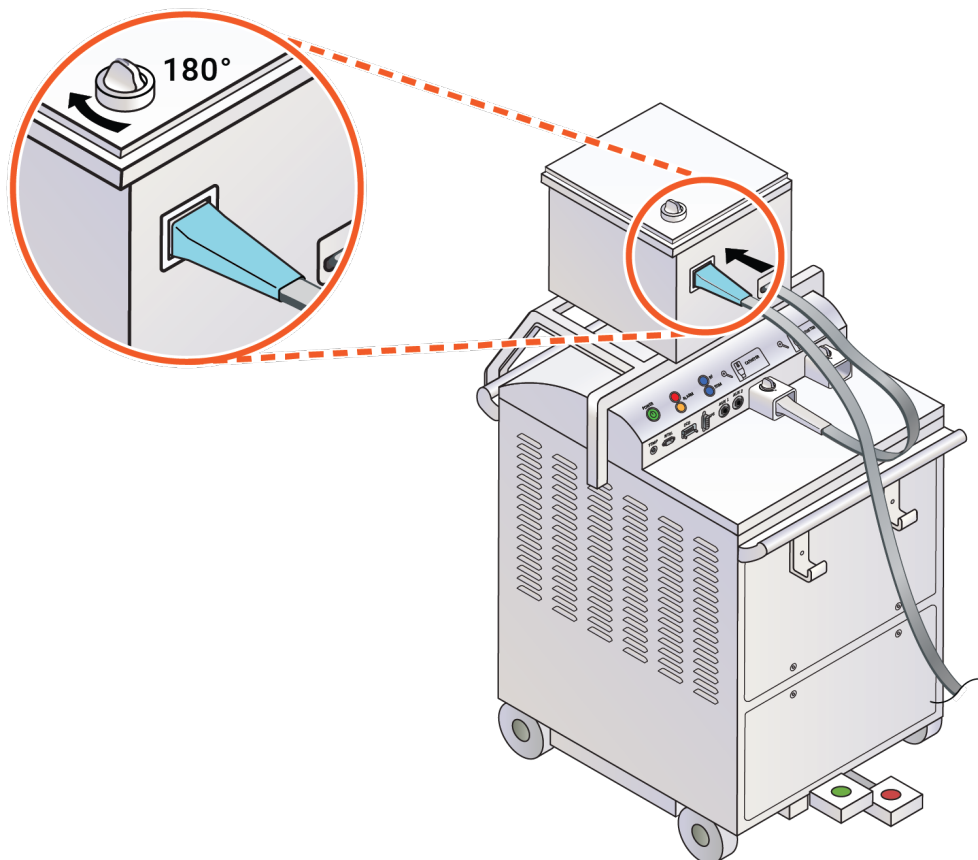
1. On the Globe Controller or Globe PF Generator, rotate the lock on the port 180° counterclockwise to unlock the cable.
2. Pull the catheter cable out of the port.

3.3.3 Connect the Globe Catheter Cable to the Globe Catheter port for patient use

Connect the Globe Catheter Cable to the Globe Controller when prompted by the Globe Software using the following steps:

1. Fully insert the catheter cable into the Globe Catheter port on the Globe Controller.
2. Rotate the lock 180° clockwise to lock the cable in place.

Figure 8: Connect the Globe Catheter Cable to the catheter port on the Globe Controller



3.4 Prepare the patient

The following steps cover how to prepare the patient with electrodes and probes for the procedure. For information about the compatible products to use for the following steps, refer to *Required equipment* on page 23. For information on sedation and access site preparation, see the *Instructions for Use: Globe Introducer and Globe Catheter*.

1. Apply the compatible neutral electrode to the back of the patient according to the manufacturer's instructions and connect the neutral electrode cable to the controller.
2. Apply the compatible ECG electrodes to clean, dry skin according to the manufacturer's instructions and connect the electrodes to the compatible ECG cable. Place all ECG electrodes as far away as possible from the neutral electrode to avoid RF interference and to reduce the risk of burns. Connect the compatible ECG cable to the controller.
3. Apply the GPS Electrodes to the patient. For proper electrode placement, see Figure 82: *Placing the GPS electrodes on the patient's body* on page 184.

If applying defibrillator electrodes, make sure that the defibrillator electrodes are at least 3 cm from the GPS Electrodes.

4. Connect the GPS Electrodes to the GPS Cable and connect the GPS Cable to the controller. For more information on the cable, refer to *Globe Positioning System Cable and Electrodes* on page 180.
5. Insert a compatible reference catheter into the patient's coronary sinus, connect the catheter to a compatible catheter cable, connect the catheter cable to the Unimed Medical Supplies 10-Pin Catheter Adapter, and connect the 10-pin catheter adapter to the controller.
6. Optionally, insert a compatible diagnostic catheter into the patient, connect the catheter to a compatible catheter cable, connect the catheter cable to the Unimed Medical Supplies 10-Pin Catheter Adapter, and connect the 10-pin catheter adapter to the controller.

3.5 Use of defibrillation equipment

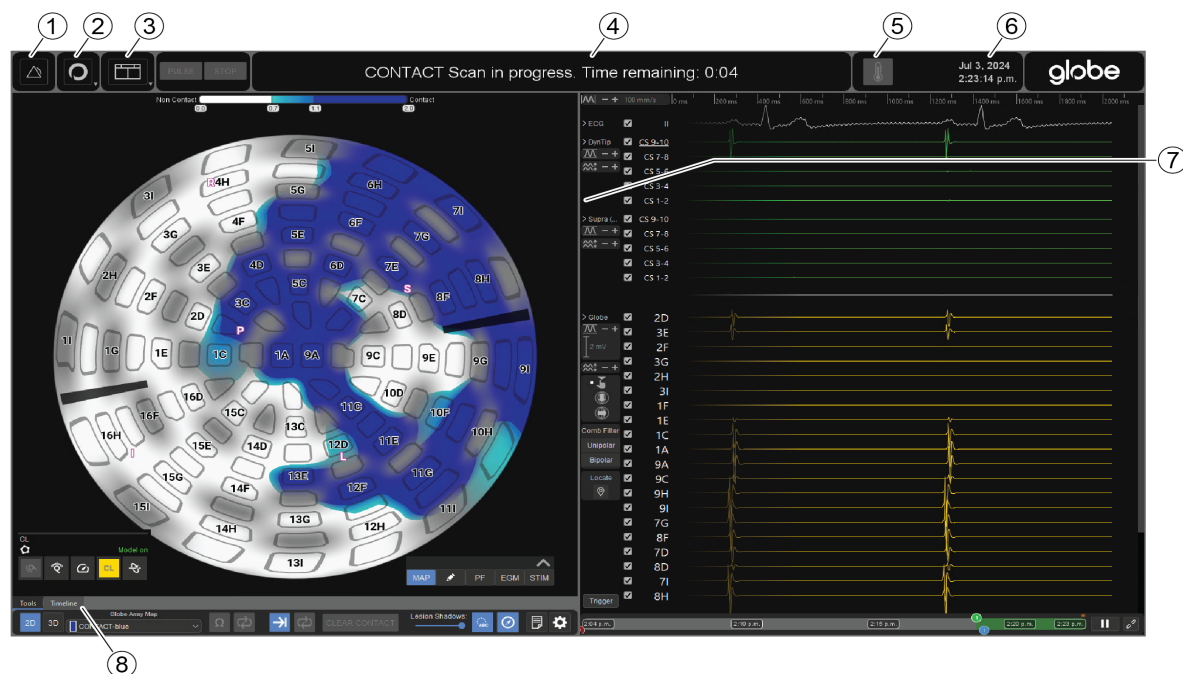
Before using an external defibrillator while the array of the Globe Catheter is inside the atrium, move the array away from the atrial walls and stop the delivery of ablation energy and stimulation energy. The use of a defibrillator may cause a temporary (less than 5 seconds) discontinuity in the intracardiac electrograms and surface ECGs. The use of a defibrillator may also disrupt the GPS. Correct operation can be restored within 20 seconds by following the instructions on the Globe Workstation.

4 Application overview

4.1 Screen elements

The Globe Software presents information in customizable panels. The following figure defines the screen elements. Two half-panels are shown in the figure—the Array panel (left) and the Electrograms panel (right).

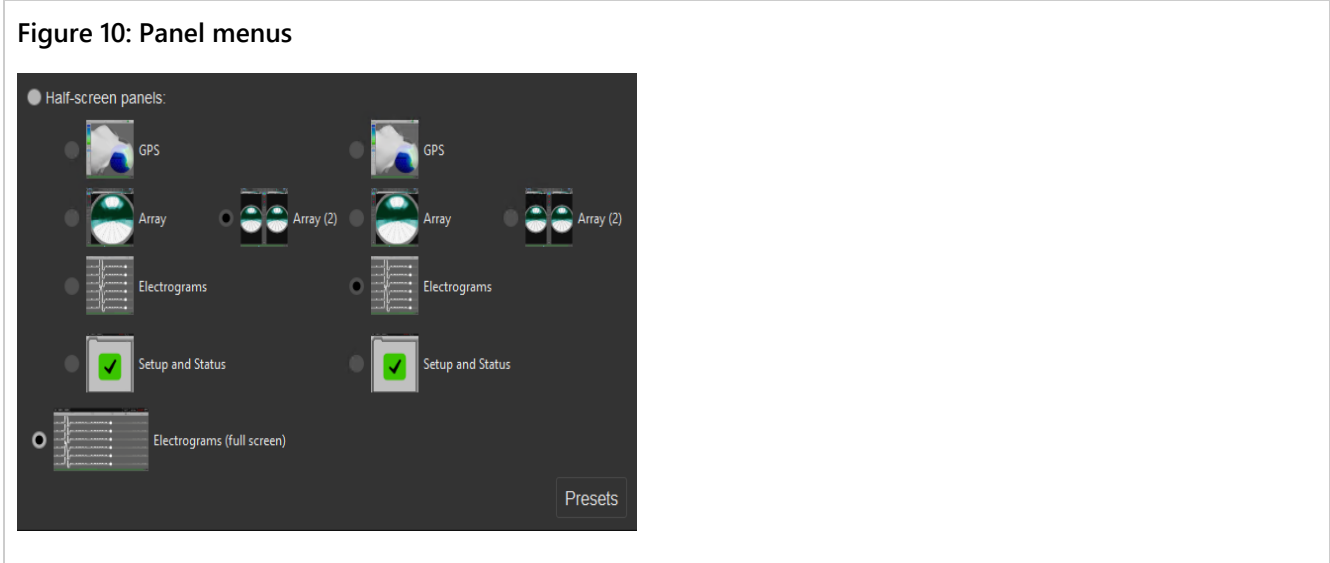
Figure 9: Screen elements



- 1 **Troubleshooting.** Click to view the system logs and manage alarms and system tests.
- 2 **Globe Software menu.** Click to set waveform filters, manage procedure notes, end a procedure, test alarm volume, and view version information.
- 3 **Panel selection and screen layout selection.** Click to customize the panels shown on the screen.
- 4 **System message area.** Display area for status messages and on-screen instructions.
- 5 **Probe temperature.** Click to calibrate the Globe Catheter temperature sensors.
- 6 **Date and time.** During a live procedure, the current date and time. During offline review, the date and time at that point in the procedure.
- 7 **Panels.** System information related to the panel type.
- 8 **Timeline.**

4.2 Screen layouts and panels

Panels are used to view the Globe model orientation, mapping, and electrophysiological activity. To open a panel, click  and select the panel from the list. For more information about the panels, see Array panel, Electrograms panel, Ablation panel, and GPS panel in this chapter.



Panels can be selected manually or using screen layouts. Screen layouts are preconfigured views of panels. To choose a screen layout, click  and **Presets** and select a layout from the list. The following table describes each preconfigured screen layout.

Table 8: Default layouts

Layout name	Screen contents
Setup	1. Globe Setup and Status panel and GPS panel 2. Array panel (FLOW Map) and Electrograms panel
GPS	1. Two GPS panels 2. Two Array panels—FLOW Map and Voltage Map
GPS with Electrograms	1. Two GPS panels 2. Array panel (FLOW Map) and Electrograms panel

Layout name	Screen contents
Mapping	1. GPS panel and Array panel (FLOW Map) 2. Array panel (Voltage Map) and Electrograms panel

To access the screen layout commands, click  and **Presets**.

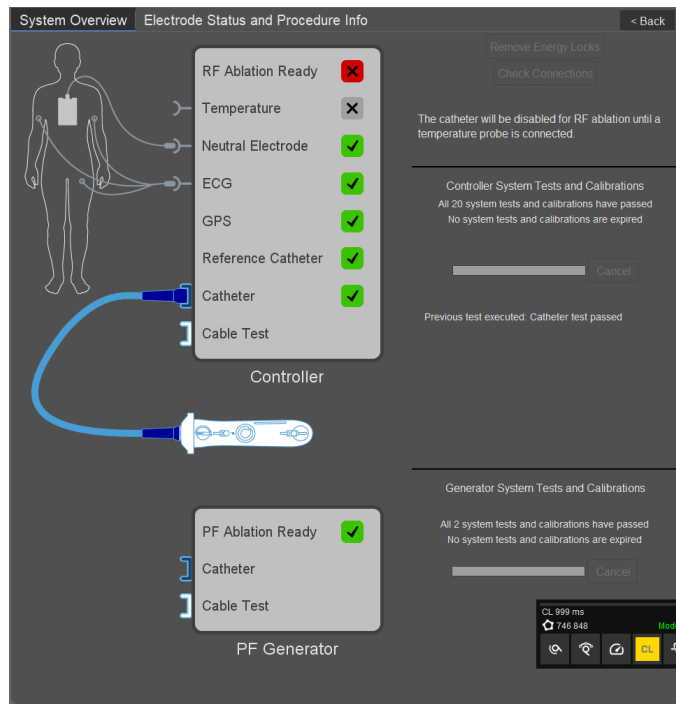
Table 9: Commands for screen layouts

Task	Steps
Select a preconfigured screen layout	Choose the layout.
Create a new layout based on the current panel configuration	1. Select New layout. 2. Type a configuration name and click Save.
Change an existing layout based on the current panel configuration	1. Select Update layouts. 2. Choose the configuration name. 3. Click Update.
Change the name of an existing layout	1. Select Update layouts. 2. Choose the layout to modify. 3. Type the new name. 4. Click Update Name Only. 5. Click Done.

4.2.1 Setup and Status panel

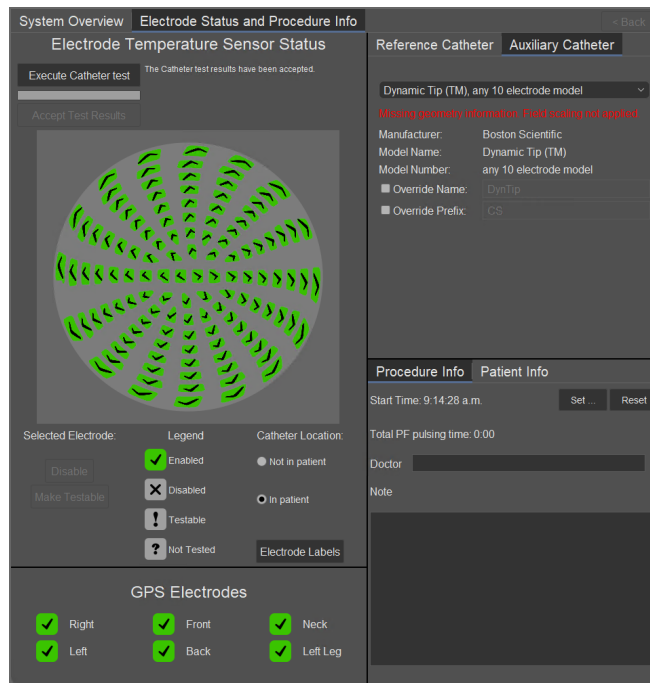
Use the Globe Setup and Status panel to view the status of the patient and system connections, monitor system test execution, and enter patient data. To display this panel, click  and select **Setup and Status**.

Figure 11: Setup and Status panel



On the Setup and Status panel, click the **Electrode Status and Procedure Info** tab to show electrode temperature sensor status, GPS Electrode status, and additional tabs for the reference and optional diagnostic catheters and procedure and patient information.

Figure 12: Electrode Status and Procedure Info tab

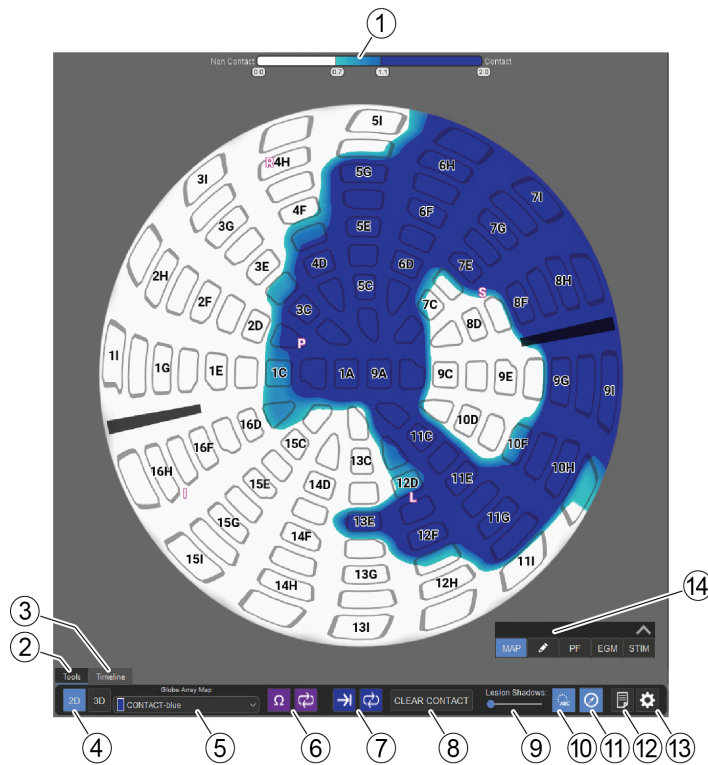


4.2.2 Array panel

Use the Array panel to:

- View three-dimensional (3D) or two-dimensional (2D) Globe models.
- View electrophysiological information.
- Create and edit graphic and text labels.
- Select which electrograms to show on the Electrograms panel.
- Select electrodes for ablation.
- Start and stop ablation.
- Select electrodes for delivery of stimulation pulses.

Figure 13: Array panel



- 1 **Globe Array Map color scale.** Adjustable color scale for each Globe Array Map type.
- 2 **Tools tab.** Click to access tools for the Globe Array Map.
- 3 **Timeline tab.** Click to access the procedure timeline.
- 4 **2D/3D view.** Click 2D or 3D to change the Globe model view.
- 5 **Select Globe Array Map.** List of Globe Array Maps (FLOW, CONTACT, FLOW-green, CONTACT-blue, LAT, Impedance, Voltage, WAVE, None) to view in the panel.
- 6 **Impedance Map.** Click to check catheter array deployment or to refresh the Impedance Map.
- 7 **CONTACT Map.** Click to refresh the CONTACT Map.
- 8 **CLEAR CONTACT.** Click to create a new deployment record.
- 9 **Lesion shadows.** Use the slider to modify the visibility of lesion shadows.
- 10 **Labels.** Click to show or hide labels.
- 11 **Compass markers.** Click to show or hide compass markers.
- 12 **Note.** Click to open the note dialog box.
- 13 **Mapping view options.** Click to open the dialog box for access to panel view options.
- 14 **Global tool palette.** Click to open tools for mapping, labels and marks, ablation, electrograms, and stimulation.

4.2.3 Electrograms panel

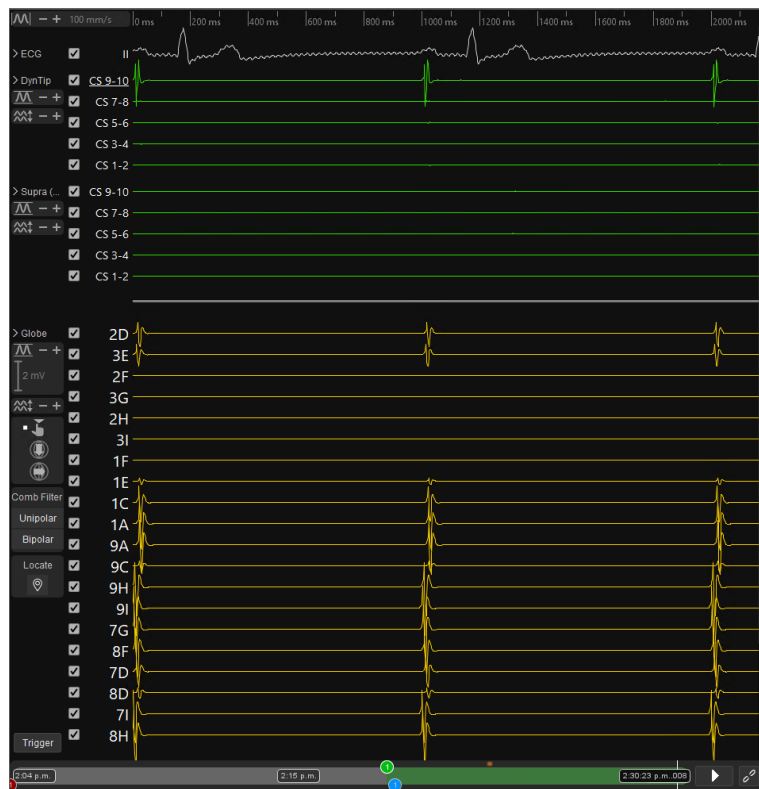
The Electrograms panel displays:

- Intracardiac electrograms measured by the electrodes on the Globe Catheter.
- ECGs measured by the surface electrodes connected to the ECG cable.
- Signals from the reference catheter and optional diagnostic catheter.

Use the Electrograms panel also to select the range for WAVE, Voltage, and LAT maps.

For more information on the Electrograms panel, see *Electrograms* on page 59.

Figure 14: Electrograms panel



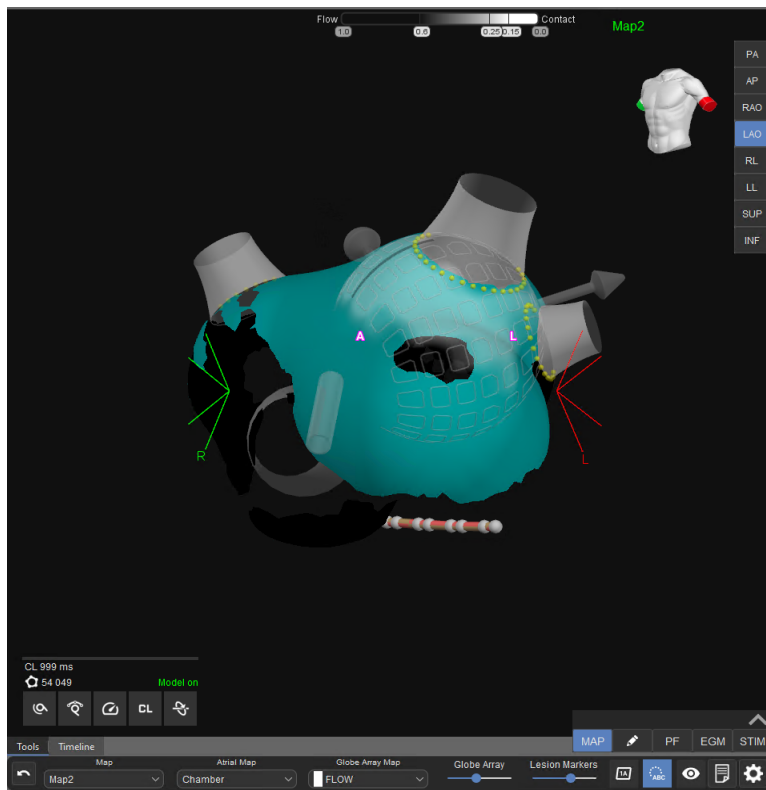
4.2.4 GPS panel

The GPS panel is used to:

- Create a model of the atrium.
- Display the position and orientation of the array relative to the patient.
- Display electrophysiological information on the model of the atrium and on the Globe model.
- Import a CT model of the patient's left atrium and superimpose it on the GPS model of the atrium.

For information on the GPS panel, see *Globe Positioning System (GPS)* on page 91.

Figure 15: GPS panel



4.3 Global tool palette

Use the **Global tool palette** to access tools for mapping, labels and marks, ablation, electrograms, and stimulation.

Table 10: Global tool palette functions

Tool	Function
MAP	Manage map and model functions.
	Create and modify labels and marks.
PF	Select electrodes for PF ablation.
EGM	Select electrodes and locate their associated electrograms on the Electrograms panel.
STIM	Select electrodes for the delivery of stimulation pulses.

4.4 Globe model

The Globe model visible on the Array panel represents the array deployed inside the left atrium. The model shows the relative size and position of the array's electrodes.

4.4.1 Electrode labels

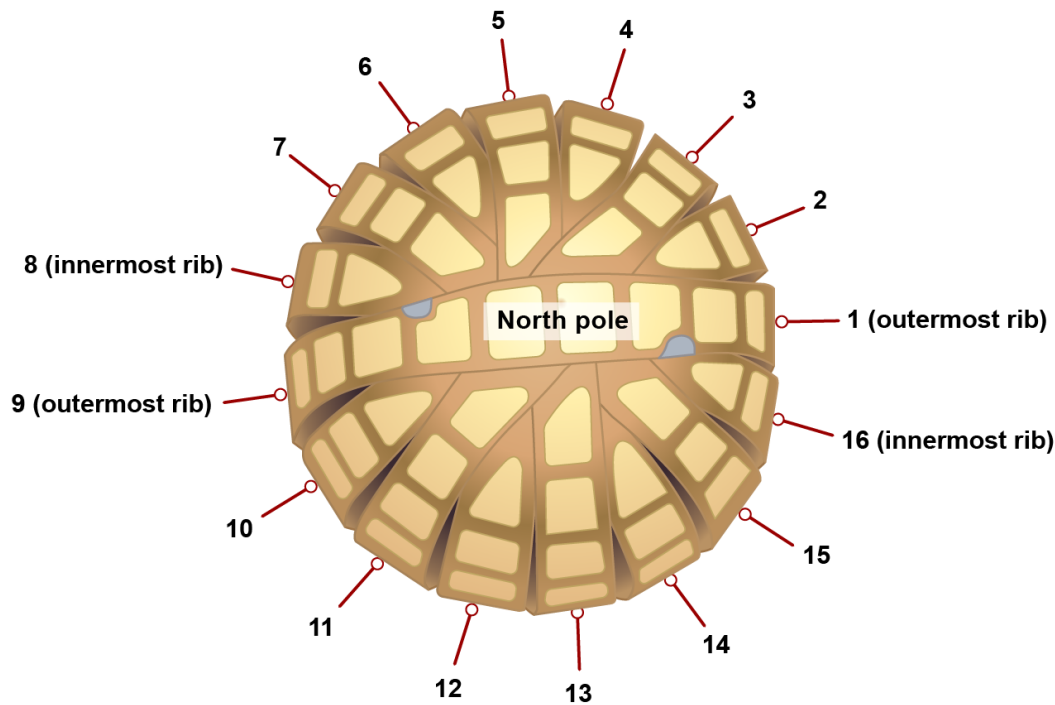
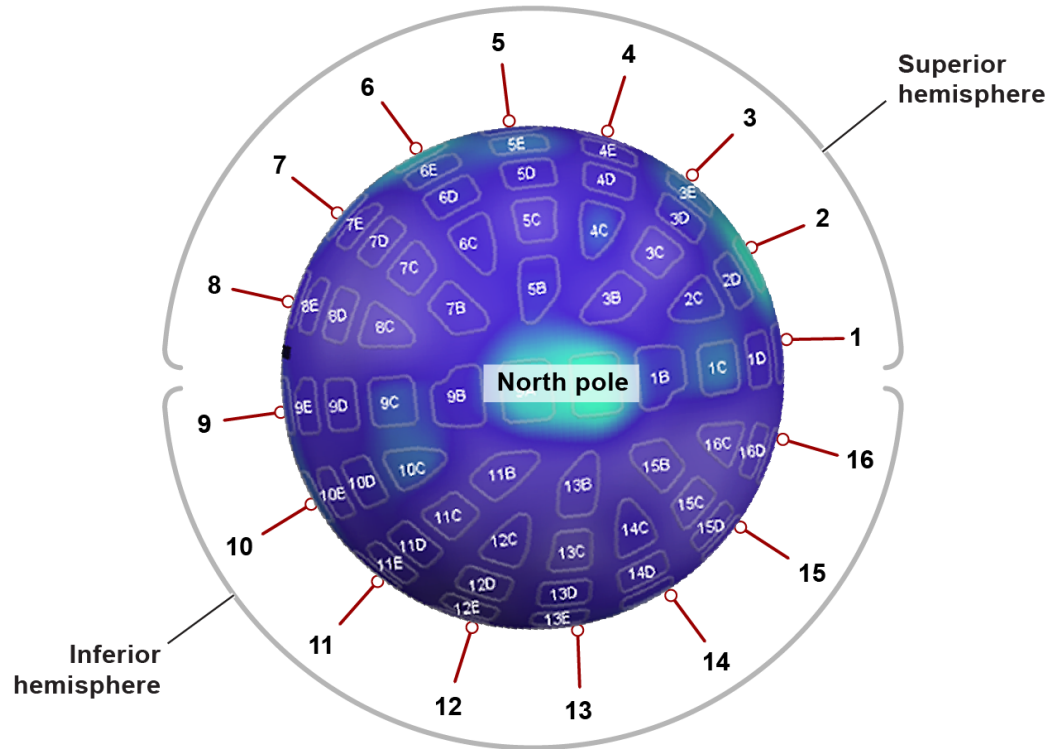
Each electrode is identified by a number followed by a letter, for example 1A or 12D.

- The number indicates the rib on which the electrode is located.
- Electrodes on ribs 1 to 8 are located on the superior hemisphere of the array.
- Electrodes on ribs 9 to 16 are located on the inferior hemisphere of the array.
- The letter indicates the position of the electrode along the rib. Electrode letters are ordered alphabetically from the north pole (A) to the south pole (I).
- The south pole is at the shaft end and the north pole is at the opposite end (electrodes 1A and 9A).

One mechanical rib of the array corresponds to two separate rib numbers on the Globe model. For example, the outermost rib of the mechanical array corresponds to ribs 1 and 9 on the Globe model displayed on the screen.

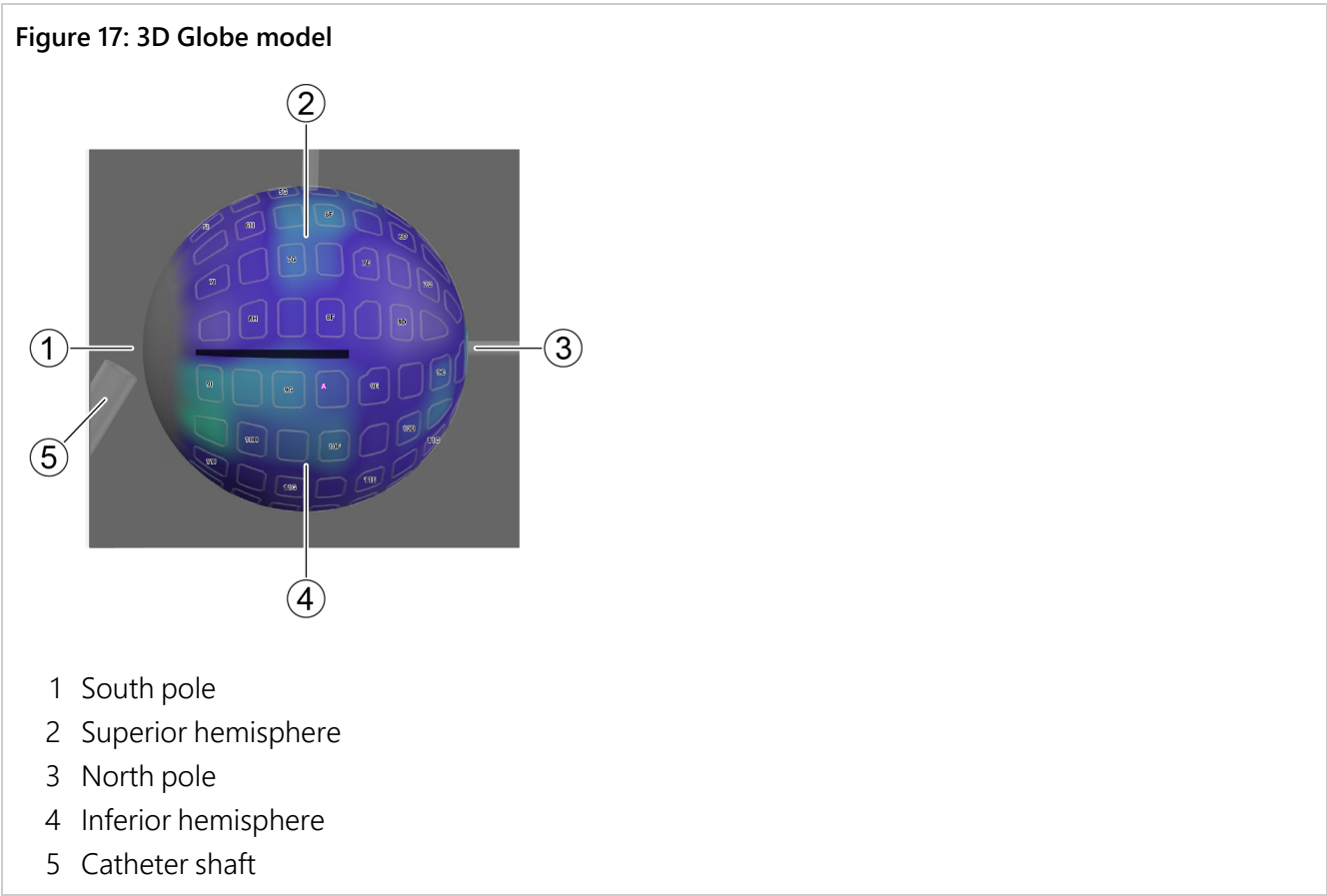
The default orientation of the Globe model corresponds to the array's nominal position for access to the left pulmonary veins. In the default orientation, ribs 8 and 9 point toward the anterior side of the patient.

Figure 16: Globe model



4.4.2 3D Globe model

The 3D Globe model is a spherical representation of the Globe Catheter’s array.



To access the commands for the Globe model on the Array panel, click  and then click the **General** tab. See the following table for more information. For display information for the GPS panel, see *Globe model* on page 93.

Table 11: Commands for the 3D Globe model

Task	Steps
Rotate the Globe model	Hold down the middle mouse button and drag the model.
Rotate the Globe model around an axis perpendicular to the screen	Hold down the  key and drag the model with the middle mouse button.

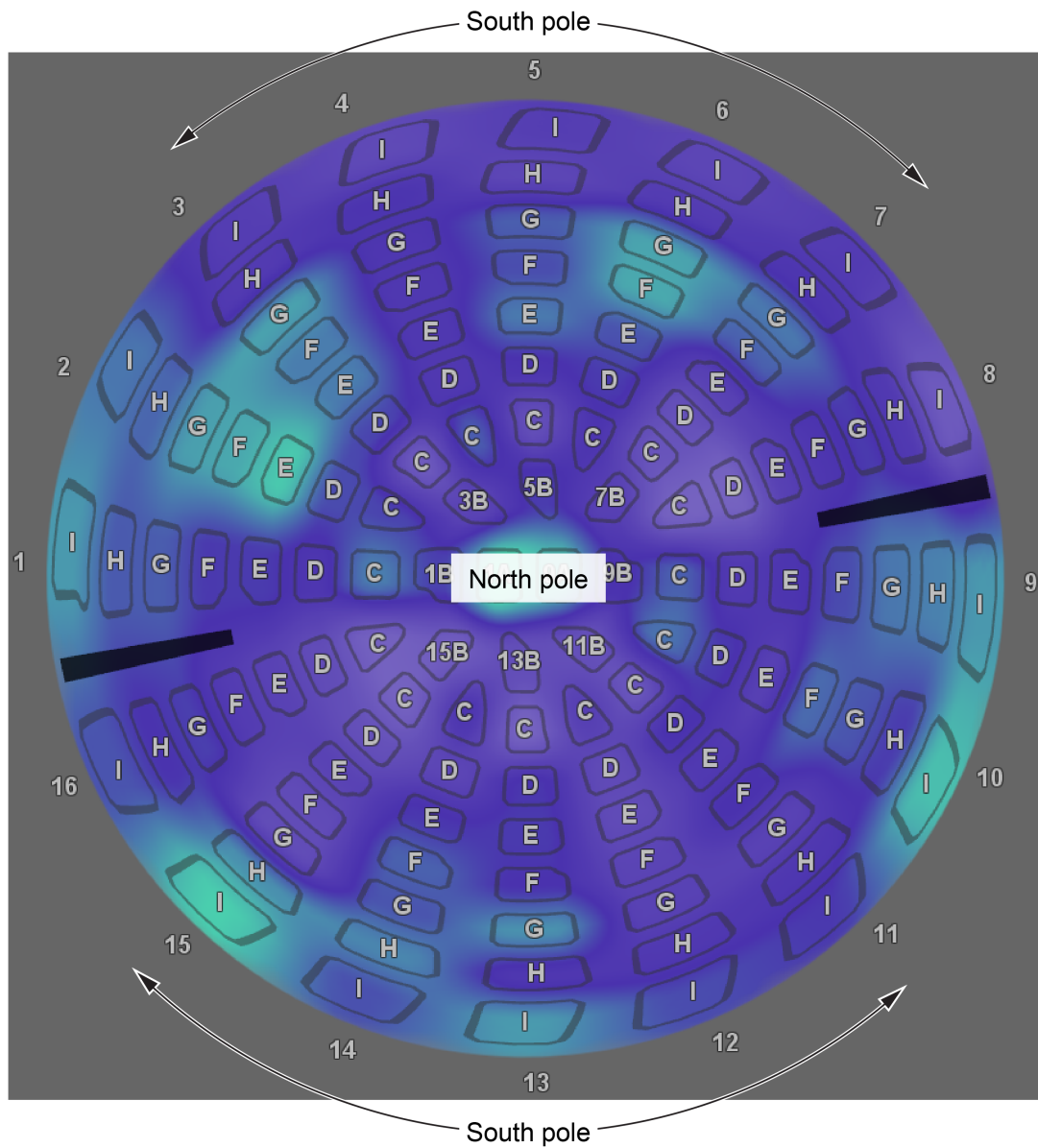
Task	Steps
Change the orientation indicator	A small black and white model of the catheter's array at the top right of the 3D map indicates the orientation of the array model. The dark electrodes correspond to the inferior hemisphere of the array, which contains the electrodes located on the distal ribs. The white electrodes correspond to the superior hemisphere of the array. An arrow pointing toward the inferior hemisphere of the array indicates the orientation. To select the indicator, click  and in the General tab select an option from the 3D Orientation Model dropdown list. 
Orient the model in one of the standard views	Click one of the preset view buttons in the upper right corner of the GPS panel. These views apply only when using the GPS because the Array panel provides an arbitrary view of the array, whereas the GPS panel provides a view of the array using the patient's body as a frame of reference. For information on the GPS, see <i>Globe Positioning System (GPS)</i> on page 91.
Change the size of the Globe model	Adjust the zoom slider or hold down the Shift key and use the scroll wheel.
Show both sides of the Globe model	Select Stacked .
Orient the Globe model in the same direction in all GPS and Array panels	Select Synchronize 3D view angle on each panel to synchronize.

4.4.3 2D Globe model

The 2D Globe model can be viewed either as a radial, Cassini, or Mercator projection.

Click  and on the **General** tab, select a 2D projection, or right-click in the panel and select a 2D projection.

Figure 18: Radial projection



The Cassini projection can be centered on the north pole, the south pole, or any electrode selected by the user.

Figure 19: 2D Cassini projections: North Polar, South Polar, and centered on electrode

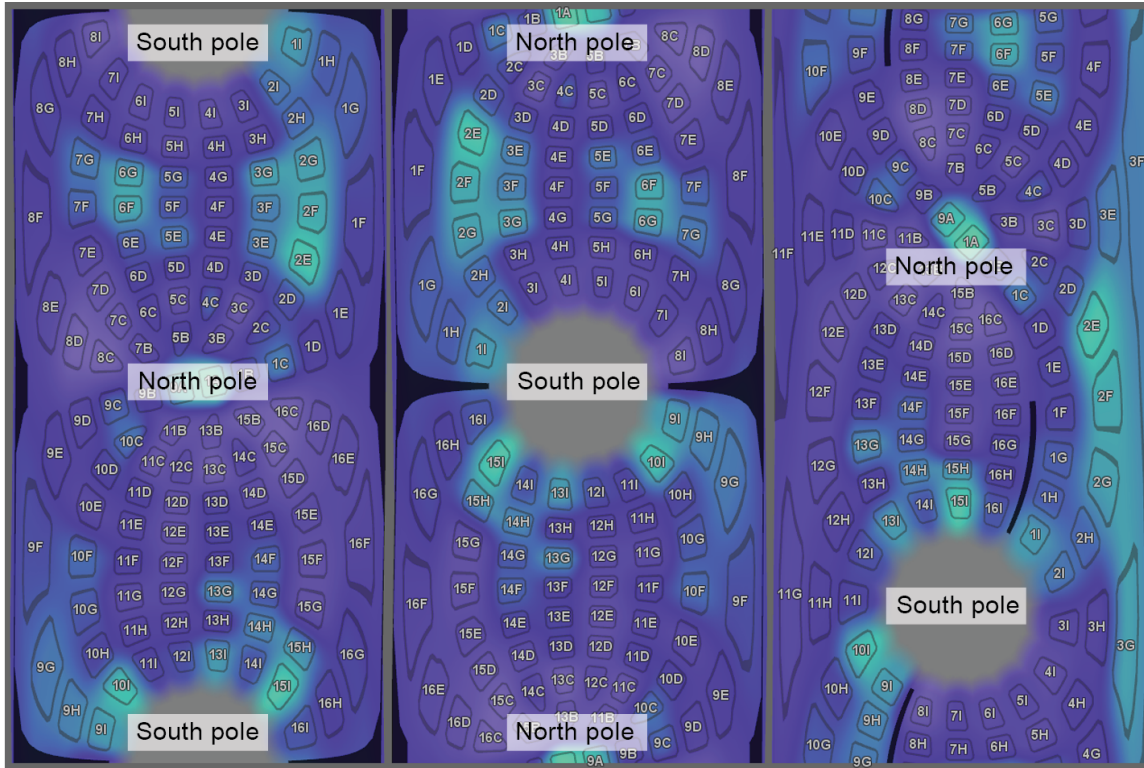


Figure 20: Mercator projection

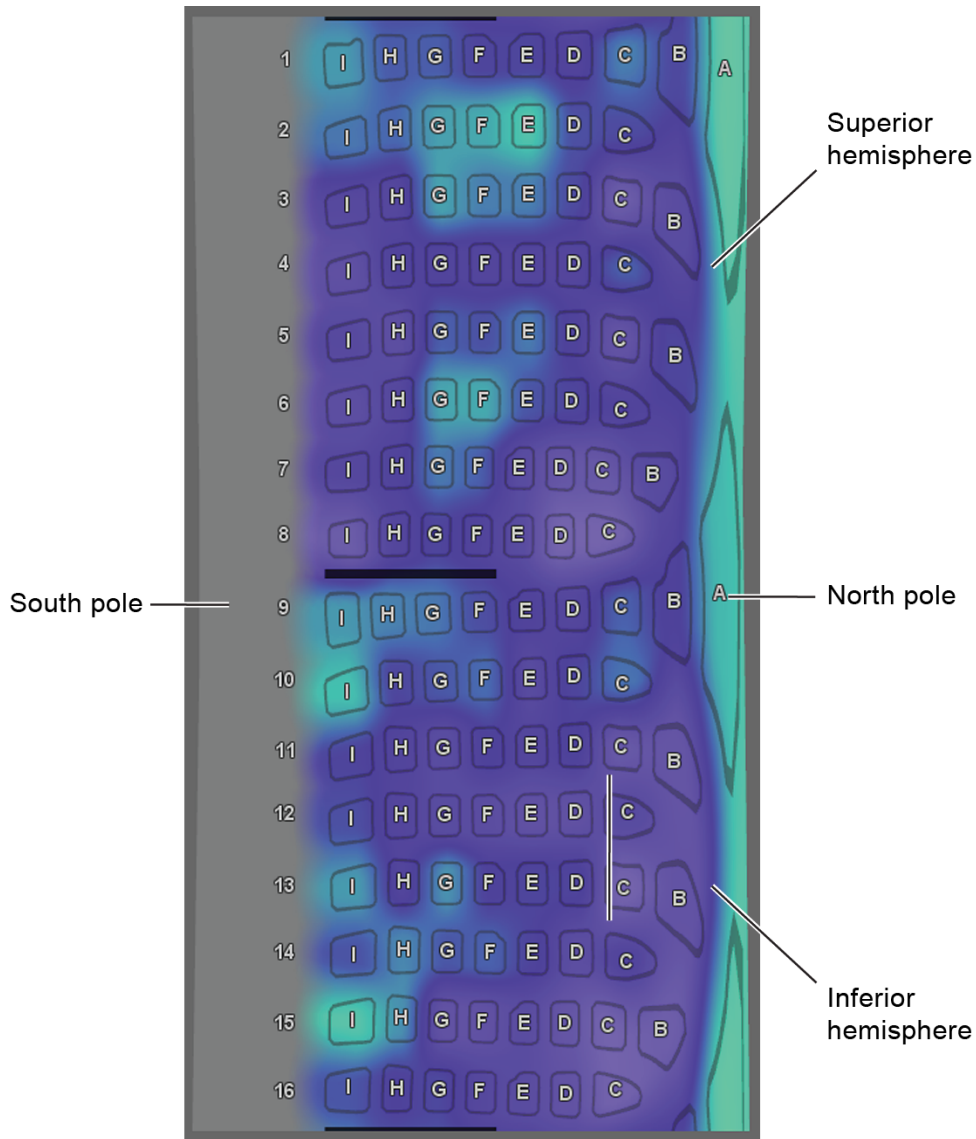


Table 12: Commands for the 2D Cassini and Mercator projections

Task	Steps
Center the Cassini projection on the north pole	Click  , and in the General tab, click Cassini North Polar , or right-click in the panel and select Cassini North Polar . This is the default setting.

Task	Steps
Center the Cassini projection on the south pole	Click  , and in the General tab, click Cassini South Polar , or right-click in the panel and select Cassini South Polar .
Center the Cassini or Mercator projection on an electrode	Right-click the electrode in the Globe model and select 2D polar projection centered on .
Shift the Cassini or Mercator projection	Click  , and in the General tab, move the Projection shift slider.
Zoom the Cassini or Mercator projection	Hold down the Shift key and scroll up and down with the mouse wheel.
Tilt the Cassini or Mercator projection	Click  , and in the General tab, move the Projection electrode tilt slider.

4.4.4 Electrode display and selection

The model shows the relative size and position of the array's electrodes.

To access the display commands for the Array panel, click  and then click the **Globe Array Map Details** tab. See the following table for more information. For display information for the GPS panel, see *Globe model* on page 93.

Table 13: Electrode display commands

Task	Steps
Hide or show the electrodes	Clear or select Show electrodes and segments .
Select a single electrode or segment	Click the electrode or segment.
Hide or show electrode labels	Clear or select Show electrode labels .
Change the display of the electrode labels	Adjust the case, size, style, density, and color of the labels.

Task	Steps
Use the same electrode display settings in all panels	Click Synchronize .
Hide maps	Clear Show surface map .

4.4.5 Electrode color

The electrode color indicates the state of the electrode and tissue. The smaller fill indicates selection and ablation state (for example, selected, pending, ablating) and the larger fill indicates tissue state (ablated, failed). The example below (a smaller bright green fill overlapping a larger pink fill) indicates that a PF ablation has already occurred at that electrode and that the electrode is selected for more pulsing.

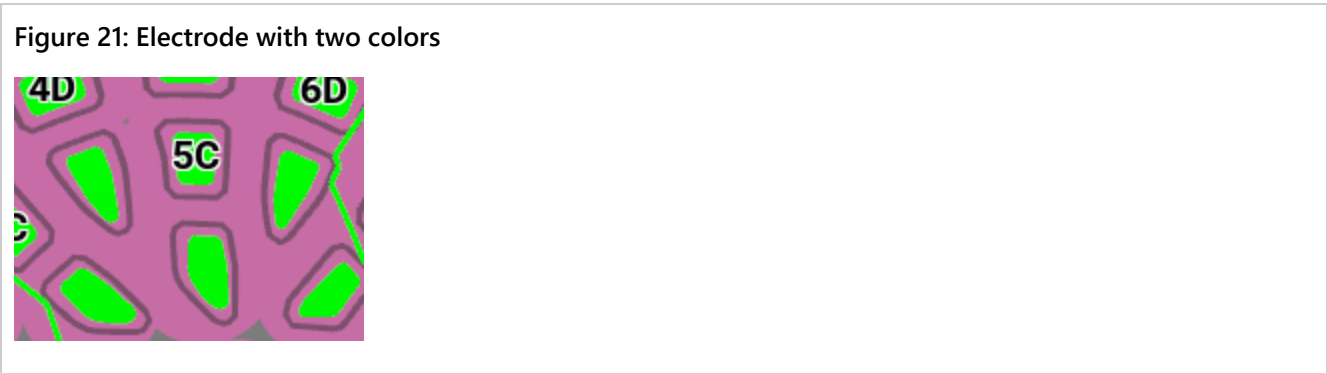


Table 14: Electrode legend

Display	Meaning
	Dotted outline. Electrode selected in the Electrograms panel.
	Animated black and white outline. Electrode located in the Electrograms panel.
	Bright green. Paired electrode selected for PF ablation.
	Bright orange. Unpaired electrode selected for PF ablation.

Display	Meaning
	Pink. Lesion from PF ablation.
	Striped yellow pattern. Ablation terminated unexpectedly or failed to start.
	Purple fill. Electrode selected for stimulation.
	Pulsating purple fill. Stimulation is in progress.
	Cross ("X"). Disabled electrode for mapping.
	Overlapped rings. Regions of low impedance indicative of electrode overlap.
	Single ring ("O"). Open circuit error.

4.5 Orientation and navigation tools

Orientation indicators facilitate understanding the orientation and navigation of the Globe array. The following orientation indicators are available in the Globe Software.

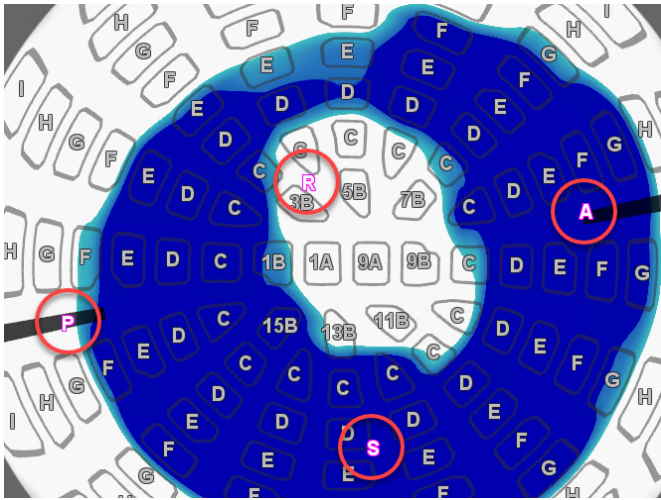
4.5.1 Compass markers

Compass markers indicate the orientation of the array. There are six markers:

- P—posterior
- A—anterior
- S—superior
- I—inferior
- L—left
- R—right

In the following figure, P indicates that the most posterior part of the array is located near 1G and 16G. The anterior part of the array is located near 8F and 9F, indicated by the location of A.

Figure 22: Compass markers



Compass markers are available on 2D and 3D projections.

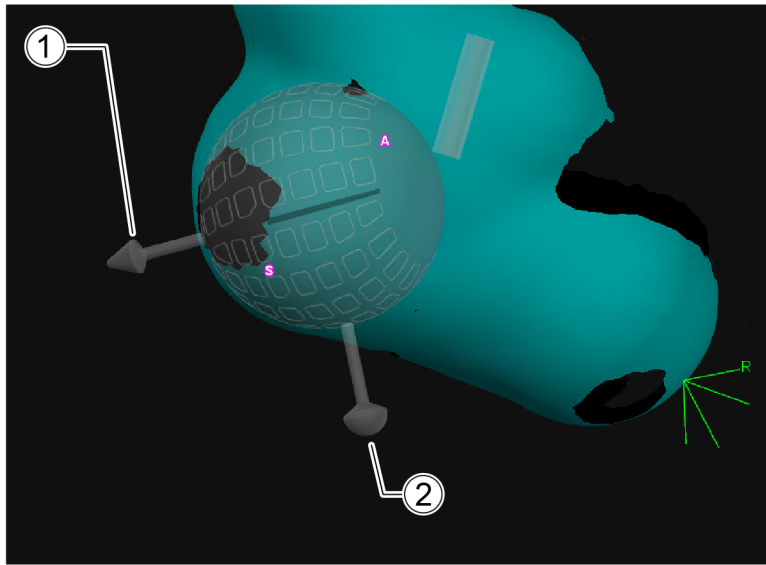
To turn off the compass markers, click  located in the Array panel. To turn off specific compass markers, right-click  and clear the desired markers.

4.5.2 Orientation arrows

You can apply the north pole arrow and superior hemisphere arrow to the Globe model in the GPS panel.

- The north pole arrow projects from the north pole of the array.
- The superior hemisphere arrow projects from the superior hemisphere of the array.

Figure 23: Orientation arrows



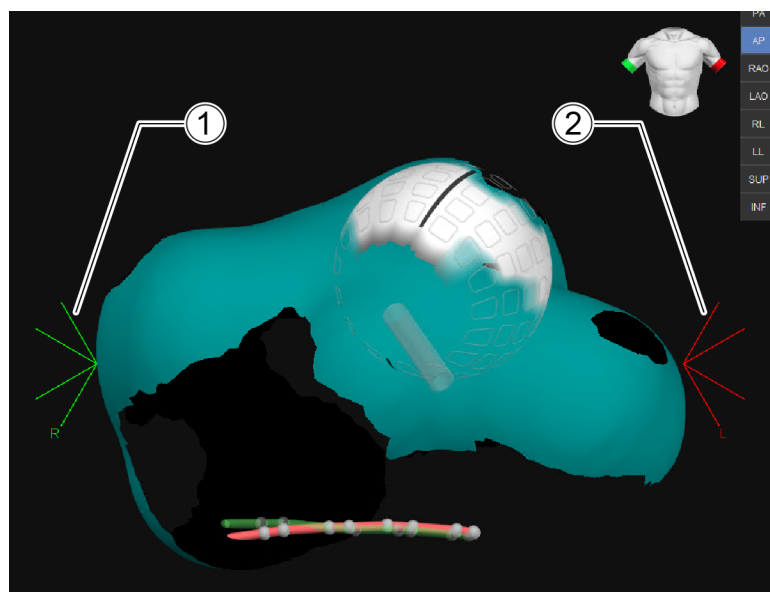
- 1 North pole arrow
- 2 Superior hemisphere arrow

To apply the arrows, click  and on the **Globe Array Map Details** tab, select the **Show north pole arrow** and **Show superior hemisphere arrow** check boxes; click **OK**. Alternatively, click  on the GPS panel and select **Show north pole arrow** and **Show superior hemisphere arrow**.

4.5.3 Bilateral orientation indicators

The bilateral orientation indicators shows the location of the patient's left and right sides on the atrial model.

Figure 24: Bilateral orientation indicators



- 1 Right bilateral orientation indicator
- 2 Left bilateral orientation indicator

To turn off the bilateral orientation indicators, click  and under the **General** tab, clear the **Render Bilateral Orientation Indicator** checkbox. Alternatively, click  and deselect **Bilateral Orientation Indicator**.

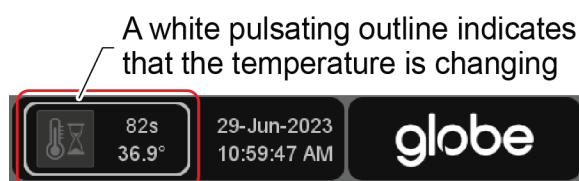
4.6 Calibration temperature

You can connect an optional temperature calibration probe to the controller. The temperature measured by the temperature calibration probe is indicated at the top of the screen.

You can check the calibration temperature measurement to confirm that the temperature value displayed on the screen corresponds to the patient's core temperature. To check the calibration temperature, click . The Globe PF System uses the temperature measured by the temperature calibration probe to ensure that a resistance temperature detector calibration has been done recently enough prior to a CONTACT scan to ensure that it is valid.

A red outline indicates a temperature error. The border around the temperature indicator changes to white and a calibration countdown is displayed if the software detects temperature fluctuations.

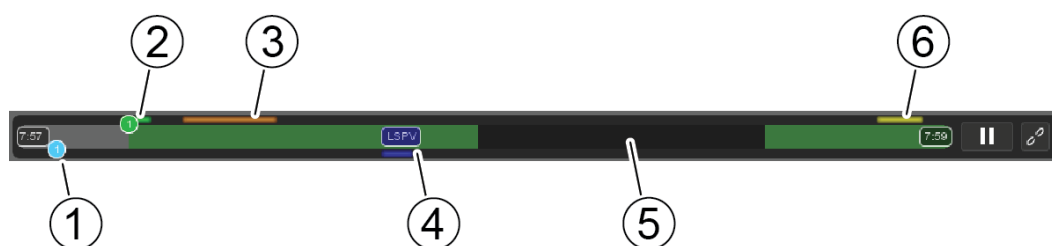
Figure 25: Temperature measurement stabilizing



4.7 Procedure timeline

The procedure timeline at the bottom of the screen indicates the timing of key procedure events.

Figure 26: Procedure timeline markers



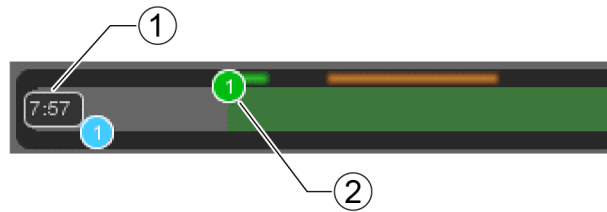
- 1  **Map range creation.** See *Map range* on page 85.
- 2  **New position record.** See *New position* on the next page. The thick green bar inside the timeline starts at the most recent position record.
- 3  **CONTACT Map.** See *CONTACT Map* on page 82.
- 4  **Procedure note.** See *Procedure notes* on page 57.
- 5  **Globe Catheter is disconnected from Globe Controller.** For example, during PF ablation. See *PF ablation* on page 109.
- 6  **Stimulation.** See *Stimulation* on page 115.

To switch between real-time mode and review mode, use the play/pause button at the right of the timeline:

- To review data recorded earlier in the procedure, click  and move the time cursor inside the timeline.
- To switch the timeline back to real-time mode, click .

At the beginning of the procedure, the start of the timeline coincides with the start of the procedure. After the catheter is connected, the start time changes to the connection time.

Figure 27: Procedure start on timeline



- 1 Procedure start
- 2 Catheter connected to controller

You can manually change the start of the timeline in the Procedure Information tab. For more information, see *Enter patient information* on page 119.

To synchronize the timeline on a panel with the timeline on other panels, click  and then on the **General** tab select **Synchronize timeline**.

Table 15: Timeline keyboard shortcuts

Action	Shortcut
Toggle review mode	
Move to beginning of timeline	
Move to end of timeline	
- 10 seconds	
+10 seconds	
- 1 second	
+ 1 second	
- 0.1 seconds	
+ 0.1 seconds	

4.8 New position

To indicate a new deployment or repositioning of the array, click **CLEAR CONTACT** on the Array panel.

Numbered green circles on the timeline indicate the recording of each new position record. The thick green bar inside the timeline starts at the most recent position record. The first record is created automatically.

Figure 28: Position records on procedure timeline



4.9 Labels

You can apply labels to the Globe array in the Array panel. Labels are used, for example, to indicate the position of atrial features. To open the Labels toolbar to add and modify annotations, click the **Pencil** icon on the **Global tool palette**.



Labels can be a mark, a set of marks, marks and text, or just text.

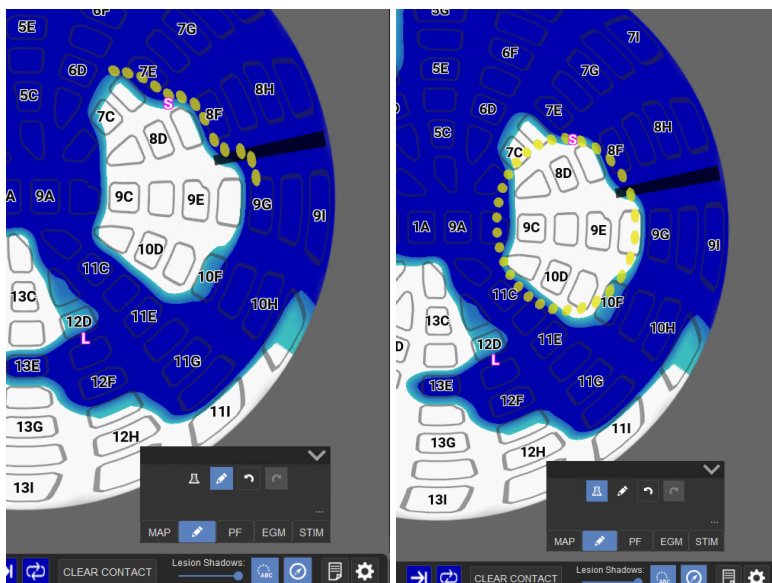
As the array is repositioned farther away from a given label, the visibility of the posted labels on the array map is diminished or nonexistent.

Table 16: Common label commands

Task	Steps
Hide or show labels	In the Array panel or GPS panel, click  to hide or show all labels. In the GPS panel, click  and in the Labels and Marks tab, select or clear Show for each note.
Free-form labels	Click  and drag the mouse to create the label.
Add a vein label	Click  and click on an edge of a vein and drag the mouse to create a circular label around a vein.
Change mark size	Click the up or down arrows in the Marks field, before adding a mark.
Change mark color	Use the color picker  .
Add text	Right-click on the array map and choose one of the options.

Task	Steps
Change text size	Click one of the three text size buttons, before adding the text. 
Undo	Press Ctrl + Z or click  .
Delete labels	Click  and in the Labels and Marks tab, click  next to the label to be deleted.

Figure 29: Free-form label (left) and vein label (right)



4.10 Procedure notes

You can attach notes about the procedure at specific points on the procedure timeline, either during the live procedure or during offline reviews. Notes are shown as a blue rectangle on the procedure timeline.



CAUTION

Do not enter personal data in procedure notes.

Figure 30: Procedure notes on timeline



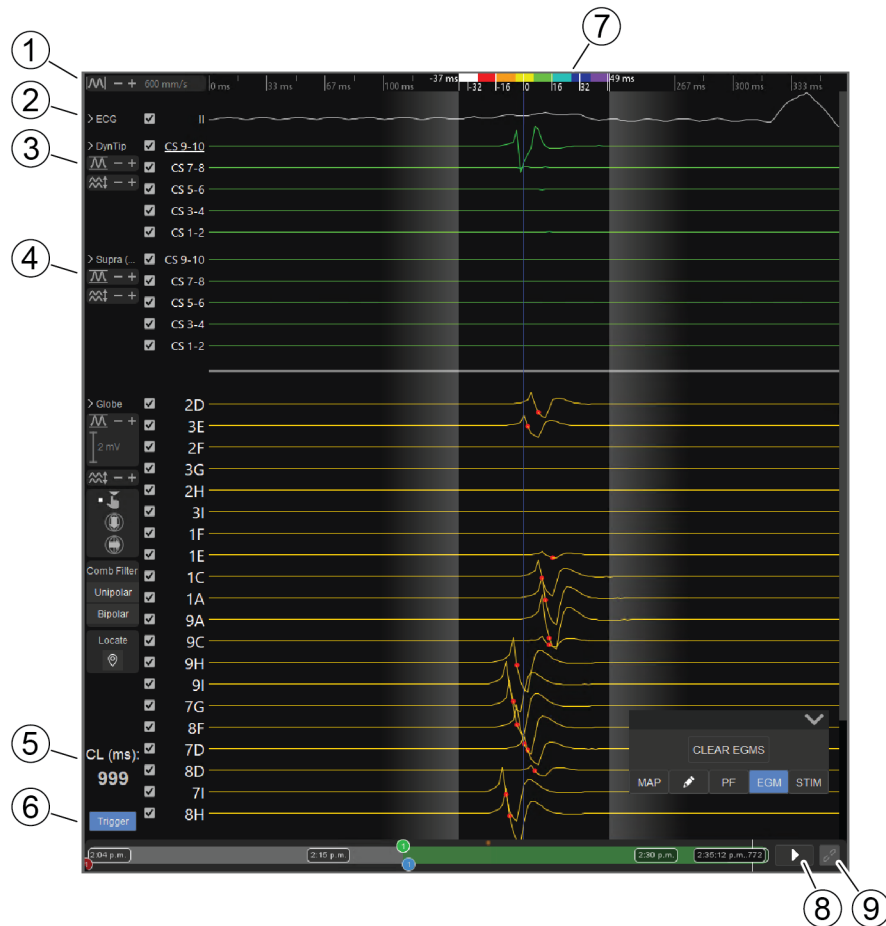
Table 17: Procedure notes

Task	Steps
Create a note	1. Click . 2. Enter text at the cursor. 3. Click OK.
Show the note text on the timeline	1. Click . 2. Click Show note text on timeline.
Modify notes	1. Click . 2. Click Show note list. 3. Click the note to open it. 4. Click . 5. Change the text or duration. 6. Click OK. Notes created during an offline procedure review or live procedure can be edited.
Delete notes	1. Click . 2. Click Show note list. 3. Click the note to open it. 4. Click Delete.

5 Electrograms

The Electrograms panel displays the electrograms measured by the Globe Catheter and the auxiliary catheters as well as the ECGs measured by the electrodes connected to the ECG cable.

Figure 31: Electrograms panel



- 1 Sweep speed for all waveforms
- 2 Signals from the ECG electrodes connected to the ECG cable
- 3 Signals from the auxiliary catheters
- 4 Signals from the Globe Catheter
- 5 Cycle length
- 6 Trigger mode button
- 7 WAVE, LAT, and Voltage Map range selector (the range selector is not visible in real-time mode)
- 8 Play/pause button to switch between review mode and real-time mode
- 9 Timeline synchronization button

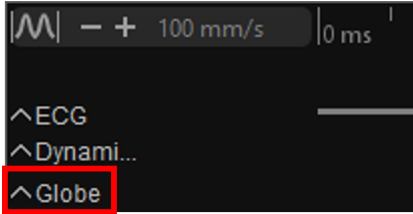
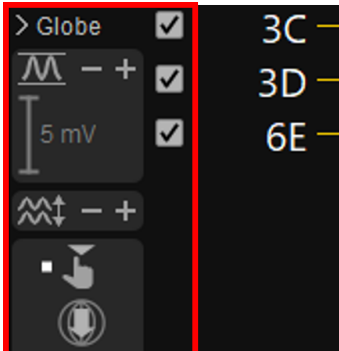
The fixed top section of the panel contains the reference waveforms (ECGs and auxiliary catheters). The scrollable bottom section contains the Globe electrograms. The electrograms can be displayed according to user preference.

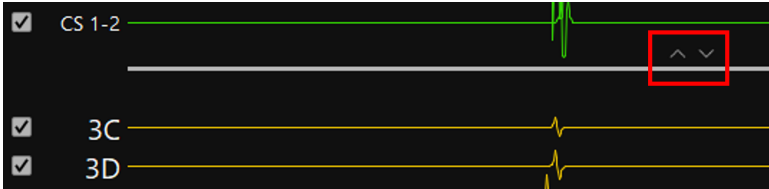
5.1 Common commands

The following table describes the commands common to all waveforms displayed on the Electrograms panel. See also the section on Electrograms panel shortcuts in *Application hotkeys* on page 169. For commands specific to the electrograms measured by the Globe Catheter, see *Globe Catheter electrograms* on page 64.

Table 18: Common commands for the Electrograms panel

Task	Steps
Adjust the sweep speed 	- Click  and  next to the sweep speed icon at the top of the panel to adjust the sweep speed between 10 mm/s and 600 mm/s. The default is 100 mm/s. - Click  to revert to the default value.
Expand a type to display all waveforms within a given type	Click the arrow next to the type's name so that it points downward. The selected waveforms are at the top. 

Task	Steps
Hide all waveforms within a given type	Click the arrow next to the type's name so that it points upward. 
Display a subset of waveforms within a given type	Click the arrow next to the type's name so that it points to the right. Only selected waveforms (those with a check mark) are shown. 
Select waveforms	To select waveforms, expand the waveform's type to display all waveforms and select the checkbox next to the waveform.
Remove waveforms	To remove waveforms, clear the checkbox.
Change the spacing above each type of waveform	Hold down the Alt key. Then, click the label of the first waveform within a type with the left mouse button, and drag the waveform up or down.

Task	Steps
Adjust the gain 	- Click + and — next to the gain icon in each type of waveforms to adjust the gain between 10 mm/0.05 mV and 10 mm/1000 mV. - Click  to return to the default value. Default gain: - ECGs: 10 mm/1 mV - Auxiliary catheters: 10 mm/ 2mV - Globe Catheter: 10 mm/5 mV If the  icon is not visible, expand the type.
Change the spacing between waveforms within a type 	- Click + and — next to the spacing icon . - Click  to go back to the default value. If the  spacing icon is not visible, expand the type.
Change the spacing below the reference waveforms or below the Globe Catheter waveforms 	Drag the thick line at the bottom or use the up and down arrows above the line. 

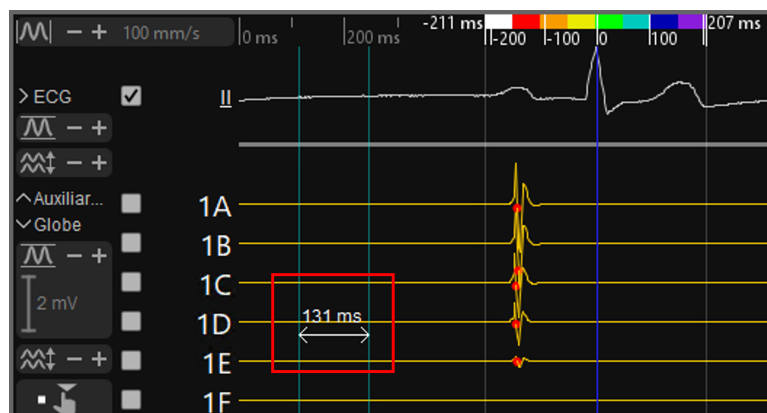
Task	Steps
------	-------

Place a time reference marker and measure a time interval

- To place a marker for a time reference, for instance to indicate the earliest activation time, put the timeline in review mode, hold down the **Ctrl** key, and click the panel.



- To adjust the position of the time reference marker, click and drag the marker left or right.
- To remove the time reference marker, right-click the line, and then select **Delete**.
- To measure a time interval, hold down the **Ctrl** key, click the panel, and then drag to display a second line. The duration is shown in milliseconds.



- To adjust the position of the measurement label, click and drag the label up or down.
- To adjust the time interval, click and drag the lines.
- To move the time measurement without changing the relative spacing of its endpoints, drag the label while holding down the middle mouse button.
- To remove the measurement marker, select it, right-click, and then select **Delete**.
- To change a time reference marker into a time interval, click the marker and then hold down the **Ctrl** key while you drag the marker to the right to split it into two lines.

Task	Steps
	To change a time interval into a time reference marker, drag the two lines together.
Place a voltage measurement	To measure the voltage difference between two points on a waveform, put the timeline in review mode and then press Alt and click the waveform.  The minimum and maximum markers are placed at the minimum and maximum voltage values within 100 ms to the right of the mouse-click point. To adjust the measurement, click and then drag the voltage markers. To delete a voltage measurement, right-click the measurement label and select Delete.

5.2 Globe Catheter electrograms

The electrodes on the Globe Catheter measure unipolar and bipolar electrograms:

- Unipolar electrograms are recorded relative to a common reference (the neutral electrode).
- Bipolar electrograms are recorded between any two adjacent electrodes on the array.

To apply filters to the electrograms signals, see *Filters* on page 75.

Signals common to all electrodes (for example, far field signals or electrical noise) are removed from the unipolar waveforms.

The color of each waveform depends on whether the electrogram is unipolar or bipolar, and whether the electrode is considered to be inside or outside an enclosed ablation path.

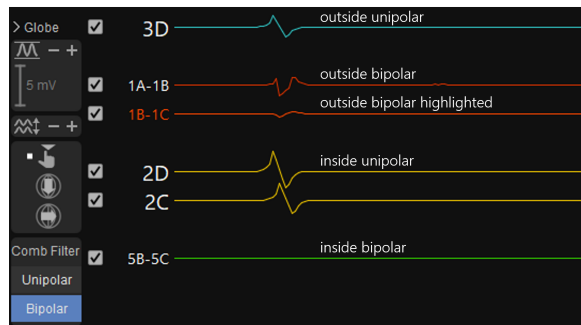
By default, all waveforms are designated as "Inside" an ablation path. To designate a waveform as "Outside", right-click a waveform electrode label and select **Outside**.

Outside unipolar: **Cyan**

Outside bipolar: **Orange**

Inside unipolar: Yellow
 Inside bipolar: Green

Figure 32: Color of Globe Catheter electrograms

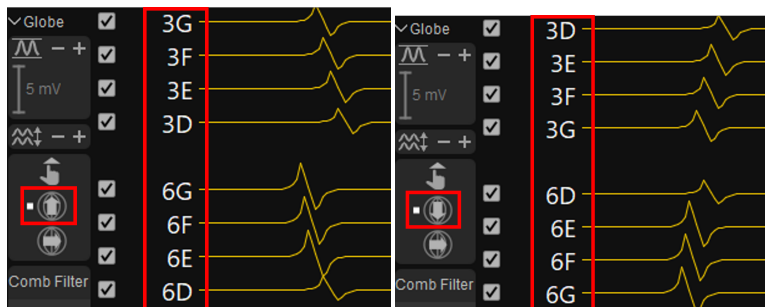
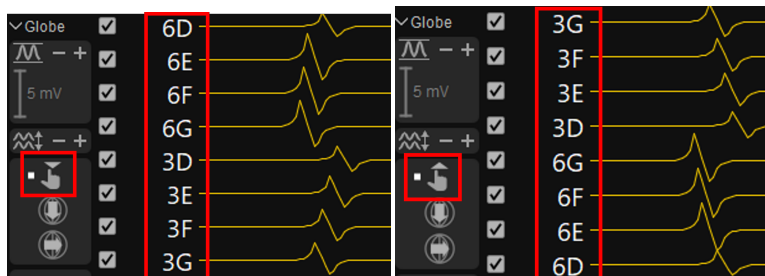


The following table describes the commands for the Globe electrograms displayed on the Electrograms panel. See also the section on Electrograms panel shortcuts in *Application hotkeys* on page 169.

Table 19: Commands for Globe Catheter electrograms

Task	Steps
Change unipolar or bipolar electrogram display	By default, unipolar electrograms and bipolar electrograms both appear on the panel and unipolar electrograms are listed at the top. To change the displayed electrograms, right-click the panel and choose one of: • Show Unipolar and Bipolar Globe Electrograms • Show only Unipolar Globe Electrograms • Show only Bipolar Globe Electrograms To change the order, right-click the panel and choose one of: • Alternate Unipolar and Bipolar Electrograms • List Unipolar Electrograms First • List Bipolar Electrograms First
Indicate the position of the electrode relative to an enclosed ablation path	Right-click the label of a waveform and select either Inside or Outside. Waveforms for Outside electrodes appear above those for Inside electrodes. To select or deselect multiple electrodes, press Ctrl.

Task	Steps
Locate corresponding electrodes on Globe model	Click the label of a waveform, then click  to animate the corresponding electrode on the Array and GPS panels. To select multiple electrodes, press Ctrl .
Move electrograms	Press the left mouse button and drag the waveform label up or down. To move several electrograms, press Ctrl or Alt , select the waveforms, and drag them up or down.
Sort selected electrograms by user order	Click  to display the electrograms in the order in which they were selected. Click  to reverse the order.
 	
Group electrograms by rib (column)	Click  or  to group the electrograms by rib number. The direction of the arrow indicates the sorting order by rib column number (ascending or descending). Ribs 1 to 8 are on the superior hemisphere and ribs 9 to 16 are on the inferior hemisphere.
 	

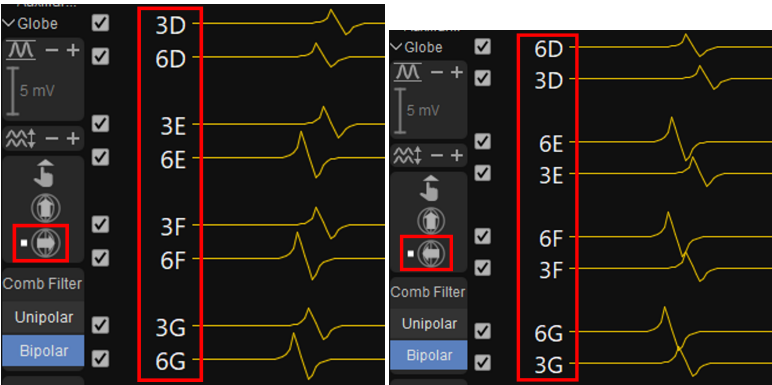


Task	Steps
------	-------

Group electrograms by row



Click or to group the electrograms by row. The direction of the arrow indicates the sorting order by rib row number (ascending or descending). The row letter indicates the position of the electrode along the rib. Electrode letters increase from the north pole (A) to the south pole (I).



Apply comb filter Under **Comb Filter**, click **Unipolar** or **Bipolar**.

5.2.1 Select and locate electrodes and electrograms

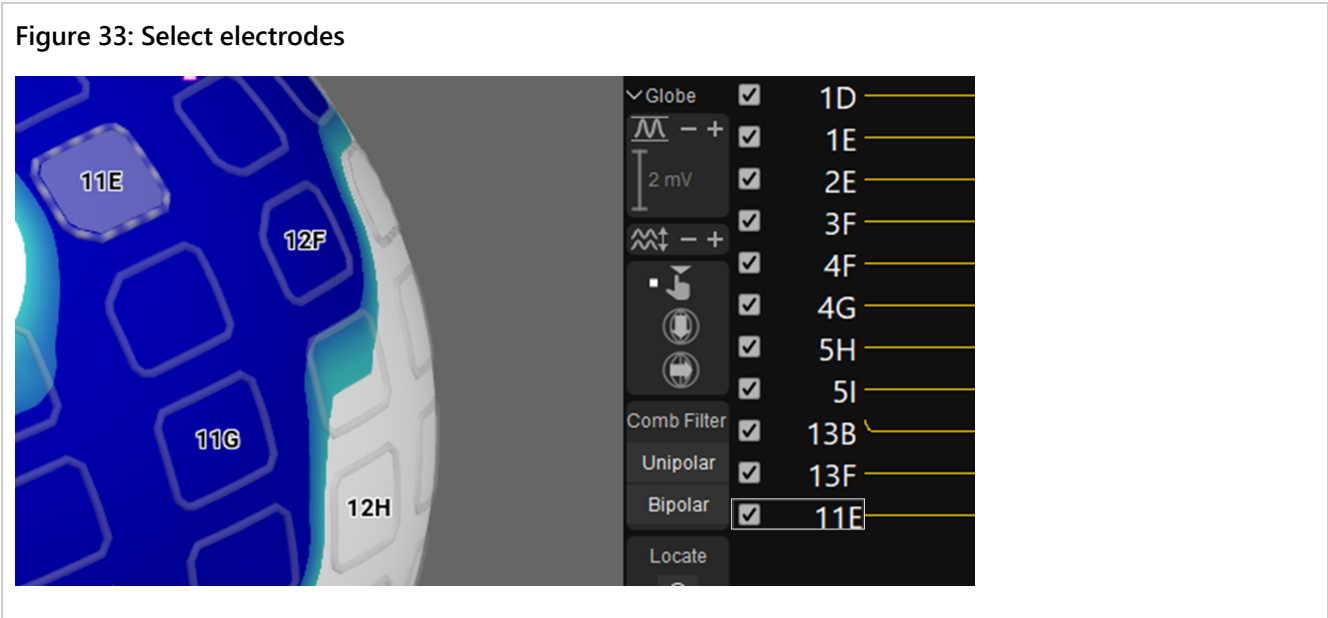
Use the Electrogram tool on the **Global tool palette** to select electrodes and enable their associated electrograms to appear on the Electrograms panel.



The following table describes the commands to select electrograms.

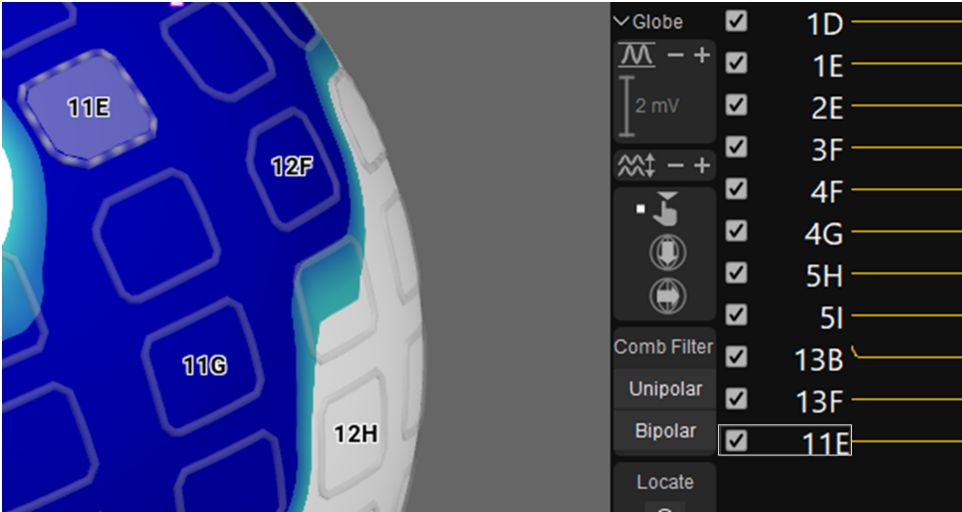
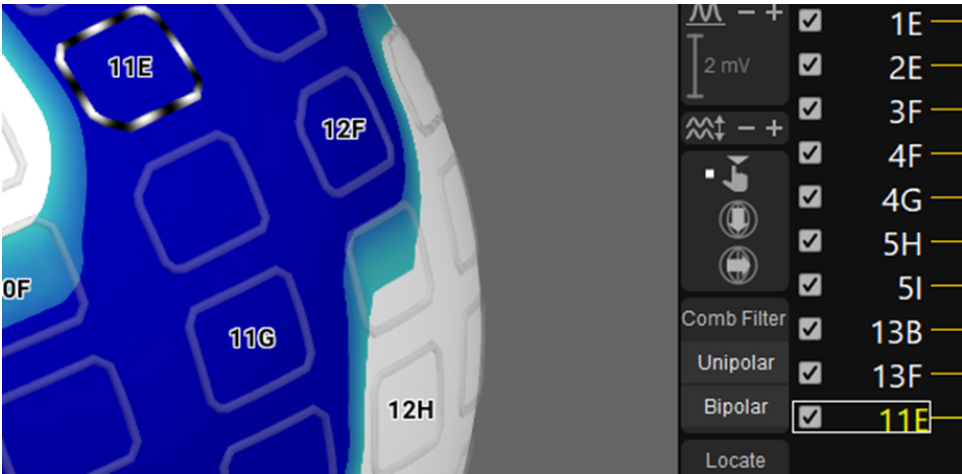
Table 20: Commands for selecting Globe Catheter electrograms

Task	Steps
Select electrograms	On the GPS or Array panel, click EGM and select desired electrodes on the model. Selected electrograms appear at the top of the Electrograms panel. To select electrograms, do one of the following: • Select the checkbox next to the waveform. • Right-click the waveform's label and select Add. • From the Array panel, click the Electrograms tool and then click the electrodes (for unipolar electrograms) or segments (for bipolar electrograms) for which you want to display the electrograms.
Remove electrograms from the selection	To remove a single electrogram, do one of the following: • Clear the checkbox next to the waveform. • Right-click the waveform's label and select Remove. To remove all electrograms, do one of the following: • From the Global tool palette, click EGM and then click CLEAR EGMS. • Right-click the panel and select Clear selected Globe Electrograms.



If the Electrograms tool is not selected, the electrodes and their electrograms can still be located using the methods described in the table below.

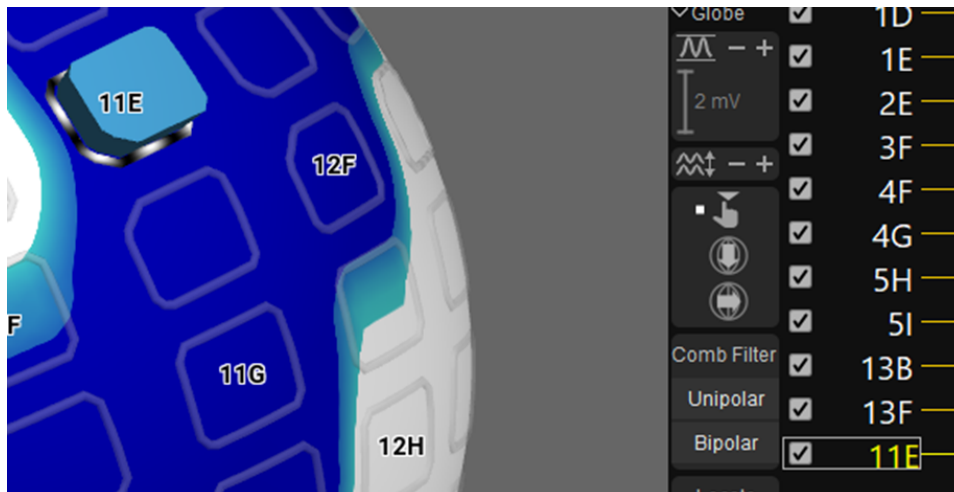
Table 21: Commands for locating Globe Catheter electrograms and electrodes

Task	Steps
Identify an electrogram associated with an electrode	Hover over an electrode. If the electrode is shown in the Electrograms panel, it will be highlighted. 
Identify an electrode associated with an electrogram	Hover over a selected electrogram. The GPS panel displays the associated electrode with a dynamic dashed black outline. 

Task	Steps
------	-------

Use 3D locator to identify an electrode associated with an electrogram

Hover over an electrogram and press the middle mouse button. A 3D locator then pulses outward from the associated electrode in the GPS panel. This function is available on the Array panel only on the 3D model view and in the GPS panel.



Change the settings for the 3D locator

1. Click  on the GPS panel.
2. On the **General** tab, make required changes to the color, height and duration of pulse.

5.3 ECG signals

The Electrograms panel can display twelve standard ECG signals.



NOTE

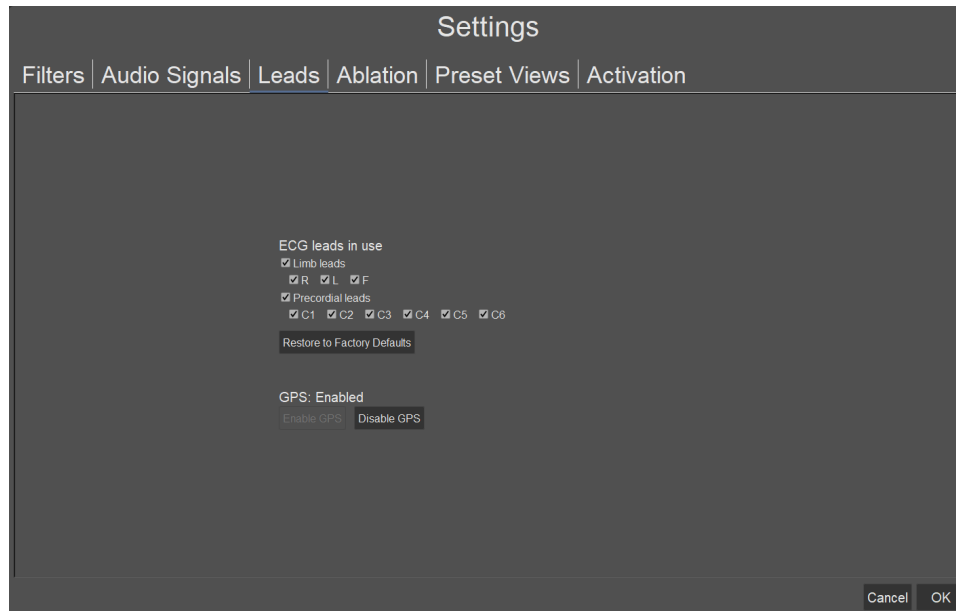
The ECG signals are intended solely for diagnostic purposes directly relating to the Globe procedure, and they are not intended for monitoring vital signs. Use the lab's primary ECG monitoring system for monitoring vital signs.

Lead II is the default reference.

To apply filters to the ECG signals, see *Filters* on page 75.

If you do not connect all ECG electrodes to the ECG cable, change the ECG settings to prevent the “ECG lead-off detected” message for the unconnected leads. Click  and then **Settings**, and then, on the **Leads** tab, specify which ECG electrodes are in use.

Figure 34: Specifying leads in use



5.4 Signals from auxiliary catheters

The signals from the auxiliary catheters connected to the Globe Controller appear on the Electrograms panel between the ECGs and the Globe Catheter electrograms.

You can customize the catheter names (e.g., CS for coronary sinus catheter in the following figure) and the waveform prefixes in the **GPS and Auxiliary Electrode Status** tab of the **Setup and Status** panel. See *Enabling the GPS* on page 91 for more information.

Figure 35: Electrograms from reference catheter



5.5 Synchronize timeline

Click the **Synchronize timeline** icon  in the Electrograms panel to toggle the synchronization mode.

By default, the timeline on the Electrograms panel is not synchronized with the timeline on other panels.

When the button is toggled, the icon changes to  to indicate that the timeline on the Electrograms panel is synchronized with the timeline on all panels where timeline synchronization is activated.

5.6 Trigger mode

The Trigger mode aligns the activation signal detected at each electrode against a designated reference activation signal that is detected at either the reference catheter or the ECG lead II. This makes the signal appear stationary on the screen and assists with confirming changes or lack of changes from beat to beat.

A white line under the label for the signal trace indicates that is currently used as the reference. If a coronary sinus catheter is connected, the first bipolar pair of the coronary sinus catheter is the default electrode pair used for trigger mode. If a coronary sinus catheter is not connected, the ECG II lead is the default electrode pair used for trigger mode.

To change the activation reference:

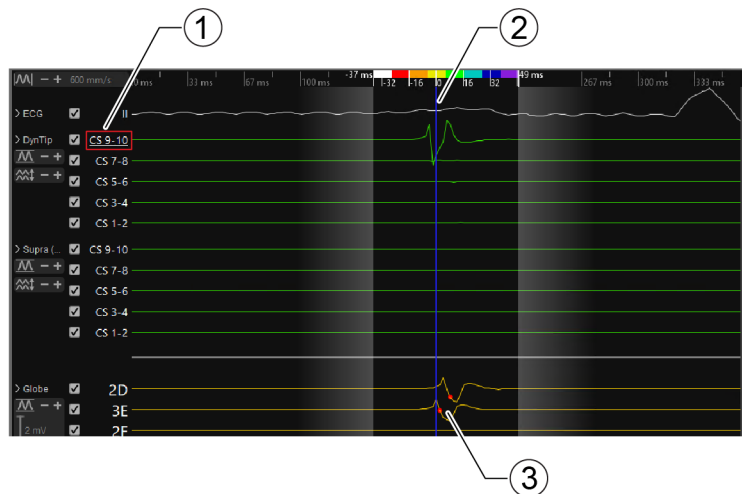
1. Click .
2. Click **Settings**.
3. In the Settings dialog, on the **Activation** tab, select either the ECG option or the CS option.
4. For the CS option, select the required electrode pair in the dropdown list. CS 9–10 is the default setting.

A blue line indicates the moment of activation on the reference signal.

A red dot on an electrode electrogram waveform indicates the moment of activation on that electrode. The system calculates the local activation time (LAT) between the moment of activation at a red dot and the reference moment of activation indicated by the blue line.

For information about LAT, see *LAT Map* on page 89.

Figure 36: Electrogram waveforms in trigger mode



- 1 Reference electrode pair
- 2 Blue line indicates the moment of activation on the reference electrode pair
- 3 Red dot indicates the moment of activation on the electrode

5.7 Keyboard shortcuts for reviewing electrograms

Use the following keystroke commands to scroll through the electrograms when the timeline is in review mode.

The shortcuts or hotkeys are particularly useful for scrolling over variable amounts of data after the procedure has been running for more than a few minutes, and especially after an hour. The controls allow both fast scrolling and paging (that is, advancing one screen's width of data at a time or just one second at a time or a few samples at a time).

Click the timeline at the bottom left of the Electrograms panel before using the shortcuts.

Table 22: Keyboard shortcuts for Electrograms panel timeline

Action	Shortcut
Toggle review mode	Space
Move to beginning of timeline	Home
Move to end of timeline	End
Move to previous or next detected cardiac cycle	Ctrl + ← Ctrl + →
± 10 screens	Shift + PageUp Shift + PageDn
± 1 screen	PageUp PageDn
± 0.1 screen	Alt + PageUp Alt + PageDn
± 10 seconds	Shift + ← Shift + →
± 1 second	← →
± 0.1 seconds (100 ms)	Alt + ← Alt + →
± 1 electrogram sample	Ctrl + Shift + Alt + ← Ctrl + Shift + Alt + →
± 10 electrogram samples	Ctrl + Shift + ← Ctrl + Shift + →

5.8 Filters

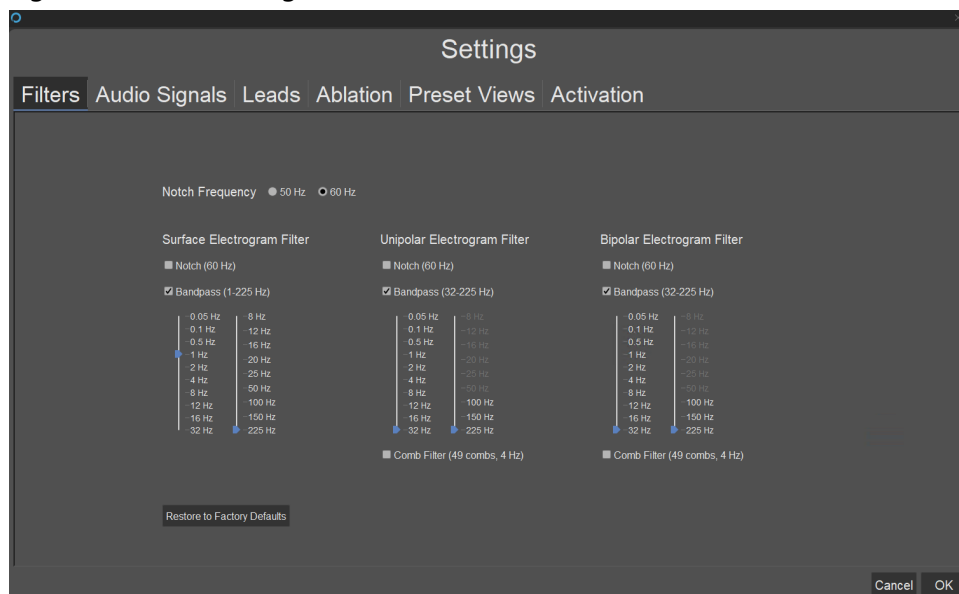
To filter waveforms, click , select **Settings**, click the **Filters** tab, specify the filters, and click **OK**.



NOTE

Filter settings are applied to both Globe Catheter electrograms and signals from auxiliary catheters.

Figure 37: Filters settings



5.8.1 Notch filter

Apply the notch filter to reduce power line noise, if present. The recommended notch filter frequency for North America is 60 Hz.

5.8.2 Bandpass filter

The bandpass filter removes both high and low frequencies. Set the low and high cutoff sliders to 1 Hz and 225 Hz respectively, before adjusting as needed.

- To correct baseline drift, increase the lower cutoff frequency of the bandpass filter.
- To filter high frequency noise, decrease the upper cutoff frequency of the bandpass filter.

5.8.3 Comb filter

You can use the comb filter to reduce the noise introduced during ablation. The comb filter may occasionally introduce an artifact in the electrograms, depending on the patient's heart rate.

You can apply the comb filter directly from the Electrograms panel also.

6 Array maps

The table below describes each type of array map in the Globe Software.

Table 23: Array map types

Map	Description
 FLOW Map	Visual representation of the degree of contact between the electrodes of the Globe Catheter and the atrial wall, where contact is inferred from convective cooling estimates of blood flow near the electrodes. The FLOW Map is used for navigation.
 Impedance Map	Visual representation of the resistivity of the medium in contact with the electrodes of the Globe Catheter. The Impedance Map is used to detect electrode overlap on the Globe Catheter array.
 CONTACT Map	Visual representation of the degree of contact between the electrodes of the Globe Catheter and the atrial wall, where contact is inferred from temperature and low non-therapeutic RF current measurements. The CONTACT Map is used to assess contact with atrial tissue.
 WAVE Map	Animation showing the propagation of the activation wavefront over a portion of the cardiac cycle. The WAVE Map is used to assess electrical activity of the atrial tissue.
 Voltage Map	Visual representation showing the intracardiac electrogram amplitude at each electrode over a portion of the cardiac cycle. The Voltage Map is used to assess electrical activity of the atrial tissue.
 Local Activation Time (LAT) Map	Visual representation showing the progression of the electrical activation across atrial tissue. The LAT Map is used to understand activation patterns in the atrial tissue.

The color scale of each map, except for the LAT Map, can be manually adjusted by sliding the gradient lines.



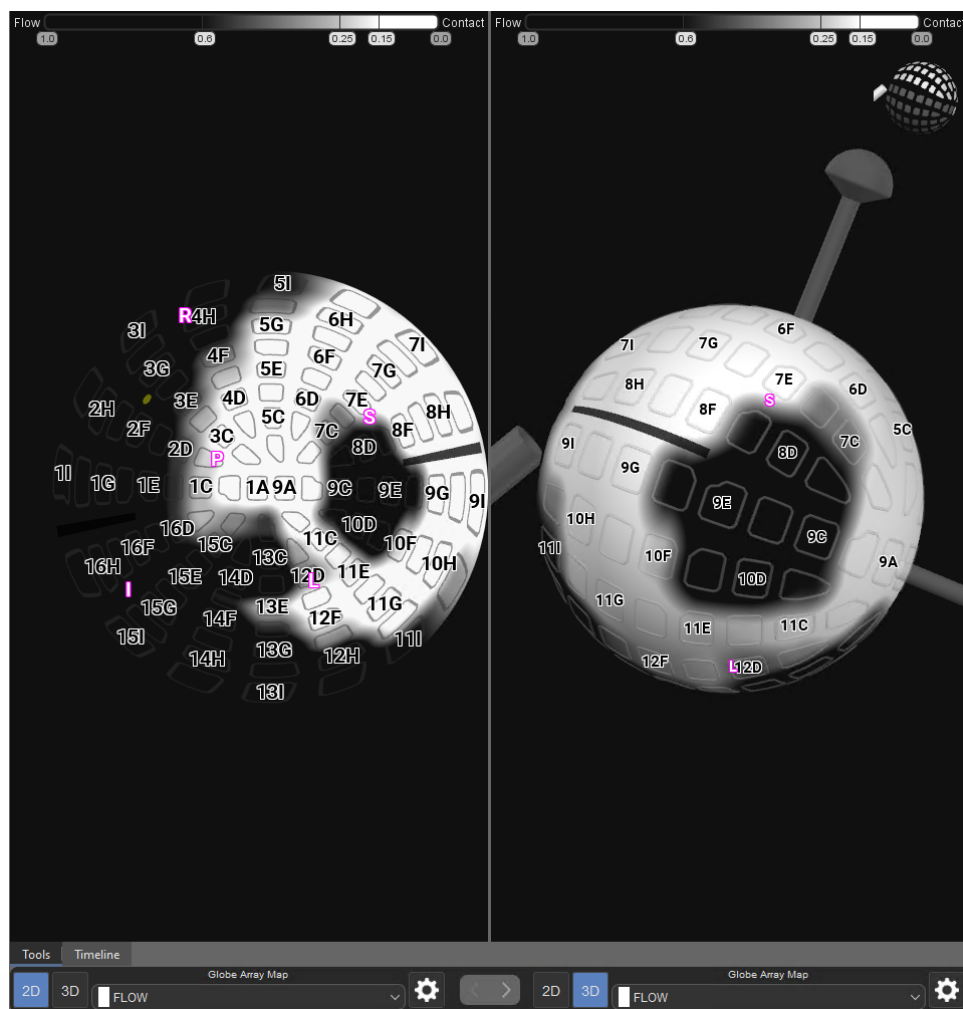
To modify the color scale for the LAT Map, click , and in the **Globe Array Map Rendering** tab choose between 8, 15, 29, or 57 color zones. To revert the changes to map color scales, right-click the color scale and select either **Reset to Gradient at Globe Software Startup** or **Reset to Factory Default Gradient**.

6.1 FLOW Map

The FLOW Map is a visual representation of the degree of contact between the electrodes of the Globe Catheter and the atrial wall, where contact is inferred from convective cooling estimates of blood flow near the electrodes. The FLOW Map is used for navigation.

To display the FLOW Map, select **FLOW** from the **Globe Array Map** list in the Array panel.

Figure 39: FLOW Map, 2D view (left) and 3D view (right)



The system infers blood flow near the electrodes of the Globe Catheter using convective cooling measurements from temperature sensors located immediately behind each electrode. The rate of heat loss

is higher when nearby blood flow is high. For example, electrodes in regions of high flow such as near the mitral valve or the pulmonary veins cool faster than electrodes that are in contact with the atrial wall, where the wall limits the ability of blood to flow.

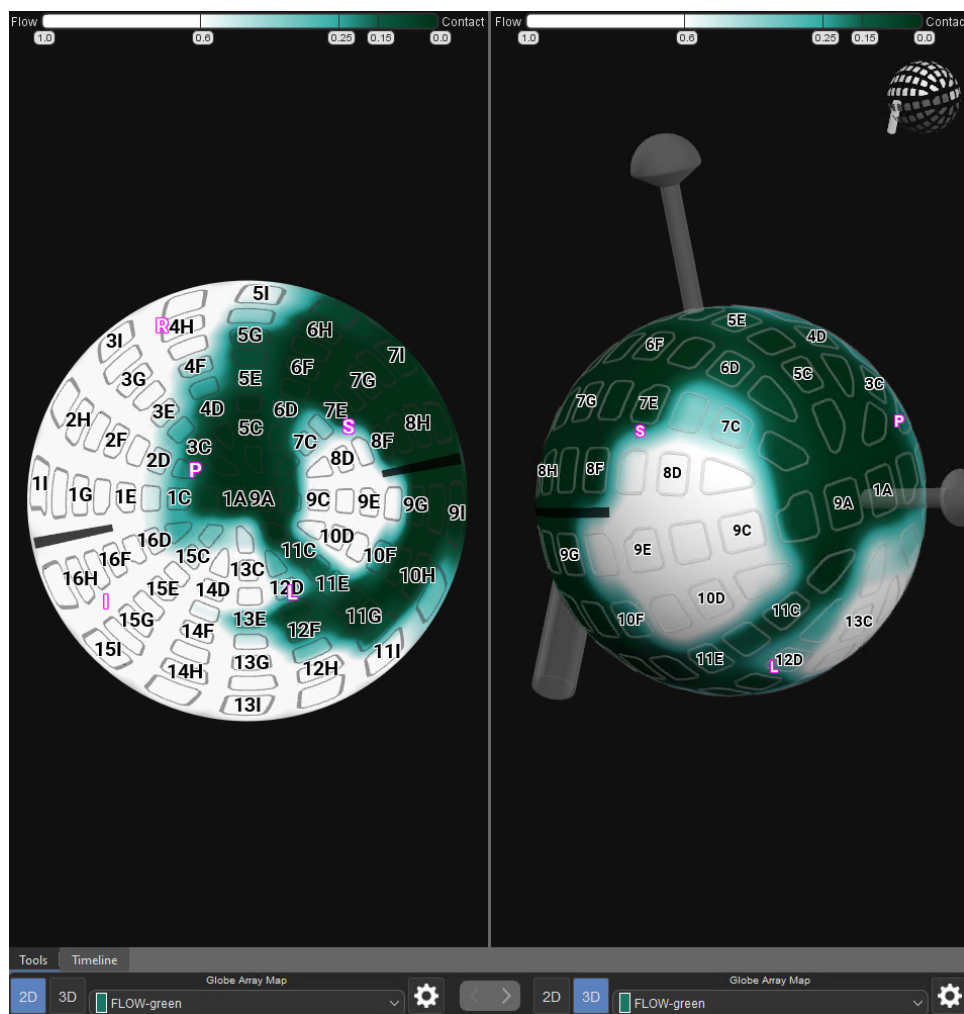
White indicates low blood flow (good contact) and black indicates high blood flow (poor contact).

Therefore:

- Black regions may correspond to atrial features where blood is flowing, such as the pulmonary veins, the mitral valve, and the left atrial appendage.
- Black areas may also indicate regions where the electrodes are not in contact with the atrial wall.
- White areas may indicate contact with the atrial wall where the wall limits the ability of blood to flow.

To display a green FLOW Map, select **FLOW-green** from the **Globe Array Map** list. Dark green indicates low blood flow (good contact) and white indicates high blood flow (poor contact).

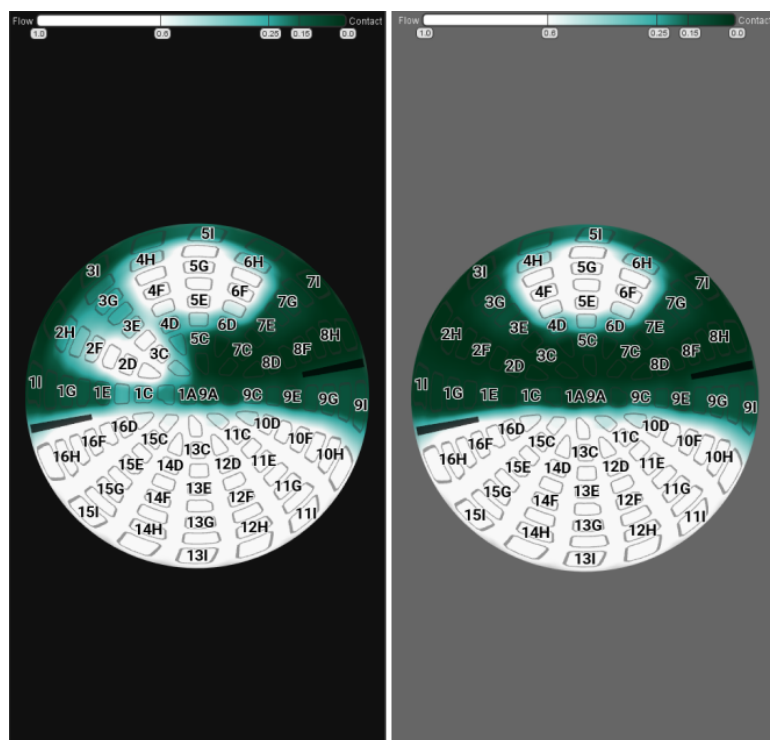
Figure 40: FLOW-green Map



The FLOW Map has a black background when it is being refreshed with real-time data. When the Globe Controller is not updating the FLOW Map, it has a gray background. For example this may occur:

- During PF ablation.
- During the generation of the CONTACT Map and Impedance Map.
- When the procedure timeline is in review mode.

Figure 41: FLOW Map with live data (left) and stale data (right)



When the FLOW Map is calculated, the flow data is averaged over a 2-second period by default ("fast" map) in order to provide more immediate information. It is also possible to average the flow data over a longer period (6 seconds) to provide a smoother display ("slow" map). To always display "slow" maps click , and then on the **Globe Array Map Rendering** tab, select **Display maximum cycle averaging in FLOW Map**.

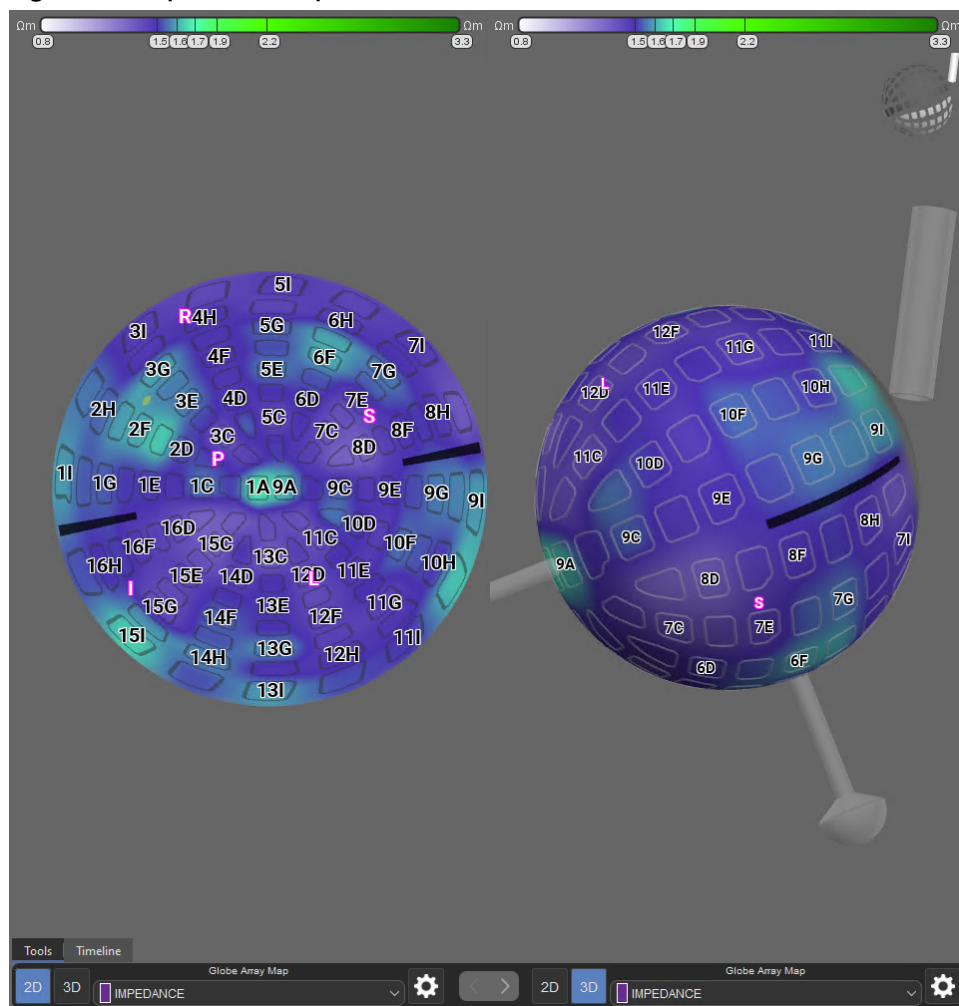
6.2 Impedance Map

The Impedance Map is a visual representation of the resistivity of the medium in contact with the electrodes of the Globe Catheter. The Impedance Map is used to detect electrode overlap on the Globe Catheter array.

Unlike the FLOW Map, which is updated in real time, the Impedance Map is updated only on demand. After changing the position or shape of the array, create a new Impedance Map.

- To generate a new Impedance Map, click .
- To update the Impedance Map continuously (for example, when positioning the array), click .
- To display the latest Impedance Map, select **IMPEDANCE** from the **Globe Array Map** list in the Array panel.

Figure 42: Impedance Map



The Impedance Map is a result of the “deployment check”, which checks whether the array is deployed correctly with no electrode overlap. During the deployment check, the system applies a voltage to each electrode, and it calculates the impedance using the measured resulting current. The displayed impedance is normalized according to electrode size.

The Impedance Map is also used for other purposes, such as detecting differences in tissue impedance versus blood impedance.

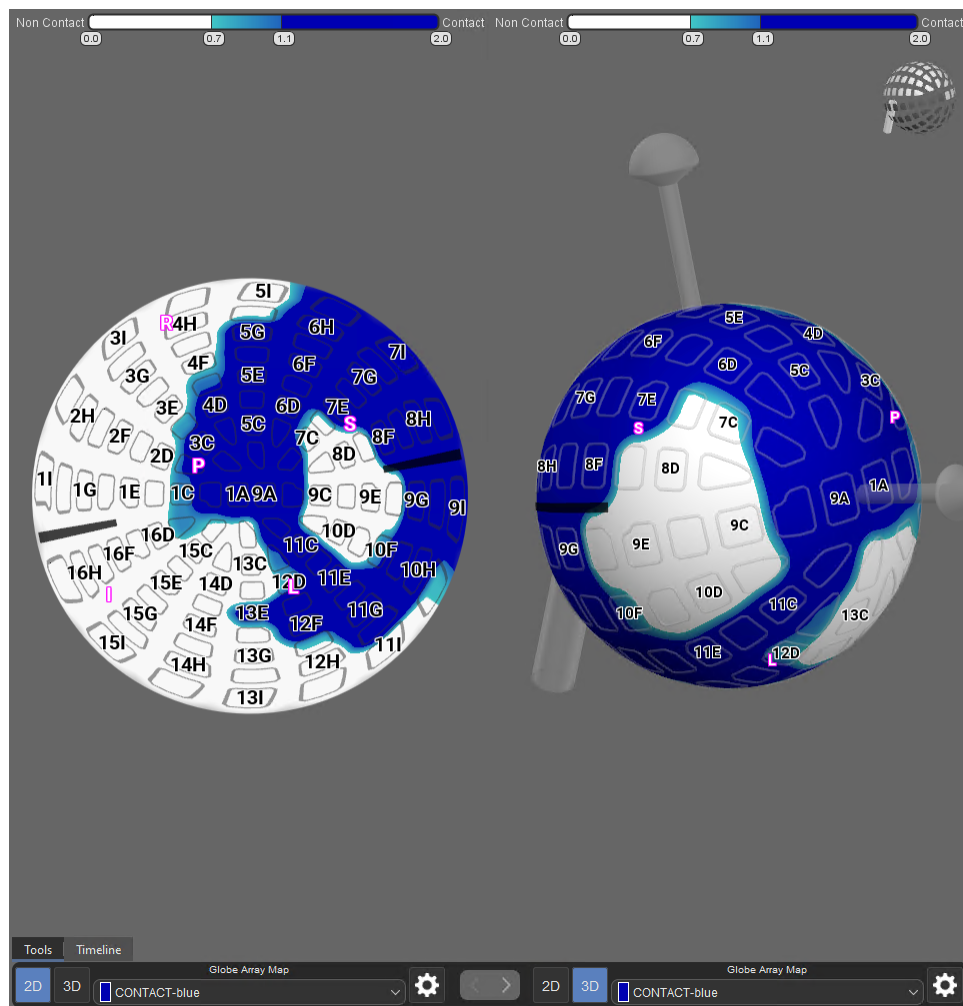
6.3 CONTACT Map

The CONTACT Map is a visual representation of the degree of contact between the electrodes of the Globe Catheter and the atrial wall, where contact is inferred from temperature and low non-therapeutic RF current measurements. The CONTACT Map is used to assess contact with atrial tissue. Blue indicates high contact and white indicates low contact.

The CONTACT Map is updated on demand, unlike the FLOW Map, which updates continuously. Create a CONTACT Map prior to selecting ablation targets.

- To generate a new CONTACT Map, click .
- To update the CONTACT Map continuously, click . Updating the CONTACT Map continuously may be useful when positioning the array or in special cases for navigation.
- To stop the scan for the CONTACT Map, click .
- To display the latest CONTACT Map, select **CONTACT-blue** from the **Globe Array Map** list in the Array panel.

Figure 43: CONTACT-blue Map

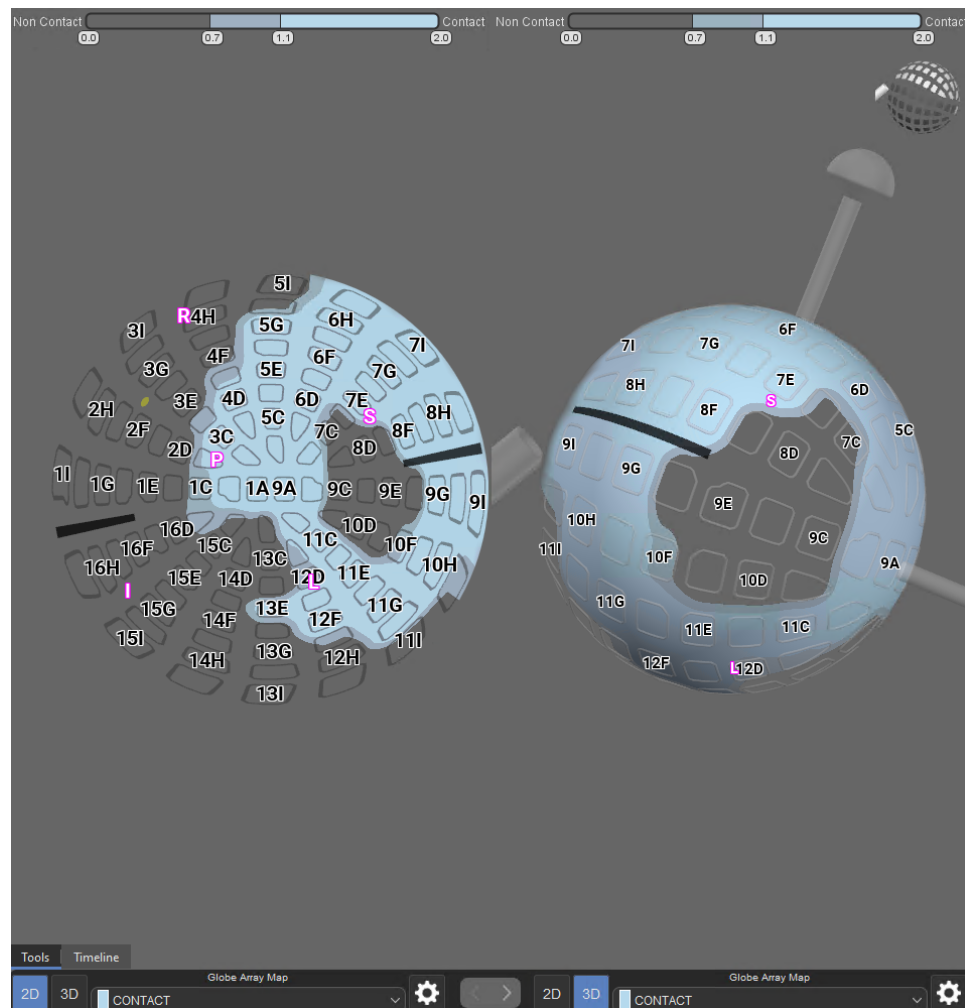


Generating a CONTACT Map takes approximately 12 seconds.

To calculate the CONTACT Map, the system briefly heats the electrodes to approximately 40 °C using a low, non-therapeutic current, and it measures the power required to reach that temperature. The required power is lower for electrodes that are in contact with the atrial wall.

To display a light blue CONTACT Map, complete a CONTACT scan, and then select **CONTACT** from the **Globe Array Map** list. Light blue indicates high contact and gray indicates low contact.

Figure 44: CONTACT Map

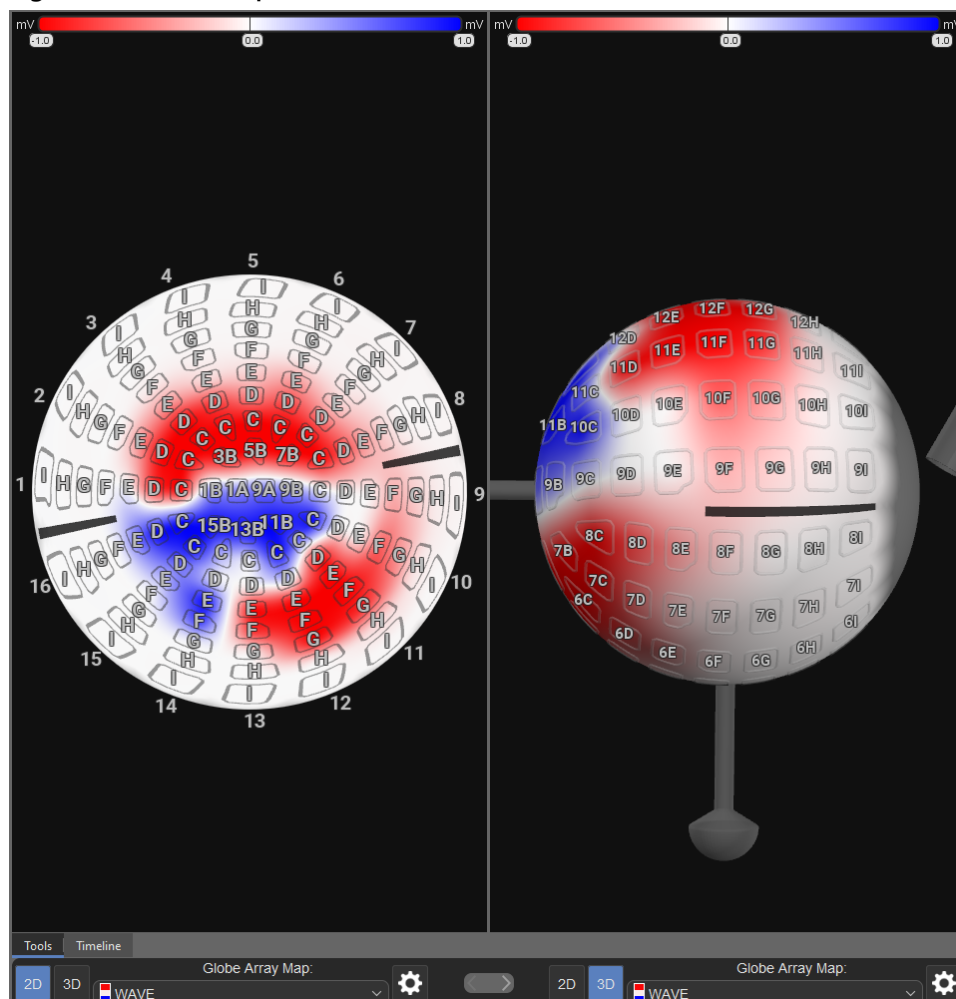


6.4 WAVE Map

The WAVE Map shows an animation of the propagation of the activation wavefront over a portion of the cardiac cycle. The WAVE Map is used to assess electrical activity of the atrial tissue.

To display the WAVE Map, select **WAVE** from the **Globe Array Map** list in the Array panel.

Figure 45: WAVE Map



The WAVE Map is an animation of the voltage measured at each electrode of the Globe Catheter's array, where each frame corresponds to a discrete point in time throughout the map range. The voltage amplitude at each electrode is rendered using color.

By default, the wave map renders a voltage range of ± 1 mV. The WAVE Map is most appropriate for displaying the direction of the activation waveform movement. For measuring voltages, see *Electrograms* on page 59.

The data used to build the WAVE Map is filtered according to the settings applied to the unipolar electrograms.

6.4.1 Map range

The map range specifies the time interval relative to the cardiac cycle that the WAVE Map will animate and the LAT Map will render.

The map range is automatically created at the start of the procedure. A blue circle below the timeline indicates that a map range has been defined, and it shows the time in the procedure where it is defined.

Figure 46: Map range on timeline



Click the range to display vertical boundary lines at either end of the range and a line for the reference peak.

- To adjust the map range relative to the reference peak, drag either end of the range or the boundary lines.
- To move the entire map range, press and hold the middle mouse button and drag it.

The range of interest depends on the clinical investigation.

- For example, when the patient is in sinus rhythm, set the range from the beginning of the P wave to just before the QRS complex.
- When studying atrial fibrillation behavior, include a few cardiac cycles in the range to look for stable features.

Figure 47: Map range



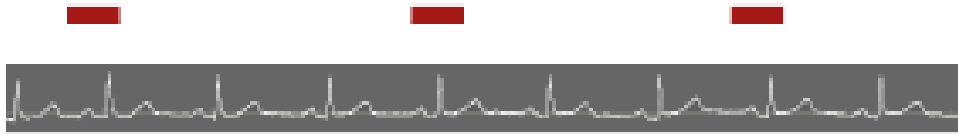
To adjust the speed of the animation, click , and then on the **Globe Array Map Rendering** tab, move the **Animation playback speed** slider to the desired speed. For example **0.02x** for 50 times slower than the actual signal speed.

To override the voltage range specified by the WAVE Map range control and change the voltage amplitude value used to normalize the WAVE Map, click , and then on the **Globe Array Map Rendering** tab, select **Use amplitude**, and specify a value.

6.4.2 Animation synchronization

In real-time mode, the animation refreshes every few cardiac cycles, typically every third or fourth, to show the same relative portion of the cardiac cycle over different heartbeats. After the time period has been animated, a new range is synchronized to the most recent data and a new animation plays.

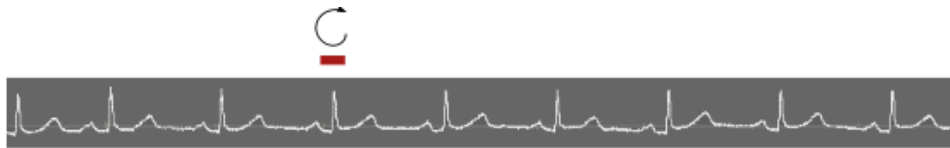
Figure 48: A new synchronized animation every few heart beats



The system ensures that the WAVE Map animation shows only the user-selected electrogram period by calculating offsets to the peak ECG every few heartbeats.

In review mode, the same portion is always animated repeatedly over the selected map range.

Figure 49: Animation played repeatedly during an offline review

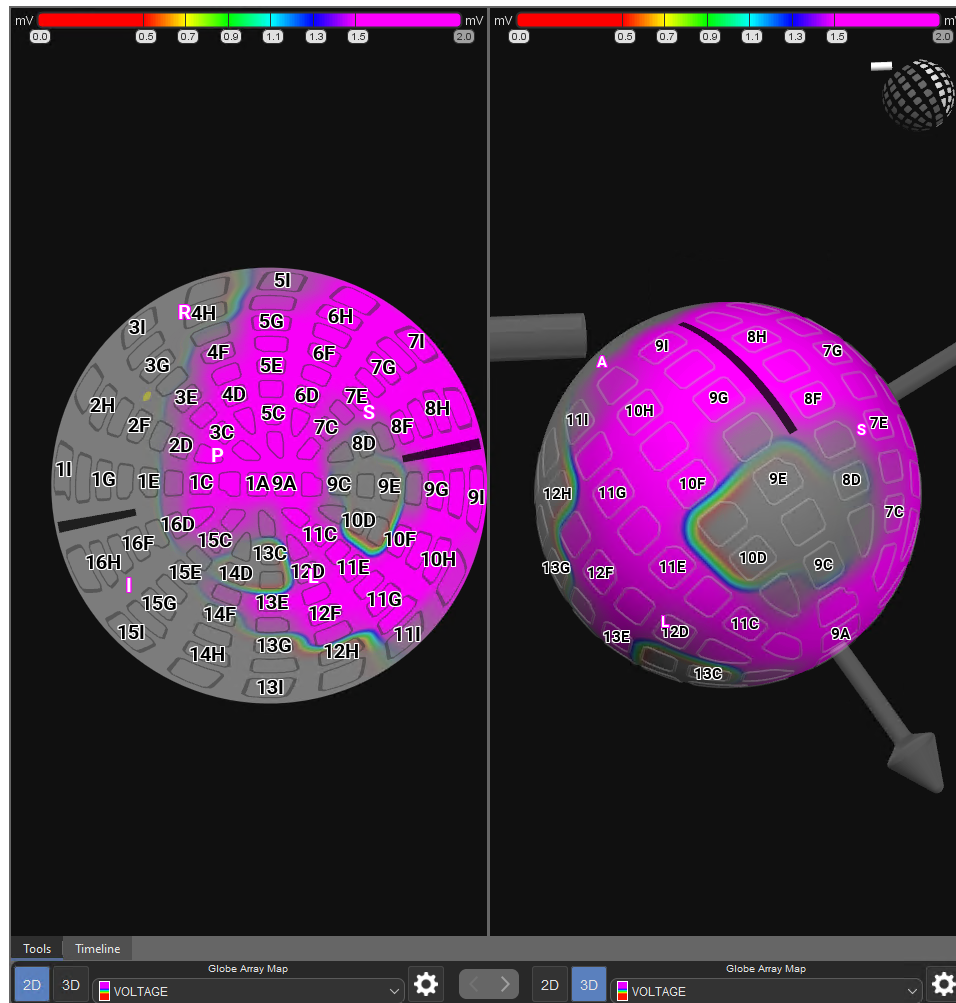


6.5 Voltage Map

The Voltage Map is a visual representation showing the intracardiac electrogram amplitude at each electrode over a portion of the cardiac cycle. The Voltage Map is used to assess electrical activity of the atrial tissue.

To display the Voltage Map, select **Voltage** from the **Globe Array Map** list in the Array panel. To select the portion of the cardiac cycle, see *Map range* on page 85.

Figure 50: Voltage Map



A single static image is created for the entire selected time range, using color to indicate maximum activity at each location in the atrium for the selected time range. By default, the display range is fixed. Alternatively, a data derived display range can be used, for which the largest negative deflection across all electrodes determines the maximum value of the display range.

The LAT Map is a color representation of the electrical activation time relative to a reference point, where:

- White indicates the earliest activation signal.
- Purple indicates the latest activation signal.

By default, the LAT Map uses the global activation range. The global activation range shows the progression of the electrical activation across the atrium. The local activation range is a subset of the global activation range that shows the progression of the electrical activation across the array.

To generate a LAT Map with a local activation range, right-click the **Array** panel and clear **Use global activation range**.

By default, the reference point is the 9-10 lead of the reference catheter. If a reference catheter is not in use, the default reference point is ECG II lead. To change the reference point, click , select **Settings**, click the **Activation** tab, and change the activation reference.

7 Globe Positioning System (GPS)

The Globe Positioning System (GPS) creates a 3D model of the left atrium and determines the position and orientation of the Globe Catheter's array relative to the atrium.

The GPS is an impedance-based mapping system. Three pairs of surface electrodes applied to the patient create three nearly orthogonal and linearly independent electric fields. The system measures voltages at the electrodes on the Globe Catheter's array and on a reference catheter and uses this information to calculate the position of the array relative to the reference catheter. The system tracks position data as the array moves along the atrial wall to create a model of the atrium.

For information on the required cables and parts, refer to *Globe Positioning System Cable and Electrodes* on page 180.

7.1 Enabling the GPS

To enable the GPS:

1. Plug a reference catheter into the AUX1 port of the Globe Controller.

The reference catheter connected to the AUX1 port on the Globe Controller must be compatible with the GPS because precise voltage readings are critical to determining the position of the array accurately.

2. Click , select **Setup and Status**, and then click the **Electrode Status and Procedure Info** tab.
3. Under the **Reference Catheter** tab, select the reference catheter from the list.

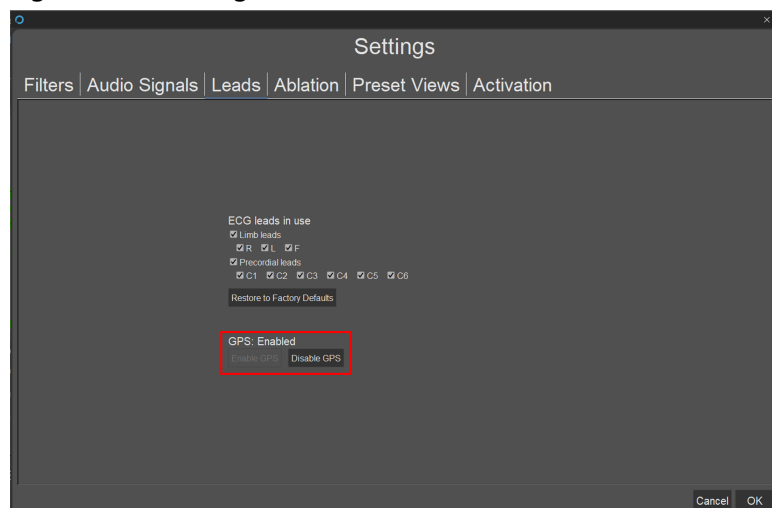
The values for **Override Name** and **Override Prefix** identify the waveforms of the auxiliary catheters in the Electrograms panel. See *Signals from auxiliary catheters* on page 71.

The  and  symbols next to the GPS Electrodes show the current state of the electrodes (enabled or disabled).

To disable the GPS, for example to terminate interference from GPS signals or if a system error prevents the GPS test from executing successfully:

1. Click  and select **Settings**.
2. Click the **Leads** tab and click **Disable GPS**.

Figure 52: Disabling the GPS



To enable the GPS again:

1. Click  and select **Settings**.
2. Click the **Leads** tab and click **Enable GPS**.

7.2 Reference catheter

The GPS uses the voltage data measured by the auxiliary catheter connected to the AUX1 port of the Globe Controller to determine the position of the array.

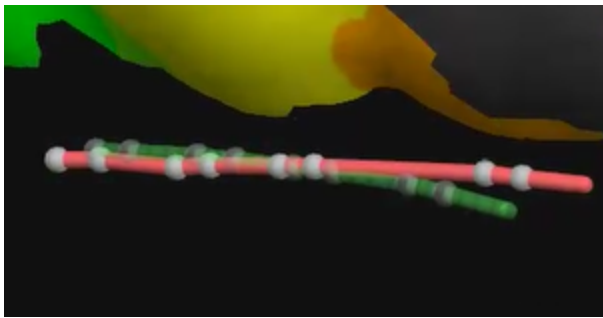
To access the commands for the reference catheter, display the GPS panel, click , and then click the **Atrium** tab.

Table 24: Commands for customizing the display of the reference catheter

Task	Steps
Set the baseline position of the reference catheter	GPS accuracy may be affected if the reference catheter moves during the procedure. If the reference catheter has been changed or the reference catheter has been moved, reset the baseline position by clicking Set the baseline position for reference catheter alignment .
Change the color of the reference catheter	By default, the reference catheter (auxiliary catheter 1) is red. Click Choose to change the color.

Task	Steps
Show or hide the baseline position of the reference catheter	Select or clear the Show baseline reference catheter checkbox.
Change the color and opacity of the baseline position of the reference catheter	By default, the baseline indicator is green. Click Choose to change the color. Move the slider to adjust the opacity of the baseline indicator.

Figure 53: Position of reference catheter relative to the baseline



7.3 Globe model

The Globe model shown on the GPS panel is very similar to the one shown on the Array panel. The difference is that the GPS panel displays the position and orientation of the array using the data collected by the GPS as a frame of reference.

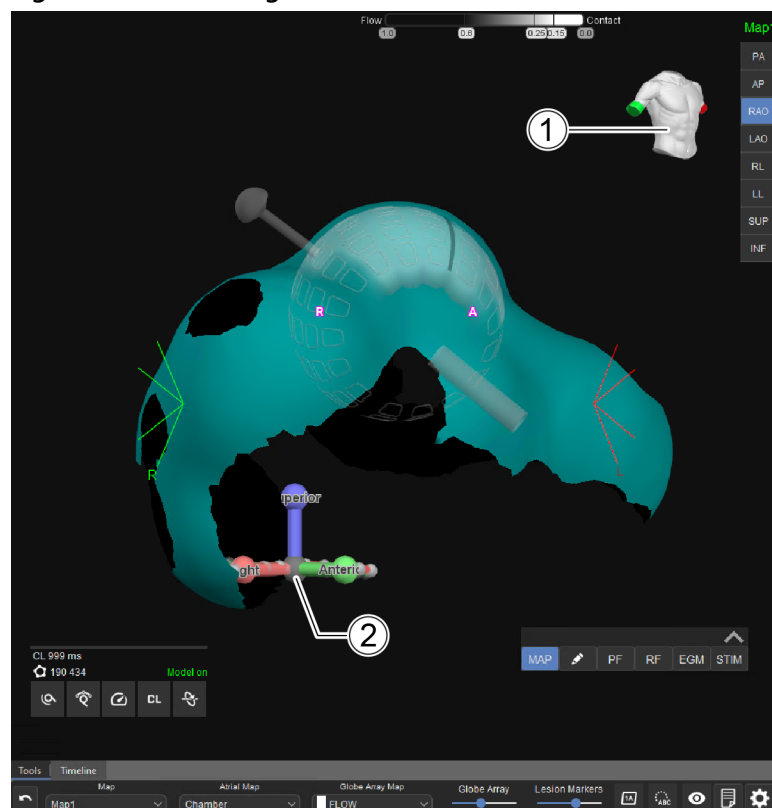
To access the commands for the Globe model on the GPS panel, display the GPS panel, click , and then click the **General** tab.

Table 25: Commands for customizing the display of the Globe model in the GPS panel

Task	Steps
Display the Globe model	Next to Array Rendering, choose one of: • Do not Render • Array Only • Array With Map To specify what to display on the Globe model, click , and then click the Globe Array Map Details tab. To hide or show electrode labels click  on the GPS panel. To control the display of the FLOW Map, Voltage Map, and LAT Map on the Globe model, click , and then click the Globe Array Map Rendering tab. For more information, see <i>FLOW Map</i> on page 78 and <i>Voltage Map</i> on page 88. To display the same information in all GPS panels, click Synchronize in the Globe Array Map Details tab.
Orient the Globe model in the same direction as in other panels	Select or clear the Synchronize 3D view angle checkbox.
Change the size of the Globe model and the atrial model	Move the zoom slider or hold down the Shift key and use the scroll wheel.
Pan the Globe model and the atrial model	Hold down the Shift key and drag with the middle mouse.
Change the opacity of the Globe model	Move the Array Opacity slider or type a value. In the GPS panel, move the Globe Array slider.
Change the opacity of the electrodes	Move the Array Electrodes Opacity slider or type a value.
Smooth the display	By default, Show Smoothed Catheter Position is selected. To disable this feature, clear Show Smoothed Catheter Position. When this option is selected, the animation is smoother but the response time increases slightly.

Task	Steps
Display the axes corresponding to the electrical fields created by the GPS	Select Render Axes at Origin. The origin corresponds to the mean position of the electrodes on the reference catheter. See Figure 54: <i>Axes at origin</i> below.
Synchronize the timeline with other panels	• Select Synchronize timeline. • In the timeline tab, click .

Figure 54: Axes at origin

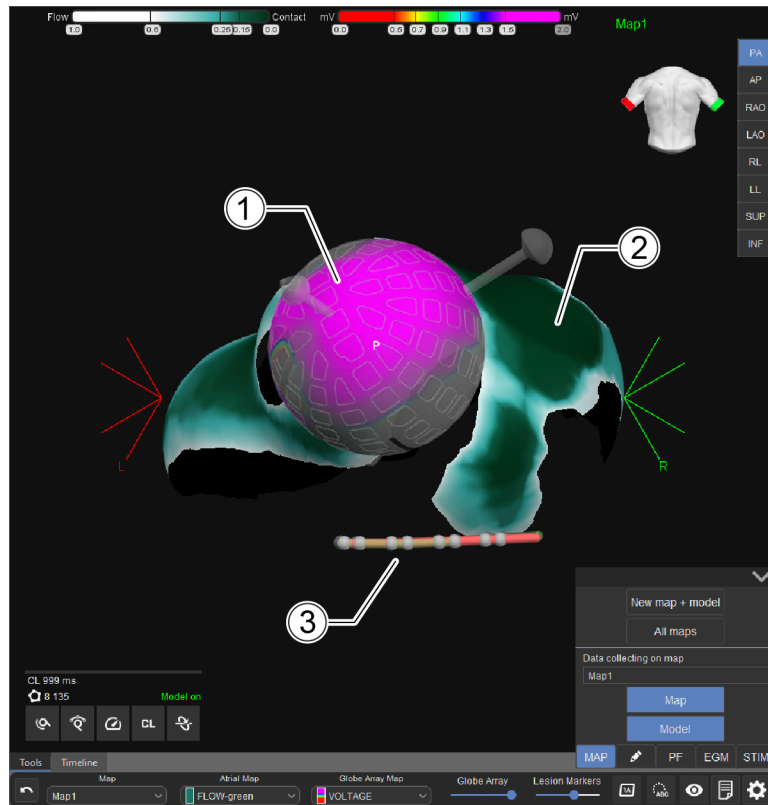


- 1 Orientation indicator
- 2 Axes at origin

7.4 Atrial model

When atrial modeling is set to **Model on**, the GPS tracks the position of the Globe Catheter's array as it moves around the atrium to build a three-dimensional model of the atrium.

Figure 55: GPS panel



- 1 Globe model with Voltage Map
- 2 Atrial model with FLOW Map
- 3 Reference catheter

Table 26: Common commands for the GPS atrial model

Task	Steps
Build the atrial model	To start the construction of a model, click Map and Model . To stop data collection, click Model .
Undo	To undo the last 15 seconds of model building, click  .
Rotate the atrial model	Drag the model while holding down the mouse scroll wheel.

Task	Steps
Rotate the atrial model around an axis perpendicular to the screen	Hold down the Ctrl key and drag the model while holding down the scroll wheel.
Match the fluoroscopy view	The system automatically determines the anteroposterior (AP) view using the information from the GPS Electrodes and the reference catheter. To set the AP view to match the image on the fluoroscopy system, orient the model as required and then do one of the following: • Press Shift and click AP. • Click  and then on the General tab click Capture AP. • Right-click AP and select Capture AP. To select any preset view, place the model in the correct orientation, and then press Shift and the appropriate view button. Alternatively, right-click and select the view to capture.
Reset the AP view to the view calculated by the GPS	Click  and on the General tab, click Default AP > OK.
Orient the atrial model in one of the standard views	Click one of the preset view buttons in the upper right corner of the GPS panel. The left anterior oblique (LAO) view and the right anterior oblique (RAO) view are both 45° from AP. To change this angle, click , select Settings, click the Preset Views tab, and then adjust the LAO and RAO angles.
Orient the atrial model in the same direction as in other panels	Click  and on the General tab select Synchronize 3D view angle .
Customize the display of the atrial model	Click  and then on the Atrium tab adjust the parameters for color, lighting, opacity, and clipping. The value for Clip before distance (mm) represents the portion of the atrium to remove closest to the screen along the axis perpendicular to the screen. The values for Distance to start visibility (mm) and Distance to max opacity (mm) are the endpoints of an opacity gradient along the axis perpendicular to the screen. Click Synchronize to use the same settings in all GPS panels.
Delete the atrial model	Click  and then on the Atrium tab click Delete Model .

7.5 Atrial maps

You can superimpose a FLOW, Voltage, or LAT Map on the atrial model. Atrial maps are created while the atrial model is being built or later using stored data.

Figure 56: GPS panel with atrial map

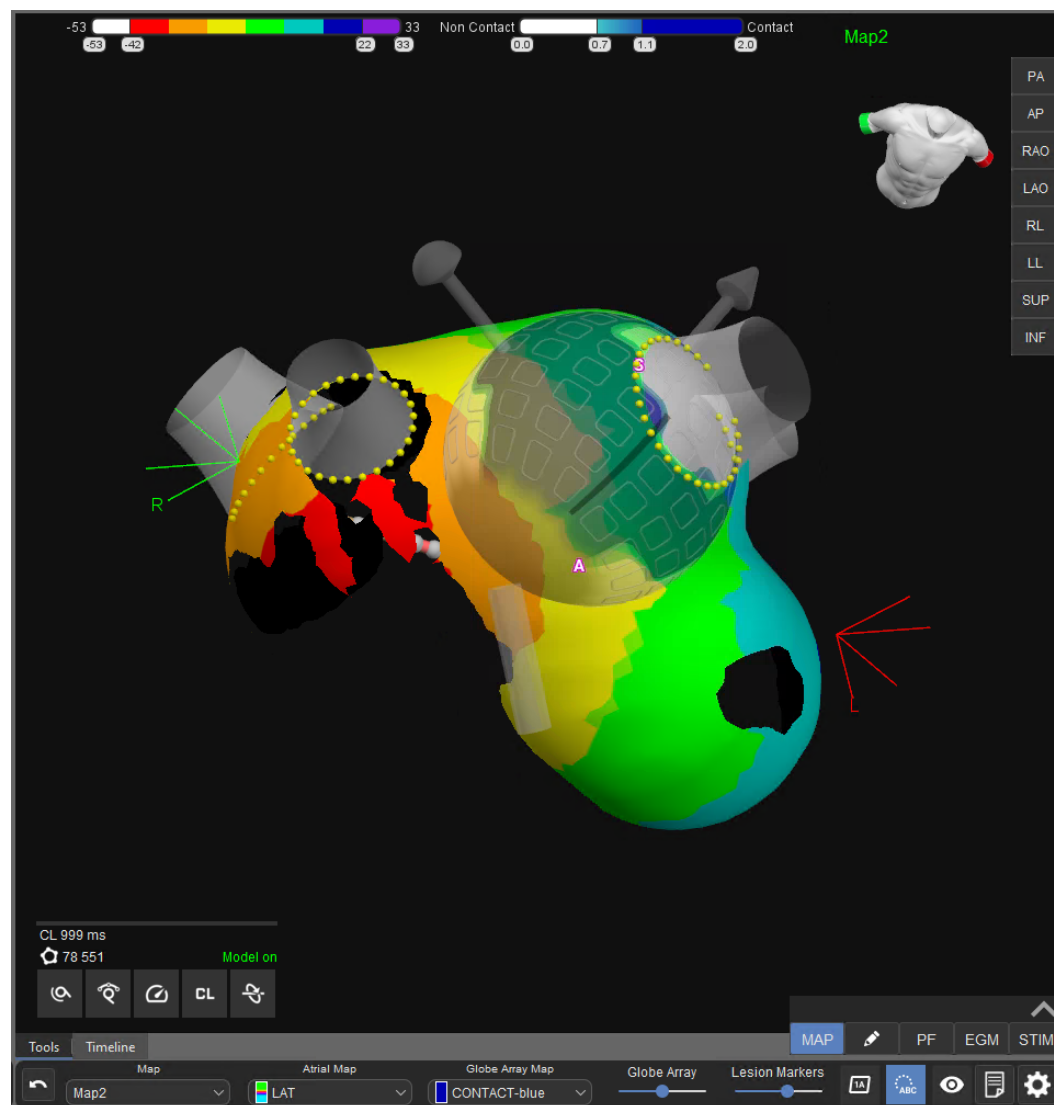


Figure 57: GPS panels with atrial Voltage Map (left) and atrial LAT Map (right)

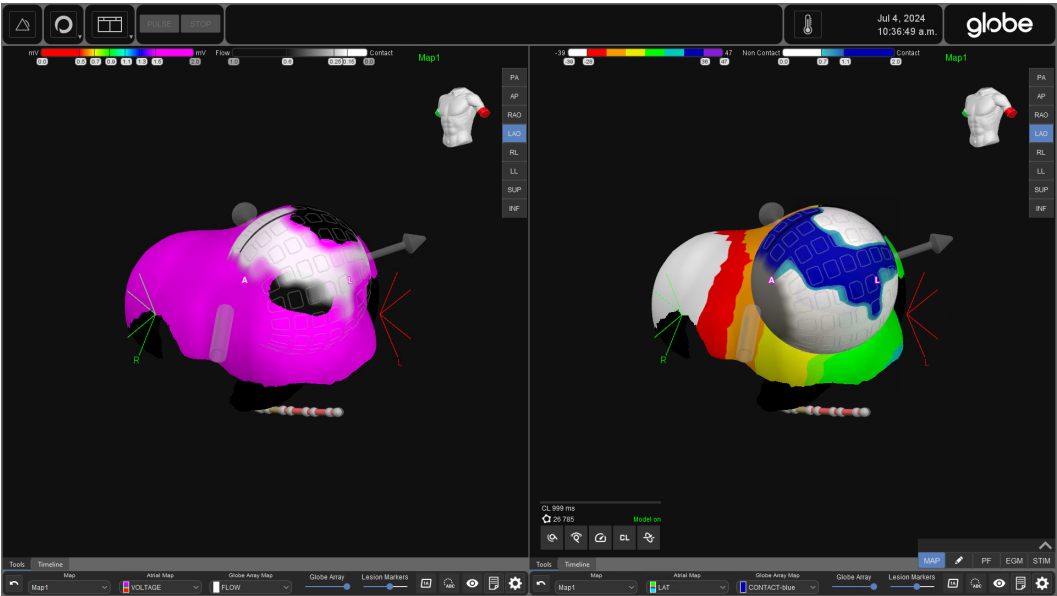


Table 27: Common commands for atrial maps

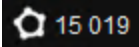
Task	Steps
Create an atrial map during construction of the atrial model	If this is the first map, click Map. Otherwise, click MAP > All maps > Create New and then adjust the parameters and click Create Map.
Undo	Click  to display the Model and Map Undo menu. To undo the last 15 seconds, click . • To accept the model edit, click OK. • To reject the model edit, click Cancel.
Redo changes that were previously undone	Click  to display the Model and Map Undo menu. To redo the last 15 seconds, click . • To accept the model edit, click OK. • To reject the model edit, click Cancel.

Task	Steps
Stop map data collection	Do one of the following: - Click Map. - Press F8. - Click All maps, and then click the Stop button next to the map.
Create a map using historical data	Click All maps > Create Historical . Specify the map type, a start time, and an end time, and then click Create Map . The system creates the historical map using previously collected data.
Rename maps	Click All maps , double-click the Label field, and then type the new name. Press Tab to save the new name.
Lock maps to prevent changes	Click All maps and check the Locked box next to the maps to be locked.
Hide maps in the map list	Check the Hidden box next to the maps to be hidden. Maps cannot be deleted.
Display surface map data on the atrial model	Click All maps, select a map, and then choose one of the following options in the Atrial Map menu: Chamber: The same data as the FLOW Map except that the areas of flow are transparent. Voltage: Voltage Map. FLOW-green: FLOW Map. LAT: LAT Map. GPS Model: The current atrial model with no map data. Selected GPS Model: The atrial model corresponding to the map selected in Map List but without map data.
Display the surface maps the same way on all GPS panels	Click  and in the Atrial Map tab select Synchronize atrial map selection .
Filter based on heart rate	Click  , click the Atrial Map tab, click Enable heartbeat filtering , and adjust the heartbeat thresholds as required. Data points collected outside the heartbeat thresholds are not used to calculate the atrial map.

Task	Steps
Filter based on array speed	Click  , click the Atrial Map tab, click Enable array speed filtering , and adjust the speed thresholds as required. Data points collected outside the speed thresholds are not used to calculate the atrial map.
Adjust the map opacity settings	Click  , click the Atrium tab and adjust these settings: • Atrium Map Opacity: Overall opacity. • Contact Low Threshold: The contact value that is considered low contact. • Opacity Level Low: Opacity factor for regions where contact is less than the threshold for low contact. • Contact High Threshold: The contact value that is considered high contact. • Opacity Level High: Opacity factor for regions where contact is higher than the threshold for high contact.
Display the point-by-point position data collected by the array	Click  , and in the Atrium tab, click Render Atrial Map Samples and adjust the display settings as required.

Table 28: Atrial map indicators

Indicator	Explanation
	FLOW/contact indicator. This indicator turns yellow when the blood flow is above the maximum threshold for all electrodes, and the atrial surface map is not updated. To modify the thresholds click MAP > All maps > View, and adjust the Flow Window Low and Flow Window High values.
	Proximity to model indicator. This indicator turns yellow when the proximity of the surface of the array to the atrial surface is above a maximum threshold, and the atrial map is not updated. To modify the thresholds click MAP > All maps > View, and adjust the Radial Near, Radial Far, Normal Near, and Normal Far thresholds.

Indicator	Explanation
	Globe array velocity indicator. This indicator turns yellow when the speed of movement of the catheter is above the maximum threshold, and the atrial map is not updated. To modify the threshold click , and in the Atrial Map tab move the Array speed threshold slider. The Globe array velocity indicator is not available when the Enable array speed filtering setting is cleared.
	Cycle length indicator. This indicator turns yellow when the cardiac cycle length is outside of the valid cycle length range that has been specified. Each cardiac cycle length is also compared to the average of the last valid cycle length and is used for the atrial surface map only if its value falls within a relative threshold of the average. To modify the thresholds click , and in the Atrial Map tab move the Low heartbeat threshold, High heartbeat threshold, and Relative heartbeat threshold sliders. The Cycle length indicator is not available when the Enable heartbeat filtering setting is cleared.
	Rotation correction [0 degrees] indicator. This indicator turns yellow when the reference catheter has moved. This indicates that data is being collected for the atrial surface map, but that the data may be distorted. To modify the threshold value, click , and in the Atrium tab adjust the Gauge warning angle slider.
	Samples contributing to map viability count. The Samples contributing to map viability count shows the number of samples that are collected within the Globe PF System's required data collection thresholds, which contribute to the values of the current atrial surface map.

7.6 Selected electrogram window

When you superimpose a Voltage Map or LAT Map on the atrial model, you can render an electrogram waveform using the **Selected electrogram** window. This feature shows:

- A weighted median electrogram calculation (light blue).
- The contributing electrogram samples (white).
- The reference catheter electrogram (dark blue).

Figure 58: Selected electrogram window

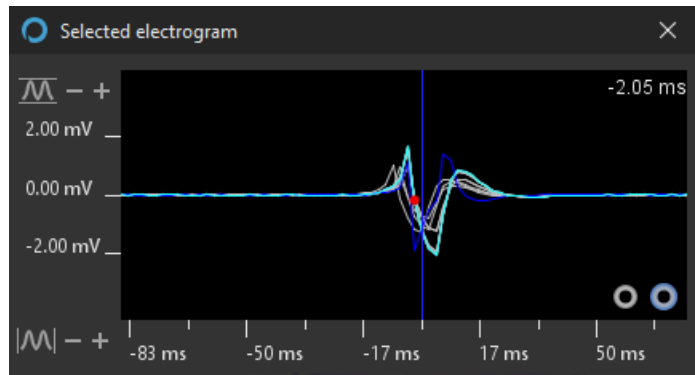


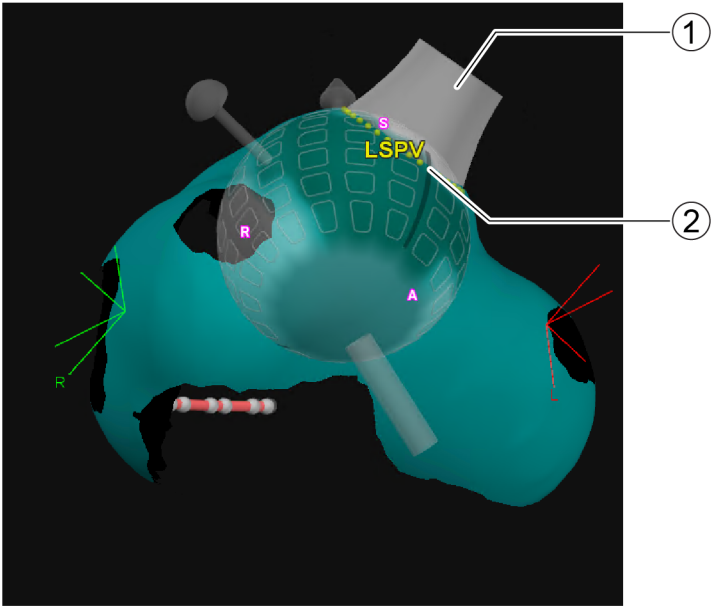
Table 29: Selected electrogram window settings

Indicator	Explanation
Display the selected electrogram window	Select MAP on the Global tool palette . Then, left-click anywhere on the map when a Voltage or LAT Map is superimposed on the atrial model.
Display the contributing electrogram samples	Click
Display the reference catheter electrogram	Click

7.7 GPS labels

Labels added to the Globe model in the Array panel with the pencil tool are automatically posted to the GPS panel. When a label and vein marker are posted to the GPS panel, the label and vein marker appear on the atrial model in the GPS panel, and a label marker is indicated on the timeline. After posting a label, it remains visible on the atrial model even if the array is repositioned, unless on the GPS panel is clicked. For information on the pencil tool, see *Labels* on page 56.

Figure 59: GPS labels



- 1 Vein marker
- 2 Label

To turn off the vein markers, click  and then on the **Atrium** tab, clear **Show 3D Vein Markers**.

To access the commands for the GPS markings, click  on the GPS panel, and then click the **Labels and Marks** tab.

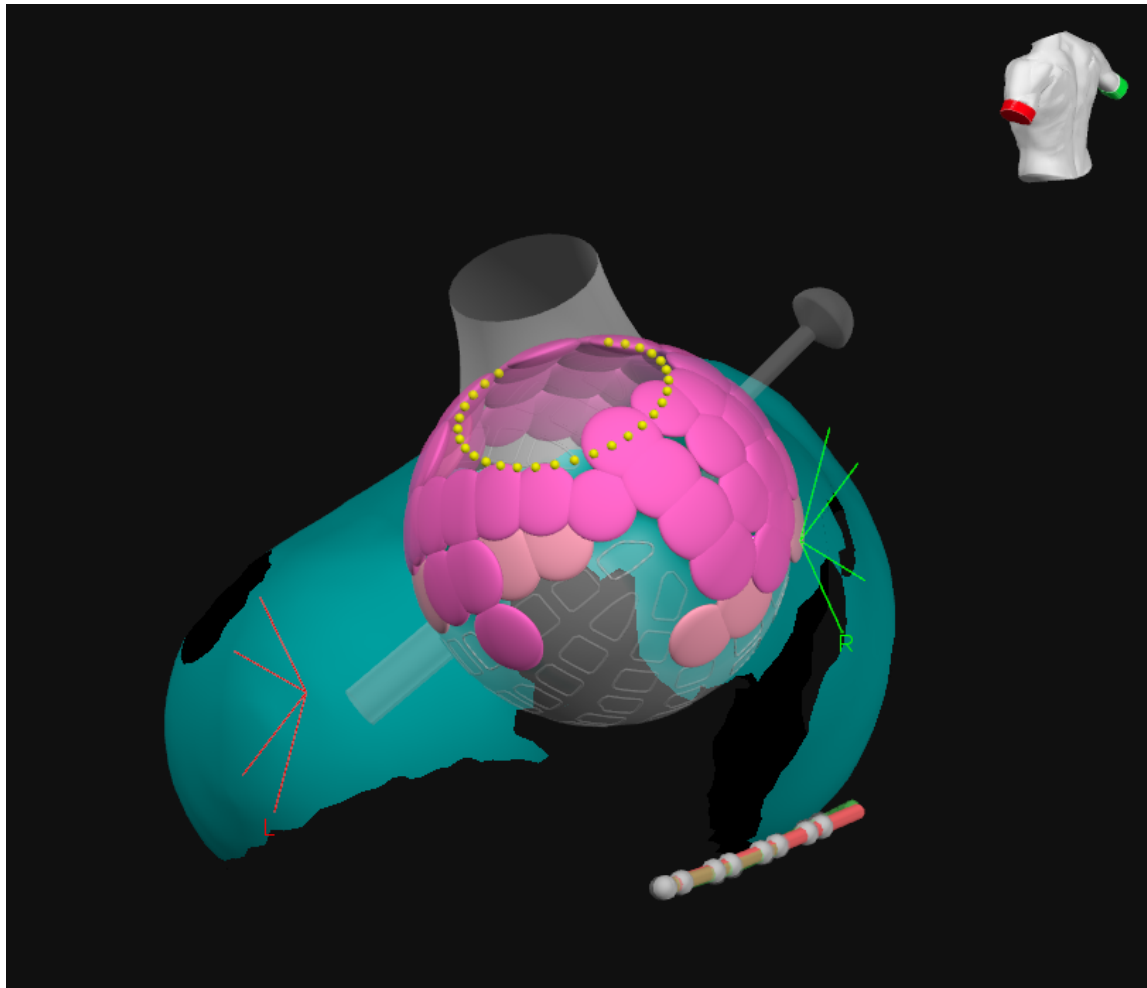
Table 30: GPS labels

Task	Steps
Hide all labels	Click Hide All or click  on the GPS panel.
Show all labels	Click Show All or click  on the GPS panel.
Delete labels	Click  , and in the Labels and Marks tab click  next to the label set to be deleted.
Show or hide a label	Click  , and in the Labels and Marks tab select or clear Show next to the label.

7.8 Lesion markers

The lesion markers on the atrial model indicate the position of the electrodes used for ablation relative to the Globe model. Lesion markers are shown in pink.

Figure 60: Lesion markers on atrial model



To access the commands for lesion markers, display the GPS panel, click , and then click the **Lesion Markers** tab.

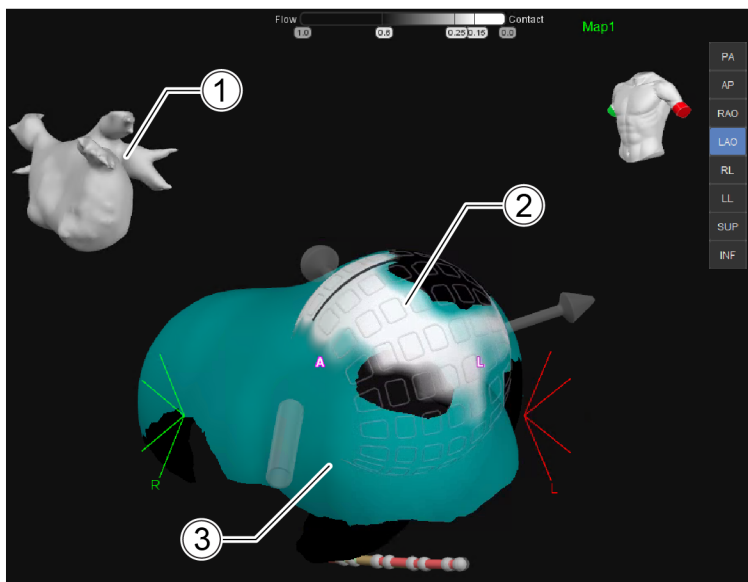
Table 31: Common commands for GPS lesion markers

Task	Steps
Adjust the fade and clip settings	Select Enable fade and clip with distance, and then adjust the following distances in mm: - Distance to start fading. - Distance to fully fade. - Clip after distance.
Change the opacity of the lesion markers	Move the Lesion Markers slider. A value of 1 corresponds to fully opaque (100% opacity).
Change the back of the lesion markers	Choose an option in the Color Lesion Marker Backs list.
Change the time after which lesion markers are displayed	Click Select time , slide the time marker on the timeline to specify the time, and click OK .
Use the same display settings in all GPS panels	Select Synchronize to use the same fading, clipping, opacity, back color, and time settings for the lesion markers in all GPS panels.

7.9 CT model

You can superimpose a CT model of the patient's left atrium on the atrial model generated by the GPS. You can display a mini or large CT.

Figure 61: CT model superimposed on atrial model created by the GPS



- 1 CT model
- 2 Globe model
- 3 Atrial model

To access the commands for CT models, display the GPS panel, click  and then click the **CT/MRI** tab.

Table 32: Commands for large CT models

Task	Steps
Import CT model	Convert the CT scan data to STL format and transfer the STL file to the Globe Workstation using a CD or a USB drive. Then, click Load CT/MRI Model , select the STL file, and click Open .
Customize the appearance of the CT model	Adjust the rendering, color, and opacity settings as required. Select Synchronize to use the same rendering, color, and opacity for the CT model in all GPS panels.
Rotate the CT model	Click Set position and orientation , and then specify the angle of the model relative to the left-right, posterior-anterior, and inferior-superior axes.

Task	Steps
Move the CT model	Click Set position and orientation , and then use sliders to adjust the position along the left-right, posterior-anterior, and inferior-superior axes.
Change the size of the CT model	Click Set position and orientation , and then change the scale using the slider.
Display the axes at the origin of CT model	Select Render Axes at CT/MRI Model Origin .
Hide the CT model	Select Do Not Render in the CT/MRI Rendering list.
Delete the CT model	Click Clear CT/MRI Model .

Table 33: Commands for mini CT models

Task	Steps
Import CT model	Convert the CT scan data to STL format and transfer the STL file to the Globe Workstation using a CD or a USB drive. Then, click Load CT/MRI Model , select the STL file, and click Open .
Change the size of the CT model	Use the Size slider under Mini CT/MRI view options .
Delete the CT model	Click Clear CT/MRI Model .

8 PF ablation

During PF ablation, the Globe PF Generator delivers pulsed field energy to the Globe Catheter in short, high voltage pulses.

8.1 Select electrodes for PF ablation

You can select between 2 and 64 electrodes for PF ablation.

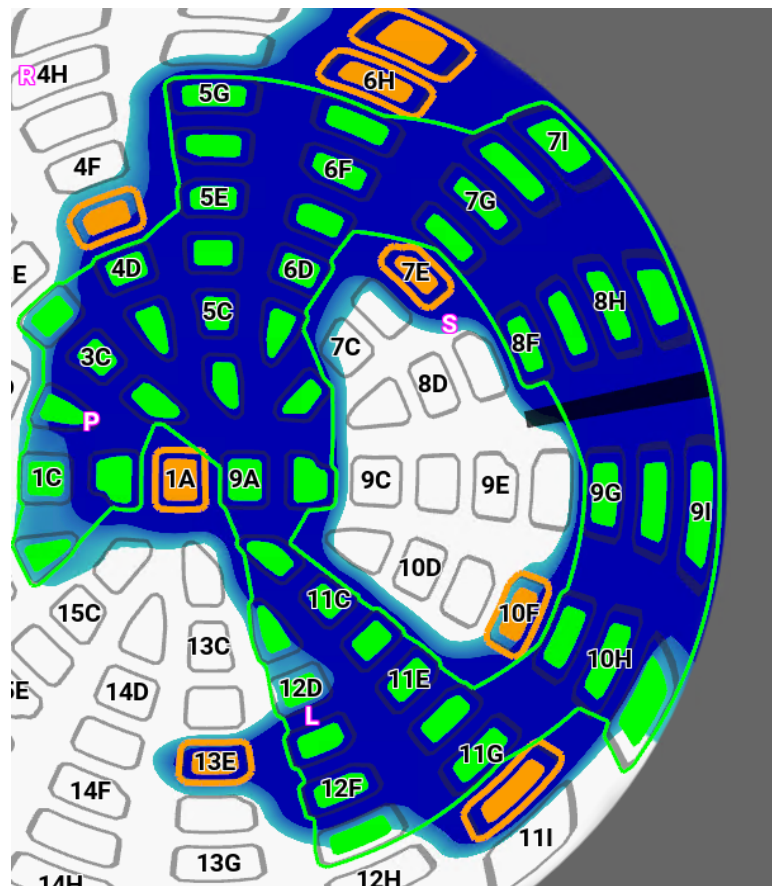
1. On the **Global tool palette**, click the PF Path tool.

A small black square button with the white text "PF" inside, representing the PF Path tool in the Global tool palette.

2. To select electrodes for pulsing, click them one by one. Electrodes can also be selected by moving the mouse pointer along the desired ablation path while holding down the left mouse button. The selected electrodes are shown in bright green. If pulsing around a feature of interest, select a two-electrode wide path.

An orange electrode indicates that the electrode cannot be paired with another electrode. Pulsing cannot proceed if unpaired electrodes are detected. To pair electrodes and enable ablation, click **Fix selected targets for ablation**. Alternatively, remove the unpaired electrodes or manually add pairing electrodes.

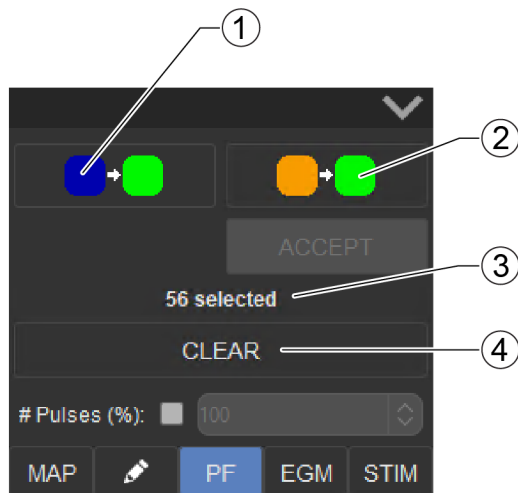
Figure 62: Selecting electrodes for PF ablation



Green Electrode selected for ablation

Orange Unpaired electrode

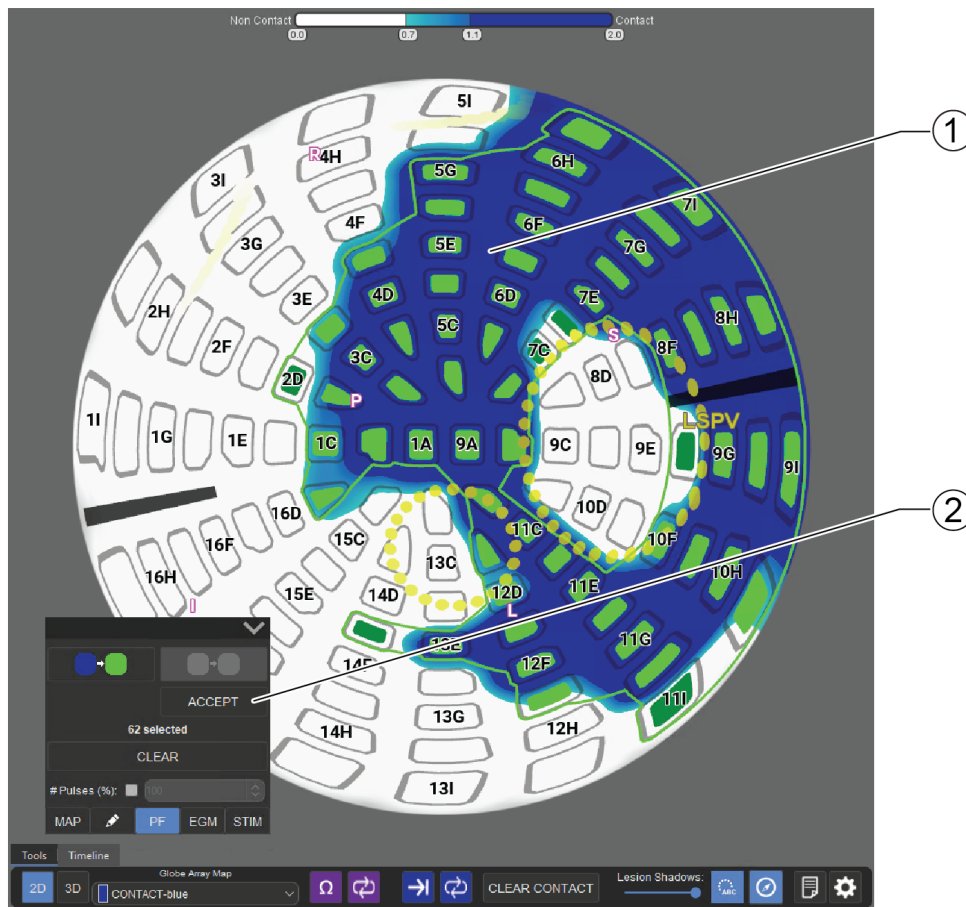
Figure 63: Tools for PF ablation



- 1 Select all high-contact electrodes for ablation
- 2 Fix selected targets for ablation
- 3 Number of electrodes selected for ablation
- 4 Deselect all electrodes

Proposed targets generated by **Fix selected targets for ablation** are shown in dark green. To accept the proposed targets for ablation, click **Accept** or select the proposed target.

Figure 64: Tools for PF ablation



- 1 Proposed targets
- 2 Accept proposed targets for ablation

To remove an electrode, click the electrode. To remove all electrodes, click **CLEAR**.

8.2 Deliver PF energy



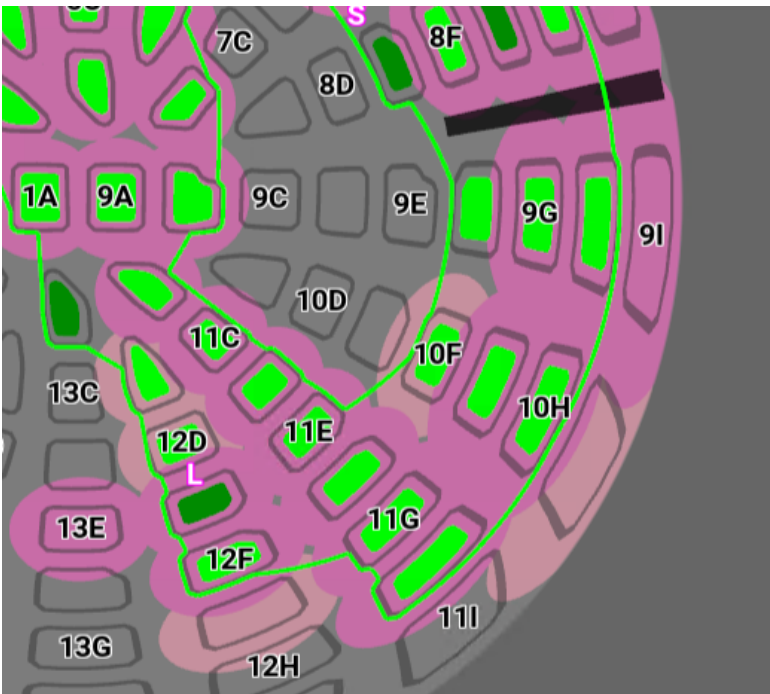
CAUTION

Do not deliver more than 200% of the default number of pulses to a given anatomical location. For example, do not deliver more than 2 applications of PF energy when the number of pulses is set to 100%.

1. Optionally, adjust the **# Pulses (%)** value, expressed as a percentage of recipe default.
2. Click **PULSE**.

Electrodes where PF energy has been delivered are shown in dark pink. Electrodes that have been selected for additional pulsing are shown in green.

Figure 65: PF ablation lesion markers



Pink	PF energy has been delivered
Green	Electrode selected for additional pulsing

To see the total PF ablation time for the procedure, click , select **Setup and Status**, and then click the **Electrode Status and Procedure Info** tab.

8.3 Stop PF ablation

The PF ablation control algorithm automatically stops delivering PF energy after completing the execution of the pulsing recipe. If the system does not deliver the requested number of pulses to all electrodes during the initial ablation sequence (for example, due to an overcurrent event) it automatically attempts to deliver the remaining pulses at the end of the ablation sequence. The system does not deliver more than the requested number of pulses to an electrode.

If the system does not deliver the requested number of pulses to all electrodes after the automatic retry, the outstanding electrode pairs and the percentage completed can be identified in the **PF System Log**. To reattempt ablation at the outstanding electrode pairs, select the outstanding electrode pairs and adjust the **# Pulses (%)** value to the remaining percentage.

Pulsing can also be stopped at any time. To stop the delivery of PF energy, click **STOP** at the top of the Array panel or press the **ESC** key.

9 Stimulation

9.1 Stimulation with the Globe Catheter

The electrodes on the Globe Catheter emit stimulation pulses that can be used for diagnostic purposes, for example to assess conduction block. To stimulate using the Globe Catheter:

1. On the **Global tool palette**, click the stimulation tool.

A small, dark rectangular button with the word "STIM" in white, sans-serif, uppercase letters.

2. Select the electrodes and segments that will deliver the stimulation pulses.

The color of the selected electrodes and segments changes to purple.

To remove the selection, click **CLEAR**.

For monopolar stimulation, select the electrode at the appropriate location. For bipolar stimulation, select a segment. When a single electrode is selected (monopolar stimulation), the stimulation current is delivered from the specified electrode to the neutral electrode. When a segment is selected (bipolar stimulation), the stimulation current is delivered from one electrode to the other electrode.

The maximum number of elements that can be selected depends on the stimulation frequency.

3. Specify the stimulation parameters:

- 3.1. Click **STIM**.

- 3.2. Select the catheter: **Array**.

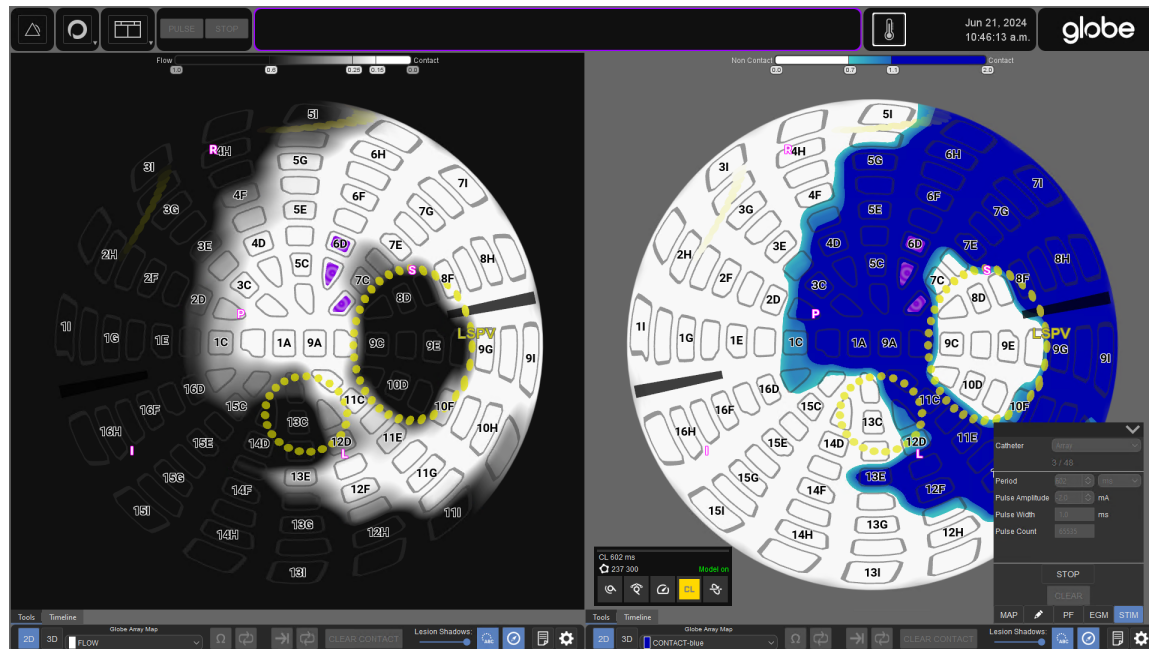
- 3.3. Specify the pulse frequency or period, width, amplitude, and count.

See Figure 67: *Globe Catheter stimulation settings on page 117* and Table 34: *Globe Catheter stimulation settings on page 117*.

4. To deliver the stimulation pulses, click **STIMULATE**.

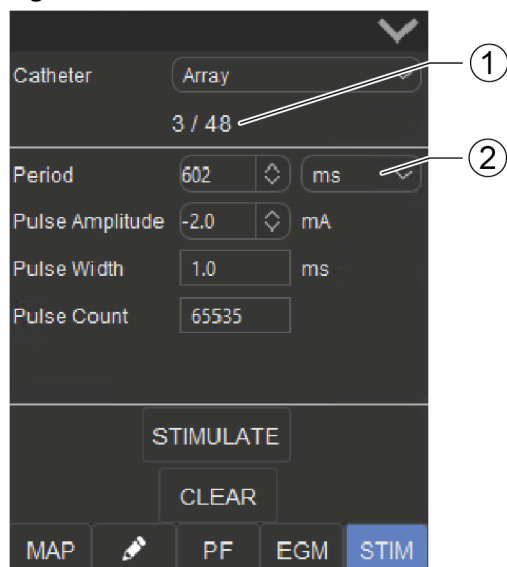
The color of the selected elements changes to pulsating purple and a purple border appears in the status bar. A yellow line appears on the procedure timeline.

Figure 66: Stimulation in progress



- To stop stimulation, click **STOP**. Stimulation is automatically disabled during the delivery of RF or PF energy to the Globe Catheter, including the delivery of RF energy for purposes other than ablation, such as CONTACT Map generation. Stimulation is automatically disabled during self-tests also.

Figure 67: Globe Catheter stimulation settings



- 1 Number of electrodes or segments selected (actual/maximum)
- 2 Period and Frequency selector

Table 34: Globe Catheter stimulation settings

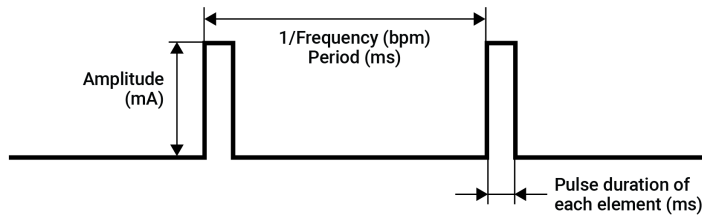
Parameter	Notes
Period and Frequency	The frequency is the rate at which stimulation pulses are delivered. The frequency value is adjustable between 30 bpm and 870 bpm. The period is the reciprocal of the frequency and is adjustable between 69 ms and 2001 ms. The default frequency is 100 bpm and the default period is 602 ms.
Pulse amplitude	The pulse amplitude is adjustable between -10 mA and -0.1 mA, or between 0.1 mA and 10 mA. The default value is -2 mA.
Pulse width	The pulse width is the duration of the stimulation pulse for each electrode or segment. The width is adjustable between 1 ms and 4 ms. The default value is 1 ms. When more than one electrode or segment is selected, the system activates each electrode or segment in sequence.
Pulse count	The pulse count is the number of stimulation pulses to be delivered per electrode or segment. The count is adjustable between 1 and 65 535. The default value is 65 535.

Figure 68: Stimulation waveform

Electrode/Segment 1



Electrode/Segment 2



9.2 Stimulation with an auxiliary catheter

An auxiliary catheter connected to the Globe Controller can generate stimulation pulses.

To stimulate with an auxiliary catheter:

1. On the **Global tool palette**, click the stimulation tool.

STIM

2. Specify the stimulation parameters:
 - 2.1. Click **STIM**.
 - 2.2. Select the catheter: **Auxiliary 1** or **Auxiliary 2**.
 - 2.3. Select an electrode pair for stimulation.
 - 2.4. Specify the pulse frequency or period, width, amplitude, and count.

3. To deliver the stimulation pulses, click **STIMULATE**.

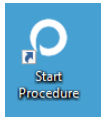
A purple border around the status bar indicates that stimulation is proceeding.

4. To stop stimulation, click **STOP**.

10 Procedure management

10.1 Start procedures

To start a procedure, double-click the **Start Procedure** desktop shortcut.



A procedure log is created in the **C:\Kardium\Canopus\deploy\LogFiles\procedures** folder. For information on this folder, see *Archive procedure logs* on page 129.

10.1.1 Enter patient information

The Procedure Information tab contains information about the patient, the procedure start time, and the total ablation time.

1. Click  and select **Setup and Status**.
2. Click the **Electrode Status and Procedure Info** tab.
3. To change the procedure start time, click the **Procedure Info** tab and click **Set**. Set a new time.
4. To enter the patient information, click the **Patient Info** tab and enter the patient information. Click **Save**.

10.2 Stop procedures

1. Click .
2. Select **Quit Globe software**.

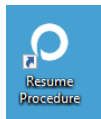
10.3 Resume procedures

You can resume a procedure that was interrupted unexpectedly, for example after a power failure.

Resuming a procedure does not trigger the entire suite of system tests that run when starting a procedure.

To resume a procedure:

1. Double-click the desktop shortcut **Resume Procedure**.

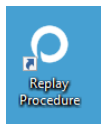


2. Choose the procedure from the list and click **OK**.

10.4 Offline review

You can review entire procedures offline after they are complete. To review a procedure:

1. Double-click the desktop shortcut **Replay Procedure**.

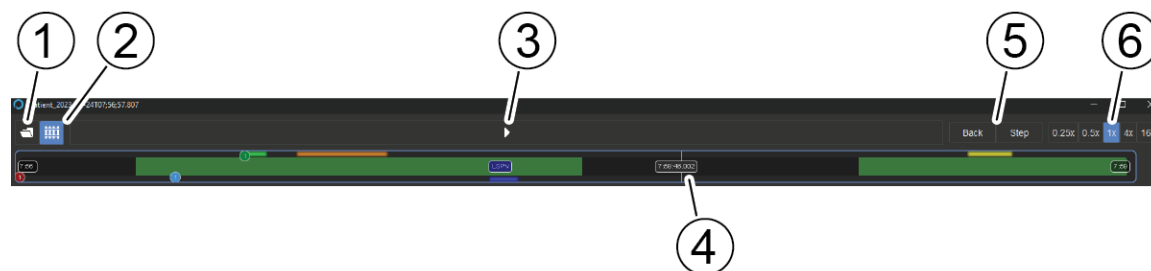


2. Choose a procedure.

The procedures are listed in ascending order of folder modification date. For example, the folder name **Patient_2022-07-10T14;21;26.250** includes the procedure start date and time. The "T" denotes the start of the time section. Semicolons separate hours, minutes, and seconds.

Use the controls on the Procedure player to adjust the playback speed and position.

Figure 69: Procedure player



- 1 List of procedures
- 2 Review mode

There are two offline review modes:

Passive (Default) The procedure data is displayed exactly as it was viewed during the live procedure. This is similar to watching a video recording. Making any view changes, for example, changing the panel configuration, switches the replay to interactive mode.

Interactive You can view the saved procedure data in different ways. For example, you can display a selected range WAVE Map at any time during the replay even if the user who performed the live procedure did not look at that map (the map is generated from the stored voltage data).

- 3 Play/pause button
- 4 Time cursor
- 5 Step forward or back approximately 1/10 of a second when the player is paused
- 6 Play speed

11 Monitoring system

11.1 Troubleshooting button

The Troubleshooting button at the top left of the screen indicates overall system status. Click the button to view the system logs and alarms, and to manage system tests. Refer to the table below for information on how to interpret the appearance of the Troubleshooting button.

Table 35: Troubleshooting button

Appearance	Meaning
	A gray button indicates normal operation.
	A red, yellow, or blue button indicates an active alarm.
	A red padlock indicates that the ability to deliver energy for therapy has been disabled. To find out why, click  and select Setup and Status .

11.2 Electrode status

When the Globe Catheter is connected to the Globe Controller, the catheter test is automatically executed to check the temperature sensor of all electrodes. You can also execute this test manually. If any electrodes fail the test during its first run, you must review and accept the test results. For subsequent tests, if the electrodes that fail the test are different than during the previous test run, you must review and accept the test results. Electrodes with potentially faulty temperature sensors are shown in red or yellow. The catheter may still be usable even if some temperature sensors are faulty. Using a catheter with faulty electrodes may increase the risk of ineffective therapy.

Figure 70: Electrode Setup and Status panel

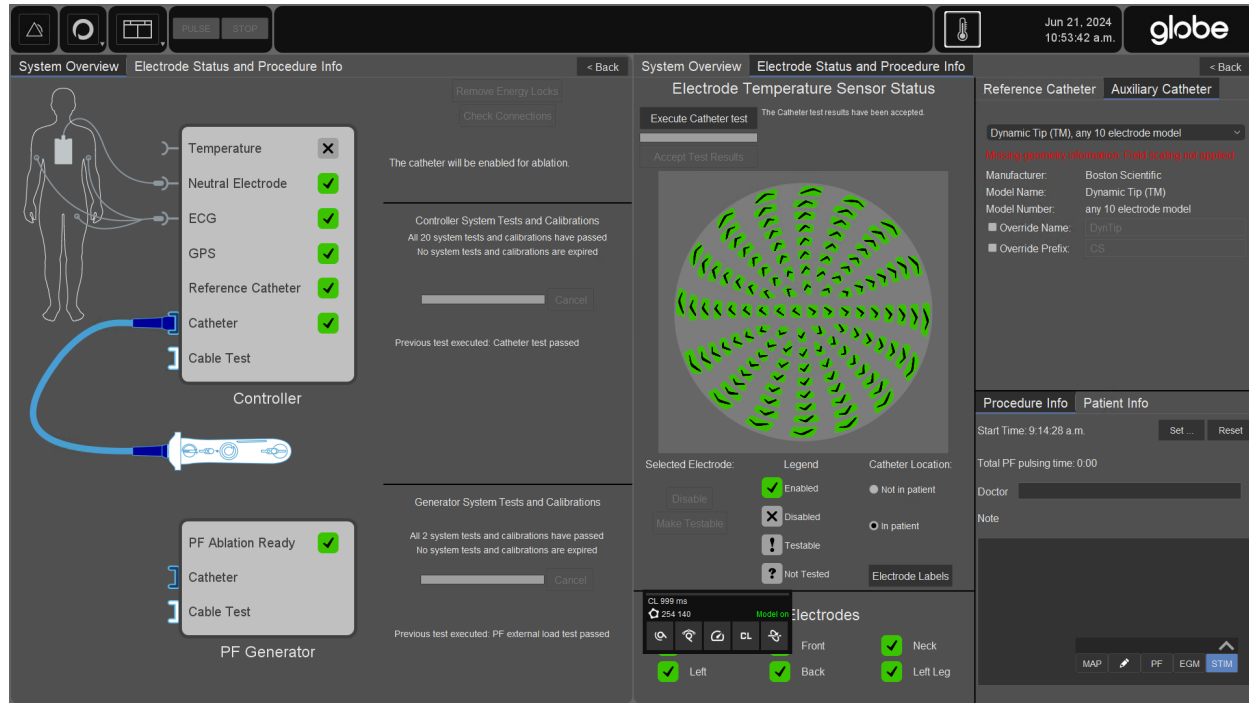


Table 36: Electrode status

Appearance		Meaning
	Enabled	The electrode is fully functional.
	Disabled	The electrode has been disabled and will not be tested again.
	Testable	The electrode has been temporarily disabled. The electrode will be enabled again if it passes the Catheter test the next time the test is run.
	Not tested	The electrode has not been tested yet. The electrode will be disabled until it passes the Catheter test.

To review and approve the status of the electrodes:

1. Click and select **Setup and Status**.
2. Click the **Electrode Status and Procedure Info** tab.
3. If running the test manually, confirm that the catheter location (**Not in patient** or **In patient**) is correct, and then click **Execute Catheter test**.

The software assumes a location based on the measured temperature. If the indicated catheter location is wrong, then change it to the correct value.

Testing outside the patient is used to check the electrodes before inserting the catheter into the patient. When testing outside the patient, the acceptance criteria are less strict than when the catheter is inside the patient. The electrode becomes available for testing, but it will not be enabled until it passes the Catheter test.

4. Examine the electrode status.

4.1. To disable an electrode, select the electrode and click **Disable**.

Consider disabling any electrodes that intermittently show as 'Testable' to avoid nuisance issues.

4.2. To enable an electrode that is currently disabled, select the electrode and click **Make Testable**.

The electrode becomes available for testing but will not be enabled until it passes the Catheter test.

5. If you decide to proceed with the catheter as is, click **Accept Test Results** to remove the energy lock.

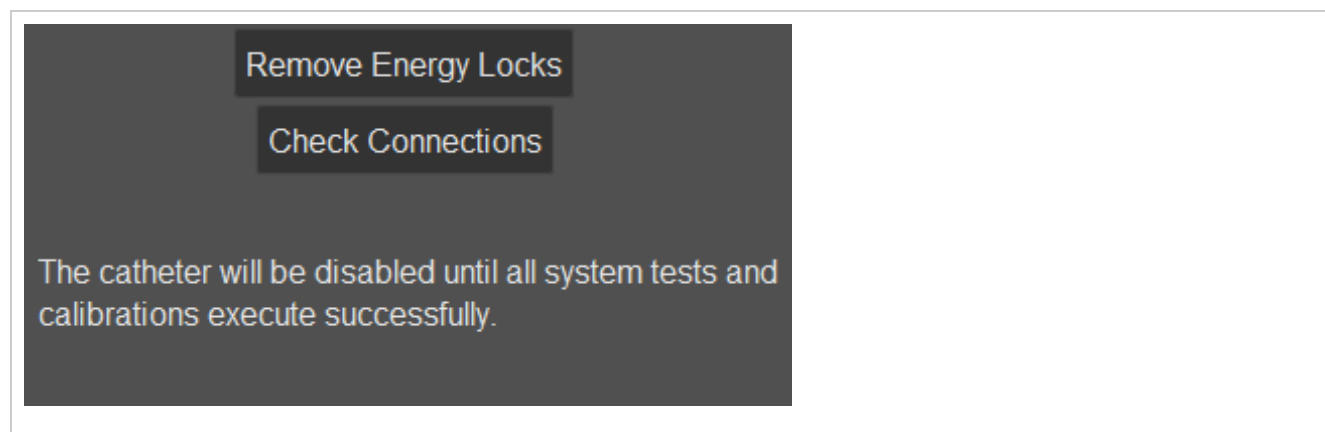
For information on the status of the GPS Electrodes and the status of the electrodes on the reference and auxiliary catheters, see *Enabling the GPS* on page 91.

11.3 Energy locks

The system messages on the **System Overview** tab of the **Setup and Status** panel provide information on the status of the Globe Catheter.

The Globe safety system prevents energy delivery to the Globe Catheter until all system tests and calibration routines execute successfully. In special cases, such as when a system test fails twice consecutively, you must click the **Remove Energy Locks** button to supply energy to the catheter.

Figure 71: Remove Energy Locks and Check Connections buttons



11.4 Neutral electrode check

After running system tests, but before connecting the Globe Catheter, if the system indicates that the neutral electrode is not connected, then force the system to update its state: In the **Setup and Status** panel, on the **System Overview** tab, click **Check Connections**. This temporarily overrides the system lockouts that prevent the system from checking the status of the neutral electrode.

11.5 System logs

The system logs for the Globe PF Generator and Globe Controller list every event, condition and alarm that occurs during the procedure. To view the system logs, click the Troubleshooting button and click either **PF System Log** or **RF System Log**.

11.6 Alarms panel

Alarm conditions trigger alarm messages on the Globe Workstation. The color of the alarm message indicates the alarm’s priority level. Corresponding alarm signals are triggered on the Globe Controller or Globe PF Generator and the Globe Workstation.

To view the alarm messages, click the Troubleshooting button, and then click **RF Alarms** or **PF Alarms**.

Table 37: Alarm priority

Alarm priority	Color	Meaning
High	Red	Condition leading to death or irreversible injury if not attended to immediately.
		
Medium	Yellow	Condition leading to reversible injury if not attended to soon.
		
Low	Blue	Condition leading to minor injury or discomfort if not addressed.
		

Alarms requiring attention (for example, alarms for which the condition persists) have a bright background. Alarms for which the condition no longer exists but which have been silenced, that is, paused or turned off, have a muted background.

To reset an alarm, click the **Reset** button. The **Reset** button is not available if the condition that triggered the alarm is still present.

To disable the audio signal while keeping the visual signal on the Globe Workstation, Globe Controller, and Globe PF Generator, click **Pause Audio** or **Turn Audio Off**. To disable both the audio and visual signals, click **Pause Alarm** or **Turn Alarm Off**.

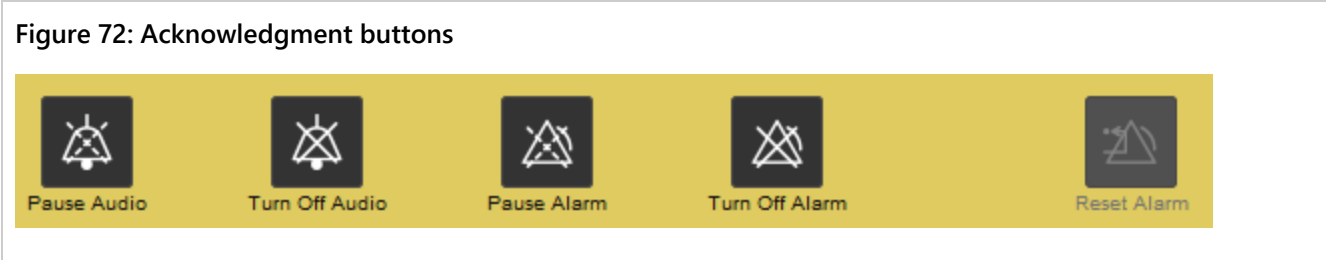


Table 38: Alarm status

Status	Meaning	Button to enable alarm
ALARM ENABLED	The alarm is operational.	-
ALARM PAUSED	The alarm has been silenced temporarily. The audio pause period is 5 minutes. The sound resumes after the pause period expires.	
AUDIO OFF	The alarm has been silenced indefinitely.	
ALARM PAUSED	The alarm has been paused temporarily, including both audio and visual signals. The alarm pause period is 5 minutes. The alarm indication resumes after the pause period expires.	
ALARM OFF	The audio and visual alarm signals have been turned off. Not all alarms can be turned off.	

11.7 Alarm messages

Table 39: Alarm conditions

Description	Resolution	Notes
Safety system error		
Automatic power-down of controller/generator failed.	Immediately turn off the controller and PF generator. Disconnect the catheter. Stop the procedure and contact Kardia technical support.	High priority Non-latching Cannot be turned off or paused
Neutral electrode error		
The neutral electrode impedance moved outside the required impedance range [x, y] Ω .	Improve the neutral electrode contact. Check the neutral electrode cable connection. If necessary, replace or move the neutral electrode. Click the Check Connections button in the Setup and Status panel.	High priority Non-latching Cannot be turned off The alarm is triggered when the impedance between the two electrodes is $<45 \Omega$ or $>435 \Omega$ after good contact had been previously achieved. The alarm is cleared when the impedance is $>65 \Omega$ and $<415 \Omega$.
Controller/generator electronics overheating		
The temperature on the controller/generator's board is too high. If the temperature keeps rising, the system will be disabled and ablations will be stopped.	You may continue the procedure but the catheter will be disabled if the temperature keeps rising. The alarm will stop when the board cools down. Wait until the alarm has stopped before starting any new ablations. Make sure the controller/generator air vents are not obstructed.	Low priority Non-latching
Controller/generator fan stopped		
One or more controller/generator cooling fans have stopped. The electronics may overheat.	Ensure all controller and generator air vents are unobstructed. Continue with the procedure. Call Kardia technical support if the condition persists beyond this procedure.	Low priority Non-latching

Description	Resolution	Notes
Approaching sheath temperature limit		
The sheath temperature is getting too high. The current sheath temperature is $x^{\circ}\text{C}$. Ablations will stop automatically if the sheath temperature reaches $y^{\circ}\text{C}$.	Reduce the total number or duration of ablations to slow down the sheath temperature rise.	Low priority Non-latching
Nearing total current limit: $x\text{A}/y\text{A}$		
The controller will stop all ablations if the current limit of $x\text{ A}$ is reached.	Stop some ablations to decrease the total current required for ablation.	Low priority Non-latching

12 System shutdown

At the end of each procedure:

1. Stop the software procedure. See *Stop procedures* on page 119.
2. Remove the ECG monitoring electrodes and the GPS Electrodes from the patient. Dispose of the ECG monitoring electrodes and the GPS Electrodes according to hospital policy and local regulations.
3. Disconnect the ECG cable from the Globe Controller. Clean or dispose of the ECG cable according to the manufacturer's instructions.
4. Clean the Globe Catheter Cable and hang it on the Globe Controller. See *Cleaning* on page 192 in Appendix B: Globe Catheter Cable for cleaning instructions. It is not necessary to disconnect the cable from the controller.
5. If necessary, disconnect the Globe Controller's long connection cable from the Globe PF Generator using the following steps:
 - 5.1. On the Globe PF Generator, rotate the lock on the port for the long connection cable 180° counterclockwise to unlock the cable.
 - 5.2. Pull the long connection cable out of the port.
6. Remove the reference catheter from the patient's coronary sinus and dispose of it according to the manufacturer's instructions.
7. If in use, remove the optional temperature calibration probe and the optional diagnostic catheter from the patient and dispose of them according to the manufacturer's instructions.
8. Disconnect the GPS Cable from the Globe Controller and clean the cable. See *Cleaning* on page 186 in Appendix A: Globe Positioning System Cable and Electrodes for cleaning instructions.
9. Disconnect the Unimed Medical Supplies 10-Pin Catheter Adapter from the Globe Controller and clean according to the manufacturer's instructions.
10. If in use, disconnect the temperature calibration probe cable from the Globe Controller and clean according to the manufacturer's instructions.

At the end of the day:

1. Shut down Windows (make sure that you select the **Shut down** command and not **Restart**).
2. Turn off the Globe Controller: push the green power enable button and flip the rocker power switch at the back.
3. Turn off the Globe PF Generator: push the green power enable button and flip the rocker power switch at the back.

13 System administration

The Globe Workstation is preconfigured with two user accounts, *Operator* and *The Administrator*.

The *Operator* account has non-administrator privileges. Consult Kardium if you have lost the password to the *Operator* account.

The *The Administrator* account is intended for Kardium personnel and has administrator privileges.

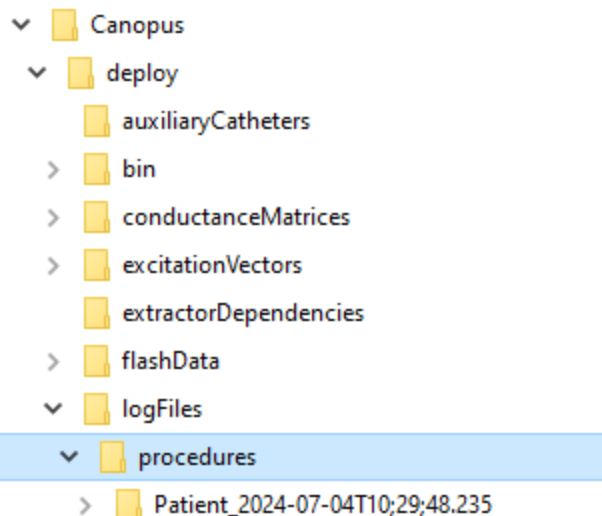
System administration tasks such as software updates, system backup and restore, and system configuration are performed by qualified Kardium personnel.

13.1 Archive procedure logs

Procedure logs are automatically saved in the

C:\Kardium\Canopus\deploy\logFiles\procedures folder.

Figure 73: Procedure logs folder



The Globe Workstation has two drives:

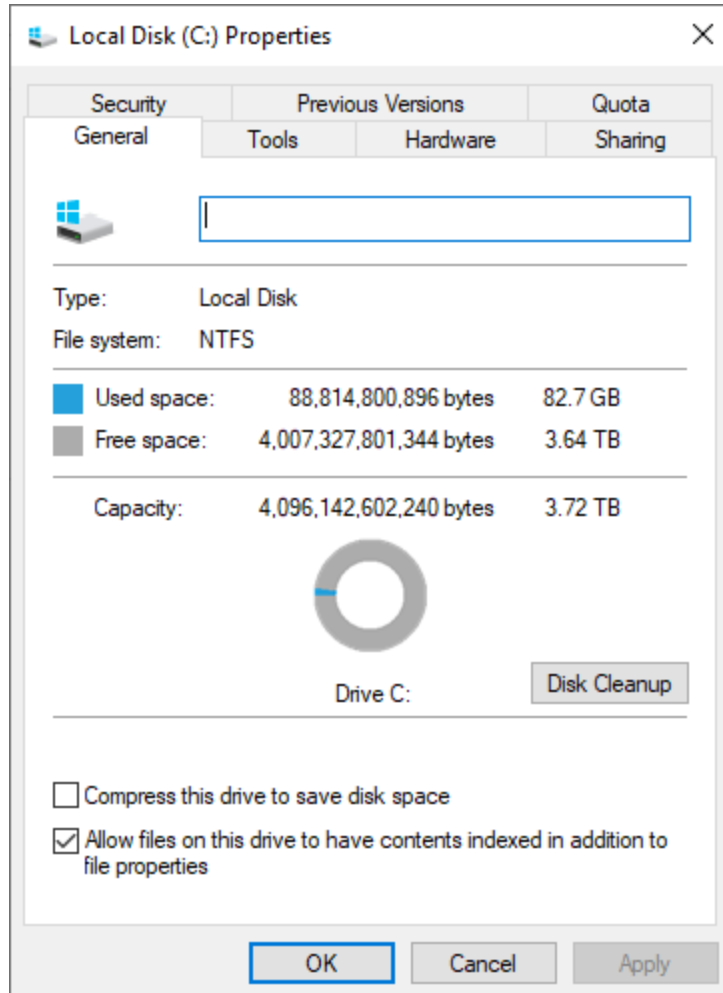
- 4 TB OS drive (C)
- 4 TB Archive drive (D)

The file size of each procedure log depends on how many GPS models and surface maps are created.

To ensure adequate disk space for procedure logs, you must copy procedure logs from the OS drive to the Archive drive when disk space on the OS drive drops below 50 GB.

To check free space on the OS drive, right-click on the OS drive from Windows Explorer and select **Properties**. The amount of free space is shown on the **General** tab.

Figure 74: Free space on OS drive



To archive procedure logs:

1. Open the **C:\Kardium\Canopus\deploy\logFiles\procedures** folder.
2. Select the procedure logs to archive.
3. Move the procedure logs from the **C:\Kardium\Canopus\deploy\logFiles\procedures** folder to the destination folder on the Archive (D) drive.

14 Maintenance

The components of the Globe PF System are not user-serviceable. Attempted repair by unqualified personnel may create a hazardous situation. If the system components fail to operate, contact Kardium.

Components of the Globe PF System that fail to operate shall only be reused after they are reconditioned by Kardium.

14.1 Maintenance schedule

Table 40: Maintenance schedule

Frequency	Component	Task
Before each use	Globe Catheter Cable	Clean the cable and inspect for damage. Replace damaged cables. Return damaged cables to Kardium for repairs. Refer to <i>Globe Catheter Cable</i> on page 189 for more information on cleaning and disposal.
	Cable for optional temperature calibration probe	Clean the cable and inspect for damage. Replace damaged cables. Clean and dispose of cables according to the manufacturer's instructions.
	GPS Cable	Clean the cable and inspect it for damage. Replace damaged cables. Refer to <i>Globe Positioning System Cable and Electrodes</i> on page 180 for information on cleaning and disposal.

Frequency	Component	Task
Weekly	Globe Controller	- Inspect the Globe Controller for damage. - Clean the Globe Controller. - Check that all indicators work. - Test the audio signals. - Report any damage or malfunction to Kardium.
	Globe PF Generator	- Inspect the Globe PF Generator for damage. - Clean the Globe PF Generator. - Check that the blue PF indicator works. - Test the audio signals. - Report any damage or malfunction to Kardium.
	Globe Workstation	- Clean and inspect for damage. Report any damage or malfunction to Kardium. - Run a Quick Scan for malware. See <i>Virus and threat protection</i> on the next page for more information.
	Globe Controller power cables, Globe PF Generator power cables, Globe Workstation power cable, USB cables, USB cable extensions	Clean and inspect for damage. Replace damaged cables.
Once every two years	Globe Controller and Globe PF Generator	Regular maintenance service to be performed by authorized Kardium service personnel.

14.2 Clean the Globe Controller

Turn off the Globe Controller. Wipe the exterior surfaces of the Globe Controller and clean with a damp cloth. If necessary, use a hospital-grade detergent. Dry thoroughly. Do not spray liquids on the Globe Controller.

14.3 Check the indicators on the Globe Controller

Turn on the Globe Controller and confirm that all the indicators illuminate.

14.4 Test the audio signals on the Globe Controller

1. Click  and then **Settings**.
2. Click the **Audio Signals** tab.

3. Click **Play** and confirm that you can hear the RF energy delivery signal on the Globe Controller.
4. Click **Raise** next to one of the alarm signals. Confirm that you can hear the signal on both the Globe Workstation and the Globe Controller, and that the corresponding visual indicators are displayed on the Globe Workstation and the Globe Controller.
5. Click **Clear** to stop the alarm.

14.5 Clean the Globe PF Generator

Turn off the Globe PF Generator. Wipe the exterior surfaces of the Globe PF Generator and clean with a damp cloth. If necessary, use a hospital-grade detergent. Dry thoroughly. Do not spray liquids on the Globe PF Generator.

14.6 Check the indicators on the Globe PF Generator

Turn on the Globe PF Generator and confirm that the blue indicators illuminate on power up.

14.7 Test the audio signals on the Globe PF Generator

1. Click  and then **Settings**.
2. Click the **Audio Signals** tab.
3. Click **Play** and confirm that you can hear the PF energy delivery signal on the Globe PF Generator.
4. Click **Raise** next to one of the alarm signals. Confirm that you can hear the signal on both the Globe Workstation and the Globe PF Generator, and that the corresponding visual indicators are displayed on the Globe Workstation and the Globe PF Generator.
5. Click **Clear** to stop the alarm.

14.8 Clean the Globe Workstation

Turn off the Globe Workstation. Wipe the exterior surfaces of the components and clean with a damp cloth. If necessary, use a hospital-grade detergent. Dry thoroughly. Do not immerse the components in water. Do not spray liquids on the components.

14.9 Clean the power cables and USB cables

Turn off the Globe Workstation, the Globe Controller, and the Globe PF Generator. Wipe the exterior surfaces of the components and clean with a damp cloth. If necessary, use a hospital-grade detergent. Dry thoroughly. Do not immerse the components in water. Do not spray liquids on the components.

14.10 Virus and threat protection

To support virus and threat protection on the workstation, run a **Quick scan** weekly.

1. Sign into the workstation using the *Operator* account.
2. Right-click **Start** and then, click **Search**. Type **Windows Security** and then, click **Open**.
3. Click **Virus & threat protection** and then, click **Quick scan**.
4. If you are notified of detected malware or you experience a security event, contact Kardia Technical Support.

15 Disposal

Dispose of the Globe Workstation, Globe Controller and Globe PF Generator in accordance with hospital policy and local regulations for equipment containing electrical and electronic parts. Before disposal, remove data from the Globe Workstation in accordance with hospital policy for data privacy and data protection. Contact your Kardium representative prior to disposal.

16 Troubleshooting

16.1 System does not respond to request to stop ablation

If the Globe Workstation reports that it has lost communication with the Globe PF Generator during ablation and the PF generator's PF indicator remains lit:

1. Disconnect the catheter from the catheter cable.
2. Push the green power enable button to turn off the PF generator.
3. Click  and then click **Quit Globe software** to close the software.
4. Push the green power enable button to turn on the PF generator.
5. Double-click the desktop shortcut **Resume Procedure**.
6. Reconnect the catheter to the catheter cable.

If the error is reported again, stop the procedure and contact Kardium Technical Support.

16.2 Temperature calibration errors

Try these solutions, in order, until the problem is solved.

1. Confirm that you are using the specified temperature calibration probe and cable. See *Required equipment* on page 23.
2. Using fluoroscopy, confirm that the temperature calibration probe is positioned approximately 2 to 4 cm below (inferior to) the array.
3. Using an independent measurement, confirm that the calibration temperature displayed on the Globe Workstation corresponds to the patient's core temperature.
4. Confirm that the temperature calibration probe is connected to the Globe Controller correctly. Disconnect and reconnect the cable.
5. Replace the temperature calibration probe and cable.
6. Contact Kardium Technical Support.

16.3 Noisy ECG signals

Try these solutions, in order, until the problem is solved.

1. Confirm that the ECG cable and ECG monitoring electrodes are compatible. See *Required equipment* on page 23.
2. Reposition the ECG cable to increase the distance between the ECG cable and the other cables.
3. Confirm that the monitoring electrodes are applied as specified in the manufacturer's instructions.

4. Confirm that the monitoring electrodes are positioned correctly.
5. Clean the ECG cable connections to the ECG electrodes.
6. Unplug the ECG cable from the Globe Controller and reconnect it.
7. Replace the ECG cable.
8. Contact Kardium Technical Support.

16.4 Noisy auxiliary catheter electrograms

Try these solutions, in order, until the problem is solved.

1. Confirm that the compatible catheter cable is connected to the Unimed Medical Supplies 10-Pin Catheter Adapter.
2. Confirm that the 10-pin catheter adapter is connected to the Globe Controller.
3. Confirm that you have selected the correct auxiliary catheter in the **GPS and Auxiliary Electrode Status** tab of the **Setup and Status** panel. See *Enabling the GPS* on page 91.
4. Replace the 10-pin catheter adapter.
5. Replace the compatible catheter cable.
6. Contact Kardium Technical Support.

16.5 Globe Catheter Cable connection errors

If a connection error occurs, try the following, in order, until the problem is solved.

1. Inspect the catheter cable for signs of damage, especially liquid ingress. Replace the catheter cable if liquid ingress has occurred or the cable has any other damage.
2. Unlock each end of the catheter cable and lock them again.
3. Unlock each end of the catheter cable, pull them out, reinsert them, and lock them again.
4. Replace the catheter cable with a new one.
5. Contact Kardium Technical Support.

16.6 Neutral electrode errors

Try these solutions, in order, until the problem is solved.

1. Confirm that you are using the specified neutral electrode. See *Required equipment* on page 23.
2. Confirm that the neutral electrode is applied as specified in the manufacturer's instructions.
3. Unplug the neutral electrode cable from the Globe Controller and connect it again.

4. Replace the neutral electrode.
5. Contact Kardium Technical Support.

16.7 GPS Electrodes connection errors

Try these solutions, in order, until the problem is solved. For more information on the GPS Cable and the GPS Electrodes refer to *Globe Positioning System Cable and Electrodes* on page 180.

1. Confirm that the GPS Cable is connected to the Globe Controller.
2. Confirm that the correct GPS Electrodes are connected to the correct inputs on the GPS Cable.
3. Confirm that the GPS Electrodes are placed in the correct locations on the patient's body.
4. Confirm that the GPS Electrodes are properly adhered to the patient's skin and that the skin preparation instructions were followed.
5. Replace the GPS Cable.
6. Replace the GPS Electrodes.
7. Contact Kardium Technical Support.

16.8 No connection between Globe Software and Globe Controller

Try these solutions, in order, until the problem is solved.

1. Restart the Globe Software:
 - 1.1. Click  and select **Quit Globe software**.
 - 1.2. Double-click the desktop shortcut **Resume Procedure**.
2. Push the green power enable button to turn off the Globe Controller, and push it again to turn it back on.
3. Unplug the USB cables from the Globe Controller and the Globe Workstation and connect again.
4. Restart the Globe Workstation:
 - 4.1. Push the green power enable button to turn off the Globe Controller.
 - 4.2. Select the **Shut down** command to shut down Windows. Do not use the **Restart** command.
 - 4.3. Push the power button on the Globe Workstation to start Windows.
 - 4.4. Push the green power enable button to turn on the Globe Controller.
 - 4.5. To start the software, double-click the desktop shortcut **Start Globe Procedure**.
5. Replace the USB cable.
6. Replace the USB cable extension.
7. Contact Kardium Technical Support.

17 Technical support

For technical questions and support for your product or to coordinate product returns, contact technical support at support@kardium.com. For additional assistance, contact your local Kardium representative.

18 Product specifications

18.1 Globe Controller

Table 41: Globe Controller physical specifications

Part number	601-00048
Mass	180 kg
Length	96 cm
Width	77 cm
Height	152 cm

Table 42: Globe Controller safety specifications

Leakage safety class	Conforms to IEC 60601-1, Class I
System electrical leakage	$\leq 10 \mu\text{A}$
Grounding system	Floating (applied parts)
Defibrillation protection	Ability to withstand a 5000 V defibrillation pulse from defibrillators that comply with IEC 60601-2-4. Conforms to IEC 60601-2-27:2011.
Isolation	$> 4000 \text{ V}$; $> 5000 \text{ V}$ surge
Protection against ingress of water and solid particles	IPX0
Flammability	Not suitable for use in presence of flammable materials
Mode of operation	Continuous use
Mains disconnection method	Unplugging

Table 43: Globe Controller - Input from patient

ECG cable	- Unimed Medical Supplies E10R/30-GL-P/I - Unimed Medical Supplies E10R/30-GL-P - Unimed Medical Supplies 24155P-I - Unimed Medical Supplies 24155P
Globe Catheter Cable	Kardium part 601-00046
Neutral electrode cable	3M Series 9100 Universal Electrosurgical Pad 9165
Temperature calibration probe cable (optional)	- Smiths Medical General Purpose Probe ER400-9 (9 Fr) or ER400-12 (12 Fr) with Smiths Medical Temperature Monitoring Reusable Cable 400 series C400-10 - Smiths Medical Esophageal Stethoscope Temperature Sensors ES400-9 (9 Fr), ES400-12 (12 Fr), ES400-18 (18 Fr), or ES400-24 (24 Fr) with Smiths Medical Temperature Monitoring Reusable Cable 400 series C400-10 - Truer General Purpose Probe, GP 14400 (14 Fr) with Truer Temperature Monitor Interface Cable 400 series 70321
GPS Cable	Kardium part 601-00036
10-pin catheter adapter	Unimed Medical Supplies AD-KAR-210148

Table 44: Globe Controller - Input from other equipment

Globe Workstation	Kardium-supplied USB cables (2 x 2-meter passive cables and 2 x 20-meter active extensions)
Globe PF Generator	Kardium part 601-00060

Table 45: Globe Controller - ECG/electrogram processing

Sampling rate	488 Hz
Resolution	5 μ V
Gain accuracy	$\pm$ 20%

Display scale range	Adjustable from $\pm 50 \mu\text{V}$ to $\pm 1 \text{ V}$
Input signal DC offset	$\pm 300 \text{ mV}$
ECG noise suppression	Performed by driving a small current ($< 10\mu\text{A}$) through a “right leg drive” circuit
Lead off detection	Performed by driving a small current ($< 1\mu\text{A}$ per electrode) between leads
Default gain value	Surface ECG: 10 mm/1 mV Intracardiac electrograms: 10 mm/10 mV
Default filters	Bandpass filter: $1\text{-}225\text{Hz}$
Available sweep speeds	10 mm/s , 25 mm/s , 50 mm/s , 100 mm/s , 200 mm/s , 400 mm/s , 600 mm/s
Default sweep speed	25 mm/s for both ECGs and intracardiac electrograms

Table 46: Globe Controller- Operating parameters

Maximum output current	5.28 A
Maximum output power	12 W/channel into 200Ω
Rated output power	70 W total
RF voltage output	84 VAC maximum (120 V peak)
RF output frequency	480 kHz
Input voltage	100 VAC - 120 VAC , 60 Hz or 200 VAC - 240 VAC , 50 Hz
Input power	600 VA
Potential equalization conductor	The potential equalization conductor terminal may be used to connect the Globe Controller to the potential equalization busbar, if present. Attention is drawn to the ME SYSTEMS requirements of IEC 60601-1.

Temperature accuracy	$\pm 2\text{ }^{\circ}\text{C}$ between $33\text{ }^{\circ}\text{C}$ and $70\text{ }^{\circ}\text{C}$
RF impedance accuracy	$\pm 20\%$
RF timer accuracy	± 2 seconds

Table 47: Globe Controller - Power cable

Power entry for the Globe Controller	IEC 60320 C14 input. Two cables with a mating C13 connector and the appropriate plugs for the installation are required.
Power supply cable	Power cable compliant with the electrical code of the jurisdiction and based on the power rating indicated on the back of the Globe Controller and on the power adapter of the Globe Controller. The Globe Controller's power entry conforms to IEC 60320 C14 and requires two power cables with a IEC 60320 C13 connector.

18.1.1 Globe Controller monopolar output power data

Monopolar electrode power is measured at the electrodes listed below during concurrent RF energy delivery to the Globe Catheter. The electrode’s power is measured relative to the neutral electrode. Output setting is the square of the current driven from the RF power amplifiers.

13D	13E	13F	13G	13H	13I
15D	15E	15F	15G	15H	15I
16D	16E	16F	16G	16H	16I

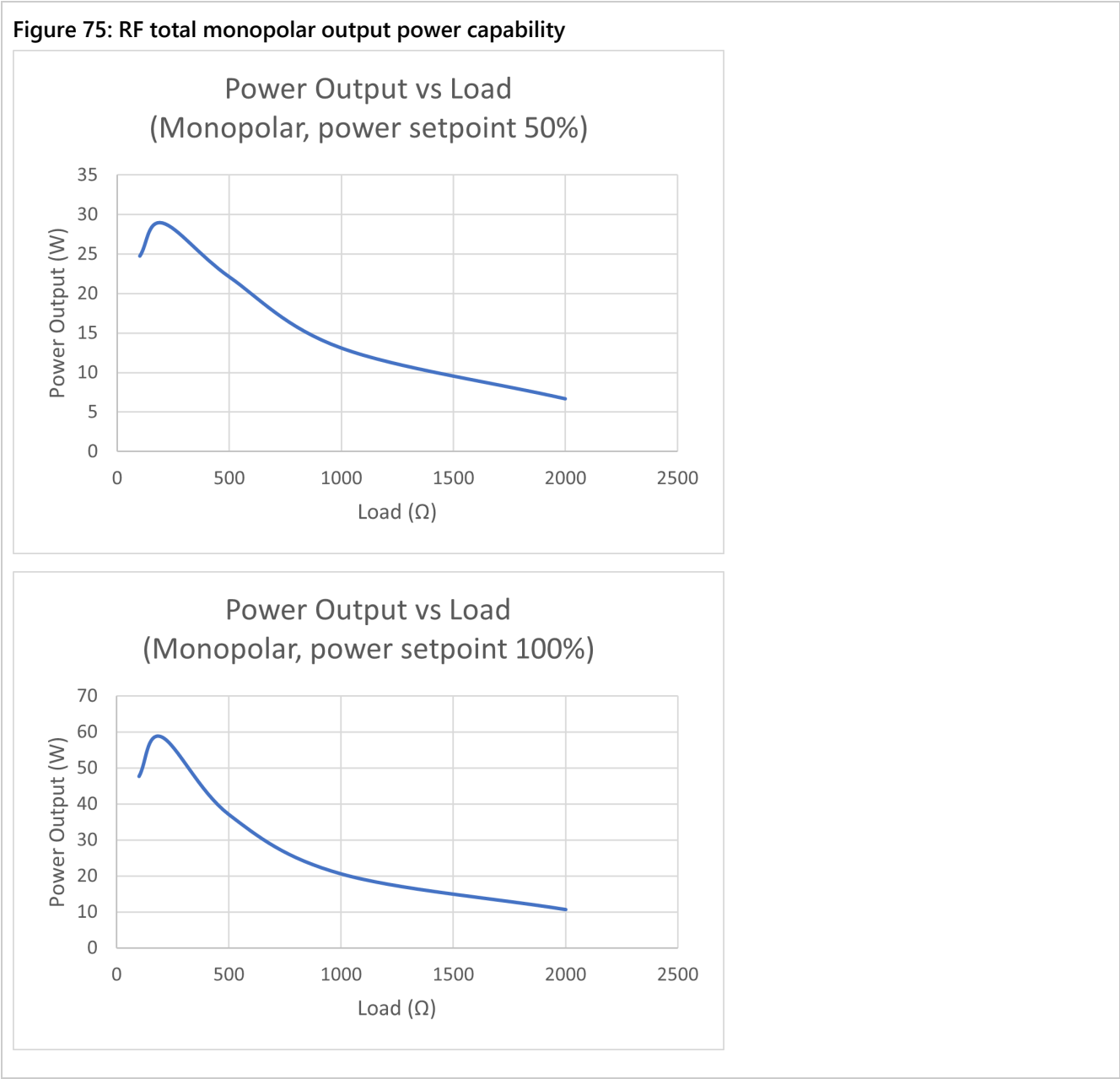
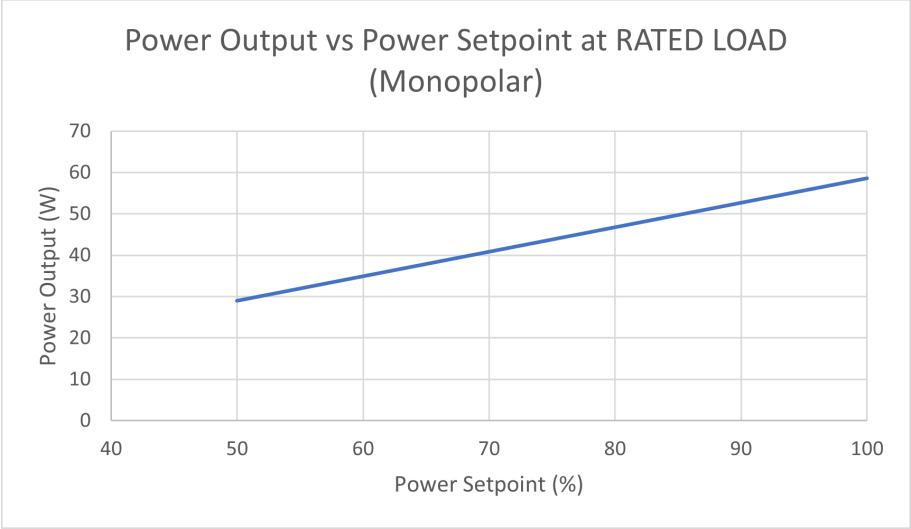


Figure 76: RF monopolar output power capability at rated load (200 ohms)



18.1.2 Globe Controller bipolar output power data

Bipolar electrode power capability is measured while the electrode pairs listed below are concurrently energized on the Globe Catheter. The output powers of the individual electrodes are summed to determine bipolar output power. Output setting is the square of the current driven from the RF power amplifiers.

4I-5H	4H-5G	4E-5D	7E-8F
7D-8E	12C-13B	12D-13C	12H-13I
15D-16C	15E-16D	15F-16E	15G-16H

Figure 77: RF total bipolar output power capability

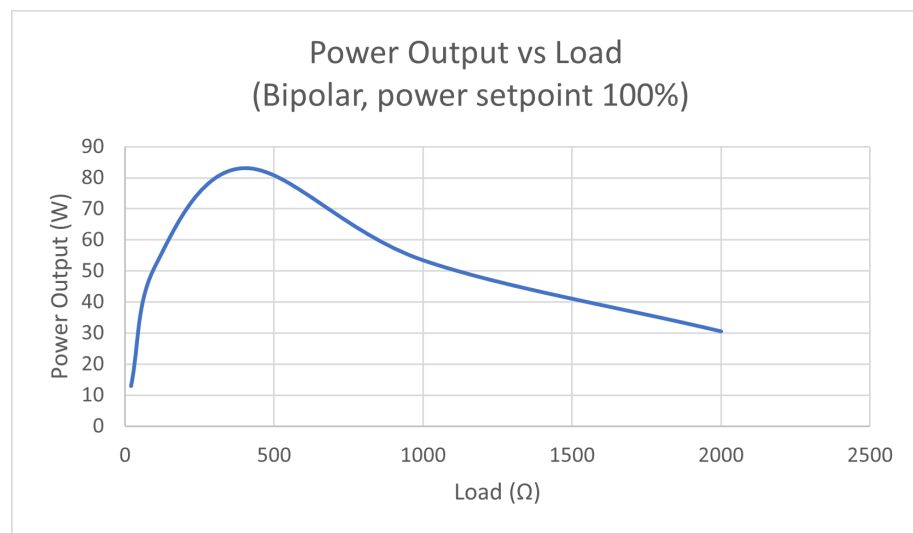
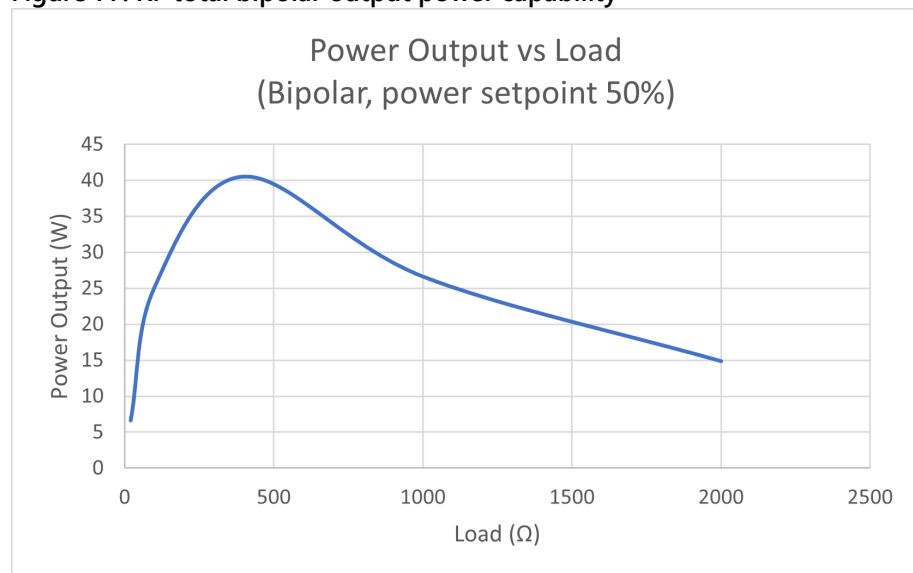
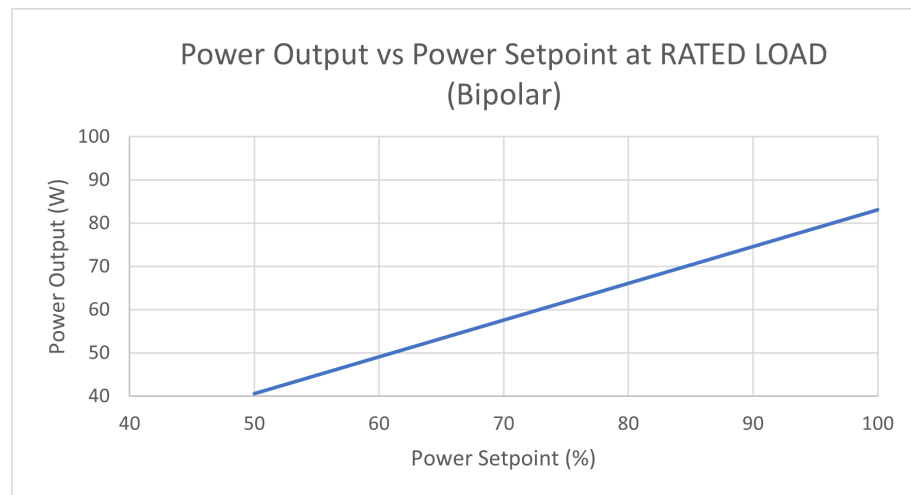


Figure 78: RF bipolar output power capability at rated load (400 ohms)



18.2 Globe PF Generator

Table 48: Globe PF Generator physical specifications

Part number	601-00060
Mass	140 kg
Length	95 cm
Width	72 cm
Height	100 cm

Table 49: Globe PF Generator safety specifications

Leakage safety class	Conforms to IEC 60601-1, Class I
System electrical leakage	$\leq 10 \mu\text{A}$
Grounding system	Floating (applied parts)
Defibrillation protection	Ability to withstand a 5000 V defibrillation pulse from defibrillators that comply with IEC 60601-2-4
Isolation	$> 4000 \text{ V}$; $> 5000 \text{ V}$ surge
Protection against ingress of water and solid particles	IPX0
Flammability	Not suitable for use in presence of flammable materials
Mode of operation	Continuous use
Mains disconnection method	Unplugging

Table 50: Globe PF Generator - Input from patient

Globe Controller	Kardium part 601-00048
------------------	------------------------

Table 51: Globe PF Generator - Input from other equipment

Globe Workstation	Kardium-supplied USB cable (2-meter passive cable and 20-meter active extension)
-------------------	--

Table 52: Globe PF Generator - Operating parameters

Input voltage	100 VAC-120 VAC, 60 Hz or 200 VAC-240 VAC, 50 Hz
Input power	600 VA
Potential equalization conductor	The potential equalization conductor terminal may be used to connect the Globe PF Generator to the potential equalization busbar, if present. Attention is drawn to the ME SYSTEMS requirements of IEC 60601-1.
Maximum output voltage	1.8 kV

Table 53: Globe PF Generator - Power cable

Power entry for the Globe PF Generator	IEC 60320 C14 input. A cable with a mating C13 connector and the appropriate plug for the installation is required.
Power supply cable	Power cable compliant with the electrical code of the jurisdiction and based on the power rating indicated on the back of the Globe PF Generator. The Globe PF Generator's power entry conforms to IEC 60320 C14 and requires a power cable with an IEC 60320 C13 connector.

18.3 Globe Workstation

Table 54: Globe Workstation - Hardware

Part number	601-00064
Computer	Computer: PC Intel Processor with nVidia Graphics card; 2 x 24" HD monitors with built-in speakers; keyboard and mouse

Operating system	Microsoft Windows 10
Software	Proprietary Kardium Globe Software

Table 55: Globe Workstation - Physical characteristics of computer tower

Weight	18 kg
Length	45 cm
Width	18 cm
Height	42 cm

18.4 Alarm system

The alarm system is designed for an operator located at the Globe Workstation or within sight of the Globe Controller and the Globe PF Generator.

An alarm condition occurring on the Globe Controller or the Globe PF Generator is displayed within 1 second on the Globe Controller or the Globe PF Generator and within 2 seconds on the Globe Workstation.

Following a power interruption of any length:

- Alarm limits are restored to their previous values.
- Alarm inactivation states are restored to their previous values when the procedure is resumed.
Inactivation states are reset for new procedures.

A log of the occurrence of all alarm conditions is maintained in the procedure log file that is saved on the Globe Workstation. The procedure log is maintained when the system is powered down. To review the log of alarms, review a procedure in offline review mode, fast-forward to the end, and then display the **PF System Log** and **RF System Log** for the procedure. These logs list every alarm for that procedure. For information on how to review procedures, see *Offline review* on page 120.

The system does not allow any configuration of alarm priorities, alarm audio signals, or default inactivation states by the operator, operator's organization, or Kardium personnel. These values are hard-coded in the application.

Table 56: Alarm tones

Alarm type	Number of pulses in burst	Delay between the start of consecutive bursts
High priority	10	15 seconds
Medium priority	3	30 seconds
Low priority	1	30 seconds
Neutral electrode	10	15 seconds

Table 57: Visual indicators on Globe Controller and Globe PF Generator

Alarm type	Color	Flashing frequency	Duty cycle
High priority	Red	10	Between 20% and 60%
Medium priority	Yellow	3	Between 20% and 60%
Low priority	Yellow	2	100%
Neutral electrode	Red	10	Between 20% and 60%

Table 58: Sound pressure range for auditory alarm signal on Globe Controller

Alarm type	Lowest volume setting (dBA)	Highest volume setting (dBA)
High priority	58	66
Medium priority	56	64
Low priority	55	63

Table 59: Sound pressure range for auditory alarm signal on Globe PF Generator

Alarm type	Lowest volume setting (dBA)	Highest volume setting (dBA)
High priority	58	67

Alarm type	Lowest volume setting (dBA)	Highest volume setting (dBA)
Medium priority	56	65
Low priority	54	62

To adjust the alarm volume on the Globe Controller:

1. Click  and then select **Settings**.
2. Click the **Audio Signals** tab.
3. Adjust the volume of the RF energy delivery signal and click **Play** to test the sound. The sound is on the Globe Controller only.
4. Adjust the volume of each alarm signal and click **Raise** to test the sound. The sound should be audible on the Globe Controller and the Globe Workstation.
5. Click **Clear** to stop the alarm.

To adjust the alarm volume on the Globe PF Generator:

1. Click  and then select **Settings**.
2. Click the **Audio Signals** tab.
3. Adjust the volume of the PF energy delivery signal and click **Play** to test the sound. The sound is on the Globe PF Generator only.
4. Adjust the volume of each alarm signal and click **Raise** to test the sound. The sound should be audible on the Globe PF Generator and the Globe Workstation.
5. Click **Clear** to stop the alarm.

19 Environmental conditions

Table 60: Globe Controller, Globe PF Generator, and Globe Workstation environmental conditions

Condition	Operating	Storage
Temperature	15–30 °C	15–30 °C
Humidity (noncondensing)	30%–70%	15%–75%
Pressure	80–106 kPa	70–106 kPa

20 Essential performance

The following functions of the Globe PF system are considered essential performance:

- Compliance with defibrillation energy reduction requirements of the IEC 60601 series of standards.
- Accuracy of electrode temperature and RF current sensing during RF energy delivery.
- Accuracy of PF voltage and current sensing during PF ablation.

21 Electromagnetic compatibility compliance

The Globe PF System is suitable for use in the professional healthcare facility environment, except within the shielded room of an MRI system, near short-wave therapy equipment, near high frequency surgical equipment (other than the Globe PF System itself), within 15 cm of sources of power frequency magnetic fields, or near wireless power transfer equipment. Special precautions should be taken regarding electromagnetic compatibility (EMC).

Interference produced by the operation of HF surgical equipment may adversely influence the operation of other electronic equipment. The Globe PF System has been designed to minimize electromagnetic disturbances that may cause interference with other devices. To prevent performance degradation in the presence of other electronic devices, use only equipment that complies with state-of-the-art standards for electromagnetic compatibility and minimize the number of electronic devices in the vicinity of the Globe PF System.

Medical electrical equipment needs special precautions regarding EMC. The Globe PF System must be installed and put into service by authorized Kardia personnel and used according to the EMC information provided in this manual.



NOTE

The characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radiofrequency (RF) communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

The Globe PF System, other than the Globe Workstation, complies with part 18 of the FCC rules.

The Globe Workstation complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.



NOTE

"Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the ITU Radio Regulations.

The following party is responsible for compliance with FCC requirements:

Kardium US Inc.
5775 Wayzata Blvd.
Suite 700
St. Louis Park, MN 55416
support@kardium.com

The Globe cables and accessories are for use only with the Globe PF System and are not to be used with any other system.

Table 61: System components

Component	Part Number
Globe Controller	601-00048
Globe PF Generator	601-00060
Globe Catheter	601-01000
Globe Workstation	601-00064

Table 62: Cables connected to the Globe Controller and the Globe PF Generator

Cable	Part Number	Length
USB extension cables for connecting to Globe Workstation	106-01695	20 m
USB cables for connecting to Globe Workstation	106-01243	2 m
Globe Catheter Cable	601-00046	3.8 m
ECG cable	Unimed Medical Supplies E10R/30-GL-P/I	3 m to yoke;
	Unimed Medical Supplies E10R/30-GL-P	0.75–1.2 m for leads
	Unimed Medical Supplies 24155P-I	3 m to yoke;
	Unimed Medical Supplies 24155P	1.2 m for leads

Cable	Part Number	Length
Neutral electrode cable	3M™ Series 9100 Universal Electrosurgical Pads 9165	2.75 m
Temperature calibration probe interface cable (optional)	- Smiths Medical General Purpose Probe ER400-9 (9 Fr) or ER400-12 (12 Fr) with Smiths Medical Temperature Monitoring Reusable Cable 400 series C400-10 - Smiths Medical Esophageal Stethoscope Temperature Sensors ES400-9 (9 Fr), ES400-12 (12 Fr), ES400-18 (18 Fr), or ES400-24 (24 Fr) with Smiths Medical Temperature Monitoring Reusable Cable 400 series C400-10 - Truer General Purpose Probe, GP 14400 (14 Fr) with Truer Temperature Monitor Interface Cable 400 series 70321	3.05 m
GPS Cable	601-00036	3.5 m
10-pin catheter adapter	Unimed Medical Supplies AD-KAR-210148	2.18 m

21.1 Electromagnetic emissions

Table 63: Electromagnetic emissions

Guidance—Electromagnetic Emissions		
Emission Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 2 (Group 1 when ablation circuits are not activated)	The Globe PF System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to RF communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic current emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

21.2 Electromagnetic immunity

The Globe PF System was tested for immunity to electromagnetic disturbances in accordance with IEC 60601-1-2:2014/A1:2020, using the immunity test levels specified in Table 64 and Table 65. The Globe PF System's RF energy temperature measurement accuracy specifications, RF energy delivery accuracy specifications, PF ablation delivery accuracy specifications, and ablation monitoring specifications were met during this testing. Exposure to electromagnetic disturbances stronger than those specified in Table 64 and Table 65 may result in one or more of reduced temperature measurement accuracy during RF energy delivery, reduced power delivery accuracy during RF energy delivery, incorrect energy delivery during PF ablation, or failure to detect abnormal ablation conditions.

Table 64: Electromagnetic immunity IEC 60601-1-2

Guidance—Electromagnetic Immunity—IEC 60601-1-2		
Immunity Test	Compliance	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	The relative humidity should be at least 5%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycles 70% U_T (30% dip in U_T) for 25/30 cycles (50/60 Hz)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage interruptions IEC 61000-4-11	0% U_T (100% dip in U_T) for 250/300 cycles (50/60 Hz)	If the user of the Globe PF System unit requires continued operation during power mains interruptions, it is recommended that the Globe System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. The Globe PF System should be located no closer than 15 cm to sources of power frequency magnetic field.

Guidance—Electromagnetic Immunity—IEC 60601-1-2

Immunity Test	Compliance	Electromagnetic Environment Guidance
Radiated RF fields IEC 61000-4-3	3 V/m, 80 MHz–2.7 GHz	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V _{RMS} , 0.15 MHz–80 MHz 6 V _{RMS} in ISM bands between 0.15 MHz and 80 MHz for both power supply lines and patient coupled cables	electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Globe PF System is used exceeds the applicable RF compliance level, degradation of the performance of this equipment could result. In the 0.15 MHz to 80 MHz frequency range, field strengths should be less than 3 V/m.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See Table 65: Proximity fields from RF wireless communications equipment IEC 60601-1-2	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the Globe PF System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
U _T is the AC mains voltage prior to application of the test level.		

Table 65: Proximity fields from RF wireless communications equipment IEC 60601-1-2

Guidance—Electromagnetic Immunity—Proximity Fields From RF Wireless Communications Equipment—IEC 60601-1-2	
Test Frequency (MHz)	Immunity Test Level (V/m)
385	27
450	28
710	9
745	9
780	9
810	28
870	28
930	28
1445.4	8
1720	28
1845	28
1970	28
2300	28
2450	28
2600	28
3500	10
5240	9
5500	9
5785	9

The Globe PF System was tested for immunity to electromagnetic disturbances in accordance with IEC TS 60601-4-2:2024, using the immunity test levels specified in Table 66 and Table 67. The Globe PF System's performance specifications relating to electrograms, ECGs, neutral electrode monitoring, GPS, stimulation, visual indicators, and audio indicators were met during this testing. Exposure to electromagnetic disturbances stronger than those specified in Table 66 and Table 67 may result in one or more of: reduced accuracy or increased noise in measured electrograms, measured ECGs, measured neutral electrode impedance, or measured array position (GPS); reduced accuracy in delivered stimulation current; failure to activate an audio or visual indicator; or unexpected activation of an audio or visual indicator. Exposure to the voltage interruption, electrostatic discharge, or power line surge disturbances described in Table 66 may cause a temporary interruption in the operation of the Globe PF System. The Globe PF System will automatically resume normal operation no more than two minutes after the disturbance ceases.

Table 66: Electromagnetic immunity IEC TS 60601-4-2

Guidance—Electromagnetic Immunity—IEC TS 60601-4-2	
Immunity Test	Compliance
Electrostatic discharge (ESD) IEC 61000-4-2	± 4 kV contact ± 8 kV air
Radiated RF fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See Table 67: Proximity fields from RF wireless communications equipment IEC TS 60601-4-2
Power frequency magnetic fields IEC 61000-4-8	3 A/m
Electrical fast transient/bursts IEC 61000-4-4	± 1 kV for power supply lines ± 0.5 kV for input/output lines
Surges IEC 61000-4-5	± 1 kV line(s)-to-line(s) ± 2 kV line(s)-to-earth
Conducted disturbances induced by RF fields IEC 61000-4-6	$3 V_{RMS}$, 0.15 MHz to 80 MHz
Voltage dips IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycles 70% U_T (30% dip in U_T) for 25/30 cycles (50/60 Hz)
Voltage interruptions IEC 61000-4-11	0% U_T (100% dip in U_T) for 250/300 cycles (50/60 Hz)

Table 67: Proximity fields from RF wireless communications equipment IEC TS 60601-4-2

Guidance—Electromagnetic Immunity—Proximity Fields From RF Wireless Communications Equipment—IEC TS 60601-4-2	
Test Frequency (MHz)	Immunity Test Level (V/m)
385	6
450	9
710	3
745	3
780	3
810	9
870	9
930	9
1720	9
1845	9
1970	9
2450	9
5240	6
5500	6
5785	6

22 Cybersecurity

The Globe PF System utilizes Microsoft® Windows® as the operating system with integrated cybersecurity controls such as Windows Defender, password controlled access, and disabled networking. The user is not responsible for implementation of any cybersecurity controls, other than understanding and observing the following notes and recommendations.



NOTE

The Globe Workstation is password-protected to prevent unauthorized access.

Network. The Globe PF System is a non-network medical device. Do not connect the Globe PF System to the internet or hospital network in any way.

Malware controls. The Microsoft® antivirus tool, Windows Defender, provides security to the Globe Workstation. The user will be notified if malware is detected on the Globe Workstation. The Globe Controller and Globe PF Generator do not run an operating system, and do not support networking, wireless, or remote access capabilities.

Event Logs. The Globe Workstation compiles event logs (e.g., security logs, application logs, etc.) as part of integrated Microsoft Windows functionality that are retained indefinitely by the system. Contact your Kardium representative for access to these event logs.

Firmware/software updates. The firmware and software (including off-the-shelf software components) of the Globe PF System cannot be updated by the user. Firmware/software upgrades (including security patches) can only be installed by authorized Kardium personnel. Kardium will directly contact customers when updates are available.

Portable media and USB security. Ensure that only authorized personnel using authorized USB storage media download data from the USB ports on the Globe Workstation. Do not insert any personal USB devices or other devices into the USB ports.

Physical security. The Globe PF System must only be accessible to qualified/authorized personnel. Store the product in a physically secured location to prevent unintentional or intentional misuse.

Product support. Kardium is committed to supporting the Globe PF System and will provide advanced notice to all customers for end of support arrangements.

Software Bill of Materials (SBOM). An SBOM, which includes information on end of support and end of life of software components, is provided to customers as part of the installation and servicing materials shared by authorized Kardium service personnel. Contact your Kardium representative if additional copies are required.

System decommissioning. Decommissioning the Globe PF System requires coordination with Kardium to ensure sensitive information is removed. Contact your Kardium representative to dispose or transfer ownership of the system.

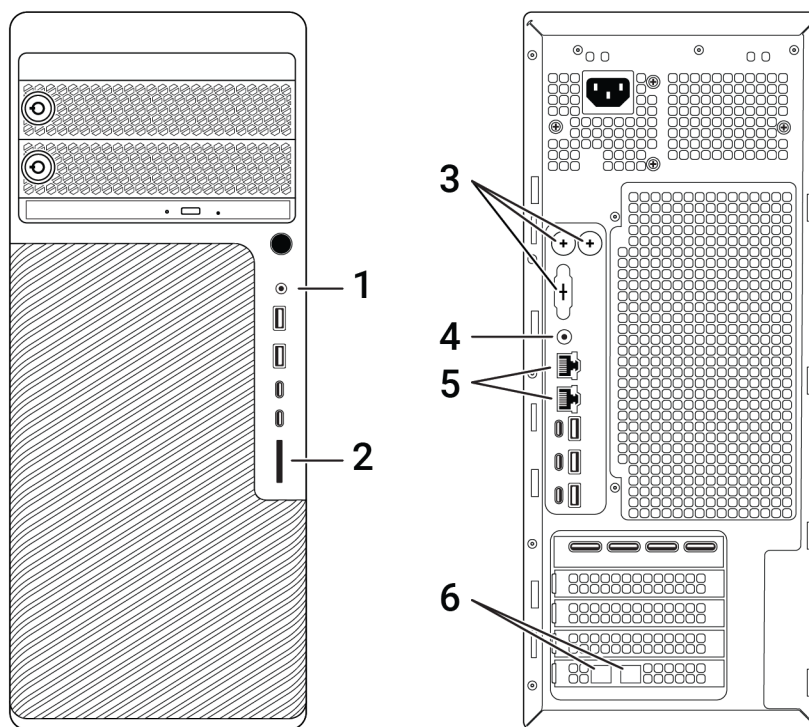
Reporting. If you are notified of detected malware or you experience a security event, contact Kardium Technical Support. If you are a security researcher and believe that you have identified a potential security vulnerability involving the Globe PF System, report the vulnerability at https://members.medisao.com/vulnerability_disclosure.

For further information on security information, contact your Kardium representative.

22.1 Inactive interfaces

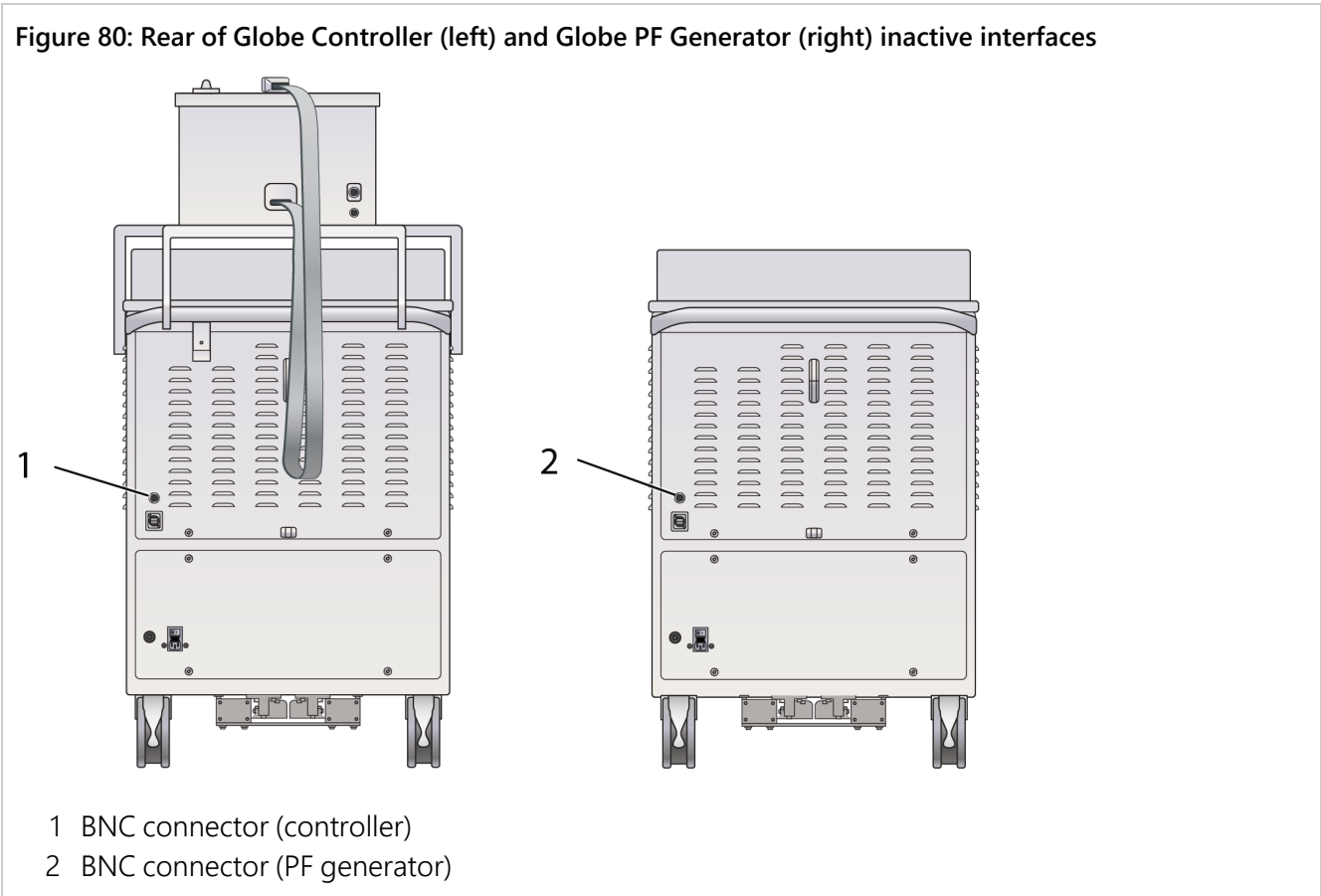
The figure below shows all interfaces on the Globe Workstation that are inactive.

Figure 79: Globe Workstation computer tower inactive interfaces



- 1 3.5-mm TRRS connector
- 2 SD card reader
- 3 Unpopulated connectors
- 4 3.5-mm TRS connector
- 5 1G/10G RJ45 Ethernet ports
- 6 Fiber optic SFP connector

The figure below shows all interfaces that are inactive on the Globe Controller and Globe PF Generator.



23 Application hotkeys

Table 68: Globe model shortcuts

Action	Shortcut
Rotate the 3D model	 (middle drag)
Rotate the 3D model around a central axis that is perpendicular to the screen	 +  (middle drag)
Zoom the 2D and 3D array map and 3D model	 +  (scroll)
Pan the 2D array map and 3D model	 +  (middle drag)
Return the 2D array map or 3D model to the default position and scale	 + 0

Table 69: Timeline shortcuts

Action	Shortcut
Toggle review mode	
Move to beginning of timeline	
Move to end of timeline	
- 10 seconds	 +   + 
+10 seconds	 +   + 
- 1 second	 
+ 1 second	 

Action	Shortcut
- 0.1 seconds	Alt + ← Alt + ↑
+ 0.1 seconds	Alt + → Alt + ↓
Move to previous or next detected cardiac cycle	Ctrl + ← Ctrl + →

Table 70: Electrograms panel shortcuts

Action	Shortcut
Select an electrode	
Add another electrode to the electrode selection	Ctrl + 
Add a range of electrodes to the electrode selection	Shift + 
Increase the space at the top of groups	Alt +  (click/drag the first waveform of the group)
Move to previous or next detected cardiac cycle	Ctrl + ← Ctrl + →
± 1 electrogram sample	Ctrl + Shift + Alt + ← Ctrl + Shift + Alt + →
± 10 electrogram samples	Ctrl + Shift + ← Ctrl + Shift + →
Scroll the displayed data range (one screen)	PgUp PgDn

Action	Shortcut
Scroll 1/10 of the displayed data range	Alt + PgUp Alt + PgDn
Scroll 10 times the displayed data range	Shift + PgUp Shift + PgDn
Move the display data range horizontally	 (horizontal click/drag)
Move the displayed traces vertically	 (vertical click/drag)
Place a time marker	Ctrl + 
Measure the time between two points	Ctrl +  (click/drag)
Move the time measurement label up and down	 (vertical click/drag)
Move the time measurement without changing the relative spacing of its endpoints	 (middle drag)
Place a voltage measurement	Alt + 
Move activation range	 (click/drag)

Table 71: Labels shortcuts

 Action	Shortcut
Undo the previous label action	Ctrl + Z
Redo the previously undone label action	Ctrl + Y

Table 72: GPS shortcuts

Action	Shortcut
Build atrial model (toggle)	 F6
Create atrial map (toggle)	 F8
Rotate map horizontally	 (middle drag left or right)
Rotate map vertically	 (middle drag up or down)

24 Acronyms

Table 73: Acronyms and definitions

Acronym	Definition
Ω	ohm
A	ampere
AC	alternating current
ACT	activated clotting time
AF	atrial fibrillation
AP	anteroposterior
bpm	beats per minute
C	Celsius
CD	compact disk
dB	decibel
ECG	electrocardiogram
EM	electromagnetic
EMC	electromagnetic compatibility
EP	electrophysiology
F	french size
GPS	Globe® Positioning System
GUI	graphical user interface
h	hour

Acronym	Definition
HF	high frequency
Hz	hertz
ICD	implantable cardioverter defibrillator
IFU	instructions for use
in	inch
INF	inferior
kPa	kilopascal
L	liter
LA	left atrium
LAA	left atrial appendage
LAT	local activation time
LAO	left anterior oblique
LIPV	left inferior pulmonary vein
LL	left lateral
LPV	left pulmonary vein
LSPV	left superior pulmonary vein
m	meter
mA	milliampere
min	minute
mL	milliliter

Acronym	Definition
mm	millimeter
ms	millisecond
MRI	magnetic resonance imaging
mV	millivolt
MV	mitral valve
OS	operating system
PA	posteroanterior
PF	pulsed field
RF	radiofrequency
RH	relative humidity
RIPV	right inferior pulmonary vein
RL	right lateral
RAO	right anterior oblique
RPV	right pulmonary vein
RSPV	right superior pulmonary vein
S	siemens
SVHC	substance of very high concern
SUP	superior
TEE	transesophageal echocardiogram
TTE	transthoracic echocardiogram

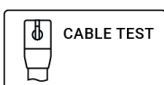
Acronym	Definition
U	Howell unit
UPS	universal power supply
μA	microampere
μs	microsecond
μV	microvolt
U_T	AC mains voltage prior to application of electromagnetic immunity test
V	volt
VAC	volt alternating current
W	watt

25 Symbols

The following symbols may be used in this document and on the products and packaging.

Table 74: Symbols and definitions

Symbol	Standard	Definition
	ISO 15223-1	Catalog number
	ISO 15223-1	Serial number
	ISO 15223-1	Batch code
	ISO 7000	Packaging unit
	ISO 15223-1	Use-by date
	ISO 15223-1	Single use only
	ASTM F2503-20	MR unsafe. Keep away from magnetic resonance imaging (MRI) equipment.
	ISO 15223-1	Unique device identifier
	21 CFR 801.109	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician
	ISO 15223-1	Caution
	ISO 15223-1	Consult instructions for use
	IEC 60601-1	Refer to instruction manual
	IEC 60601-1	General warning sign

Symbol	Standard	Definition
	ISO 15223-1	Manufacturer
	ISO 15223-1	Date of manufacture
	ISO 15223-1	Do not use if package is damaged and consult instructions for use
	ISO 15223-1	Temperature limit
	ISO 15223-1	Humidity limitation
	ISO 15223-1	Atmospheric pressure limitation
	IEC 60601-1	Defibrillation-proof type CF applied part
	IEC 60601-1	Defibrillation-proof type BF applied part
	IEC 60601-1	Power standby
	IEC 60601-1	Neutral electrode isolated from earth
	N/A	Port for connection cable
	N/A	Port for testing catheter cable
	N/A	Locked catheter cable connection
	N/A	Unlocked catheter cable connection
	N/A	Neck

Symbol	Standard	Definition
	N/A	Left leg
	N/A	Right
	N/A	Left
	N/A	Front
	N/A	Back
	N/A	Certification mark for Canadian and United States products
	WEEE Directive 2012/19/EU	Electrical or electronic product subject to the Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU. At the end of the product's working life, it should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.

21 CFR 801.109: United States Code of Federal Regulations, Title 21, Food and Drugs

ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

ISO 7000: Graphical symbols for use on equipment

IEC 60417: Graphical symbols for use on equipment

ASTM F2503-20: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Appendix A: Globe Positioning System Cable and Electrodes

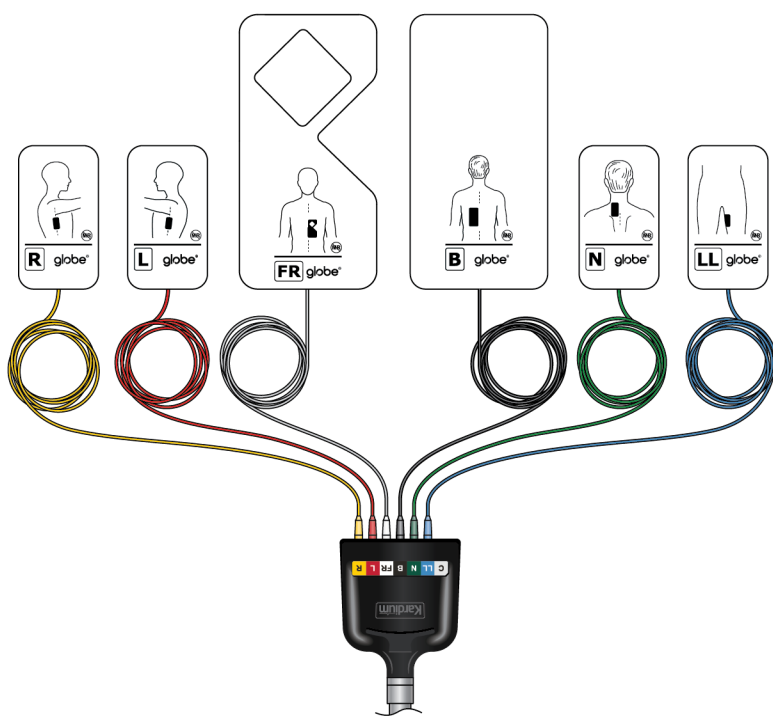
A.1 Product Description

The Globe® Positioning System (GPS) Cable and the Globe Positioning System (GPS) Electrodes are components of the Globe Pulsed Field System (Globe PF System). They are designed to be used with each other and with the Globe Controller.

The GPS Cable connects the six GPS Electrodes to the Globe Controller. The cable carries the currents that produce the GPS electric fields within the body of the patient. The GPS Cable is a nonsterile reusable device.

The GPS Electrodes are required to create the 3D model of the atrium and display the position and orientation of the Globe Catheter's array inside the atrium. A set of GPS electrodes consists of six disposable, single-use, nonsterile surface electrodes.

Figure 81: GPS Electrodes connected to the GPS Cable



Contents of package

The packaging of the GPS Cable (601-00036) contains one (1) reusable GPS Cable.

The packaging of the GPS Electrodes (601-00037) contains one (1) set of six single-use GPS Electrodes.

Product compatibility

The GPS Electrodes (601-00037) are compatible with the GPS Cable (601-00036). The GPS Cable is compatible with the Globe Controller (601-00048).

A.2 Prescription and safety information

Intended use

The GPS Cable is intended to connect the GPS Electrodes to the Globe Controller.

The GPS Electrodes are intended to deliver the currents that generate the electric fields used for cardiac anatomical mapping.

Additional prescription information

For information on indications for use, contraindications and adverse events, consult *Instructions for Use: Globe Introducer and Globe Catheter*.

Warnings

Note the following warnings for these devices. A warning indicates a potentially hazardous situation that, if not avoided, could cause serious injury or death.

Device inspection. To minimize the risk of patient injury or illness, inspect the device components before use and do not use if you suspect damage in any way.

Expiration date. Do not use the GPS Electrodes after the expiration date (use-by date) printed on the packaging label.

GPS Electrode application. The GPS Electrodes are only intended for transient patient contact. Apply transparent film dressing and sterile cord covers to provide a barrier between the hydrogel patches and cables and the patient's skin to avoid prolonged exposure.

Interference from GPS signals. The GPS signals may cause interference with other devices connected to the patient (e.g., defibrillator ECG sensing). The GPS can be temporarily disabled using the Globe Software to stop the interference.

Magnetic resonance imaging. The components of the GPS Electrodes are not compatible with magnetic resonance imaging (MRI). The use of MRI while the GPS Electrodes are applied to the body of the patient may cause skin burns or other injury.

Qualified users only. Use of the Globe PF System is intended for physicians who have completed the Kardia training program on catheter mapping and ablation procedures with the Globe PF System, and who have been trained in the techniques of vascular access, transseptal access, percutaneous catheter

delivery, and intracardiac electrophysiology studies. Device preparation of the Globe PF System should only be performed by electrophysiology lab staff who have completed the Kardia training program on device preparation.

Read product documentation. Before using this device, carefully read all instructions, warnings, and cautions in this document and all other system documentation. In addition, carefully read the instructions and safety information for all ancillary devices or products that are used for the procedure before use.

Cautions

Note the following cautions for these devices. A caution indicates a potentially hazardous situation that, if not avoided, could damage equipment or cause minor to moderate injury.

Device compatibility. Use the GPS Electrodes only with the GPS Cable, and use the GPS Cable with the Globe Controller as specified in this document. Use of an incompatible cable or electrodes may result in inaccurate GPS measurements.

Inspect GPS Electrodes packaging. Using components that have been stored in open or damaged packaging can compromise the performance of the GPS Electrodes. Inspect the packaging prior to use and do not use the GPS Electrodes if the packaging exhibits signs of damage or was previously open.

Single use only. The GPS Electrodes are single use only and should only be used for a single Globe PF System procedure. To avoid component damage and reduce the risk of patient contamination and infection, do not resterilize, reprocess, or reuse the GPS Electrodes.

A.3 Directions for use

Read this section carefully for recommended directions for use related to the GPS Cable and GPS Electrodes. For directions for use for other components not covered in this document, refer to the associated instructions for use for each component.

Apply the GPS Electrodes



NOTES

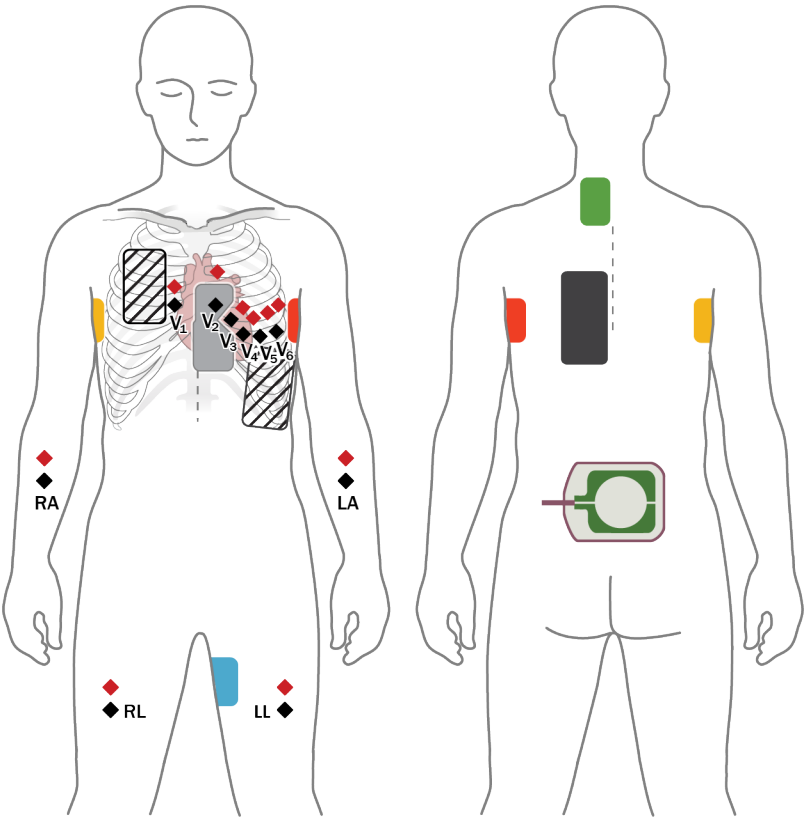
- Before use, inspect the packaging of the GPS Electrodes. Do not use if the packaging is damaged or has been previously opened, and do not use past the expiry date (use-by date). Inspect the device for damage and do not use if the electrodes or cords appear damaged.
- The three pairs of GPS Electrodes (Right-Left, Neck-Left Leg, Front-Back) must be orthogonal to each other and aligned so that direct signals between electrode pairs will travel through the patient's heart.
- Do not reapply or reposition a GPS Electrode after the initial application.
- If applying defibrillator electrodes, make sure that the defibrillator electrodes are at least 3 cm from the GPS Electrodes.

1. Ensure that the application site is clean, dry, and free of hair.
2. Remove the protective film from the GPS Electrode and apply the GPS Electrode to the patient's intact skin in the location specified on the electrode. Refer to the table and figure below for instructions on where to apply the electrodes.
3. Smooth out any wrinkles and make sure that the entire surface of the GPS Electrode is in contact with the patient's skin. Avoid air entrapment.

Table 75: Placement of GPS Electrodes

Symbol	Electrode	Wire Color	Placement Notes
N	Neck	Green	Place slightly left to align with the heart.
LL	Left leg	Blue	Align with the neck electrode.
R	Right	Yellow	Align vertically with the heart.
L	Left	Red	Place directly opposite the right electrode.
FR	Front	White	Place slightly left of the sternum to align with the heart, and place the diamond cutout around the V ₂ ECG electrode.
B	Back	Black	Place directly opposite the front electrode.

Figure 82: Placing the GPS electrodes on the patient’s body



GPS Electrodes



ECG electrodes for connection to primary patient monitor
*For ECG electrodes, **V1** to **V6** – Chest electrodes, **RL** – right leg, **LL** – left leg, **RA** – right arm, and **LA** – left arm.



ECG electrodes for connection to Globe PF System
*For ECG electrodes, **V1** to **V6** – Chest electrodes (optional), **RL** – right leg, **LL** – left leg, **RA** – right arm, and **LA** – left arm.



Defibrillator electrodes

*If applying defibrillator electrodes, make sure that the defibrillator electrodes are at least 3 cm from the GPS Electrodes. Defibrillator electrode position should be in accordance with the manufacturer's instructions for use and may be different than what is shown here.



Neutral electrode

Connect the GPS Cable



NOTES

- Before use, inspect the GPS Cable for damage or degradation, and do not use if the cable appears damaged or degraded.
- Before use, inspect the GPS Cable for cleanliness, and clean according to the instructions in this document if the cable appears dirty.

1. Confirm the GPS Electrodes are applied to the patient according to *Apply the GPS Electrodes* on page 182.
2. Connect the GPS Electrodes to the GPS Cable. The electrode connections are color-coded. Do not connect anything to the connector labeled C.

Figure 83: GPS Electrodes connected to the GPS Cable



3. Plug the GPS Cable into the GPS connector of the Globe Controller.

Remove the GPS Electrodes

1. Disconnect the GPS Electrodes from the GPS Cable.
2. Peel off each GPS Electrode carefully, starting from one corner. Use slow movements to minimize skin trauma.

A.4 Cleaning

Clean the GPS Cable after each use by following these steps.



NOTES

- Do not immerse the cable in liquids or spray liquids onto the cable.
- Do not clean the cable if it is damaged or shows signs of degradation.

1. Disconnect the cable from the controller.
2. Remove gross soils with a clean cloth.
3. Wipe the exterior surfaces of the cable with a pre-wetted wipe or cloth using a quaternary ammonium detergent (e.g., Pursept AF or Super Sani Cloth AF).
4. Allow the wiped surface to remain wet for the contact time specified by the detergent manufacturer or for 7 minutes, whichever is longer.
5. Let the cable air dry.

A.5 Disposal

The GPS Electrodes are intended for single-use only. Dispose of the GPS Electrodes and GPS Cable in accordance with hospital policy and local regulations.

A.6 Product specifications

Table 76: GPS Cable specifications

Part number	601-00036
Length	3.5 m

Table 77: GPS Electrodes specifications

Part number	601-00037
Neck electrode (green connection)	50 mm x 90 mm
Left leg (blue connection)	50 mm x 90 mm
Right (yellow connection)	50 mm x 90 mm
Left (red connection)	50 mm x 90 mm
Front (white connection)	90 mm x 180 mm with cutouts
Back (black connection)	90 mm x 180 mm

A.7 Environmental conditions

Table 78: GPS Cable and GPS Electrodes operating conditions

Temperature	15–30 °C
Humidity (noncondensing)	30%–70%
Pressure	80–106 kPa

Table 79: GPS Cable and GPS Electrodes storage conditions

Condition	GPS Cable	GPS Electrodes
Temperature	15–30 °C	5–27 °C
Humidity (noncondensing)	15%–75%	15%–75%
Pressure	70–106 kPa	70–106 kPa

Appendix B: Globe Catheter Cable

B.1 Product description

The Globe® Catheter Cable is a component of the Globe Pulsed Field System (Globe PF System) and is designed to connect the Globe Catheter to the Globe Controller.

The cable is bidirectional, and either connector end of the cable is designed to fit and lock into the cable connection port of the controller or catheter handle. During a procedure, the catheter cable is stabilized using the Globe Catheter Cable Support attached to the patient table.

The catheter cable is a nonsterile, reusable device that can be used in the sterile field only after it is covered with a sterile catheter cable cover.

Contents of package

The packaging of the Globe Catheter Cable contains one (1) reusable catheter cable.

Product compatibility

The Globe Catheter Cable (601-00046) is compatible with the following devices and accessories.

Table 80: Globe PF System compatibility information

Device or Accessory	Part Number
Globe Catheter	601-01000
Globe Controller	601-00048
Globe PF Generator	601-00060
Globe Catheter Cable Support	601-00067
Catheter cable cover	1 each included in the packaging of the Globe Introducer (601-01001) and the Globe Catheter (601-01000)

B.2 Prescriptions and safety information

This section contains prescriptive and safety information related to the use of this device.

Intended use

The Globe Catheter Cable is intended to transmit energy and signals between the Globe Catheter and the Globe Controller.

Additional prescription information

For information on indications for use, contraindications and adverse events, consult *Instructions for Use: Globe Introducer and Globe Catheter*.

Warnings

Note the following warnings for this device. A warning indicates a hazardous situation that, if not avoided, could cause serious injury or death.

Aseptic technique. Use aseptic technique when introducing the catheter cable into the sterile field and connecting to the catheter. To maintain the sterile field and reduce the risk of cross-contamination and infection, cover the catheter cable with a sterile catheter cable cover before introducing the catheter cable in the sterile field and connecting the catheter cable to the catheter.

Device inspection. Inspect the catheter cable before each use. To avoid a potential fire hazard or injury to the patient or user, do not use the catheter cable if you suspect damage in any way. Return damaged products to Kardium.

Keep the catheter cable connection dry. Liquids can damage the internal electronics of the catheter handle and the catheter cable, leading to adverse performance. Whenever the catheter handle is not connected to the catheter cable:

- Ensure the round gray splash guard remains in place on the catheter handle to keep the circuit board dry.
- Ensure the clear catheter cable cap remains in place on the end of the catheter cable to keep the connection dry.

Qualified users only. Use of the Globe PF System is intended for physicians who have completed the Kardium training program on catheter mapping and ablation procedures with the Globe PF System, and who have been trained in the techniques of vascular access, transseptal access, percutaneous catheter delivery, and intracardiac electrophysiology studies. Device preparation of the Globe PF System should only be performed by electrophysiology lab staff who have completed the Kardium training program on device preparation.

Radiofrequency (RF) interference. To minimize RF interference with electrocardiogram (ECG) signals and GPS signals, make sure that the catheter cable does not come in close proximity to ECG leads or GPS Electrodes.

Read product documentation. Before using this device, carefully read all instructions, warnings, and cautions in this document and all other system documentation. In addition, carefully read the instructions and safety information for all ancillary devices or products that are used for the procedure before use.

System compatibility. Use the Globe Catheter Cable only with the compatible Globe Catheter, Globe Controller, and Globe PF Generator as specified in this document. Using any other catheter, catheter cable, controller, or generator can impair system performance and can create a risk of burns and electrical shock for the patient or user.

B.3 Directions for use

Read this section carefully for recommended directions for use related to the catheter cable. For directions for use for other components not covered in this document, refer to the associated instructions for use for

that component.



NOTE

Consider keeping a functional backup Globe Catheter Cable available during a procedure in case the current cable fails.

Connect and test the catheter cable

For steps about connecting the catheter cable to the Globe Controller and for testing the Globe PF System, refer to *Connect the Globe Catheter Cable* on page 30.



NOTES

- Test the catheter cable before each procedure and if the cable is changed during a procedure.
- Inspect the catheter cable for visible damage or degradation before use and do not use a cable that appears damaged or degraded.

Cover the catheter cable

Before introducing the catheter cable into the sterile field, you must cover the cable with the sterile catheter cable cover using the help of an assistant outside the sterile field.

1. Orient the cover so that the pull tab is up and the position of the slot on the cover is aligned with the slot on the catheter cable.
2. An assistant outside the sterile field fully inserts the end of the catheter cable into the cover.
3. Using aseptic technique, extend the cover along the length of the cable.
4. Secure the catheter cable in the Globe Catheter Cable Support.

Connect the catheter cable to the catheter

For steps about connecting the catheter cable to the catheter, refer to *Instructions for Use: Globe Introducer and Globe Catheter*.

Disconnect the catheter cable

For steps about disconnecting the catheter cable from the catheter, refer to *Instructions for Use: Globe Introducer and Globe Catheter*.

For steps about disconnecting the catheter cable from the controller, refer to *Disconnect the Globe Catheter Cable from the Globe Controller or Globe PF Generator* on page 30.

B.4 Cleaning



NOTES

- Do not allow liquids to drip or seep into the connector ends, and do not soak the cable.
- Do not clean the cable if it is damaged or shows signs of degradation.

Clean the catheter cable after each use by following these steps:

1. Remove gross soils with a clean cloth.
2. Wipe the exterior surfaces of the cable with a pre-wetted wipe or cloth using a quaternary ammonium detergent (e.g., Pursept AF or Super Sani Cloth AF).
3. Allow the wiped surface to remain wet for the contact time specified by the detergent manufacturer or for 7 minutes, whichever is longer.
4. Let the cable air dry.

In the event of contamination by soils that cannot be effectively cleaned by wiping external surfaces, consult with a Kardium representative on the appropriate course of action prior to using the affected components.

B.5 Storage

Store the catheter cable where it will remain dry, according to the storage conditions in *Environmental conditions* on the next page. If leaving the catheter cable connected to the controller between uses, hang the cable on a cable hook on the front of the controller.

B.6 Disposal

Dispose of the Globe Catheter Cable in accordance with hospital policy and local regulations for equipment containing electrical and electronic parts. Contact your Kardium representative prior to disposal.

B.7 Product specifications

Table 81: Globe Catheter Cable specifications

Part number	601-00046
Weight	3.4 kg
Length	3.8 m
Height	4.2 cm
Width	5.8 cm

B.8 Environmental conditions

Table 82: Globe Catheter Cable environmental conditions

Condition	Operating	Storage
Temperature	15–30 °C	15–30 °C
Humidity (noncondensing)	30%–70%	15%–75%
Pressure	80–106 kPa	70–106 kPa

Kardium Inc.

155 - 8518 Glenlyon Parkway
Burnaby, BC V5J 0B6
Canada

kardium.com
info@kardium.com

Kardium[®]

407-00003-EN-USA-4.7 REV-G DRAFT
2025-06-20