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Every pulsed field ablation catheter and system licensed in Canada is conditional

Five Class IV licences, five Issued/Conditional statuses, against a register-wide rate of 0.35 per cent

Five Class IV licences for pulsed field ablation catheters or systems sit on Health Canada's active listing, and every one is Issued/Conditional, against a register-wide rate of 0.35 per cent. A sponsor planning a Canadian PFA launch should expect a conditional licence, and should not expect the register to say what the conditions are.

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Executive summary

Five Class IV licences for pulsed field ablation catheters or systems sit on Health Canada's active listing, and every one is Issued/Conditional, against a register-wide rate of 0.35 per cent. A sponsor planning a Canadian PFA launch should expect a conditional licence, and should not expect the register to say what the conditions are.

Health Canada's active licence listing, read on 20 September 2026, contains five Class IV licences whose names identify a pulsed field ablation catheter or system: Medtronic's PulseSelect (licence 110572), Boston Scientific's Farapulse (111047), Biosense Webster's Varipulse (111495), Abbott's Volt (115142) and Kardium's Globe (115863). All five carry licence status D, which the MDALL documentation defines as Issued/Conditional. A sixth licence, Abbott's Current PFA (115141), is Class III and Issued/Active; the FDA record for Abbott's Volt PMA names it as the system's generator.

Conditional status is rare on the register. Of 35,744 licences in the active listing, 124 are conditional, 0.35 per cent. Among the 1,575 Class IV licences, 70 are conditional, 4.44 per cent. Among the 133 licences ArrHub has confirmed as electrophysiology devices, five are conditional: the four pulsed field systems in that set and Abbott's Aveir leadless pacemaker. Every radiofrequency and cryoablation licence in the confirmed set, 43 licences, is Issued/Active.

All five systems also hold FDA premarket approval, and all five took supplements this year. Between 2 January and 4 September 2026 the FDA recorded 28 supplement decisions on the five PMAs, out of 343 electrophysiology supplement decisions ArrHub holds for that window.

For market-access planning the register supports one expectation and one warning. The expectation: a pulsed field ablation system entering Canada should be planned as a conditional licence, not treated as an exception when one arrives. The warning: the register will not say what the conditions are, when they were imposed, or what would discharge

them. That information exists only in the sponsor's own licence correspondence.

1. The licences

Every pulsed field ablation catheter or system on Health Canada's active licence listing holds status D. Table 1 lists the five Class IV licences and the one Class III licence whose names identify pulsed field ablation, as the register spells them.

Table 1. Pulsed field ablation licences on Health Canada's active licence listing

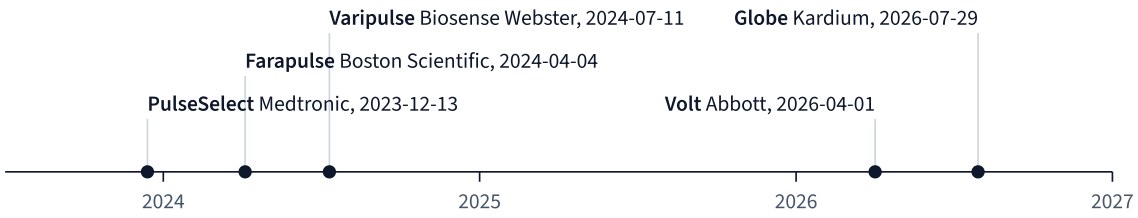
Licence	Licence name	Manufacturer	Class	Status	First licence status date
110572	PULSESELECT PULSED FIELD ABLATION SYSTEM	MEDTRONIC INC.	IV	D	2023-12-13
111047	FARAPULSE PULSED FIELD ABLATION SYSTEM	BOSTON SCIENTIFIC CORPORATION	IV	D	2024-04-04
111495	VARIPULSE BI-DIRECTIONAL ABLATION CATHETER	BIOSENSE WEBSTER, INC.	IV	D	2024-07-11
115142	VOLT PFA CATHETER, SENSOR ENABLED	ABBOTT MEDICAL	IV	D	2026-04-01
115863	GLOBE PULSED FIELD SYSTEM	KARDIUM INC.	IV	D	2026-07-29
115141	CURRENT PFA	ABBOTT MEDICAL	III	I	2026-04-01

Source: Health Canada MDALL, licence records 110572, 111047, 111495, 115142, 115863 and 115141. Extracted 20 September 2026; records last refreshed by Health Canada 18 September 2026.

Status D is defined in the MDALL documentation as Issued/Conditional and status I as Issued/Active. All six records carry a null end date. Licence 115141, Current PFA, is not itself a catheter or system by name; the FDA supplement record P250022/S005 lists its trade name as "Current PFA Generator", which places it as the generator for Abbott's Volt catheter. It is included in Table 1 so that the register's complete pulsed field ablation holdings are visible, and it is the only one of the six that is not conditional.

The five conditional licences span thirty-one months of issue dates, from 13 December 2023 to 29 July 2026 (Figure 1). The status has not converged towards Issued/Active with time: the oldest of the five, PulseSelect, has been conditional for the whole period the register shows.

Figure 1. First licence status dates of the five Class IV pulsed field ablation licences



First licence status date, all five licences status D (Issued/Conditional), Health Canada MDALL

Source: Health Canada MDALL, licence records `110572`, `111047`, `111495`, `115142`, `115863`. Extracted 20 September 2026.

2. The base rate

Conditional status is unusual on the register and pulsed field ablation is an outlier within it. Table 2 gives the rate by risk class for the whole active listing.

Table 2. Licences by risk class and status on Health Canada's active licence listing

Risk class	Licences	Issued/Conditional	Share conditional
II	26,344	15	0.06%
III	7,825	39	0.50%
IV	1,575	70	4.44%
All	35,744	124	0.35%

Source: Health Canada MDALL active licence listing, all 35,744 licence records returned by the licence endpoint with state=active. Extracted 20 September 2026.

Within electrophysiology the contrast is sharper. ArrHub has confirmed 133 licences on the register as electrophysiology devices (the scope is set out in the methodology). Of those, 128 are Issued/Active and five are Issued/Conditional. The five are the four pulsed field ablation systems that fall inside the confirmed set (PulseSelect, Farapulse, Varipulse and Globe) and Abbott's Aveir leadless pacemaker, licence 107649, conditional since 22 April 2022. Abbott's Volt catheter lies outside the confirmed set for a reason explained in the methodology, which is why the confirmed count is four and the register count is five.

Table 3. Confirmed electrophysiology licences by status

Status	Licences	Of which pulsed field ablation
I, Issued/Active	128	0
D, Issued/Conditional	5	4
Confirmed set	133	4

Source: Health Canada MDALL, the 133 licence records ArrHub has confirmed as electrophysiology devices as at 20 September 2026, including licence records 107649, 110572, 111047, 111495 and 115863 for the conditional rows.

No radiofrequency or cryoablation licence in the confirmed set is conditional. Forty-seven confirmed licences carry "ablation" in their

names; four are the pulsed field systems above, and the other 43, the radiofrequency and cryoablation catheters, consoles and cables from Abbott, AtriCure, Biosense Webster, Boston Scientific, Medtronic and St. Jude Medical, are all Issued/Active. Within the confirmed set, conditional status attaches to pulsed field ablation and to one leadless pacemaker, and to nothing else.

3. The US side

Each of the five systems holds an FDA premarket approval, and each PMA took supplements during the ingested window. Table 4 counts the supplement decisions the FDA published between 2 January and 4 September 2026, by PMA and supplement type, with the applicant as the FDA record names it.

Table 4. FDA PMA supplement decisions on the five systems, 2 January to 4 September 2026

PMA	System	Applicant on FDA record	Supplements	30-day notice	180-day track	Panel track	Real-time	Latest decision
P230017	PulseSelect	Medtronic, Inc.	3	1	2	0	0	2026-06-30
P230030	Farapulse	Farapulse, Inc.	9	5	2	1	1	2026-09-04
P240006	Varipulse	Biosense Webster, Inc.	3	1	2	0	0	2026-06-30
P240044	Globe	Kardium, Inc.	6	4	1	0	1	2026-08-20
P250022	Volt	ABBOTT MEDICAL	7	3	2	0	2	2026-08-11
Total			28	14	9	1	4	

Source: openFDA device/pma, PMA records P230017, P230030, P240006, P240044 and P250022, supplement decisions dated 2 January to 4 September 2026, as held in ArrHub's verified registry on 20 September 2026. "180-day track" combines the FDA types "Normal 180 Day Track" and "Normal 180 Day Track No User Fee".

The 28 decisions are 8.2 per cent of the 343 electrophysiology PMA supplement decisions ArrHub recorded in the window, spread across 69 PMAs. Farapulse, Inc. is the applicant of record for P230030; Boston Scientific acquired Farapulse in 2021, and the two are treated as one organisation throughout this document.

4. What the register does and does not say

The register says that a licence exists, what it is called, who holds it, its risk class, its status as a one-letter code, the date of its first status and whether it has ended. For the five licences in Table 1 that is the complete public record: status D, defined by the MDALL documentation as Issued/Conditional, first licence status dates from 2023 to 2026, no end date, and a last refresh by Health Canada on 18 September 2026.

The register does not say what the conditions are. No field in the licence record carries condition text, a reference to a condition letter, the date a condition was imposed, or the date one was discharged. It does not say whether a licence has ever changed status, because it publishes the current status and the date of the first status only. It does not say what would move a licence from D to I, or whether any of the five is under review.

The MDALL documentation defines eleven status codes: C (Cancelled), D (Issued/Conditional), I (Issued/Active), M (Merge), O (Discontinued at Renewal), P (Pending signature), Q (Suspended/Invalid QS Certification), R (Cancelled Renewal No Response), S (Suspended), W (Withdrawn) and X (Cancelled QS/2003). The active listing this document reads contains only two of them, I and D. A licence that leaves the active listing leaves this dataset, so the register as read here cannot show a pulsed field ablation licence being cancelled, suspended or withdrawn. Nothing in this document should be read as a statement about what the conditions on any licence are, or about the reasons Health Canada attached them.

Methodology

Sources

Health Canada Medical Devices Active Licence Listing (MDALL), read through its public API at health-products.canada.ca/api/medical-devices. The licence endpoint with state=active returned 35,744 licence records, and the company endpoint 7,653 company records, on 20 September 2026 at 02:17 UTC. Each licence record reports a last refresh date of 18 September 2026. The MDALL API documentation supplies the status code definitions used throughout.

openFDA device/pma, from which ArrHub ingests premarket approval supplement decisions for electrophysiology product codes. The verified registry held 343 supplement decisions on 69 PMAs dated between 2 January and 4 September 2026 when this document was written. Every US figure in this document comes from that registry; the FDA PMA database at accessdata.fda.gov was used only to verify records, not as a source of facts.

Field-level verification

Every Canadian licence cited in this document was re-read from its MDALL API record on 20 September 2026, after the registry extract, and compared field by field: licence number, licence name, status code, risk class, first licence status date and end date. All six records (110572, 111047, 111495, 115142, 115863 and 115141) matched the registry on every field. Every FDA PMA cited was opened at accessdata.fda.gov on the same day; the applicant, trade name and supplement numbers on the FDA page matched the supplements held in the registry for the window. Each licence number and PMA number in a source line links to the agency record it was verified against.

Names are printed as the registers spell them, with one display-time correction. openFDA publishes some trade names with C1 control characters (U+0080 to U+009F) where the FDA's own record shows a typographic symbol; U+0099 stands where the record shows ™. Those characters are displayed as the Windows-1252 symbols they represent.

The stored data is not altered, and no other character is touched. The system names in Table 4 are shortened forms, so none of them is affected.

Organisation resolution

Applicants and licence holders are matched to organisations through ArrHub's verified alias table, and the raw names are kept as the registers spell them. Five aliases bear on this document. Farapulse, Inc. resolves to Boston Scientific on the basis of the 2021 acquisition disclosed in Boston Scientific's SEC filing. Biosense Webster, Inc. resolves to Johnson & Johnson on the basis of the 1997 acquisition disclosed in Johnson & Johnson's SEC filing. ABBOTT MEDICAL resolves to Abbott, and Medtronic, Inc. and Kardium, Inc. resolve to Medtronic and Kardium, by name normalisation. Each alias carries a verified flag and the name of the person or rule that set it.

Scope

The confirmed electrophysiology set is the 133 licences on the active listing that ArrHub had confirmed as electrophysiology devices as at 20 September 2026. A licence enters the candidate pool when its English licence name contains one of the keywords held in ArrHub's controlled vocabulary; at extraction there were fourteen (ablation, arrhythm, cardioverter, cryoablation, defibrillator, electrophysiol, holter, intracardiac, leadless, loop recorder, mapping, pacemaker, pulsed field, resynchron), and a fifteenth, "PFA catheter", was added afterwards for the reason given under Limitations. The pool held 250 candidates at extraction. Membership of the confirmed set was then decided per licence, either by a human reviewing a proposal or by a deterministic rule matching a known electrophysiology manufacturer and a cardiac keyword; each confirmed record carries the method that confirmed it.

The pulsed field ablation set in Table 1 was not taken from the confirmed set. It comes from a search of all 35,744 licence names for "pulsed field", "PFA" and the five product names, so that the finding rests on the whole register and not on the reviewed subset.

Limitations

At the extraction of 20 September 2026 the pool held 250 candidates, of which 133 were confirmed and 117 unreviewed. The register was re-ingested later the same day with the extended keyword set described below; the pool now holds 256 candidates, 133 confirmed, four rejected and 119 unreviewed as at the re-ingestion date. The counts in Table 3 will change as review continues. The unreviewed candidates cannot change the finding in Table 1, which comes from the whole register, but they can change the confirmed-set ratio in Table 3.

The keyword rule in force at extraction missed one pulsed field ablation licence. Abbott's Volt catheter, licence 115142, is named "VOLT PFA CATHETER, SENSOR ENABLED"; the abbreviation PFA was not among the fourteen keywords, so at the time of extraction on 20 September the licence was outside the candidate pool and is not in the confirmed set. It was found by the whole-register name search and is included in Table 1 on that basis. The keyword set has since been extended with "PFA catheter", which brings the Volt licence into the pool as an unreviewed candidate; the bare term "PFA" was tried first and withdrawn after it matched four Siemens platelet function analyser licences. Any pulsed field ablation licence whose name contains neither "pulsed field", "PFA" nor one of the five product names would be missed by the same search; none was found by a search for "electroporation".

Exclusions

Four Class II licences held by Siemens Healthcare Diagnostics Products GmbH whose names contain "PFA" (PFA-100, INNOVANCE PFA-200, INNOVANCE PFA P2Y and DADE PFA REAGENTS) are excluded from Table 1. They are in vitro diagnostics licences, not ablation devices, and all four are Issued/Active.

The archived MDALL listing, which holds licences no longer active, was not read. Health Canada Class I devices, which are not licensed, are outside the register.

Not covered

The register does not publish the conditions attached to a conditional licence, the correspondence that set them, or any history of status changes. This document therefore makes no statement about what the conditions are, why they were attached, whether they differ between the five licences, or whether any has been discharged. Commercial availability in Canada is not a register fact and is not addressed.

Disclaimer

ArrHub reports public register records. It does not assess patent scope, validity or infringement, and nothing in this document should be read as doing so. Records are transcribed from the sources named in the methodology and verified against those sources before publication. Corrections: alerts@arrhub.com.

About the editor

Bruno Deslauriers is the editor of ArrHub. He built the ingestion and verification pipeline that produces these documents from public regulatory registers. ArrHub is published by Dalimer Corporation, Toronto.