Health Technology Review	
Technology Ref.:	HTA24060
Applicant's contact Email: **Mobile no:**	raed.a@akigroup.com 0505117516
Technology Name/Version/Model:	FARAPULSE (PFA) system Pulsed Field Ablation Generator Model: 61M401
Approvals by International Bodies (year):	FDA, MOHAP and CE mark
Manufacturer/ Company name, country of Origin	Boston Scientific USA
Agent in UAE:	Al Khayyat Investments (AKI) Dubai
Class/ Type	Therapeutic Device
Licensed Indications	Treatment of Paroxysmal Atrial Fibrillation (PAF)
Cost and Comparisons with standard of Care	The cost of the new technology is about 25-30% higher than the current therapy, but it has potential savings in procedural time, safety improvements, and lower recurrence rates compared to traditional methods like radiofrequency and cryotherapy.
Administration/ Use	Used during cardiovascular electrophysiology (EP) procedures.

Short Description of the Technology:	Farapulse™ bipolar and biphasic energy has a low impact on skeletal muscle, a large local electric field, more controlled lesion generation, is not arrhythmogenic and is well tolerated by the patient. **Clinical Evidence/ Efficacy:** Clinical studies have shown that FARAPULSE™ PFA reduces procedural time, minimizes the risk of complications, and improves both safety and efficacy. Compared to standard treatments, it shows better outcomes with fewer recurrences of atrial fibrillation. – 82-87% success rate for arrhythmia-free survival at 12 months. – Reduced procedural time by 30-50%. – Acute PVI success rate of 99-100%. **Journal of the American College of Cardiology (May 2024):** – The impact of post ablation AA burden on outcomes was assessed as well as the effect of ablation modality on AA burden in the ADVENT clinical trial. – AA burden was calculated from percentage AA on Holters (6 and 12 months) and transtelephonic electrocardiogram monitors (weekly and symptomatic monitoring).

	– From 593 randomized patients (299 FARAPULSE, 294 thermal), using aggregate PFA/thermal data, an AA burden exceeding 0.1% was associated with a significantly reduced quality of life and an increase in clinical interventions (i.e. redo ablation, cardioversion, and hospitalization. – Compared with thermal ablation, FARAPULSE ablation more often resulted in an AA burden less than the clinically significant threshold of 0.1% AA burden **Results from the Multicenter EU-PORIA Registry** Kueffer T, Bordignon S, Neven K, et al. JACC: Clinical Electrophysiology (April 2024). – In the EU-PORIA registry 1,184 patients (62% paroxysmal atrial fibrillation) underwent de novo ablation with FARAPULSE with 272 (23%) having an arrhythmia recurrence. – There were 144 (53%) redo procedures at a median of 7 months after the first ablation. – Three-dimensional EAM identified 404 of 567 pulmonary veins (71%) were durability isolated with 54 patients (38%) all having their pulmonary veins durably isolated. – Prior operator experience with CBA was associated with a higher PVI durability compared to operators with only RFA experience. – Operator experience and device size had no impact on lesion durability **Safety** of Pulsed Field Ablation in more than 17,000 Patients with Atrial Fibrillation in the MANIFEST-17K Study Ekanem E, Neuzil P, Reichlin T. et al. Nature Medicine (July 2024). This safety registry included 17,642 patients treated across 106 centers and 413 operators, encompassing 91.4% of all centers using FARAPULSE. 1. Population: ▪ The primary population for the FARAPULSE™ system consists of patients with paroxysmal atrial fibrillation (PAF) who have not responded adequately to antiarrhythmic drug therapy (AADs). The target group includes individuals at risk of arrhythmia recurrence and those who may face adverse effects from existing treatments like radiofrequency or cryoablation. ▪ Typical patients include older adults (as AF prevalence increases with age) and those with comorbidities that make them susceptible to AF recurrence. Special attention is given to patients with structural heart disease or those who are unsuitable for thermal ablation techniques due to safety concerns. 2. Intervention: ▪ The intervention is the use of the FARAPULSE™ Pulsed Field Ablation (PFA) system for catheter ablation in patients with atrial

	fibrillation. ▪ The device delivers pulsed electric fields to selectively ablate myocardial tissue while sparing surrounding structures, including the esophagus and phrenic nerve. ▪ This method aims to improve the isolation of pulmonary veins, which is a critical factor in managing atrial fibrillation. 3. Comparator: ▪ The main comparators in clinical studies include radiofrequency ablation (RFA) and cryoablation, both of which are well-established techniques for atrial fibrillation ablation. ▪ These methods have known success rates but also carry risks such as collateral damage to surrounding tissues, longer procedure times, and a higher incidence of complications like atrial esophageal fistula and phrenic nerve injury. ▪ Antiarrhythmic drugs (AADs) may also be considered as a comparator, although they are often less effective, with a high recurrence rate of AF within 6-12 months. 4. Outcomes: The outcomes assessed in clinical studies of FARAPULSE™ include: ▪ Acute success rate: High rates of pulmonary vein isolation (PVI) with immediate results comparable or superior to those achieved with RFA and cryoablation. ▪ Long-term efficacy: Studies report a lower recurrence of atrial fibrillation within 12 months, with fewer repeat procedures required compared to radiofrequency and cryoablation techniques. ▪ Safety profile: FARAPULSE™ has demonstrated fewer complications such as esophageal injury, phrenic nerve damage, or cardiac tamponade, making it a safer alternative to thermal ablation. ▪ Reduced procedural time: PFA often results in shorter procedural times, leading to reduced exposure to anesthesia and a quicker recovery for patients. ▪ Patient outcomes and quality of life: Patients treated with PFA reported improved recovery times, better post-procedural outcomes, and overall higher satisfaction compared to traditional ablation techniques. ▪ Healthcare cost impact: While the upfront cost of PFA may be higher than traditional methods, the reduced need for repeat procedures and fewer complications are expected to result in overall cost savings for healthcare systems. **Safety/ Risk issues:** ▪ FARAPULSE™ has demonstrated an improved safety profile with minimal risks, such as reduced phrenic nerve injury and no significant post-procedural complications compared to conventional treatments. ▪ The major adverse event rate was <1% with no reports of

	esophageal fistula or dysmotility, pulmonary vein stenosis or persistent phrenic nerve injury **Place in therapy/ diagnosis:** FARAPULSE™ is a therapeutic device primarily used to treat patients with paroxysmal atrial fibrillation who may not have responded well to antiarrhythmic drugs. The FARAWAVE Catheter is indicated for the isolation of pulmonary veins in the treatment of drug-refractory, recurrent, symptomatic Paroxysmal Atrial Fibrillation (PAF).

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The FARAPULSE™ Pulsed Field Ablation (PFA) system represents an innovative advancement in the treatment of paroxysmal atrial fibrillation (PAF). This technology offers several benefits compared to current standard therapies such as radiofrequency and cryotherapy, providing a solution to unmet clinical needs through its superior safety, efficiency, and efficacy.

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. FARAPULSE™ PFA system should be used in patients with paroxysmal atrial fibrillation (PAF)
2. The procedure should be performed only in specialized centers with electrophysiologists experienced in catheter ablation techniques.
3. Physicians using the FARAPULSE™ system should undergo specific training and certification in the use of PFA technology.
4. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
5. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image


Population, setting and intended user for Technology "FARAPULSE™ PFA system"

- **Population/ Intended User**:
  - Patients with paroxysmal atrial fibrillation who may not have responded well to antiarrhythmic drugs.
  - The FARAWAVE Catheter is indicated for the isolation of pulmonary veins in the treatment of drug-refractory, recurrent, symptomatic Paroxysmal Atrial Fibrillation (PAF).
- **To be performed by**:
  - Cardiologists specializing in electrophysiology.
- **Clinical Setting:**
  - Cardiovascular EP procedural settings.
- **Condition of use:**
  - For patients with AF where antiarrhythmic drugs or other forms of ablation are not effective or appropriate.
- **Exclusion criteria:**
  - Any conflicting medical issues or comorbidities that increase risk or contraindicate the use of PFA.