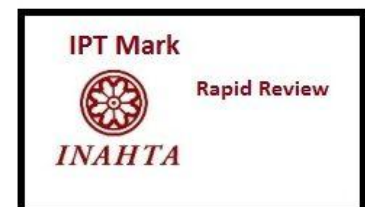




## **INFORMATION BRIEF (RAPID REVIEW)**

# **PULSED FIELD ABLATION SYSTEM FOR CATHETER ABLATION OF ATRIAL FIBRILLATION**

**Malaysian Health Technology Assessment Section (MaHTAS)  
Medical Development Division  
Ministry of Health Malaysia  
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Please contact [htamalaysia@moh.gov.my](mailto:htamalaysia@moh.gov.my) if further information is required.

Malaysian Health Technology Assessment Section (MaHTAS)  
Medical Development Division  
Ministry of Health Malaysia  
Level 4, Block E1, Precinct 1  
Government Office Complex  
62590, Putrajaya  
Tel: 603 8883 1229

Available online via the official Ministry of Health Malaysia website:  
<http://www.moh.gov.my>

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## **TITLE: PULSED FIELD ABLATION SYSTEM FOR CATHETER ABLATION OF ATRIAL FIBRILLATION**

### **PURPOSE**

This review was conducted upon request by the Senior Consultant Physician and Cardiologist from Hospital Sultan Idris Shah to provide information on the effectiveness, safety and cost-effectiveness of the pulsed field ablation system for catheter ablation of atrial fibrillation for procurement in advancing cardiovascular services that better meet the patients' needs.

### **BACKGROUND**

Atrial fibrillation (AF) is a supraventricular arrhythmia distinguished by disorganized atrial activity and inefficient atrial contraction that affects approximately 52.6 million people globally in 2021.<sup>1</sup> Locally, AF prevalence is the highest at 2.26% for 75 years old and older group, followed by 2.03% for those between 65 to 74 years old, meanwhile 0.14%, 0.09% and 0.64% in less than 45 years old, between 45 to 54 and 55 to 64 groups, respectively.<sup>2</sup> The primary prevention of AF as focused by both American and European guidelines, is by maintaining a healthy body weight, active lifestyle, abstinence from nicotine, and moderate alcohol consumption.<sup>3</sup>

Traditionally, atrial fibrillation is primarily classified by its duration and pattern into paroxysmal, persistent and permanent AF.<sup>3</sup> On the other hand, recent guidelines has introduced four main stages of AF that is based on duration of the disease and the effectiveness of treatment for delaying permanent AF or restoring the sinus rhythm.<sup>1, 3</sup> The main objective in managing AF is to improve symptoms and quality of life, maintain sinus rhythm, delaying the progression of AF and to reduce the morbidity related to AF, such as stroke.<sup>4,5</sup> Several approaches of treatments have been established such as cardioversion, anti-arrhythmic drugs (AADs), percutaneous catheter ablation, endoscopic and hybrid ablation, as well as open surgical.<sup>4</sup>

Pulmonary vein isolation (PVI) is a minimally invasive heart ablation procedure that is used to manage atrial fibrillation.<sup>6</sup> Primarily it uses hot or cold substances such as radiofrequency to create scar tissue inside the pulmonary vein.<sup>6</sup> The scar tissue will then disrupt the electrical signals preventing it from reaching the atria. Commonly, there are two types of ablation therapy used in PVI, i.e. radiofrequency ablation and cryoablation as in Figure 1.<sup>6,5</sup> In recent years, pulsed field ablation was introduced as one of the latest innovation in the ablation technology alongside the thermal ablation methods.<sup>5</sup>

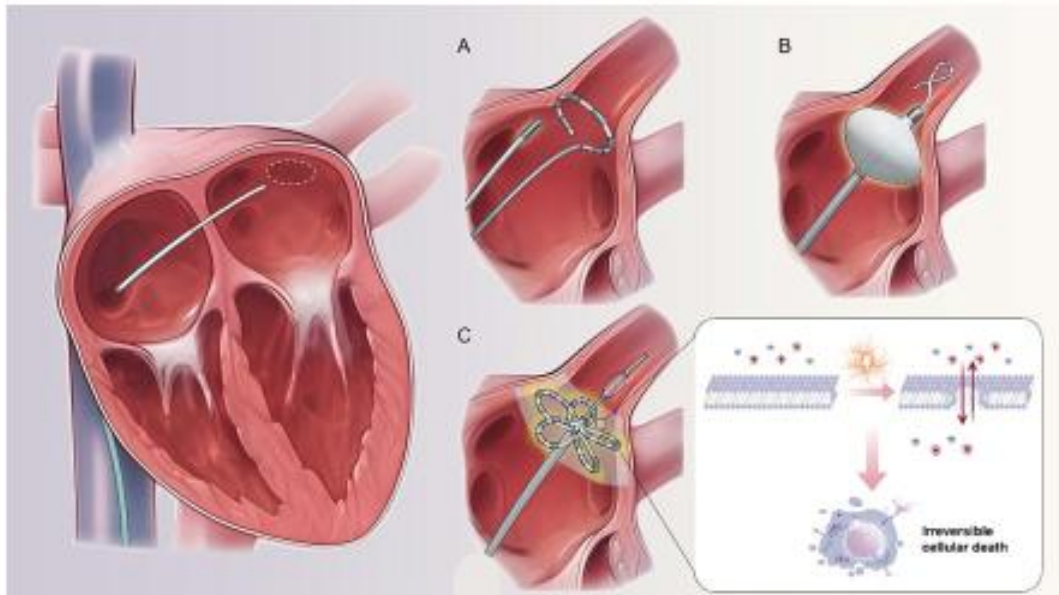


Figure 1: Three types of ablation techniques. Figure A Radiofrequency catheter ablation (Thermal ablation), Figure B Cryoballoon ablation (Cryo ablation), Figure C Pulsed field ablation<sup>7</sup>

Pulsed Field Ablation (PFA) is an innovative non-thermal ablation technology utilises ultra-rapid (microseconds to nanoseconds) electrical pulses that generates strong electrical fields creating irreversible nano-scale pore formation in the cellular membrane, eventually causing cellular death.<sup>5, 8</sup> It uses direct current power supply to charge the capacitors, then discharge through a high-voltage switch. The high voltage pulses produced ranging from hundreds of volts to tens of kilovolts between electrodes forms electric field.<sup>5</sup> This phenomenon is known as electroporation.<sup>5, 8</sup> Lesion formation during PFA is dependent on multiple pulse and system parameters, including pulse amplitude, pulse width, number of pulses, pulse repetition cycle, waveform configuration (monophasic or biphasic polarity), electrode geometry, catheter configuration, and the spatial relationship between electrodes and the target tissue.<sup>8</sup> These parameters collectively determine whether electroporation is reversible or irreversible and thereby govern the extent and durability of tissue injury.

In the treatment of atrial fibrillation, PFA delivers high voltage, ultra short electrical pulses to atrial myocardium via catheter-based electrodes introduced through femoral venous access. The system stores electrical energy in capacitors and discharges it in a controlled manner to generate intense, non-thermal electric fields at the tissue-electrode interface. Catheter positioning and lesion delivery are guided by fluoroscopy, often in combination with electroanatomical mapping and intracardiac echocardiography. Application of pulsed electric fields induces a transmembrane potential across cardiomyocyte plasma membranes. At lower field strengths or subthreshold pulse conditions, electroporation may be reversible, with subsequent membrane resealing and cell survival. In contrast, at sufficiently high field strengths and short pulse durations, the induced transmembrane voltage exceeds a critical threshold, resulting in irreversible electroporation rather than electrical excitation. Irreversible electroporation is characterised by the formation of nanoscale, non-reversible membrane defects that lead to sustained loss of membrane integrity, disruption of ionic gradients and failure of cellular homeostasis, culminating in cardiomyocyte death. (Figure 2) Unlike other thermal ablations techniques, PFA does not rely on thermal energy deposition, thereby minimising conductive heating and reducing the risk of collateral injury to adjacent non-cardiac structure.<sup>8</sup>

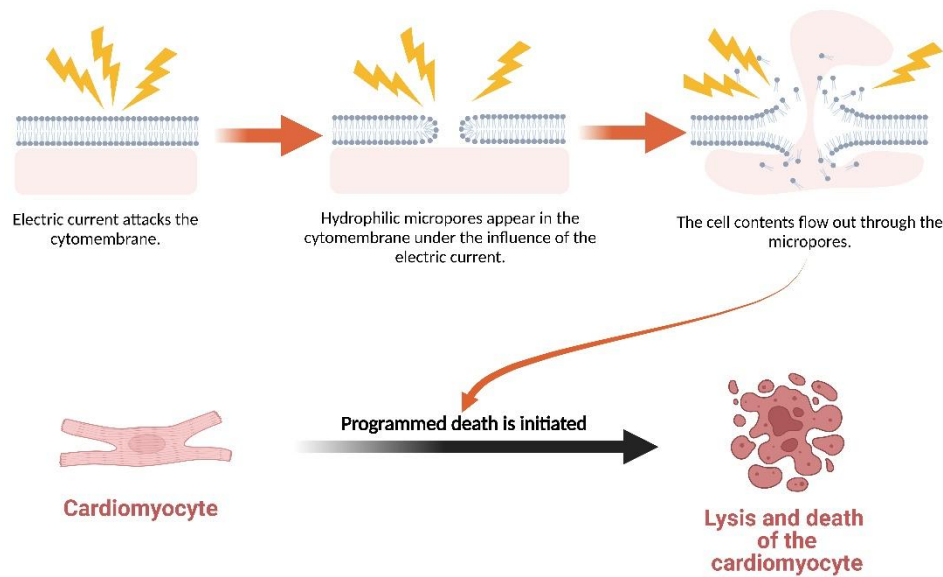


Figure 2: Mechanism of the electroporation inducing the death of cardiomyocyte<sup>9</sup>

## EVIDENCE SUMMARY

The systematic search found **three** relevant articles related to pulsed field ablation in the treatment of atrial fibrillation from the scientific databases such as EMBASE Medline, EBM Reviews via OVID, PubMed and from general search engines up to December 2025 using the following search terms: “*Pulsed field ablation*”, “*cardiac ablation*”, “*atrial fibrillation*”, “*paroxysmal atrial fibrillation*”

## EFFICACY/ EFFECTIVENESS

A systematic review and meta-analysis was conducted by Li R et al. (2025) to assess the effectiveness and safety of pulsed field ablation (PFA) in patients with atrial fibrillation (AF) in comparison to conventional thermal ablation. In total, there were 46 studies were included with one RCT whilst the remaining were observational studies. A total of 11,469 patients were involved in single-arm analysis and 5,266 patients were included in the comparative analysis. The RCT study was rated as low risk of bias, 91% of the observational papers were moderate to high quality, meanwhile, four single-arm observational studies received NOS score of 5 points indicating moderate quality risk of bias. In term of effectiveness, PFA demonstrated high acute efficacy of 99.79% per vein and 99.47% per patients in the single-arm analysis. In the comparative analysis, PFA showed non-inferiority to thermal ablation for acute PVI per patient (OR 1.25; 95% CI 0.57 to 2.74) and per vein (OR 1.27; 95% CI 0.45 to 3.57). Other than that, PFA was superior to thermal ablation, achieving a significantly higher rate of first-pass isolation (OR: 9.23; 95% CI 1.60 to 53.37). Pulsed field ablation (PFA) also exhibited superior single-shot success rates for both per-patient (OR 4.09 95% CI 2.31 to 7.24) and per vein (OR 20.88 95% CI 12.41 to 35.13) in comparison to cryoballoon ablation in the subgroup analysis. In procedural outcomes, PFA resulted in significantly

shorter procedure times compared to thermal ablation, with a weighted mean difference (WMD) of -19.74 minutes 95% -23.47 to -16.00. The average PFA procedure time was 84.88 minutes. PFA was associated with longer fluoroscopy times compared to thermal ablation overall (WMD 3.77 minutes 95% CI 1.74 to 5.81). Atrial arrhythmia recurrence rates for PFA were reported 12.36% at 3 months, 12.42% at 6 months, and 23.28% at 12 months. In the comparative recurrence, PFA was associated with a significantly lower incidence of atrial arrhythmia recurrence after the 3-month blanking period compared to thermal ablation (OR 0.77; 95% CI 0.64 to 0.92). The PFA showed lower 3-month recurrence (OR: 0.61; 95% CI 0.45 to 0.83) against RFA, whereas against CBA, there was no significant difference in 3-month recurrence (OR 0.81; 95% CI 0.64 to 1.04). The rate of repeat ablation was 7.68% in the PFA single-arm analysis, with no significant difference found between PFA and thermal ablation groups (OR: 0.95; CI 0.73 to 1.23). The authors concluded that PFA exhibited noninferiority to thermal ablation in acute PVI and superiority in first-pass isolation rate, recurrence of atrial arrhythmias, phrenic nerve paralysis or injury, and duration of the procedure.<sup>10</sup> Level I

Esteves M et al. (2025) has systematically reviewed and conducted meta-analysis comparing the effectiveness and safety of pulse field ablation (PFA) versus radiofrequency ablation (RFA) for paroxysmal atrial fibrillation (AF) among adults. There were one randomised controlled trial and five observational studies consisted of 3,163 patients, with 972 patients underwent PFA with follow-up range from 12 to 30 months. The meta-analysis included 2,353 patients. There are three outcomes of interest identified, i.e. procedural outcomes (duration, fluoroscopy time and dose, left atrial dwell time), efficacy outcomes of the recurrence of arrhythmia after 3-month blanking period (especially after one year follow up), the requirement for redoing ablation procedures and success of treatment at one year, and lastly, the safety outcomes comprise of overall complication rate, major complication rate, specific major complication, i.e. mortality, stroke, transient ischaemic attack (TIA), cardiac tamponade, persistent phrenic nerve injury and vascular complications. The patients' demographics covered mean age of  $65.3 \pm 10.6$  years with majority of the 1,449 patients were male and receiving anti-coagulants at the time of procedure. The comorbidities reported are hypertension, diabetes mellitus, those with cardiovascular risk factors such as coronary artery disease, heart failure, and prior case of stroke or TIA. The result of the analysis of the procedural outcomes reported that PFA has statistically significantly shorter total procedural time but longer fluoroscopy time (MD -39.15min; 95% CI -58.19 to -20.11,  $p < 0.01$ ;  $I^2 = 94\%$  and MD 10.75min; 95% CI 5.58 to 15.92,  $p < 0.01$ ;  $I^2 = 98.9\%$ ). The fluoroscopy dose also reported higher in PFA with MD 3.32 Gy  $\text{cm}^2$ ; 95% CI 2.83 to 3.80,  $p < 0.01$ ;  $I^2 = 0\%$ . As for left atrial dwell time was significantly shorter with PFA (MD -35.79min; 95% CI -50.37 to -21.20,  $p < 0.01$ ;  $I^2 = 94.6\%$ ). The recurrence of arrhythmia after three month blanking period was reported to be significantly lower with PFA (RR 0.75; 95% CI 0.57 to 0.99,  $p = 0.05$ ;  $I^2 = 17.8\%$ ). On the other hand, there was no significant difference reported at one-year follow up between two modalities (RR 0.85; 95% CI 0.64 to 1.44,  $p = 0.29$ ;  $I^2 = 47.8\%$ ). Similar outcomes were reported after one year in the rate of redo ablation procedures for both modalities (RR 1.02; 95% CI 0.83 to 1.26,  $p = 0.82$ ;  $I^2 = 0\%$ ) and overall treatment success (RR 1.04; 95% CI 0.77 to 1.41,  $p = 0.79$ ;  $I^2 = 88.7\%$ ). High heterogeneity was reported for total procedural time, fluoroscopy time, left atrial dwell time and the rate of overall treatment success at one year. However, upon an exclusion of a study focused on  $\geq 75$  years old groups, substantial reduced in heterogeneity was reported and shifted the pooled estimated favouring PFA for treatment success and one-year arrhythmia recurrence suggesting patient age and associated atrial substrate complexity modulated the therapeutic impact of PFA. In conclusion, this study reported that significant

reduction in overall procedural duration and left-atrial dwell times in comparison to RFA, despite increased fluoroscopy exposure. It was also reported PFA demonstrated equivalent clinical efficacy to RFA in relation to atrial arrhythmia recurrence and treatment success.<sup>11</sup>  
Level I

A single centre real-world cohort study conducted in the Netherlands by van de Kar MRD et al. (2024) with the objective to compare the effectiveness and safety of PFA and cryoballoon ablation involving 1,714 first time patients underwent PVI for atrial fibrillation (473 in PFA and 1,241 in cryoballoon). The study focused on the outcome of procedural complications, specifically phrenic nerve palsy during admission, cardiac tamponade in  $\leq 30$  days, thromboembolic complications in  $\leq 72$  hours, bleeding complications during admission and 30-day mortality. Meanwhile, secondary outcomes were procedural aspects such as procedure duration, admission duration, and re-do ablation rates within six months. There was no statistically difference in the rate of re-do ablation procedures within six months with 9.6% and 9.8% for PFA and cryoballoon, respectively. The adjusted odds ratio for this outcome was OR 1.00, 95% CI 0.68 to 1.47,  $p = 0.99$  indicating comparable short-term efficacy. PFA group was reported with significant reduction in procedure duration of 74.0 min; IQR: 65.0 to 87.5;  $p < 0.001$  compared to cryoballoon of 95.0 min; IQR: 85.0 to 108.0;  $p = 0.12$ . There was significant difference in admission duration for patients receiving PFA (OR -0.08 95% CI -0.16 to -0.004,  $p = 0.04$ ). It was concluded that the evidence demonstrated that the multi-electrode PFA is a safe and effective apart from cryoballoon ablation in the treatment of AF. It offers shorter procedural time and reduced risk of phrenic nerve palsy.<sup>12</sup> Level II-2

## SAFETY

The PFA devices were registered under the Malaysian Medical Device Authority (MDA) with an indication for cardiac tissue ablation using Pulsed Electric Field (PEF) energy in the treatment of paroxysmal atrial fibrillation.<sup>13</sup> It was also listed under US FDA as percutaneous cardiac ablation catheter for the treatment of atrial fibrillation with irreversible electroporation.<sup>14</sup> A number of PFA systems had received CE Mark approval in Europe with the indication to treat atrial fibrillation.<sup>15,16,17,18</sup>

In the systematic review conducted by Li et al (2025), PFA demonstrated a significant lower incidence of phrenic nerve paralysis or injury in comparison to thermal ablation modalities (OR: 0.35; 95% CI 0.17 to 0.70) and 0.39% in the single-arm studies, as well as oesophageal complications (OR 0.11 95% CI 0.03 to 0.45) and 0.04% complication rate for the single arm studies.<sup>10</sup> However, there was no significant difference in atrioesophageal fistula (OR 1.49 95% CI 0.34 to 6.60) and 0.08% in the single arm.<sup>10</sup> Another study reported PFA provided better safety with phrenic nerve protection with zero case for PFA against 15 cases (1.2% out of 1,241 patients) in cryoballoon.<sup>12</sup> There was comparable pulmonary vein stenosis (OR 0.21 95% CI 0.04 to 1.12) between the modalities, and 0.03% in the single arm.<sup>10</sup>

For other safety outcomes, there were no significant differences between PFA and thermal ablation regarding cerebrovascular accidents (OR 1.15 95% CI 0.37 to 3.55), transient ischaemic attack (TIA) (OR 0.91 95% CI 0.23 to 3.14), vascular access complications (OR 1.06 95% CI 0.64 to 1.74), major bleeding (OR 0.75 95% CI 0.31 to 1.82) and all-cause mortality (OR 0.83 95% CI 0.22 to 3.08).<sup>10</sup> In the single arms studies, the secondary safety outcomes reported 0.13% for vagal nerve injury, 0.66% for pericarditis, 0.42% for pericardial

effusion, 0.31% for cardiovascular accidents, 0.18% for TIA, 1.79% for vascular access complications, 0.49% for major bleeding, 0.34% for aeroembolism, 0.19% for thrombotic events, 0.36% for heart block, 0.16% for coronary spasm or occasional ST-segment elevation, 0.18% for myocardial infarction, 0.21% for all-cause mortality, 0.39% for pneumonia, and 11.64% for asymptomatic cerebral infarction.<sup>10</sup> Pulsed field ablation was associated with a higher risk of cardiac tamponade compared to thermal ablation (OR 3.02 95% CI 1.37 to 6.65) with 0.90% incidence in the single arm studies.<sup>10</sup> A total of seven cases of cardiac tamponade from both groups were reported (three cases in PFA; four cases in cryoballoon).<sup>12</sup>

## **COST-EFFECTIVENESS**

A cost consequence analysis from hospital payer perspective using a decision-tree model was conducted by van de Kar MRD et al (2024) from three medical centres in Belgium, Germany and the Netherlands covering one-year horizon involving 91 patients with mean age of  $64 \pm 10$  years with paroxysmal atrial fibrillation. It utilises data related to procedural times (pre-procedural, skin-to-skin and post-procedural), resource use, and staff burden. In this study, PFA demonstrated significantly shorter procedural times compared to other thermal modalities;  $50.9 \pm 22.4$  minutes (PFA) vs.  $74.5 \pm 24.5$  minutes (cryoballoon) and  $140.2 \pm 82.4$  minutes (RFA). The total cost per 100 patients includes the index procedure, complications, and redo procedures which translated to €216,535 ( $\approx$  RM1,049,350) for PFA, €301,510 ( $\approx$  RM1,461,148) for cryoballoon and €346,594 ( $\approx$  RM1,697,629) for radiofrequency ablation (RFA). However, this total cost excluded the cost of the specific ablation catheter kits. Pulsed field ablation resulted in substantial operational savings due to reduced procedural time and resource consumption of €850 ( $\approx$  RM4,120) per patient and €1,301 ( $\approx$  RM6,305) per patients in comparison to cryoballoon and RFA, respectively. These savings were driven by the shorter procedural duration (skin-to-skin), reduced staff workload, and reduced pre-procedural setup times, in turn allowing higher daily caseload capacity.<sup>19</sup>

Another cost consequence analysis was conducted using a decision-tree model involving 270 adult patients with mean age of  $60 \pm 10$  years with paroxysmal atrial fibrillation in multi centre hospitals in Czech Republic, Italy, and Spain over a one-year time horizon. The model estimated the costs of index procedure, complications, re-interventions to be €2,403 ( $\approx$  RM11,645) for PFA, €2,540 ( $\approx$  RM11,873) for cryoballoon and €3,349 ( $\approx$  RM16,230) for RFA. In turn, PFA demonstrated 10% and 22% cost savings compared to cryoballoon and RFA. It is also reported that PFA was the most efficient modality at €2,566 ( $\approx$  RM12,435) compared to €3,043 ( $\approx$  RM14,747) (cryoballoon) and €3,629 ( $\approx$  RM17,587) (RFA) when costs was adjusted for clinical efficacy, defined as  $<0.1\%$  atrial arrhythmia burden. It was concluded that PFA offers significant economic and operational benefits over thermal modalities in treating paroxysmal atrial fibrillation. It is driven by the higher procedural efficiency of shorter and more predictable skin-to-skin times. Other than that, PFA provides a superior cost per responder indicating proper balance between lower procedural costs and high clinical efficacy.<sup>20</sup>

## CONCLUSION

Based on the review, the retrieved evidence supports the potential benefits of PFA in the treatment of atrial fibrillation in terms of lowering rate of arrhythmia recurrence after three months, procedural efficiency (total procedure time, atrial dwell time) and lower complications rate compared to RFA. Based on the cost consequence analysis, PFA has shown to be more economical and had operational advantages than thermal ablation modalities mostly due to higher clinical efficacy and higher procedural efficiency (pre-, during and post-procedural).

In terms of overall treatment success, PFA is comparable to RFA in the treatment of atrial fibrillation. Pulsed field ablation has been approved by several regulatory bodies including MDA, phrenic nerve protection against cryoballoon, however with higher risk of cardiac tamponade compared to thermal ablation.

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**Prepared by**

Nurul Nashriq Md Hamsin  
*Pharmacist*  
Senior Principal Assistant Director  
Health Technology Assessment Section (MaHTAS)  
Medical Development Division  
Ministry of Health Malaysia

**Reviewed by**

Dr. Roza Sarimin  
*Public Health Physician*  
Senior Principal Assistant Director  
Health Technology Assessment Section (MaHTAS)  
Medical Development Division  
Ministry of Health Malaysia

Dr. Syaqirah Akmal  
*Public Health Physician*  
Deputy Director  
Health Technology Assessment Section (MaHTAS)  
Medical Development Division  
Ministry of Health Malaysia

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