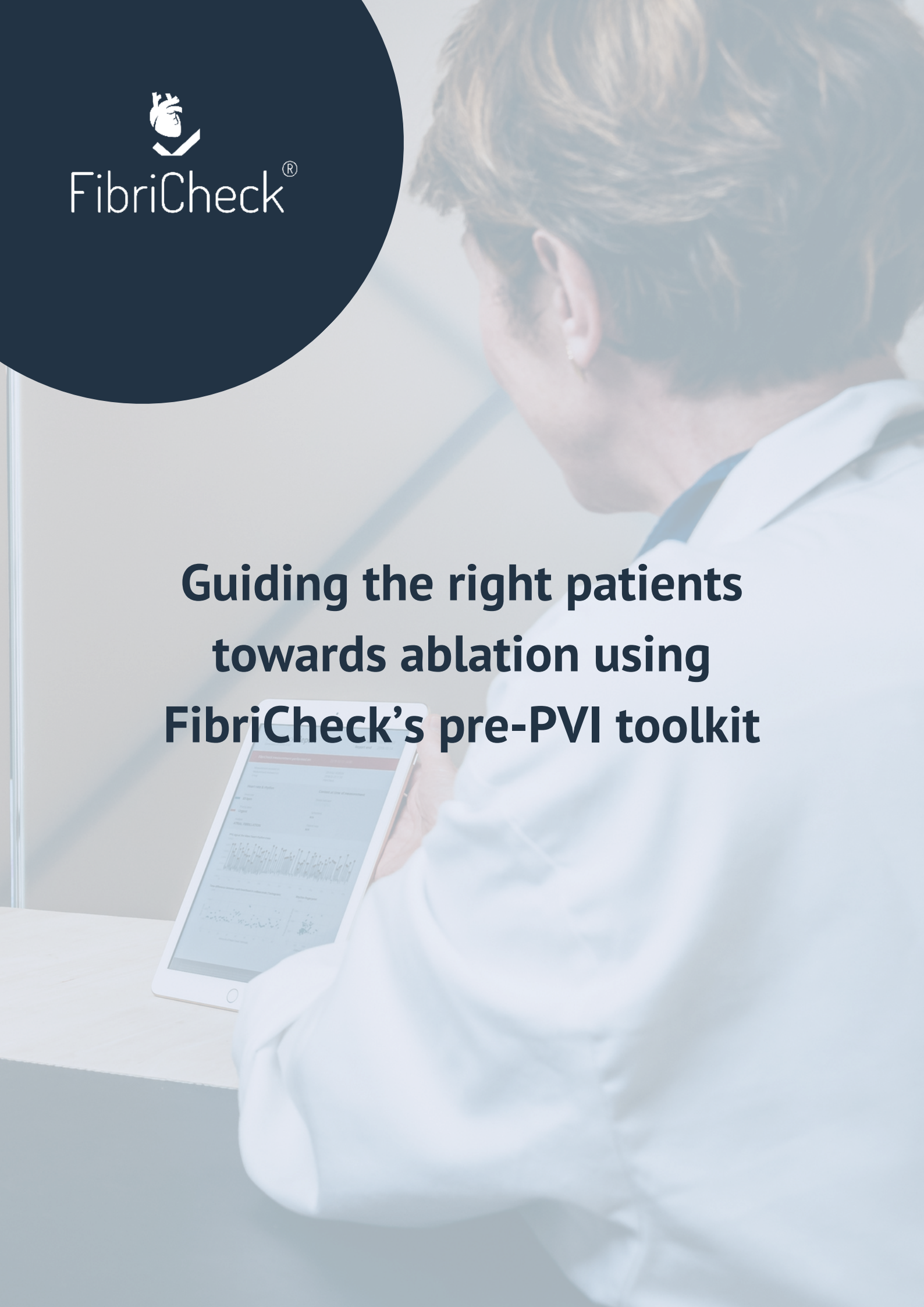
FibriCheck®

Guiding the right patients towards ablation using FibriCheck's pre-PVI toolkit



Introduction

Atrial fibrillation (AF), the **most common type of cardiac arrhythmia**, has a significant global impact, affecting **59 million** individuals worldwide.[1] Alarmingly, **1 in 3 adults** over the age of 55 is at risk of developing AF.[2] Effective **management of AF** has become a pressing **challenge** for healthcare providers, especially since the number of individuals affected by the condition continues to rise.

Minimally invasive ablation techniques such as **pulmonary vein isolation** (PVI), **cryoablation**, and the emerging **pulsed field ablation** (PFA) are recommended by the 2024 European Society of Cardiology (ESC) guidelines as preferred interventions for many AF patients. These[2] procedures offer a **safe and effective alternative to anti-arrhythmic drugs** (AADs), **reduce symptoms**, **prevent AF progression**, and **enhance patient outcomes**. Moreover, innovations like PFA are improving procedural efficiency and expanding ablation capacity.

The growing number of patients eligible for ablation procedures presents significant challenges:

- **Identifying eligible patients efficiently**: Determining which patients would benefit most from ablation amidst growing referral volumes is crucial.
- **Optimizing resource utilization**: Once identified, these patients should be planned and prioritized effectively to reduce procedural delays, minimize wait times and maximize ablation center efficiency.
- **Streamlining workflows:** Reducing logistical complexity and integrating patient management into existing care pathways is critical for operational efficiency.

FibriCheck's pre-PVI toolkit offers a scalable, cost-effective solution to address these challenges, helping healthcare providers efficiently identify and guide the right patients towards ablation.

What the guidelines say

ESC 2024 guidelines

The ESC 2024 guidelines for the diagnosis and management of atrial fibrillation emphasize a patient-centred approach through the AF-CARE framework, which highlights:

- **Comorbidity management (C)**: Identifying risk factors such as hypertension, diabetes, obesity, and sleep apnea as a crucial part in managing patients with diagnosed AF.
- **Stroke prevention via anticoagulation (A)**: Anticoagulant therapy as a key element to reduce stroke risk.
- **Reduce symptoms (R)**: Strategies include rate and rhythm control, with ablation increasingly recommended for many patients.
- **Dynamic evaluation (E)**: Continuous assessment of rhythm, symptoms, and overall health as a critical part of long-term care.

NICE guidelines

In the UK, the NICE guidelines for the diagnosis and management of atrial fibrillation do not specifically recommend ECG-based monitoring for the detection of AF or for patients with previously diagnosed AF. This allows for **informed clinical decision making and detection based on PPG data** in patients with an established AF diagnosis.

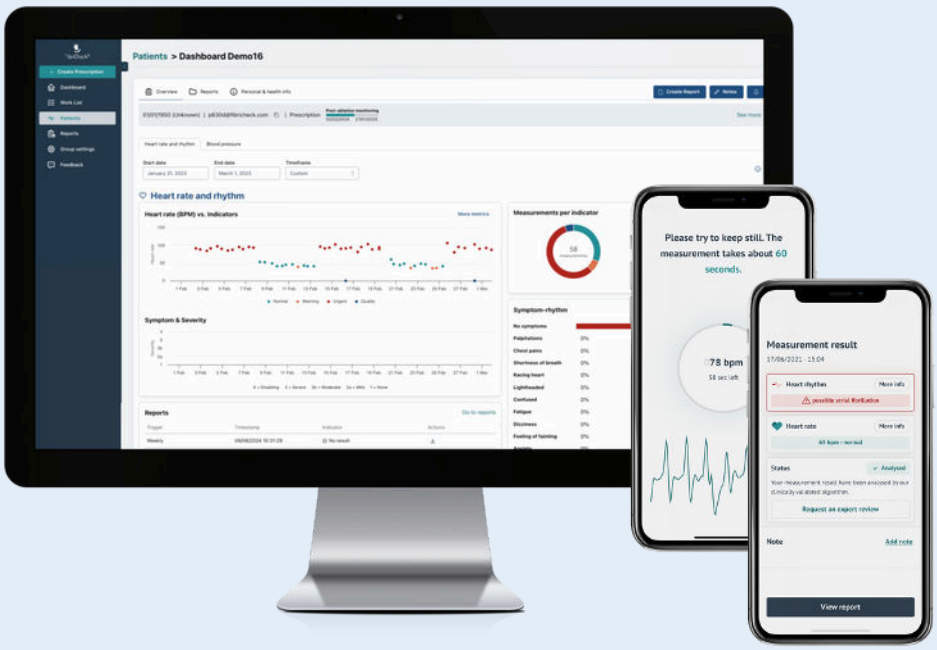
Challenges in pre-PVI settings

Despite the guidelines, ablation centers face key obstacles:

1. **Patient identification**: Many eligible candidates remain undiagnosed or overlooked due to the lack of scalable, efficient detection tools. Patients with comorbidities or risk factors are often not diagnosed early on.
2. **Workflow complexity:** Traditional methods of monitoring, such as Holter monitors and clinic visits, are resource-intensive and inconvenient for both patients and providers.
3. **Data fragmentation**: Patient data from traditional in-office examinations only does not provide a full overview fit for clinical decision-making, making it challenging to identify appropriate candidates for ablation.

FibriCheck: A scalable, clinical-grade solution

FibriCheck is a **CE1639** (Class II medical device) and **FDA-cleared clinical-grade smartphone application** designed for the efficient **detection and management of cardiac arrhythmias**. By combining a user-friendly **patient app** with an **AI-powered portal** for healthcare providers, FibriCheck transforms how healthcare providers identify and manage AF patients.



How FibriCheck solves current challenges

1. Efficient patient identification:

- Patients use their own smartphone to perform simple, 60-second heart rhythm measurements using the FibriCheck application.
- The app's AI algorithm provides immediate, accurate insights in the patients heart rhythm (sensitivity: 98.3%, specificity: 99.9%) reducing the workload for healthcare providers.

2. Streamlined workflow:

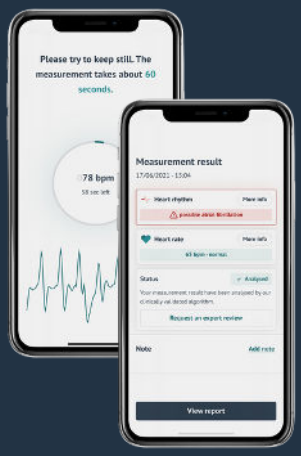
- FibriCheck eliminates logistical hurdles by enabling remote monitoring and data collection, making it a highly scalable solution for AF detection.
- The digital ecosystem easily integrates into existing clinical pathways, enhancing efficiency and scalability.

3. Comprehensive data integration:

- FibriCheck's HCP-facing portal visualises the complete AF profile, including heart rhythm, heart rate, symptoms, symptom severity, and rhythm-symptom correlation.
- Data on comorbidities, risk factors, and treatment history are seamlessly integrated into the patient's profile.

FibriCheck's core features

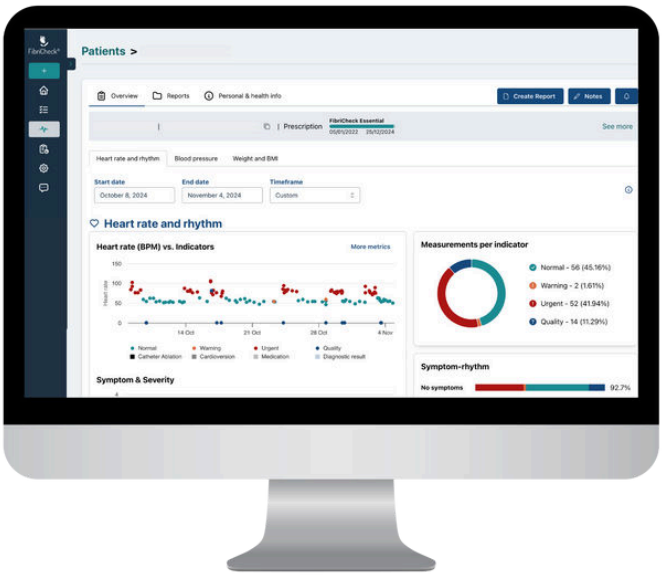
The patient-app



- Heart rhythm and heart rate measurements
- Risk factor tracking (e.g., blood pressure, weight)
- Symptom and symptom severity logging
- Tailored education to empower patients
- PROM questionnaires

The HCP-portal

- AI-labeled rhythm traces with optional overreading services
- Longitudinal rhythm, symptom, burden & comorbidity insights
- Treatment and diagnostic logging
- Remotely manage when patients collect data
- Notifications for clinical action
- Summary reports for the patient's electronic health record



Implementation in a usual care pathway

FibriCheck's pre-PVI solution can be integrated flexibly into usual care pathways:

Short-term passive monitoring

Targeted monitoring for 7 consecutive days, repeated at defined intervals.

Long-term active monitoring

Consistent active monitoring to identify changes in rhythm or symptoms over time.

Custom configurations

Tailored setups to meet the specific needs of ablation centers and patient populations.

FibriCheck's pre-PVI solution

The impact of FibriCheck's digital enhanced pathway

Optimized patient selection

Quickly identify eligible ablation candidates using actionable insights in their AF profile.

Enhanced procedural efficiency

Insights into AF profiles enable better scheduling, increasing daily procedural capacity.

Scalable and cost-effective

FibriCheck leverages patients' own devices, reducing hardware costs and logistical complexity.

Insightful clinical outcomes

Our technology tracks AF progression and symptom relief, enabling dynamic evaluation before and after ablation.

Clinical evidence

FibriCheck's efficacy is supported by over 80 peer-reviewed publications. Highlights include:

- **Improved detection**:
  Real-world validation studies report double detection yield versus conventional care that was highly sensitive (98.3%) and specific (99.9%).[3]

- **Reduced resource utilization**:
  Implementation led to a 75% reduction in consultation time and significant decreases in ECG and Holter monitor use.[4]

- **Enhanced clinical decision-making**:
  On-demand simultaneous rhythm and symptom assessment can provide objective insights into AF, AF symptoms and symptom-rhythm correlation.[5]

- **PPG data integration**:
  Both Fernstad et al. and Gruwez et al. have shown that the collected PPG data was readable and interpretable when implemented in a clinical workflow.[3,6]

- **Symptom-rhythm correlation**:
  Hermans et al. demonstrated that simultaneous mobile app-based symptom and rhythm monitoring revealed a relatively low overall symptom-rhythm correlation in persistent atrial fibrillation patients. With FibriCheck's technology, symptoms and rhythm can be correlated objectively for improved clinical decision-making.[7]

FibriCheck® ACADEMY

Visit our FibriCheck Academy to find all our publications

FibriCheck®

Get started with FibriCheck

FibriCheck's pre-PVI toolkit is revolutionizing AF care by helping ablation centers efficiently identify and manage the right patients. To learn more or to discuss how FibriCheck can be integrated into your workflow, contact us at clinical@fibricheck.com.

References

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2. Van Gelder et al. (2024). [ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): Developed by the task force for the management of atrial fibrillation of the European Society of Cardiology (ESC), with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. Endorsed by the European Stroke Organisation (ESO)] (https://doi.org/10.1093/eurheartj/ehae176

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5. Sangren et al. (2024). [Smartphone app-based approximation of time spent with atrial fibrillation and symptoms in patients after catheter ablation: Data from the TeleCheck-AF project] (https://doi.org/10.1093/europace/euae247)

6. Gruwez et al (2024). [Accuracy of Physicians Interpreting Photoplethysmography and Electrocardiography Tracings to Detect Atrial Fibrillation: INTERPRET-AF] (https://doi.org/10.3389/fcvm.2021.734737)

7. Hermans, A. (2022). [Mobile app-based symptom-rhythm correlation assessment in patients with persistent atrial fibrillation] (https://doi.org/10.1016/j.ijcard.2022.08.021)