FibriCheck®

Smartphone monitoring for procedural success and symptom-rhythm correlation in post-PVI patients

Introduction

Atrial fibrillation (AF) is the **most common type of cardiac arrhythmia**. The disease has a significant global impact, affecting 59 million individuals worldwide.[1] Today the risk of developing AF is a concern for approximately **1 in 3 adults** over 55 years old.[2]

Pulmonary vein isolation (PVI), a type of catheter ablation, is a minimally invasive procedure to treat atrial fibrillation. The procedure is a safe and superior alternative to anti-arrhythmic drugs (ADDs) to maintain sinus rhythm and to improve symptoms.[1]

The indications for AF catheter ablation were recently further broadened in the 2024 EHRA consensus statement on catheter and surgical ablation of atrial fibrillation. The therapy is now deemed relevant for **paroxysmal symptomatic patients**, **persistent AF patients** with intolerance to previous treatments, and patients with **AF recurrence** after a first PVI that improved symptoms.[3]

Whereas in the past therapy success after catheter ablation was looked at only from a binary recurrence perspective, we're now moving into a **more holistic outcome analysis** taking into account the full AF phenotype. Healthcare providers increasingly consider **AF load, symptoms, symptom severity, symptom-rhythm correlation, the impact of treatment** on the patient's quality of life and risk factor management around AF when assessing therapy success and further treatment steps.

Routine clinical practice and atrial fibrillation guideline management dictate that patients should be **reviewed at a minimum of 3 months** and annually thereafter to **assess therapy efficacy by monitoring the heart rhythm and capturing the patient's testimonial around symptoms**. 24h Holter monitoring has long been the standard follow-up method, but digital devices are now finding their place in AF ablation follow-up.

The main reasons for this shift are:

- The rising evidence and acceptance around the use of digital devices in AF monitoring
- The wide availability of digital devices vs lengthy Holter waitlists
- Lower cost of digital device solutions compared to classic Holter-monitoring
- The possibilities of linking symptoms to heart rhythm with digital devices
- The possibility to capture longitudinal insights over a longer period with digital devices
- The possibility of digital devices to include questionnaires about comorbidities and quality of life
- Remote set-up possibilities and ease of use for both patients and hospital staff with digital devices, saving time and costs while reducing the climate impact

What the guidelines say

Clinical practice guidelines such as those issued by the **European Society of Cardiology** (ESC)[2] and the **National Institute for Health and Care Excellence** in the UK (NICE)[4] form the foundation for evidence-based management of atrial fibrillation (AF) patients.

ESC 2024 guidelines

The guidelines stress the **importance of post-ablation follow-up** to assess procedural success and correlate symptom status with rhythm. Post-ablation monitoring is crucial and may be performed using various methods, including:

Intermittent ECG **Holter monitoring** **Patch recordings**
External or implanted loop recorders **Smartphone-based monitors**

The ESC 2024 guidelines emphasise that recent technological developments such as **smartphone-based photoplethysmography** may have an emerging role in post-ablation monitoring. In order to improve the outcomes of AF, the ESC 2024 guidelines recommend a patient-centred approach in their new **AF-CARE** framework:

Comorbidities [C]

Comorbidities should be addressed as an essential part in AF care. By identifying and managing comorbidities such as hypertension, heart failure, and obesity, outcomes in post-ablation AF patients can be improved. With our **blood pressure** and **weight functionalities** and our **patient questionnaires**, comorbidities and key risk factors can be identified and monitored efficiently. Through our **educational content**, patients are better informed about key risk factors, which can help guide them to make beneficial lifestyle changes.

Avoid stroke [A]

Avoiding stroke can often be realised by the use of appropriate anticoagulant medication.

Reduce symptoms [R]

Reducing symptoms with **rate and rhythm control** is the next important step in this framework. With FibriCheck's **heart rate and heart rhythm measurements**, AF recurrence can be detected early on, which can lead to **insights into success of the treatment**. Data on ablation treatments can be added to our portal, which allows for an easy visualization of data and insights about the patient's AF profile, before and after treatment.

Dynamic evalutation [E]

Evaluating quality of care and identifying opportunities for improved treatment of AF is an important part of AF-CARE. At FibriCheck, we support healthcare providers with this evaluation by providing **surveys** that collect **patient reported outcome measures**.

NICE guidelines

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

FibriCheck's post-PVI solution

What is FibriCheck?

FibriCheck is a **medically approved** (CE1639 and FDA-cleared), **clinical-grade smartphone app** combined with a **physician portal**. These highly accurate solutions (Specificity: 99.9%, Sensitivity: 98.3%)[5] are extensively clinically validated in over **80 peer-reviewed publications** including real-world **validation in PVI patients**.

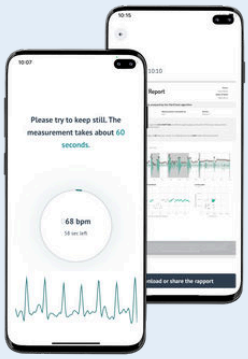
The FibriCheck solution allows for cost-effective follow-up without logistical or hardware challenges. **High usability** (91% of patients report that FibriCheck is easy to use) and **good adherence** (94% adherence to HCP instructions)[7] were proven in many existing implementations.

Our post-PVI toolkit

The FibriCheck ecosystem consists of three elements. The first one is a **patient-facing smartphone or wearable application** that allows patients to follow up on their heart rhythm and symptom status from the comfort of their homes using their own devices.

Secondly, the heart rhythm traces collected through the app are analysed by FibriCheck's **extensively validated AI-powered algorithm**.

Thirdly, the ecosystem is designed so that healthcare providers (HCPs) can orchestrate the timing of rhythm recordings to ensure maximal data relevance. The resulting data is presented in an easily interpretable and structured format within the **FibriCheck healthcare provider (HCP) portal**. This streamlined visualisation allows for seamless integration into clinical pathways, enhancing both time and cost efficiency in patient management.

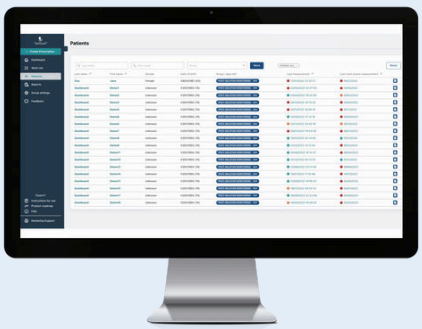


The patient-facing app

- Heart rhythm registration
- Blood pressure logging
- Tailored education
- Heart rate registration
- Weight logging
- Symptom logging
- PROM questionnaires (AFEQTS, QoL)
- Symptom severity logging (mEHRA score)

The HCP-facing portal

- AI labelled heart rhythm traces with optional overreading services
- Procedure and diagnostic result logging
- Manage when patients collect data
- AF load & burden analysis
- Longitudinal rhythm & symptom insights
- Risk factor follow-up (blood pressure, weight, CHA2DS2-VASC)
- Symptom-rhythm correlation
- Summary reports for the patient's EHR
- Symptom severity insights
- Set notifications for important actions



FibriCheck's post-PVI solution

Implementation in a usual care pathway

After a PVI ablation, a patient will traditionally be monitored with a 24h Holter before a follow-up consultation. FibriCheck is providing a digital alternative to this usual care pathway. In this augmented carepath, the patient does not receive a Holter monitor, but is provided with a FibriCheck prescription that allows him/her access to the certified FibriCheck app. This prescription also links the patient to the care team to ensure proper follow-up in the HCP portal.

The setup of the augmented carepath is flexible. Options include:

Short-term passive monitoring

7 consecutive days of monitoring after 3, 6 and 9 months, annually thereafter

Long-term active monitoring

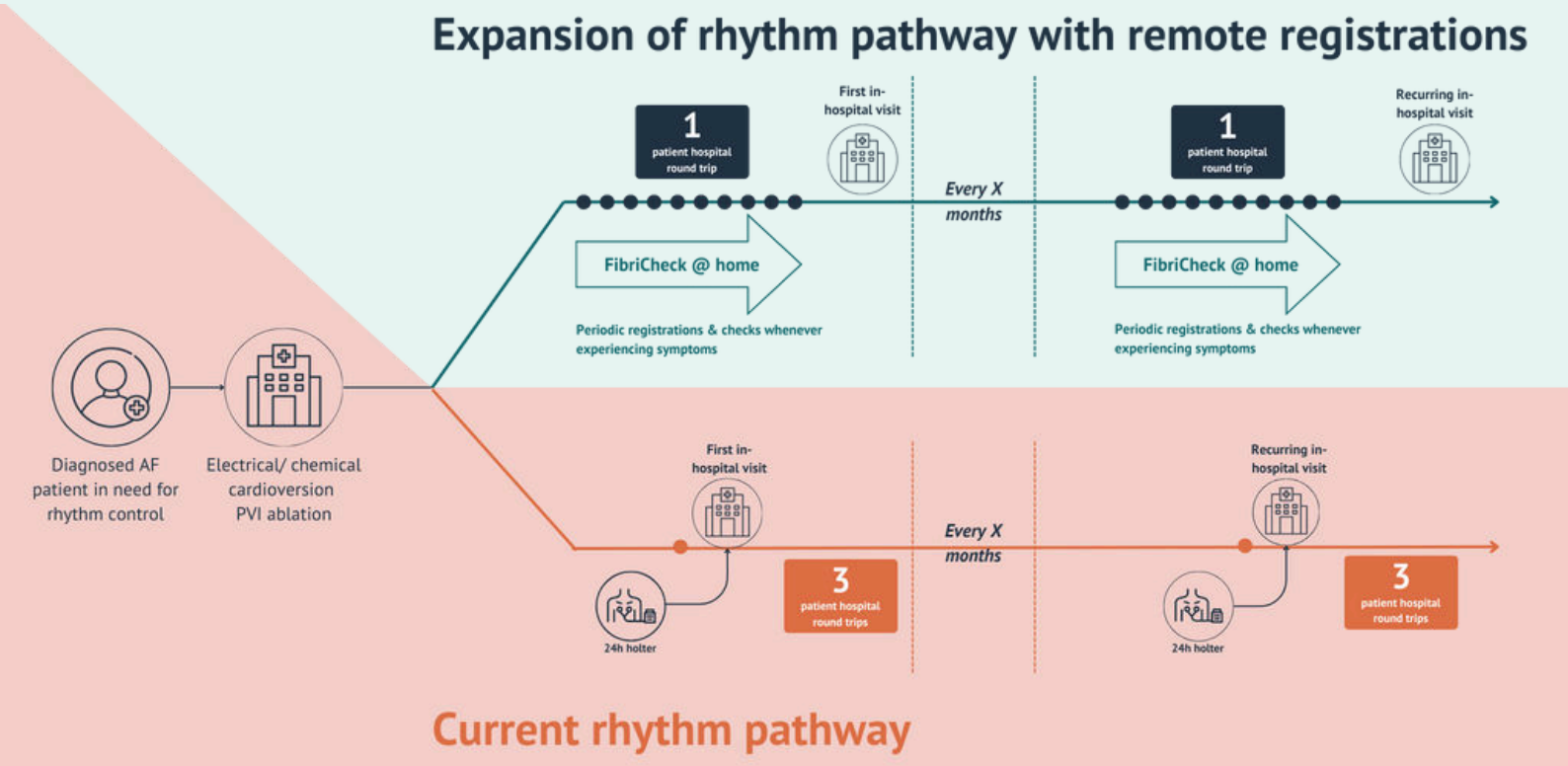
Frequent recording, 365 days a year

Dynamic monitoring

During the first 3 months post-PVI the patient only measures when symptomatic, afterwards these measurements can be performed weekly

Custom set-up on request

Duration and number of measurements can be customized



Partners that already implemented these pathways include:

NHS Mid and South Essex NHS Foundation Trust

Ziekenhuis Oost-Limburg

NHS The Leeds Teaching Hospitals NHS Trust

Maastricht UMC+

FibriCheck's post-PVI solution

The impact of FibriCheck digital enhanced pathway

- **Improved clinical decision making**[2]

  FibriCheck supports you in clinical decision-making by providing actionable and interpretable insights in symptoms, AF recurrence, AF load

- **No logistical hassle or complexities**

  Patients use their own smartphone

- **Time-savings**[8]

  30 minutes of nurse time saved in post-ablation follow-up per patient

- **Cost-savings**[9]

  >70% less need for ECGs and Holter monitors

- **Reduction of carbon footprint**[10]

  88% reduction in carbon footprint compared to traditional pathways

- **HCP coordinated with high patient adherence**[7]

  Healthcare providers orchestrate when data collection is relevant
  Documented patient adherence to HCP instructions as high as 94%

FibriCheck's post-PVI solution

An interesting use case

Patient profile

- Age: 74
- Gender: Male
- Condition: AF
- Procedure: PVI Ablation

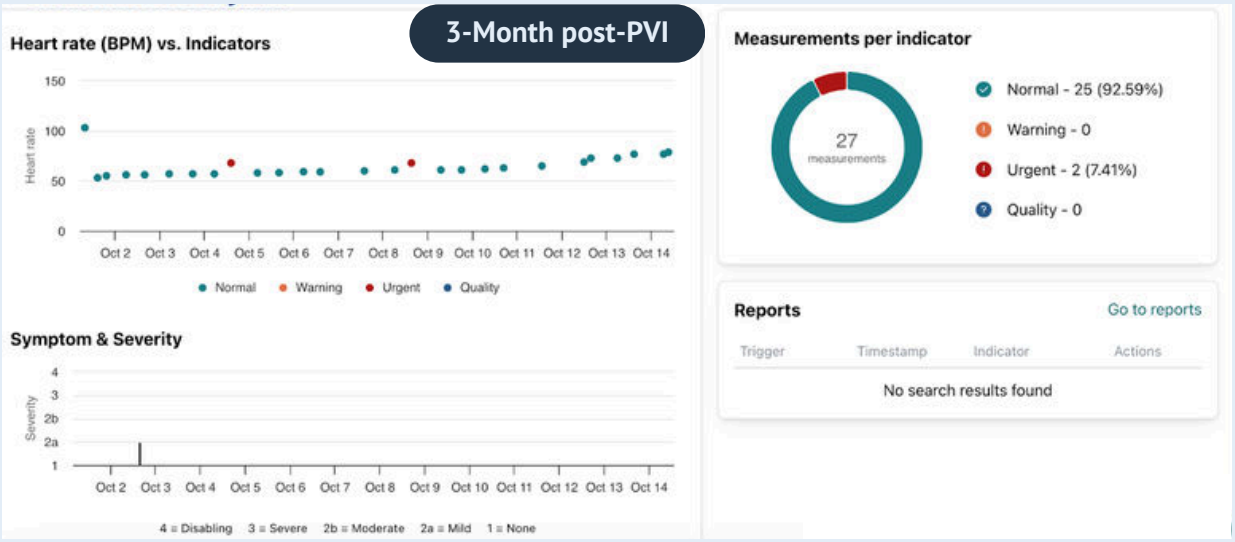
Follow-up consultations

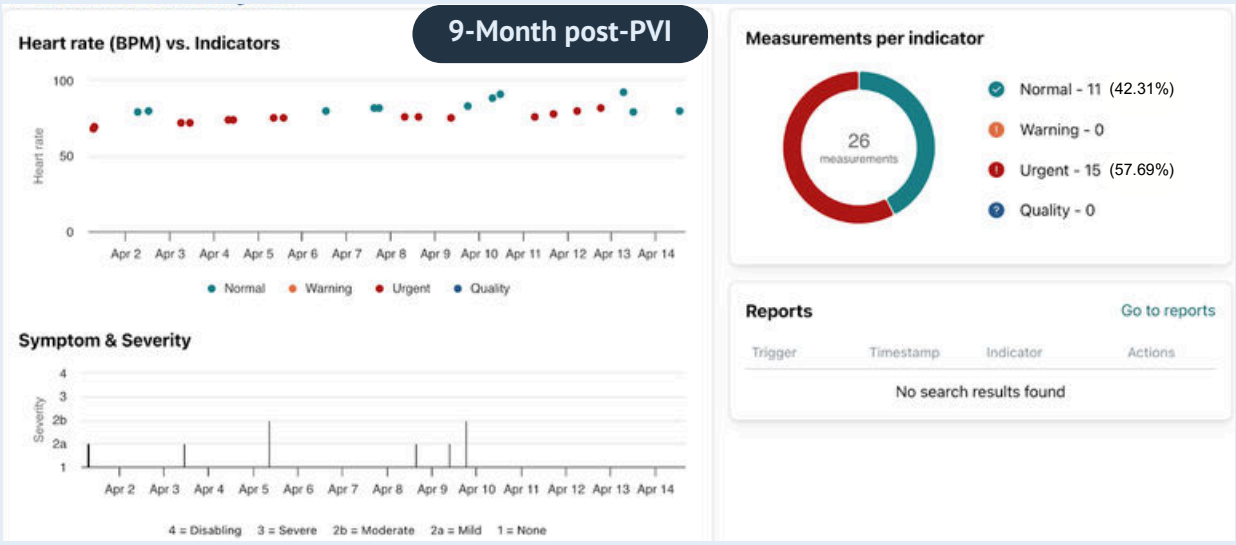
3-Month post-PVI follow-up

At the 3-month follow-up appointment post-ablation, the patient exhibited a low AF load of 7% and reported living symptom-free. The continuation of anticoagulation therapy was recommended due to an increased stroke risk. No further interventions were deemed necessary at this stage.

9-Month post-PVI follow-up

During the 9-month follow-up, the patient reported a recurrence of symptoms, with severity comparable to the pre-ablation period. An increase in AF load was noted, alongside a significant correlation between the symptoms and the rhythm disturbances.





Management Decision

Given the initial positive response to the PVI ablation and the current high symptom-rhythm correlation, a redo ablation was planned for the patient.

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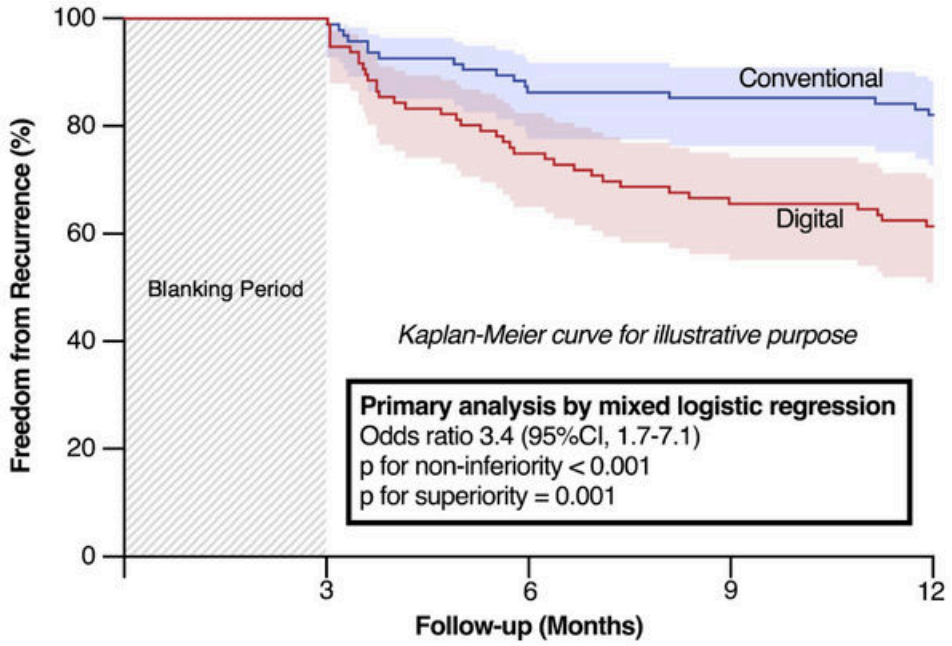
Clinical evidence

FibriCheck has been **extensively validated in over 80 peer-reviewed clinical studies**, including research on its real-world effectiveness in patients undergoing pulmonary vein isolation (PVI) and comparisons between FibriCheck-enabled pathways and traditional care methods. Recent research by Gruwez et al. showed the **superiority of FibriCheck in post-PVI follow-up** compared to traditional ECG-monitoring in the DIGITOTAL study (NCT05486364). In this study, FibriCheck detected twice as much AF recurrence compared to a repeated 24h holter ECG and provided more longitudinal insights in symptoms. FibriCheck also assessed AF load and treatment effectiveness efficiently, thereby demonstrating superiority over conventional care.



- The real-world validation study reassured that the double detection yield versus conventional care was highly sensitive (98.3%) and specific (99.9%).[5]
- 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.[5, 11]
- Toora et al. saved 64,762 GBP and 250 outpatient clinic hours per 500 patients in post-ablation follow-up by integrating FibriCheck into their digitally enabled pathway.[8]
- By implementing FibriCheck in clinical practice, Gawalko et al. demonstrated a 75% reduction in the length of consultations next to 71% less ECGS and 72% less Holter monitors.[9]

FibriCheck®

Get in touch

Interested to find out more about our possibilities?

Get in contact with our team to find a solution that fits your needs and the needs of your patients.

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