



Improving efficiency and quality of care of remote heart failure (HF) alert management through workflow optimization and automation

Executive Summary

Boston Scientific and Leiden University Medical Center (LUMC) have developed an advisory project in 2021 to analyze and streamline the interdisciplinary protocol for the handling and follow-up of HeartLogic™ alerts while enhancing the collaboration between device and heart failure clinical teams. ClearPath HeartLogic™ was then configured to mirror the resulting workflow and to support the standardization and automation of the workflow's steps. The resulting benefits were identified in the improvement of time response and in the workload reduction.

Introducing ClearPath HeartLogic™, a configurable platform to automate and accelerate the proactive management of worsening heart failure.

Anticipating and preventing heart failure (HF) events is crucial to limit the adverse impact on mortality and morbidity.^{1,2} Preventing heart failure related hospitalizations can reduce the burden on patients, care givers and healthcare systems.

To support clinical teams to take actions for patients with worsening HF, Boston Scientific has introduced HeartLogic™, an algorithm for the timely detection of impending HF events. The HeartLogic™ index aggregates measurements from multiple device-based sensors of ICDs and CRT-Ds (heart sounds, thoracic impedance, respiration, heart rate, activity). As shown in the MultiSENSE study, the HeartLogic™ index and alert effectively detect 70% of worsening HF events at a median of 34 days upfront.³

To increase efficiency and quality of care in HF alert management, Boston Scientific has developed ClearPath HeartLogic™, a platform to standardize, automate and reduce the workload of HeartLogic™ alerts workflow management, in line with the hospital-specific workflow and setting. The platform supports the alert case management by:

- Grouping and filtering alerts by patient and alert episode enhancing alert visibility;
- Providing a configurable checklist approach to easily follow specific clinical protocols and detect protocol deviations;
- Keeping track of and setting reminders for timely actions as defined in clinical protocols;
- Facilitating information-sharing and communication between rhythm device and heart failure teams.

The alerts are retrieved by a standard interoperability engine from the patient data generated by Latitude NXT, the in-home monitoring systems of Boston Scientific devices. The alerts are transferred to the hospital as Implantable Device Cardiac Observation (IDCO) profiles or generic HL7 feed. ClearPath HeartLogic™ is classified as Health Software.

Objectives

Boston Scientific and Leiden University Medical Center (LUMC) in the Netherlands piloted ClearPath HeartLogic™ to jointly assess whether it helps to:

1. Accelerate clinical response to HF alerts;
2. Save time of the clinical teams to adequately manage HF alerts.
3. Improve clinical team cohesion within the workflow.

In parallel, the LUMC team assessed the performance of ClearPath HeartLogic™ in terms of functionalities and usability.

Methods

The pilot covered 10,5 months from Go Live on December 14th, 2021 until October 31st, 2022. The project included all adult HF patients with an activated HeartLogic™ algorithm managed by LUMC in this period. It started with 97 patients at the beginning of the pilot and at the end covered 118 patient in total. 59% (n=70) of these patients showed an alert state and were managed via ClearPath during the pilot.

As a prelude to this digital pilot, Boston Scientific and LUMC have realized an advisory project in 2021 to analyze and streamline the protocol for the handling and follow-up of HeartLogic™ alerts and integrate standardized checklists. ClearPath HeartLogic™ was then configured to mirror the resulting workflow (Figure 1). Any HeartLogic™ alert starts the workflow with ClearPath HeartLogic™.

At LUMC, alert episodes are triggered as soon as the HeartLogic™ index reaches or surpasses a nominal value of 16. Patients that generated alerts are presented to the device technicians on ClearPath HeartLogic™ in the status "New." The technicians review alerts for a specialised evaluation of the implantable cardiac device and to detect potential arrhythmias. They can access all relevant reports using ClearPath HeartLogic™. If a patient needs to be referred to the heart failure nurses, the case can be commented and moved to the status "Push to Heart Failure Team."

The patient will then be flagged to the heart failure nurses in the status "Contact" with all details enabling the patient follow-up. When contacting a patient, the heart failure nurses will open and fill the clinic's decompensation checklist integrated in ClearPath HeartLogic™. This helps to assess and automatically document any decompensation signs and symptoms. In case of (impending) decompensation, the treatment is adjusted according to the ESC HF guidelines and the patient is moved to the respective status for follow-up.² Without symptoms, the nurses follow-up with the patient in a sequence of 2, 6 and 10 weeks.⁴ For this, the team can create automatic reminders on actions to be taken to follow LUMC's protocol of care.

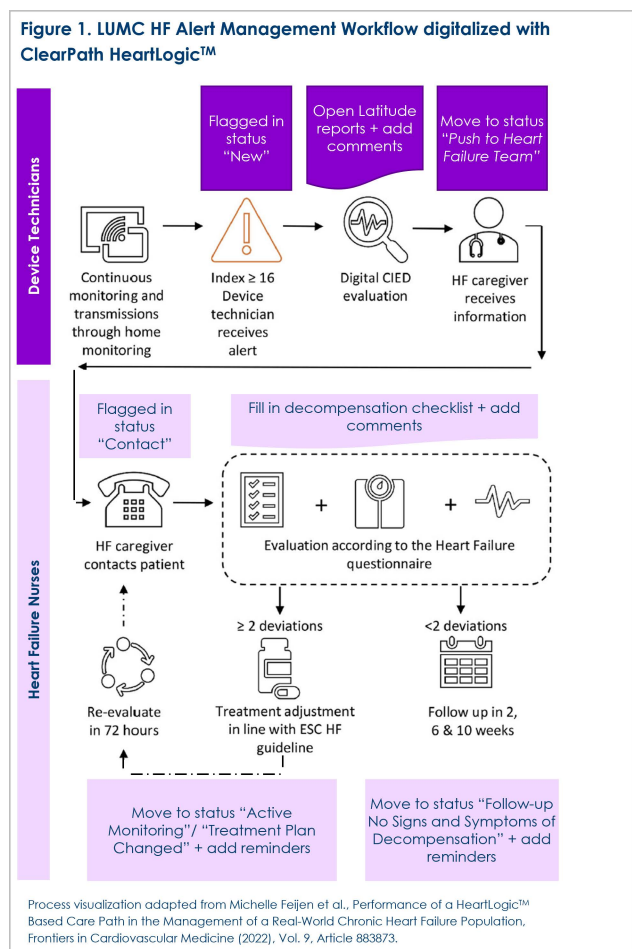
¹ Gupta A, Fonarow GC. The hospital readmissions reduction program: evidence for harm, JACC Heart failure (2018) 6:607-9.

² McDonagh TA et al., 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure, European Heart Journal (2021) 42:3599-726.

³ John P. Boehmer et al., A Multisensor Algorithm Predicts Heart Failure Events in Patients With Implanted Devices - Results from the MultiSENSE Study, The American College of Cardiology Foundation (2017), Vol. 5, No. 3, 216-225.

⁴ Michelle Feijen et al., Performance of a HeartLogic™ Based Care Path in the Management of a Real-World Chronic Heart Failure Population, Frontiers in Cardiovascular Medicine (2022), Vol. 9, Article 883873.

Physicians are consulted by the device technicians and heart failure nurses for complex cases or patients that have (progressive) heart failure despite pharmacological escalation. To better visualize the process, every team member can access all details on the patient status and interchange information via ClearPath HeartLogic™ at any time from their workspace.



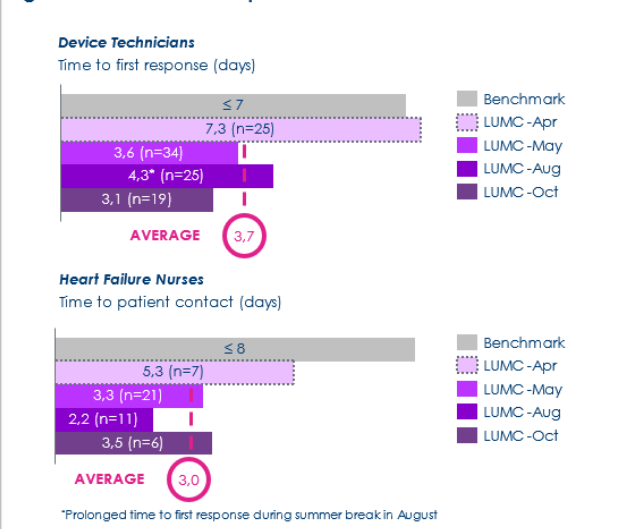
Results

Accelerate Clinical Response to HF Alerts

To evaluate whether the clinical response to alerts could be further accelerated using ClearPath HeartLogic™, the platform tracked the time from alert to first response and to patient contact. Time to first response was calculated as period from alert to when the device technicians opened the Combined Follow-up Report to analyse and triage all patients with an alert. Time to patient contact was measured from alert to patients being moved to the status "contact" status for heart failure nurses.

By digitalizing the workflow, ClearPath HeartLogic™ enabled **time reduction in clinical response of around 50% for device technicians and 40% for heart failure nurses**. Time to first response decreased from 7,3 days in April 2022 to an average of 3,7 days over the following months. Time to patient contact was accelerated from 5,3 days to an average of 3,0 days. (Figure 2)

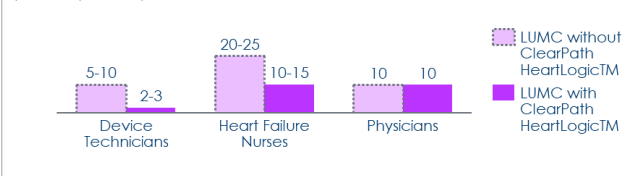
Figure 2. Time to clinical response



Workload Reduction

To assess whether ClearPath HeartLogic™ helped LUMC's team to save time managing HF patients, interviews were conducted. The average time required per alert before and after the introduction of the platform was analyzed (Figure 3). The results show that ClearPath HeartLogic™ enabled **time savings of about 50% for the clinical team**.

Figure 3. Average time required for HF alert workflow management (minutes per alert)

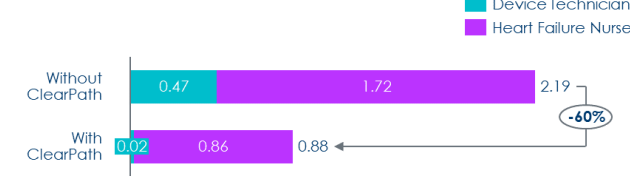


At pilot start the device technician team required on average 5-10 minutes to triage an alert. With ClearPath HeartLogic™ this was reduced to 2-3 minutes. The time required for heart failures nurses to manage an alert and document the actions decreased from 20-25 to 10-15 minutes. As physicians are consulted for complex cases only, their workload stayed unchanged with an average of 10 minutes per patient.

The potential workload reduction per patient (Figure 4) was estimated considering LUMC alert management workflow, average time spent per alert and the following measures:

- average number of 0,62 alert per patient and 8,08 re-alerts in the same worsening heart failure episode
- 91% of patients were sent to the HeartFailure team

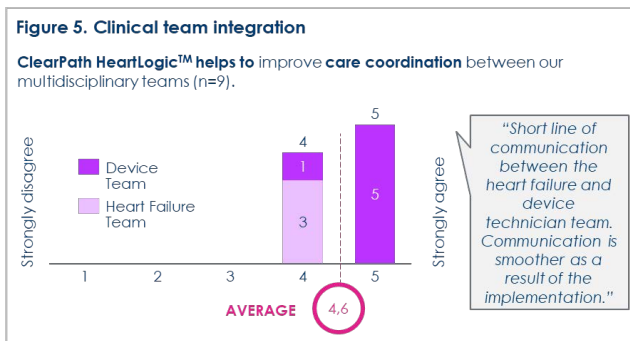
Figure 4. Workload reduction in the workflow management per patient (hours/year)



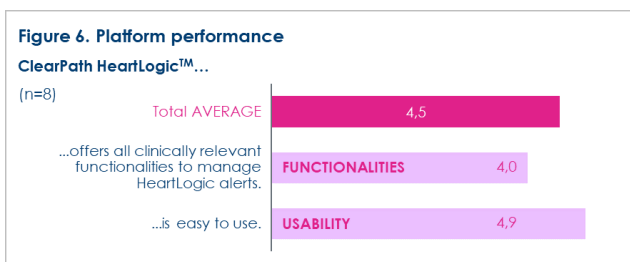
The device technician time is reduced 96% with a Heart Failure time reduction of 50%. The overall reduction is 60% considering the physician time won't change. This improvement is achieved by minimizing the administrative and operational time needed to perform clinical task without impacting the clinical activities and the value-add time spent with the patients.

Improve Clinical Team Cohesion Within the Workflow

The clinical team was asked whether they believe that ClearPath HeartLogic™ improved the integrated approach of the team (Figure 5). On a scale from 1 (strongly disagree) to 5 (strongly agree) **LUMC's team agreed at an average level of 4,6 that ClearPath HeartLogic™ has helped to improve collaboration** by giving everyone visibility of the process at any time (n=9).



When evaluating the overall functionalities and usability of ClearPath HeartLogic™, the team of LUMC also showed high confidence in the platform (Figure 6). **Rating 4,5 out of 5, ClearPath HeartLogic™ has been confirmed as effective and user-friendly platform.**



Conclusions

In the joint pilot, Boston Scientific and LUMC have shown ClearPath HeartLogic™ to improve efficiency and quality of care of remote HF alert management through workflow digitalization and automation. The platform helped to:

- 1. Save time of the clinical teams to manage HF alerts**
Clinical workload has been reduced by approximately 50% by aggregating all relevant information on one platform, streamlining the HF alert management workflow and automatically documenting all actions.
- 2. Accelerate clinical response to HF alerts**
Time from alert to first response by device technicians was reduced by about 50%. Time to patient contact by the heart failure nurses decreased by approximately 40%.
- 3. Improve clinical team integration**
The clinical team highly agrees that ClearPath HeartLogic™ improved the collaboration between LUMC's teams (level of agreement 4,6 out of 5). Communication was highlighted to be smoother due to the platform.

As a next step, ClearPath HeartLogic™ will be implemented to help LUMC's device technician team to triage HF alerts for an external referring clinic according to a hub and spoke model. Patients implanted by LUMC for this external clinic, who go into alert state and need HF management will be pushed by LUMC's technicians to the referring clinic's heart failure team. In the future, further of these use cases will be tested to understand the effects and benefits of workflow digitalization with ClearPath HeartLogic™ in other settings.

Disclaimer

This whitepaper and the associated pilot project are resulting from a close collaboration with, and continuous feedback provided by the HF management team of LUMC led by Dr. Saskia Beeres and Dr. Anastasia Egorova. Boston Scientific has been providing advisory support on alert workflow streamlining and technical support for digitalized alert workflow management with ClearPath HeartLogic™. Flagging of patients with a HeartLogic™ alert in ClearPath HeartLogic™ alert does not dispense the healthcare team from further screening activities. The approach does not provide treatment recommendations. Results from case studies are not predictive of outcomes in other projects. Actual results in different environments may vary.

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