### Reporting

#### Project Information

<table>
<thead>
<tr>
<th>ProbeFix</th>
<th>Funded under</th>
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<tr>
<td>Grant agreement ID: 817156</td>
<td>H2020-EU.3.</td>
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<td>Project website [🔗]</td>
<td>H2020-EU.2.3.</td>
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<tr>
<td>Status</td>
<td>H2020-EU.2.1.</td>
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<tr>
<td>Closed project</td>
<td>Overall budget</td>
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<tr>
<td>Start date 1 June 2018</td>
<td>€ 71 429</td>
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<td>End date 30 November 2018</td>
<td>EU contribution</td>
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<td>€ 50 000</td>
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<td>Coordinated by</td>
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<td>USONO B.V.</td>
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<td>Netherlands</td>
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### Periodic Reporting for period 1 - ProbeFix (ProbeFix: an Innovative MedTech Solution to improve the use of ultrasound for better Cardiac diagnosis in the EU)

**Reporting period:** 2018-06-01 to 2018-09-30

### Summary of the context and overall objectives of the project

Cardiovascular Disease (CVD) accounts for 45% of mortality in the EU, a number which will increase as more and more people reach old age. This has caused an enormous pressure on cardiac health care professionals, whose working conditions have been suffering as a result. In sonography, which is crucial in diagnosing and monitoring CVD, up to 90% of professionals are experiencing work-related musculoskeletal disorders (WRMSD, also called RSI), resulting from the strain put on the body by
handling the ultrasound probe during examinations. There is evidence that 20% of sonographers suffering from WRMSD eventually suffer a career ending injury.

In 2016, new industry standards for the prevention of WRMSD in sonographers have been introduced, but these have not eradicated the problem. USONO has developed the ProbeFix, a fixation device for ultrasound probes, which removes the need to manually keep the ultrasound probe in place. This solution greatly improves sonographer’s working conditions, with the added benefits of increasing reproducibility of scanned images across different operators and patients, and significantly reducing the time an echo scan takes. These are two other problems cardiology departments have been struggling with for decades.

USONO is looking to take the ProbeFix to market in all of Europe in the near future, quickly realizing an impact on cardiac health care and sonographer’s working conditions. Before this project, USONO had already made a start selling the ProbeFix in Europe, focusing mainly on the Dutch, Spanish, German and Belgian markets. The main objective of this SME Phase 1 project was to explore and assess the possibilities of scaling-up the ProbeFix in the EU, and eventually the rest of the world, and bring it ultimately to TRL 9. Furthermore, the business case and plan needed to be updated, elaborated and further improved, in order to effectively and efficiently introduce the ProbeFix in hospitals and cardiac centers the EU and, later on, in the world market. Also an objective was to assess the commercial potential and to develop a technical development agenda for the ProbeFix Dynamic in the SME Instrument Phase 2.

In order to achieve these objectives, a technical and commercial feasibility study were executed. We will discuss the details of these studies below. The conclusion of these studies is that scaling-up the ProbeFix in the EU is both technically and financially feasible for USONO.

Work performed from the beginning of the project to the end of the period covered by the report and main results achieved so far

To achieve the project goals, a commercial feasibility study was performed alongside a technical feasibility study. This work was performed by USONO’s CEO, COO, CTO and two interns, with assistance of business innovation consultants employed by Leap BV. As USONO is focused on finding investors and hospital users, the commercial feasibility study was prioritized. The study process proceeded at an unexpected pace for both feasibility studies, which resulted in the studies being finished two months earlier than originally planned.

Next, an overview of the results and employed methods will be given for both the commercial and technical feasibility study.

Commercial feasibility

Results
The commercial feasibility study leads to the conclusion it is commercially feasible for USONO to continue with the ProbeFix and roll-out sales throughout Europe. This is based on:
• Hospitals feedback validated the ProbeFix value propositions;
• Market potential is attractive with a sufficient number of potential ProbeFix and straps sales;
• Germany, France, UK and Spain have highest sales potential;
• Current distributor coverage includes UK and 7 other European countries;
• USONO has a high dependency on distributors;
• Competition and barriers of entry play a minor role;
• USONO estimates a huge return on investment for the distributors;
• There is a plan for extending the reference centre to the key regions;
• Even with a conservative ramp-up of the roll-out, profit can be made as of 2020 evidencing economic viability.

Methods
• USONO researched the industry top down by desk research regarding industry figures in existing studies. Among other topics, this research was executed with regards to the amount of musculoskeletal injuries in sonographers and the cost and consequences thereof for hospital.
• USONO researched the industry bottom up by contacting hospitals across Europe to understand and calculate the number of hospitals and ProbeFix related procedures. Research has (so far) been executed in The Netherlands, Belgium, Germany, the UK, Poland, France and Switzerland.
• A large part of the work were the financial analyses for roll-out and budgeting.
• Value proposition and business model canvas were used; also a SWOT-analysis was performed;
• USONO identified the main medical distributors and potential ambassadors in its target countries.
  o In Poland, a distribution agreement was signed with MDS Cardio and Professor Jaroslaw Kasprzak was as the first official international USONO ambassador.
  o USONO is in talks with a distributor in Germany, Belgium and Luxembourg and France.

Technical feasibility

Results
The technical feasibility analysis leads to the conclusion the ProbeFix, production and logistics is technically feasible. The results show that the product is technically feasible for reducing RSI and creating a higher reproducibility during lengthy sonography procedures in cardiology departments of hospitals and cardiac centers. In addition, the product is likely applicable for other medical procedures, such as Pace Maker Optimization and Heart Valve Replacement procedures. This is based on:
• The ProbeFix is CE-certified and clinical trials for the use for diagnostic echoes and stress tests in hospitals validate the usability and benefits of the ProbeFix. Using the ProbeFix was not detrimental to the echo performance;
• Risk of not using the ProbeFix properly is mitigated by creating instructions for the users;
• Production supplier risks are mitigated by having new and alternative suppliers.

Methods
• Clinical trials and surveys at the Deventer Hospital and the Catharina Ziekenhuis.
• Demonstrations and stress tests across different hospitals in The Netherlands, Belgium and Poland.
The focus of this project was to explore and assess the possibilities of scaling-up the ProbeFix in the EU, alongside with assessing the commercial potential and developing a technical development agenda for the ProbeFix and possible new applications in the SME Instrument Phase 2. As the project was focused on feasibility, direct progress beyond the state of the art and direct (socio-economic) impact as a result of the project was limited. The technical and commercial feasibility reports this project set out to obtain have been delivered, and as such no further results are expected within this project.

However, as the outcome of the feasibility studies was very positive, USONO will start scaling up the ProbeFix in the EU after the conclusion of this project. USONO will submit an SME phase 2 proposal regarding this scale-up process shortly. Regardless of the outcome of this proposal, USONO will set out to achieve the societal impact described earlier: to improve CVD sonographer’s working conditions, to increase the quality and reproducibility of cardiac echo images and to increase speed of sonography procedures.

In recent months, USONO has begun scaling up its activities in Europe, and is now active in twelve European countries. A lot of progress was made in Poland specifically, where USONO has appointed Professor Jaroslaw Kasprzak in Lodz, as the first official international USONO ambassador. Prof.Dr. Kasprzak is one of the top authors in the field of stress echo and possesses a big European network. He is very enthusiastic about the ProbeFix. Furthermore, USONO has signed a distribution agreement with MDS Cardio, a big Polish medical distributor.
USONO's CEO with Professor Jaroslaw Kasprzak, the first USONO ambassador

**Last update:** 1 April 2019
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