DiCART

An Automatic Medical Device to Diagnose Safely Critical Patients in Emergency Departments

Consortium

- Dicartech SAS, France
- Emka-Medical GmbH, Germany
- MIA Lab LaRochelle, France

Sector

HEALTH

Duration

13
MONTHS

Challenge

The Capillary Refill Time (CRT) is used to monitor the microcirculation of patients suspected of circulatory failure which presents poor tissue perfusion. CRT is a sensitive parameter that has been the subject of several medical studies. These studies are demonstrating that CRT is the right parameter to detect circulatory failure. Until now, CRT is measured manually by practitioners/doctors and is not repeatable and reproducible. The alternative of this visual and subjective CRT evaluation is a blood test of lactate concentration which is an indication to detect circulatory failure. However, such tests take about 20 – 30 minutes to be analysed and is less significant. Every year about 140 000 patients suffer a critical circulatory failure in France and about 40 000 even die. With the use of the DiCART medical device, 10% of these people can be saved.

DIATOMIC Support

DIATOMIC has helped our project by providing us guidance during the Periodic Coaches session and providing help when requested and connexion to their network for next steps.

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Solution

The current solution to detect circulatory failure is either the lactate concentration blood test or performing CRT manually. The lactate concentration is a slow and invasive solution compared to the manual CRT which is a good solution but is operator-dependant as the doctor applies pressure to the tissue.
With DiCART, this measure is repeatable, accurate and reproducible, since DiCART is using a high definition image and real time calculation providing a value which allows clinicians to know the CRT result immediately. In terms of costs the blood test to measure the lactate costs over 10€ whereas DiCART costs only 3€ by patient by 24h as this only the cost of the protector tips used in the device in order to fulfil hygienic concerns and to not have cross-contamination.

Lessons Learned

We learned what the active management of a development project, oriented to industrial transfer and marketing viability entails and how to professionally handle the different phases.
We would have appreciated another bootcamp and physical meeting, as it was planned, to discuss all projects and the work of the various organizations however it is evident that due to COVID this was not possible.

TRL & Adopters

TRL level at the beginning of the experiment: **3**
TRL level at the end of the experiment: **8**
Number of early/first adopters raised during the experiment: **5**

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Timeline

We have predesigned the DiCART CRT medical device that is composed of a camera, a finger-type mechanical structure to apply a calibrated pressure on skin, battery, RGB and white LEDs to light the skin, LCD display and an electronic card. Within Development phase, we had the final selection of the components and the realisation of the DiCART prototype. The first software version permitted to capture the action of the "finger", record the video, and permitted to select the colour of LEDs. The DiCART automatic CRT was compared to manually performed CRT and the first results are very significant. Within Market phase, we have implemented the software into the DiCART with a short interface. During testing phase the first end-users were very enthusiastic and medical studies on healthy volunteer are underway.

Stakeholders

- University Lab Mathématique Image Application MIA that has worked on the Algorithm development and validation
- Emka Medical (Germany) that is preparing the regulatory guideline
- Hospital Hospices civils de Lyon that performs Clinical test on healthy volunteers

DICARTECH has be the project leader in the development and worked with Axandus on the prototype design, development as well as on testing and tuning.

End Users

The initial end-users are Medical doctors in emergency departments, intensivists and paediatricians. From feedback received these users are ready to adopt the DiCART medical device as it allows them to have a reliable CRT that is objective and reproducible. DiCART allows end-users to overcome a "pain point" as manual CRT is subjective and depends on the pressure the practitioner applies whereas the automated CRT can be performed by anybody presenting objective and correct results.

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Key Results

The most important result is the first calculation of the CRT with the algorithm we created. It is the first time that CRT is calculated using video imaging and an algorithm, with results comparable to manual CRT.

The current algorithm gives good results, but we are working on an improved new algorithm based on deep learning approach that will further enhance our work. We learned during testing that utilising the physical device, the video treatment needs higher computing power, mostly due to the videos in High Definition and thus in order to embed the algorithm with faster response time, we needed to decrease a bit the quality of video. However, even with this reduction of video quality the CRT calculation is not impacted and an accurate result is displayed in the LCD display.

Impact

Provide a short summary of the actual impact (eg. on industry, knowledge, attitude, skills, practice, or policy, etc.) that took place and how this could lead to large-scale impact.
The impact is very important because the end-users restrict CRT evaluation as this measure is currently subjective, operator-dependant and also a pain point as it is not reproducible. With DiCART, CRT becomes a current diagnosis , the automatic CRT measure is standardised and is not any more operator/practitioner dependant. With our medical device CRT is usable and can be measured by a non-expert (in this case nurses). Therefore, DiCART medical device allows CRT to be measured as easy as we measure temperature.
Since the measurement of CRT is the most sensitive diagnosis of the clinical severity of patients, it will make it possible to manage more accurately and efficiently the patients who were previously poorly evaluated. Treating patients based on CRT results the mortality rate has been shown to decrease by 10% and thus about 25,000 lives can be saved per year in Europe. The clinical implications of our DiCART medical device will be presented in a medical publication that is currently being prepared.

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Testimonials

> *Based on a patent on the development of a very innovative tool (DiCART) for a digital, reliable and rapid measurement of CRT (Skin Recoloration Time) in hospital emergency and resuscitation services. The feedback from clinical trials on DiCART prototypes is particularly promising. The market is very large (12 million emergency patients concerned per year in Europe). The product will be marketed in 2021. DiCART will tomorrow be the "electronic thermometer" for measuring CRT in hospitals.*
> — Jean-Luc Lavenir, Strategic Advisor at DICARTECH

> *In clinical practice, the capillary refill time is the only daily test that can be used to detect acute circulatory insufficiency.*
> — Dr P. Portran, Intensivist at Hospices civils Lyon

> *Having a device that is reproducible standardized allowing to refine the microcirculatory parameters is extremely precious in paediatric intensive care.*
> — Dr L. Chardonal Pediatric intensivist at Hospices civils Lyon

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