NON-INVASIVE HEMODYNAMIC MONITOR FOR MANAGEMENT OF HEART FAILURE

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February 2019
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HEART FAILURE

WHAT IS HF?
The heart’s inability to efficiently pump blood to the body and maintain blood flow.

WHAT CAUSES HF?
- Coronary and heart disease
- High blood pressure
- Arteriosclerosis

INITIAL SYMPTOMS
- Shortness of breath
- Excessive tiredness
- Leg swelling
**Heart Failure Global Epidemic**

Effects

27M worldwide

In the U.S alone

- 5.7M People suffer from HF
- ~50% Die within 5 years of diagnosis
- $30B Associated yearly expenses
SO WHAT’S THE PROBLEM?

There is no easy, non-invasive test to detect heart failure resulting in a high mortality rate and a high cost of treating HF.
WHAT HAPPENS TODAY?

Undetected in the ER

Difficult to diagnose and monitor in the ICU

Difficult to monitor in the home
A real-time system to assist with early detection and monitoring of HF
Non-invasively, accurately estimate LVEDP; a well-known predictor of HF that is not measured today because it requires an invasive, high-risk procedure.

What is LVEDP?

The pressure in the left ventricle after it has rested and filled with blood and before it contracts.
COMPLETE HEMODYNAMIC PROFILE

for INDIVIDUALIZED treatment

DIASTOLIC DYSFUNCTION = high LVEDP + high MAX DP/DT

SYSTOLIC DYSFUNCTION = high LVEDP + low MAX DP/DT
• Algorithm guides user in every step of the measurement to assure correct sensor placement and usage of the device

• Using AI the algorithm regulates inflation and deflation numbers and rate in order to adjust for different heart rates, body types etc.

• Based on a unique method, the Algorithm is able to recreate the ascending portion of the aortic pressure wave form

• Using original mathematical developed using big data analysis of hundreds of Cath Lab pressure recordings model, the Algorithm is capable of estimating hemodynamic parameters including LVEDP, dP/dT etc.
The Model behind the algorithm was developed by analyzing hundreds of Cath lab recordings in order to understand how pressure is transferred from the isovolumetric stage to ejection.

All images above are taken from actual screen shots of the beta model device.

Final results presentation in beta model.
CLOUD APP
Long term HF management

Personal devices → Cloud app → User interface → Big Data → Better treatment and lower healthcare costs
EVERYONE BENEFITS ALL

- Earlier diagnosis
- Improved management and treatment
- Reduced hospitalizations

PATIENT
HOSPITAL
PAYOR
CorAlert’s LVEDP measurement obtained a correlation of 0.9 with invasive LVEDP measurements taken in the Cath Lab.
Class II
requires 510(k)
pivotal trial (~50 patients)
to begin Q1/2019
submission planned Q2/2019

Class IIa
submission planned Q2/2019

Net clinic per use revenue in/out patient setting: $1145 / $349
### COMPETITIVE OVERVIEW

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>Implantated devices such as CARDIOMEMS...</th>
<th>LVEDP measurement based on Valsalva – VIXIAR...</th>
<th>Liquid detection in lungs or general – SENSIBLE...</th>
<th>CORALERT</th>
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<tbody>
<tr>
<td>Non-Invasive</td>
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<td><img src="blue.png" alt="Blue" /></td>
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<td>Fit for ER and ICCU</td>
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<tr>
<td>Exact diagnosis (HFrEF/HFpEF)</td>
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<td><img src="gray.png" alt="Gray" /></td>
<td><img src="blue.png" alt="Blue" /></td>
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<tr>
<td>Accuracy</td>
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<td><img src="gray.png" alt="Gray" /></td>
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<tr>
<td>Early detection of acute event or Hemodynamic stability</td>
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<tr>
<td>Continuous remote monitoring</td>
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INITIAL MARKET

Hospitals:
- Lease/Rental plan:
  - Inpatient Reimbursement
  - Outpatient Reimbursement
  - Direct Sales (ER, ICU...)

SECONDARY MARKETS

GP offices – Direct Sales

Home-Care Setting

REVENUE GENERATED FROM

- Lease agreements
- Direct device sales
- Disposable sensor

- Real-time/historical patient data + management software
- Big Data Monetization [Future]

Everyone benefits – the patient, hospital and payor
$1.9 BILLION OPPORTUNITY: U.S. HOSPITALS

Lease Plan: $2000 per device/y

~$675 million/year

Disposables: $3/sensor

~$790 million/year

Cloud Application (mthly fee)

~$405 million/year

Estimated based on the # of ICU beds, and # of ER, Cardiology, and Internal Medicine departments and average number of outpatient procedures for HF patients in US MC’s

EXPERIENCED TEAM

AMIR MARMOR
Co-founder and CEO

Software Engineer
Algorithms Engineer
Software Development Team Leader

Bsc. Computer Sciences
(Open University)

PROF. ALON MARMOR (MD)
Co-founder and CMO

Professor of medicine and chair of cardiology, faculty of medicine, Bar-Ilan University, Israel

Head of the heart institute, director of cardiology department, Sieff Medical Center, Safed, Israel
**TIMELINE**

- **Q4 2018**: Finalized Beta
- **Q1 2019**: Beta multi centered clinical trial
- **Q2 2019**: FDA/CE submission
- **Q3 2019**: post validation clinical trials
- **Q1 2020**: Marketing launch
USE OF FUNDS

Seeking funding

- Complete product development
- Additional clinical studies
- Regulatory approvals
Thank You!

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