# hartfunction quantification software for hand held echocardiography

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON19980

**Source**
Nationaal Trial Register

**Health condition**

Evaluating the cardiac function can play a highly valuable role in POCT for patients in cardiac distress or to check the volume status of a patient

### Sponsors and support

**Primary sponsor:** N.A.
**Source(s) of monetary or material Support:** N.A.

### Intervention

### Outcome measures

**Primary outcome**

Cardiac output (CO), Stroke volume (SV) and Left ventricle ejection fraction (LVEF)

**Secondary outcome**

None

# Study description

### Background summary

Echocardiography is the primary imaging modality for diagnosing cardiac conditions especially in point of care treatment (POCT).1 Over the past two decades, technological advancements have resulted in the emergence of miniaturized handheld ultrasound equipment that is compact and battery operated. The simplicity of use, availability at the patient's bedside, easy transportability, and relatively low cost have encouraged physicians to use these hand held echocardiography (HHE) devices for prompt medical decision making in POCT.23–5 As a consequence, the use of HHE is on the rise even among non-echocardiographers (intensivists, emergency care physicians).6 However, bedside quantification of cardiac output (CO), stroke volume (SV) and left ventricular ejection fraction (LVEF) with such devices is yet impossible and needs to be performed offline at the office. Evaluating the cardiac function can play a highly valuable role in POCT for patients in cardiac distress or to check the volume status of a patient.7–10 By incorporating an automated quantification tool (DIA app) in a commercially and clinically available HHE device (Lumify, Philips), bedside measurements of CO, SV and LVEF are among the possibilities. In this observational study we want to evaluate the performance of the Lumify/DIA system and assess its accuracy in quantifying CO, SV and LVEF compared to conventional offline methods. It is hypothesized that measurement of CO, SV and LVEF with the Lumify/DIA system corresponds with CO, SV and LVEF measurements with conventional non-automated echocardiography. With the Lumify/DIA system we are striving for improvement of our daily cardiac POC assessment.

### Study objective

It is hypothesized that measurement of CO, SV and LVEF with the Lumify/DIA system corresponds with CO, SV and LVEF measurements with conventional non-automated echocardiography.

### Study design

one time at the diagnostic procedure for a echocardiogram of the heart

### Intervention

None, prospective data gathering

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Patient > 18 years old
2. Signed informed consent
3. Clear delineation of the endocardial border in all segments of the myocardium in apical 2 chamber and 4 chamber view.

## Exclusion criteria

1. Patient with supraventricular arrhythmias (atrial fibrillation / atrial flutter)
2. Patient with severe valvular disease(aortic stenosis / insufficiency, mitral valve stenosis / insufficiency)
3. Patient with moderate to severe pulmonary hypertension
4. Patient with high BMI (>25, relative)
5. Patient with moderate or poor left ventricular function
6. Patients with poor thransthoracic ultrasound images

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 13-01-2021 |
| Enrollment: | 35 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** No

**Plan description**
NO

# Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL9199 |
| Other | MEC-U : waiting for MECU approval |

# Study results

**Summary results**
None