

# Edema Stocking

- For Researchers

Edema of the lower extremities is an indicator of the degree of the underlying disease, regardless of whether the edema is caused by heart failure, lymphedema, varicose veins or other conditions. Until now it has been challenging to assess the degree of lower extremity edema. This is now feasible with the Edema Stocking that can instantly monitor volume changes over a short duration.

The Edema Stocking allows detailed, quantitative monitoring of lower extremity edema as a response to physical activity leg elevation and medical therapy.

# Edema Stocking

- Monitoring fluid accumulation of excess fluid in the lower extremities

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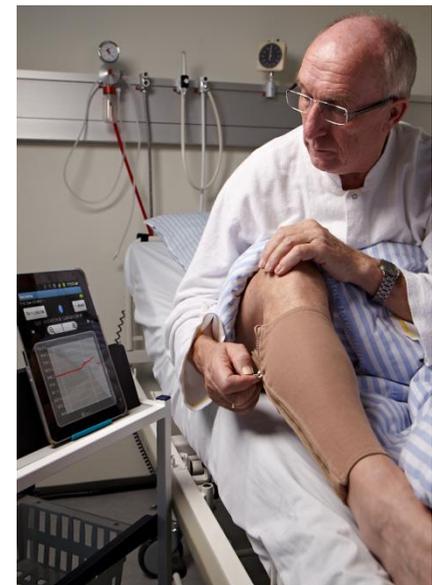


# Introduction

Patients suffering from lower extremity edema often make frequent visits to the hospital or GP to avoid the condition from advancing and to adjust medication.

Today healthcare staff uses subjective measures at imprecise measurements of leg circumference for assessment of edema. However this assessment is only one instantaneous recording in the long term cause of the disease. The temporal development of lower extremity edema is therefore unrecorded and represents a flow in most clinical studies on patients with peripheral edema. Frequent assessment of lower extremity volume and especially changes during the day may provide valuable information regarding the quality and impact of interventions against the condition.

As we do not have data about diurnal changes in leg volume as a representation of tissue fluid flux in the interstitial space, the new edema stocking may also be a valid contribution to study tissue fluid changes in normal placing.



# Edema Stocking

## Product key features:

- The close-fitting, ergonomic design of the stocking ensures that the placement of sensors is kept at the same position, to ensure precise and reliable data
- Functions as a compression stocking
- Non-invasive, non-obtrusive and comfortable monitoring
- Android application for online monitoring of measurements

## Edema Stocking

The Edema Stocking is a device that monitors and measures changes in leg volume for patients suffering from edema in the lower limbs.

The fabric of the stocking has been specially designed and functions as a compression stocking. Strain gauges are embedded as a stretch sensor that measures every change in resistance.

The design makes it possible to adapt the size and circumference of the stocking, by being able to zip different insert sizes on to the electronic part - S, M, L and XL.

The measured data is wirelessly transferred to an android application in close proximity to the patient, to be displayed as progressive changes in leg volume.

The data may also be transferred to the clinicians via real time technique or transferred in required data packages, making monitoring more secure and reliable.

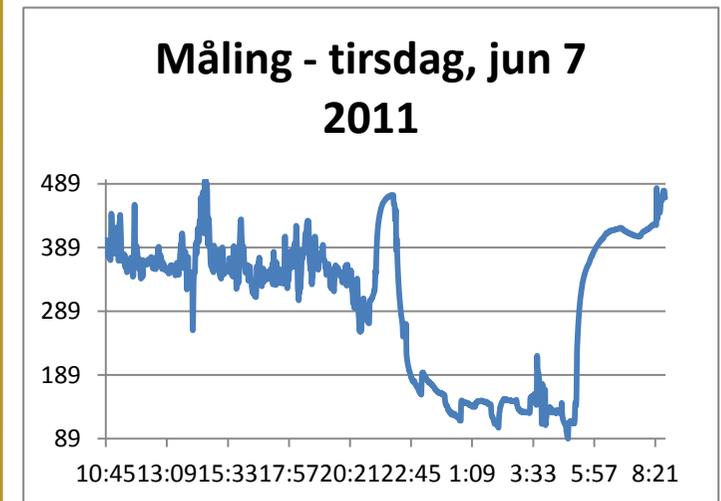
## Telecare

Telecare is a technological concept that allows a modern approach to patient monitoring and intensive surveillance of the disease condition.

The extent of this detailed monitoring approach for leg edema opens new perspectives of individualized medical therapy which meets the patients' actual needs and requirements instead of providing an average dose of medication.

## The Edema Stocking and Telecare

The Edema Stocking can be used as an integrated part of telecare, adapting and stabilizing medication. Patients suffering from heart failure, pre-eclampsia and other edema related prognosis can utilize the Edema Stocking as an integrated element in the telemedicine concept, thus opening up a new possibility of tailored treatment for patients with this condition.



# Benefits

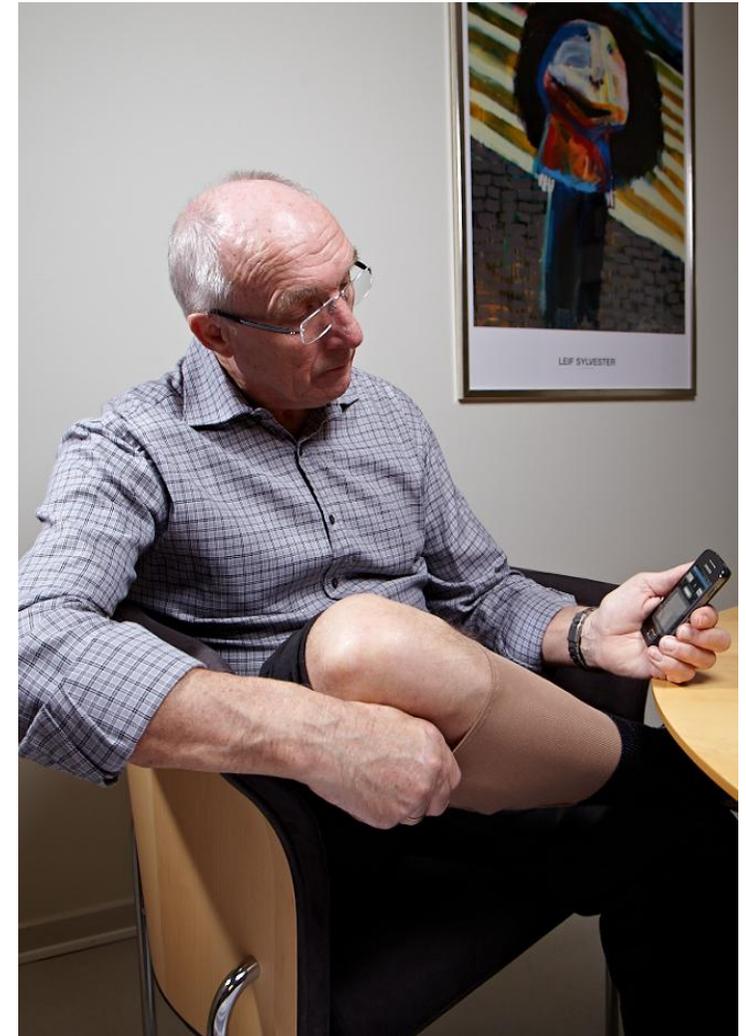
Patients suffering from severe forms of edema are hospitalized to receive intensive diuretic treatment that excretes the excess water from the body. The Edema Stocking makes it promising for health care staff to get a better understanding of the drainage procedure and treatment.

There is a need to expand and improve knowledge about fluid accumulation and treatment therapy for drainage. The Edema Stocking is designed as a scientific tool and can be used by researchers for experimental and clinical studies related to edema. It is a practical tool giving the opportunity to develop data analysis for specific research goals.

For researchers using the Edema Stocking it is possible to:

- Measure the pace of the changing leg volume in relation to the amount of medication the patient receives
- Measure the amount of diuretics needed before leg volume decreases
- Measure the duration of time it takes to excrete fluids
- Makes the excretion process cleaner by measuring the overall leg volume; eliminating physical measurements of fluid volume excess and fluid volume deficit
- By using the Edema Stocking combined with the telecare application, makes it feasible to receive very precise records of small changes in leg volume
- Study in detail the effect of different therapeutic options for moderating fluid accumulation.

By using the Edema Stocking it is possible to obtain objective measurements and it provides hitherto unsurpassed detailed information about fluid accumulation and excretion rates.



## Limitations

The Edema Stocking is designed as a scientific tool and is not yet characterized in surficial detail to be used for routine clinical use.

Scientific studies should be designed in order to validate which patients may be candidates and under which circumstances.

It should be underlined that recordings of lower extremity volume are only a surrogate measure for the amount of body fluid accumulation.



# Potential clinical scenarios

## Fact:

- **'An estimated 60.000 Danish citizens suffers from heart failure, and the incidence is increasing'**
  - *Patienthaandbogen.dk (2012)*
- **'There are approximately 11.000 hospitalizations in Denmark per year caused by heart failure'**
  - *Patienthaandbogen.dk (2012)*
- **'Hospitalization for a heart failure patient cost on average 5.000 USD'**
  - *Hjerteforeningen.dk (2012)*
- **'An estimated 10 million people in Europe are suffering of CHF'**
  - *Webdokterportal.dk*

## **Congestive Heart Failure**

In right sided heart failure, edema of the lower extremities will be one of the first symptoms experienced. For patients situated in an upright position, congestion of the venous is returned to the heart leading to tissue fluid accumulation; this is where gravity has its greatest impact.

Today heart failure patients are being regularly monitored in hospital or by a GP for clinical assessment and adjustment to medication. This can have a detrimental effect on patients and relatives, partly because of the amount of time used on outpatient visits.

The disease is treated with a wide spectrum of drugs; among these are diuretics that are used to stabilize the body's fluid balance. Reducing the amount of fluid accumulation in the right side of the circulation and in the main coronary artery in particular reduces the work load on the heart. However, the amount of fluid accumulated on the right side of the circulation is difficult to assess and it often changes within hours. Such rapid changes cannot be monitored during hospital or general practitioner visits, it requires the intensive monitoring facility which the Edema Stocking offers.

### **The Edema Stocking enhances the telecare system to improve heart failure:**

- More qualified and comprehensive level of online communication and forums are available
- Both doctor and patient are able to respond to changes and pre-detect deterioration of the disease
- Ability to monitor and detect water surplus at home - early warnings
- Patients can feel safe when they know they are monitored
- A large reduction of outpatient visits to the GP and hospital equal allows more efficiency and cost effectiveness

# Potential clinical scenarios

## Fact:

- *The incidence of pre-eclampsia has been estimated between 5% - 14% of all pregnancies globally'*
- *'Pre-eclampsia is mild in 75% of cases and severe in 25%'*
- *'Pre-eclampsia occurs often after 20 weeks gestation'*
- <http://emedicine.medscape.com/article/1476919-overview>

## **Pre-eclampsia**

**Pre-eclampsia** is a condition which can occur during pregnancy and is characterized by high blood pressure (hypertension), edema of the lower extremities and protein in the urine. The spectrum of symptoms can range from none, to life threatening kidney damage, bleeding and heart failure due to hypertension. Severe eclampsia must be treated with termination of the pregnancy.

Frequently visits to the hospital or GP are necessary to monitor any advancement in the disease condition, and to adjust medication. During these compulsory visits, only a momentary assessment of the condition is shown. However, the patient's condition is likely to fluctuate whereby stability is uncertain from one day to the next, for instance during the appointment the patient maybe ok, however two days later the condition may have exacerbated. Therefore it is not guaranteed that the patient receives timely treatment.

The opportunity of monitoring the condition continuously by using an overall package that patients can apply alone at home, will make it possible for care-givers to prescribe a more intensive and adapted treatment. The home monitoring package consists of; a blood pressure measurement, sticks for measuring urine and the Edema Stocking.

### **The Edema Stocking benefits the process of telecare to improve monitoring of pre-eclampsia:**

- Leg volume data is directly transferred to the hospital for monitoring and observation saving frequent hospital visits
- Both doctor and patient are able to respond to changes and observe early signs of deterioration of the disease
- Reduction of travel and enhanced safety for the patient and her relatives when they know she is monitored
- Patients will benefit from being involved in disease monitoring at a higher level of interaction

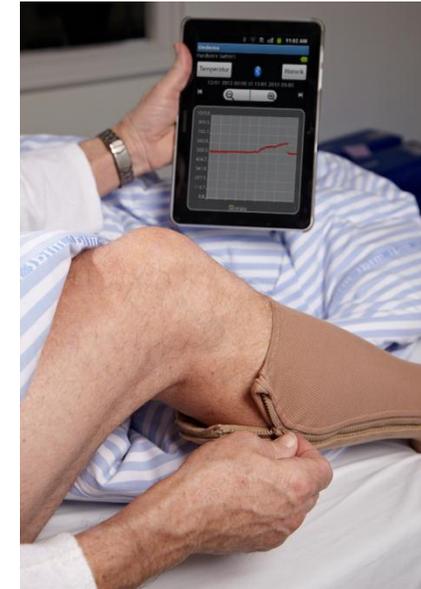
# Potential clinical scenarios

## Related causes of Edema

Edema can occur for many other reasons than heart failure and pre-eclampsia. Varicose veins, impaired lymphatic drainage and diseases of the kidney and liver are known causes of edema, but a large contingency of patients have lower extremity edema without any verified underlying disease condition.

Edema should be treated with elevation of the legs and muscular exercise to engage venous drainage. Medical therapy predominantly entails diuretics.

The Edema Stocking can be used as a pedagogical tool for patients suffering from all forms of edema. By using the stocking with this approach, it is possible for the patient to be interactive and get a feeling of responsibility for their own disease; this gives the patient the opportunity of adapting to everyday life while living with their condition.



# Status

## History

The Edema Stocking concept was conceived by Prof. J. Michael Hasenkam, where he wanted to find a simple, effective and reliable solution for patients and medical staff to measure significant changes in volume of the lower limbs, and the theory of using a stocking with an electronic strain gauge was created.

Ohmatex ApS is an intelligent textile company that was approached to explore the feasibility of the concept and is now developing the final stages of the Edema Stocking.

## Status

The first version of the stocking has been designed and developed, and is able to transfer real-time data via a Bluetooth connection for mobile phones. Data can be stored on an excel file that is directly transferred for clinical evaluation. It is also possible to store data on an SD card.

A new spin-off company, Edema ApS, has been launched with Ohmatex ApS and prof. Michael Hasenkam as owners, working exclusively with the development of medical and biological measuring equipment concerning edema.

## Contact

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