# Evaluation of an electronic device to objectively monitor energy expenditure, physical activity, unrest and autonomic nervous system function in patients admitted to the Intensive Care

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The objective of the study is to explore the performance of the Sensewear device during various levels of activation of the autonomic nervous system and sedation in a population patients admitted to an ICU.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

# Summary

### ID

NL-OMON31133

**Source** ToetsingOnline

**Brief title** Evaluation of a Sensewear device at the ICU

# Condition

- Other condition
- Cardiac therapeutic procedures

**Synonym** consciousness, sedation

#### **Health condition**

sedatie op ICU, nav mechanische beademing

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#### **Research involving** Human

### **Sponsors and support**

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

### Intervention

Keyword: autonomic nervous system, ICU, monitoring, sedation

### **Outcome measures**

#### **Primary outcome**

For the study part where patients are undergoing elective cardiosurgery, the

primary study parameter will be the function of the autonomic nervous system,

which can be evaluated by measurements of the galvanic skin response (with the

Sensewear device) and heart rate variability.

For the study part where other ICu patients are studied, the primary study

parameter will be the depth of sedation, which can be evaluated by measurements

of BIS registration and acceleration (with the Sensewear device0.

#### Secondary outcome

For both groups of patients, the secundary study parameters will be the other parameters of autonomic nervous system function as measured with the Sensewear device.

# **Study description**

#### **Background summary**

Patients admitted to an Intensive Care Unit are well-monitored to evaluate their clinical condition. Although in general the so-called vital signs (blood

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pressure, heart rate and temperature) are well monitored, there is a paucity of information on other relevant parameters. This includes, among others, information on the amount of energy expenditure and scoring of physical activity. Recent technological developments have resulted in the introduction of small electronic devices (such as the SenseWear® armband) that provide non-invasive measures of total energy expenditure and physical activity. This is based upon recording of skin temperature, the galvanic skin response, the heat flux and accelerometry.

#### Study objective

The objective of the study is to explore the performance of the Sensewear device during various levels of activation of the autonomic nervous system and sedation in a population patients admitted to an ICU.

#### Study design

Outline of study activities cardiosurgery patients: Eligible patients will undergo the scheduled surgical procedure. The only deviation from the routine care is that an armband with the device will be strapped around their right upper arm. The armband will be applied for one hour at the evening before surgery and for a period of 24 hours that will start when the patient is transferred to the surgery room. Most patients are already commonly monitored using a BIS-monitor and special attention will be given that all patients participating in this study will have such a monitor. Also, in these patients 1-lead ECG recordings will be made which will enable to study the Heart Rate Variability, which is considered a measure for the activity of the autonomic nervous system.

Outline of study activities ICU patients: Eligible patients will, during the routine care, be equipped with an armband with the device strapped around their right upper arm. The armband will be applied for periods of 24 hours. Most patients are already commonly monitored using a BIS-monitor and special attention will be given that all patients participating in this study will have such a monitor.

#### Study burden and risks

As this experiment is carried out during the routine medical care of the patients, this implies that all procedures and activities necessary for the care of the patients will not be altered, so participation in the study will have minimal burden and risks.

# Contacts

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

20 patients scheduled for elective cardiosurgery.20 patients admitted to the ICU and are receiving sedation medication.

# **Exclusion criteria**

Patients treated with a pacemaker

# Study design

# Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Health services research	

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	40
Type:	Anticipated

# **Ethics review**

Approved WMO	
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

# **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** CCMO **ID** NL16686.058.07