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CLINICAL INVESTIGATION PLAN (CIP)

CLINICAL INVESTIGATION TITLE: An explorative, open, single-arm clinical investigation to collect real-life measurement data in order to assess the mathematical algorithms involved in TENA SmartCare Change Indicator.
CLINICAL INVESTIGATION CODE: FUEL
INVESTIGATIONAL DEVICE: TENA SmartCare Urine Sensor and Gateway
PRINCIPAL INVESTIGATOR: Ulla Molander
INVESTIGATIONAL SITE: Tre Stiftelser Vegahusen Vegagatan 55 413 11 Gothenburg Sweden
SPONSOR: Essity Hygiene and Health AB 405 03, Gothenburg Sweden
DATE: 19-Jul-2019

Version	Revision history
A	First release
B	Minor updates and clarifications

This clinical investigation will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. Furthermore, the clinical investigation will be performed in compliance with ISO 14155:2011, the Medical Device Directive (MDD) 93/42/EEC, Medical Device Regulation (MDR) 2017/745, and applicable regional or national regulations.

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1 SYNOPSIS

NAME OF THE SPONSOR: Essity Hygiene and Health AB
CLINICAL INVESTIGATION TITLE: An explorative, open, single-arm clinical investigation to collect real-life measurement data in order to assess the mathematical algorithms involved in TENA SmartCare Change Indicator.
CLINICAL INVESTIGATION CODE: FUEL
INVESTIGATIONAL DEVICE: TENA SmartCare Urine Sensor and Gateway
OBJECTIVES: **Primary Objective** The primary objective is to collect real-life measurement data using the Urine Sensor to assess the mathematical algorithms for wetness detection in TENA absorption products by urine volume quantification and [redacted] measurements. **Secondary Objective** The secondary objective is to evaluate safety through analyzing device-related adverse events reported during the investigation.
OVERALL CLINICAL INVESTIGATION DESIGN: The purpose of this exploratory clinical investigation is to evaluate safety and to collect real-life measurement data using the Urine Sensor. The collected data will be used to assess the device related algorithms. The primary algorithms have been established and verified in a laboratory environment. However, several parameters differ between real-life and laboratory settings and can therefor be hard to predict. Consequently, real-life measurement data has been determined necessary to continue the product development. To assess the mathematical algorithms, the urine volume needs to be quantified (ml urine) and the [redacted] values from the Urine Sensor captured. Data such as; date and time of application, date and time of removal, Urine Sensor ID, absorbent product information (type, absorption level and size), leakage outside product, precence of feces, and subject's main position since last absorbent product change will be recorded by the caregiver on a label located on a plastic bag. The absorbent product is thereafter placed in the plastic bag and provided to a Sponsor' represetative. The plastic bag is weightened on a calibrated scale by the Sponsor' representative and the weight documented in the electronic Case Report Form (eCRF). The urine spreading in the absorbent product is documented by taking a photo of the absorbent area of the product. The photo is uploaded in the eCRF system. All data documented by the caregiver on the plastic bag label are transferred to the eCRF by the Sponsor' representative. The label is thereafter detached from the plastic bag and placed on a paper. The paper is considered source data and will be stored in a study specific binder for quality assurance and archiving. The clinical investigation will be carried out in the nursing home Tre Stiftelser in Gothenburg and include subjects affected with Urinary Incontinence (UI). In total 15 subjects are estimated to be enrolled in the exploratory clinical investigation. The clinical investigation is designed to be conducted in a controlled professional environment for a duration of 8 weeks. The clinical investigation involves two visits; one screening visit and one follow-up visit, as well as absorbent

product related data capturing between these visits. The follow-up visit will be scheduled in conjunction with the completion of data capturing.

Visit 1: Screening visit

- Subject information and informed consent
- Eligibility confirmation
- Enrollment
- Demographic data and baseline information; year of birth, gender, incontinence product(s) of use the previous 6 months, bedridden/not bedridden
- Documentation of relevant concomitant medication(s)
- Documentation of relevant medical and surgical history
- Evaluation of general health status
- Urine pregnancy test in subjects with childbearing potential
- Allocation to suitable absorbent product type(s) and size(s)

Visit 2: Follow-up visit

- Documentation and/or follow-up on Adverse Event (AE)/Adverse Devicie Effect (ADE)/Serious Adverse Event (SAE)/Serious Adverse Device Effect (SADE)/Device Deficiency (DD)
- Concomitant medication review
- Verification of eCRF completion
- Study termination

INCLUSION AND EXCLUSION CRITERIA:

Inclusion Criteria

The subject must meet all of the following criteria to be eligible for this clinical investigation:

1. The subject is willing and able to provide informed consent and to participate in the clinical investigation.
2. The subject is ≥ 18 years of age.
3. The subject is diagnosed with urinary incontinence.
4. The subject is being cared for at Tre Stiftelser.

Exclusion Criteria

Subjects meeting any of the following criteria will not be permitted to participate in the clinical investigation:

1. The subject has ≥ 4 fecal ”incidences” per week.
2. The subject has severe absorbent product related skin problems, as judged by the investigator.
3. The subject is hypersensitive related to allergic reaction to any of the included materials, as judged by the investigator.
4. The subject has ≥ 2 intermittent urinary catheters per day.
5. The subject has a pacemaker or an implantable cardioverter-defibrillator.
6. The subject removes the incontinence product.
7. The subject demonstrates responsive behavior towards sensors.
8. The subject has any other condition that may make participation in the clinical investigation inappropriate, as judged by investigator.
9. The subject is not cared for at Tre Stiftelser.
10. The subject is pregnant or lactating.

PERFORMANCE AND SAFETY ENDPOINTS:

Primary Endpoint
Summarize the individual differences (predicted urine volume* - true urine volume**) using descriptive statistics. The data*** will later be used to optimize mathematical algorithms for the TENA SmartCare Change Indicator.

**Prediction calculated from urine sensor values*
*** Urine volume determined from absorbent product weights*
****Data is the combination of urine sensor values and absorbent product weights.*

Secondary Endpoint:
Incidence of adverse events and device deficiencies; AEs, ADEs, SAEs, SADEs and DDs.

Clinical Investigation Duration:

Point of enrolment:	End of Aug/beginning of Sep 2019
Total expected duration of the clinical investigation:	8 weeks
Expected duration of each subject's participation:	6 weeks
Enrollment period:	1 week

STATISTICAL METHODS:
Sample Size:
As this is an exploratory clinical investigation, no formal sample size calculation has been performed. Instead, it has been assumed that [redacted] measurement points (absorption product registrations) will be required per product type. In total [redacted] product types will be evaluated resulting in a need of [redacted] measurement points. 12 subjects are considered appropriate to adapt for individual spreading. Consequently, the aim is to enroll 15 subjects (20% drop-out rate) to capture [redacted] measurement points during a period of 8 weeks.

No formal analysis of data will be conducted for the FUEL clinical investigation. Primary endpoint data will be summarized using descriptive statistics, and incidences of adverse events and device deficiencies will be listed and visualized in tables.

2 SPONSOR CIP APPROVAL PAGE

The undersigned hereby confirms that they have read and understood the content of this Clinical Investigation Plan (CIP) and further approves its content.

_____ _____

Arne Böhling
Clinical Affairs Director, Essity

Date (dd-Mmm-yyyy)

_____ _____

Sofia Hagman
Global Product Owner, Essity

Date (dd-Mmm-yyyy)

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4 DEFINITIONS AND ACRONYMS

ADE	Adverse Device Effect
AE	Adverse Event
App	Application
ASADE	Anticipated Serious Adverse Device Effect
BMI	Body Mass Index
CA	Competent Authority
CIP	Clinical Investigation Plan
CIR	Clinical Investigation Report
eCRF	Electronic Case Report Form
CRO	Contract Research Organization
DD	Device Deficiency
DEU	Dependent End User, synonymous with “subject”
DMC	Data Monitoring Committee
DMP	Data Management Plan
DMR	Data Management Report
DVP	Data Validation Plan
EDC	Electronic Data Capture
EEA	European Economic Area
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation (EU) 2016/679
IB	Investigator’s Brochure
ICF	Informed Consent Form
ICS	International Continence Society
IEC	Independent Ethics Committee
IFU	Instructions for Use
ISF	Investigation Site File
ISO	International Organization for Standardization
MDD	Medical Device Directive 93/42/EEC
MDR	Medical Device Regulation (EU) 2017/745
PCB	Printed circuit board
PI	Principal Investigator
QoL	Quality of Life
Residual Risk	Risk remaining after risk control measures has been taken
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SDV	Source Data Verification
SOP	Standard Operating Procedure
UI	Urinary Incontinence
USADE	Unanticipated Serious Adverse Device Effect
WHO	World Health Organization

5 INTRODUCTION

5.1 Background

The definition of Urinary Incontinence (UI) is “the complaint of any involuntary leakage of urine”, according to the International Continence Society (ICS). UI is a common complaint throughout the world known to carry a profound effect on social and physiological well-being. However, estimates of prevalence depend on the definition of incontinence and the population studied. Consequently, the estimates varies in the literature (1) (2). Among adults older than 65 years and living at home while receiving home care services a prevalence rate of 46% has been identified. Factors associated with higher incidence of UI are e.g. high age, high Body Mass Index (BMI), a large number of reasons for admission to homecare, impaired mobility, diabetes mellitus and fecal incontinence (3). Even if not proven to have negative impact on interactions with family and friends in all populations UI has been reported to impact on self-rated health and other measures of quality of life (QoL). Positive associations between UI and depression have been identified (4), as well as to isolation, skin ulceration/ moisture-associated skin damage, urinary tract infection, sleep disturbances, fatigue, falls and fractures (5).

Among a plethora of treatment options, conservative management is the first-in-line option for most patients with UI. Conservative management comprises lifestyle interventions (weight loss, smoking cessation, fluid reduction, constipation management), physical therapies (pelvic floor muscle training/exercises (PFMT/PFME) and vaginal cones), behavioral therapies (bladder training, prompted or scheduled/timed voiding) and mechanical devices (continence pessaries, urethral plugs). Little evidence is available to support use of drug therapy over conservative treatment options. In addition, patient satisfaction is generally lower (1). As such, pharmacological treatments are generally indicated if conservative management options have failed. Pharmaceutical options include antimuscarinic drugs, β3-antagonists, duloxetine, estrogen, desmopressin, and botulinum toxin type A injections. Surgical management (e.g. open abdominal retropubic suspension, laparoscopic retropubic suspension, midurethral sling procedures, traditional suburethral sling procedures, anterior vaginal repair, bladder neck needle suspensions, peri-urethral injections and artificial sphincters) is the highest risk option available for treatment of UI and mainly aim to lift and support the urethrovesical junction (1) (6) (7) (8) (9) (10) (11) (12). As described, a wide range of active treatments are available for UI. For use in addition, or as separate measures, conservative and passive containment strategies such as toileting programs, pads etc. may be used for management of UI. Containment is important for UI patients when active treatment does not cure the problem, or is not available/possible and in patients who prefer containment over active treatment with its associated risks. This includes the use of absorbent pads, urinary catheters, external collection devices, penile clamps for men and intravaginal devices for women (1).

During the ongoing marketing of the TENA product line of incontinence products the need for easy-to-use products and solutions to support caregivers have been identified. Typically, an absorbing incontinence product is changed three to four times per day. Changing too early leads to unutilized products being discarded and changing too late implies a risk of leakages onto garments and furniture as well as risk of moisture-associated skin damage. To provide quality care and reassure that the incontinent individual is comfortable, a caregiver checks the saturation status of each pad on average 2-3 times between changes. These checks involve components such as touch-feel, looking, and/or asking that not only implies worry for the caregiver but also is an invasion of the privacy of the incontinent individual being cared for.

The TENA SmartCare Change Indicator is an accessory to TENA incontinence products. The accessory is designed to facilitate the caregiver’s decision to change the TENA incontinence

product by informing the caregiver about increasing saturation of the absorbent core. Market introduction of the TENA SmartCare Change Indicator aims to reduce the number of manual checks resulting in a simplified and more comfortable life of caregivers as well as the subjects suffering from UI However, before market introduction of the TENA SmartCare Change Indicator can commence the involved mathematical algorithms needs to be evaluated and assessed.

The purpose of this exploratory clinical investigation is to collect real-life measurement data using the TENA SmartCare Urine Sensor and Gateway. The collected data will be used to evaluate and assess the involved device related algorithms.

6 IDENTIFICATION AND DESCRIPTION OF THE INVESTIGATIONAL DEVICE

The TENA SmartCare Change Indicator consists of a reusable Urine Sensor, attached to the outside of a TENA absorbent incontinence product and an app installed on one or more smartphones.

The TENA SmartCare Change Indicator provides decision support for caregivers to know when it is time to change their Dependent End User's (DEU) absorbent incontinence product, replacing the traditional checking procedure. The system shows the urine saturation level of the absorbing incontinence product making manual checking superfluous.

The TENA SmartCare Change Indicator continuously monitors the saturation level of the TENA absorbent incontinence product by using a sensor placed on the outside of the absorbent incontinence product.

The status is shown in a User Interface (app). The saturation level may be shown/shared with one or more caregivers smartphones using a cloud-based solution.

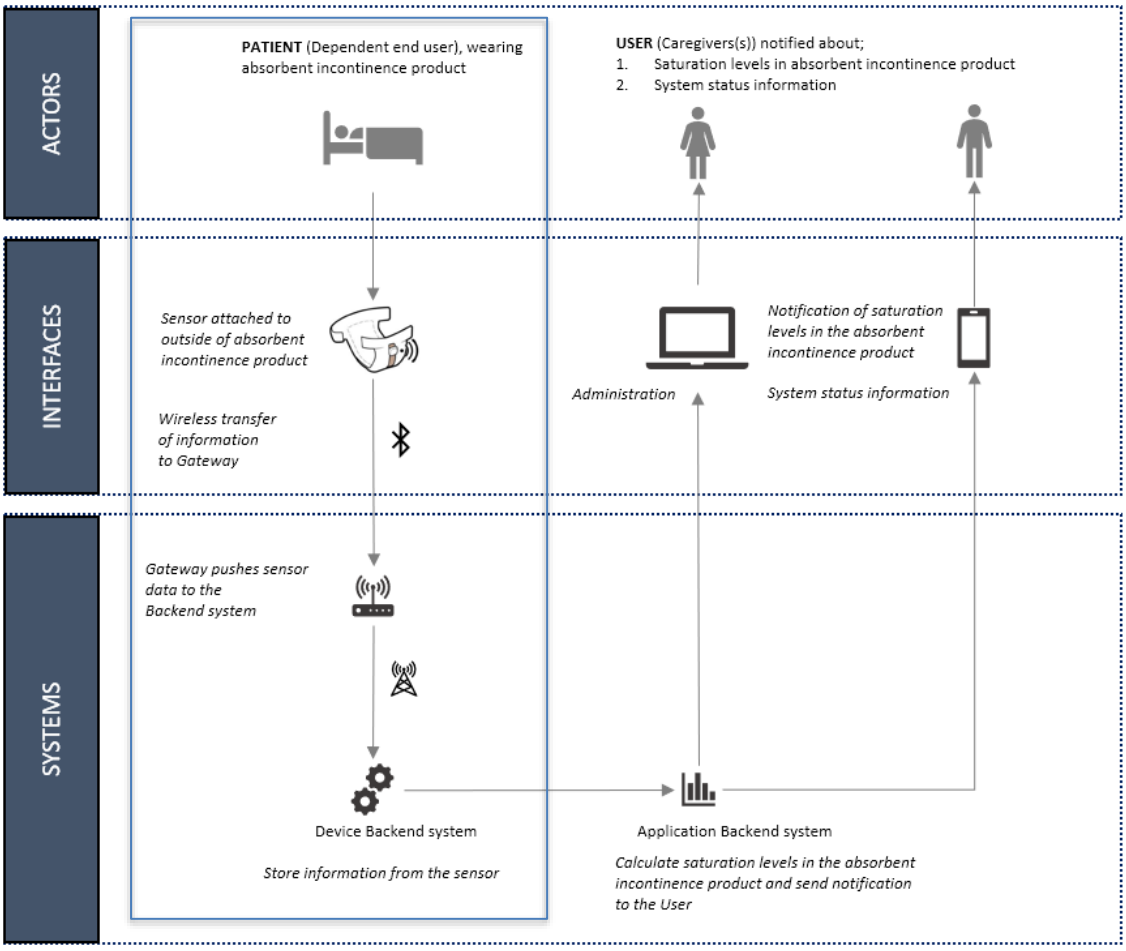

Figure 1. Visualization of the TENA SmartCare Change Indicator system. The modules involved in this investigation is within the blue box.

In the FUEL clinical investigation only the subparts Urine Sensor (with sensor strip and transmitter) and Gateway will be involved. For visualization of TENA SmartCare Change Indicator system, see figure 1 above. For more information on the device see the Investigator's Brochure (IB) (13).

6.1 Manufacturer

Essity Hygiene and Health AB

405 03 Gothenburg
Sweden

Essity Hygiene and Health AB (Essity) is the manufacturer of the TENA SmartCare Change Indicator (including the Urine Sensor and Gateway). Manufacturing and packaging of the TENA SmartCare Change Indicator are all conducted by or on behalf of Essity.

6.2 Identification of Clinical Investigational Medical Device

6.2.1 Classification According to MDR

Incontinence is classified as a disease by ICS in cooperation with World Health Organization (WHO), and together with the intended use being to give alleviation of a disease, the incontinence products are thus classified as Medical Devices per the definition in Article 2(1), of Regulation (EU) 2017/745 (MDR).

According to MDR Annex VIII, TENA SmartCare Change Indicator, being a non-invasive accessory to the medical device, TENA absorbent incontinence product, complies to Rule 1 and is thereby classified as a Class I medical device. However, as the TENA SmartCare Change Indicator also have embedded software, which do not pose any risk to the user if failure occurs, Rule 11 is also applicable.

In conclusion, TENA SmartCare Change Indicator has been classified according to Annex VIII of MDR as a non-invasive accessory to the medical device TENA absorbing incontinence product according to Rule 1 and Rule 11 and consequently classified as a Class I medical device. The TENA SmartCare Change Indicator is currently not CE marked.

6.2.2 Urine Sensor

The Urine Sensor, see figure 2, is the combination of the Transmitter and the Sensor Strip when combined and attached to each other. For this clinical investigation, the Urine Sensor hardware version no. 5 will be used. [redacted]

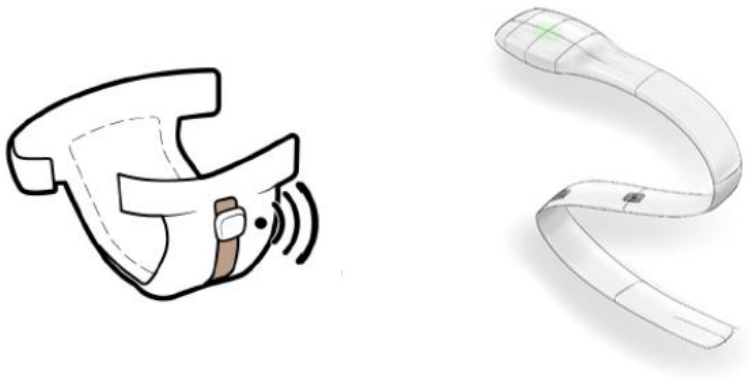

Figure 1. The Urine Sensor is placed on the outside of an absorbing incontinence product.

6.2.2.1 Transmitter

The Urine Sensor is attached to the outside of a TENA absorbent incontinence product. Periodically, the sensor estimates [redacted] the absorbent incontinence product,

processes the estimates and transmits the data wirelessly, using Bluetooth, to the Gateway. Data is collected from the outside of the absorbing incontinence product.

The Transmitter consists of the following components:

- A plastic housing provides necessary protection [redacted]
- An electronic circuit board is internally connected to electrodes that measure [redacted] and stores the data. All data is transferred wireless to the caregivers User Interface/App for presentation.
- A coin cell battery provides energy to the sensor. [redacted]
- A Bluetooth radio modem allows the sensor to wirelessly transmit the collected [redacted]
- [redacted]

6.2.2.2 Sensor Strip

The Sensor Strip extend the Transmitter to collect [redacted] signals from the TENA absorbent incontinence product. [redacted]

The Sensor Strip consists of the following components:

- [redacted] A flexible, [redacted] circuit board [redacted] provides the extension of signals from the Transmitter [redacted]
- A [redacted] material provides attachment of the Sensor Strip to the outside of the absorbent incontinence product.
- A cover material provides necessary protection [redacted]
- A [redacted] contact establishes the contact between the Strip and the Transmitter.
- [redacted]

6.2.3 Gateway

The Gateway is a unit communicating in two directions. Its sole purpose is to receive the collected data from the Transmitter and forward the data to the Cloud solution via a cellular network. [redacted]

The Gateway consists of the following components:

- A plastic housing provides necessary protection against ingress.
- An electronic circuit board [redacted] antennas and passive components.
- A [redacted] radio modem allows the gateway to wireless receive the collected data from the Transmitter using standardized protocols.
- A [redacted] modem allows the Gateway to wireless transmit the collected data to the Cloud solution.
- A power supply supports the gateway with power to operate.

6.2.4 TENA SmartCare Backend Services

The Backend Services consists of two different parts, the Device Backend Service and the Application Backend Service. The TENA SmartCare Backend Services are not part of this clinical investigation.

6.2.4.1 Device Backend Service

The Cloud Solution provides the communication path between the Gateway and the TENA SmartCare Applications using public cellular networks and internet infrastructure.

6.2.4.2 Application Backend Service

The Backend services in the cloud are used to handle application specific services [redacted] used to ensure secure data handling and privacy.

6.2.5 TENA SmartCare Change Indicator Application

The application software can be installed on one or more smartphones. It receives data from the cloud solution and presents status information to the caregivers.

For professional caregivers managing several resident in one home, additional management tools and consoles to overview and manage the residents are needed, in combination with handhelds smartphones. The application is not part this clinical investigation.

6.2.6 Device Labeling

Urine Sensors used in the investigation will be labeled with “For use in clinical study only”, date and ID No, see figure 3.

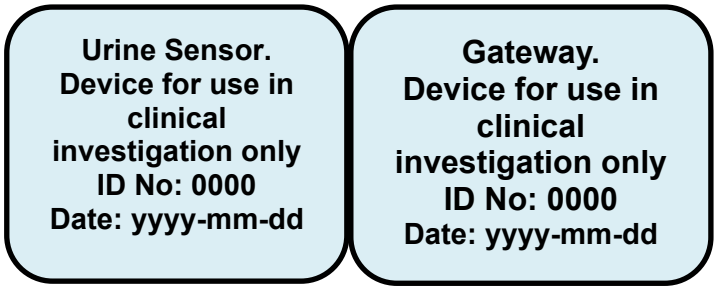

Figure 3. Labeling of the Urine Sensor (not to scale). The labeling will be present as stickers put clearly visible on the Urine Sensor and Gateway.

6.3 Device Traceability

The Sponsor and site personnel will keep records documenting the location of all investigational devices from shipment from Sponsor, usage by study participants, and return to Sponsor (if applicable). This will be documented by a shipment log at the Sponsor and in device accountability log(s) stored at the site. The device accountability log at site will include the following information:

- Date and ID Number for each delivered device.
- Date and subject Number for each used device.
- Date for each device returned to Sponsor from site (if applicable).

The investigational devices will be handled and stored safely, properly and in agreement with the provided storage conditions. Returned and unused investigational devices are accounted for at the return to the Sponsor.

The monitor will verify the accountability process at the site during the site monitoring visits.

6.4 Intended Use

The TENA SmartCare Change Indicator is an accessory to absorbent incontinence products, intended for use on individual(s) suffering from urinary incontinence in a home or professional

environment who are dependent on one or more caregivers to change the absorbent incontinence products. The TENA SmartCare Change Indicator estimates the degree of urine saturation in the absorbent incontinence product and notifies the caregiver(s). This facilitates the caregiver's decision regarding when to change the absorbent incontinence product (14).

Note, based on the objective for the FUEL exploratory clinical investigation only TENA SmartCare Urine Sensor and Gateway will be used.

6.5 Indication and Population

The target population in the FUEL exploratory clinical investigation is adult subjects diagnosed with UI and cared for at Tre Stiftelser. Tre Stiftelser is a professional nursing home located in Gothenburg. The intended user are professional and qualified nursing staff at Tre Stiftelser.

6.6 Manufacturing and Materials

Manufacturing and packaging of the TENA SmartCare Change Indicator are all conducted by or for Essity. Details regarding manufacturing of study devices are given in the IB (13).

No parts of the TENA SmartCare Change Indicator are in direct contact with the subject' tissues or body fluids. In addition, TENA SmartCare Change Indicator does not contain any medicinal products, human or animal tissues or their derivates or other biological active substances.

The only products in direct contact with the subject' tissues and body fluids are the TENA absorbent products used during the clinical investigation. These products are CE-marked Class I medical devices and will be used according to their approved intended use. As for TENA SmartCare Change Indicator, the TENA absorbent products do not contain any medicinal products, human or animal tissues or their derivates or other biological active substances.

6.7 Training and Experience

The Principal Investigator (PI) and designated nurses/coordinators/assistant nurses will receive device related training prior to clinical investigation initiation to ensure that the Urine Sensor, Gateway and TENA incontinence products are used according to Sponsor's instructions. It is the responsibility of the Sponsor to ensure that involved staff is appropriately trained on the investigational devices.

Prior to involvement in the clinical investigation the PI and nurses/coordinators involved in any investigational visit will receive relevant investigational training(s), e.g. CIP content, safety reporting procedures and timelines, informed consent process and forms, regulatory requirements including Good Clinical Practice (GCP), electronic Case Report Form (eCRF) content, use and registration, and content/logs etc. of the Investigator's Site File (ISF) etc. The training is conducted to ensure subject safety, compliance to approved CIP and applicable regulations/guidelines, and accuracy of obtained clinical data.

Assistant nurses only involved in the absorbent product change procedure will receive training relevant for their delegated task(s), e.g. how and when to complete the absorption product documentation, information of AE occurrence to be forwarded to the PI, nurse and relevant coordinator(s) etc.

The PI will ensure that appropriate training relevant to the clinical investigation is given to any other site personnel involved in the investigation and that new information of relevance to the performance of the investigation is forwarded to staff involved.

6.8 Installation and Use

6.8.1 Normal Use

- The Urine Sensor is intended to be single patient use.
- The incontinence product is single use.
- If the Urine Sensor or Gateway is broken, it will be replaced [redacted]
- The Urine Sensor will not be used attached to the patient's skin during normal use. It is attached to the outside of the incontinence product which is in contact with the patient's skin.
- The operator of the Urine Sensor is the caregiver of the patient in a home or healthcare environment. When used in professional healthcare environment, a professional caregiver will perform the same operations.
- Attachment of the Urine Sensor on the incontinence product is considered primary operating function.
- The Urine Sensor should only interact with the caregiver, not the patient. [redacted]

6.8.2 Installation and Use

The Sensor Strip assembling will be performed by a Sponsor' representative at the start of the clinical investigation. This installation will not be handled by involved site personnel. For details on the sensor strip assembling and change, see figure 3.

Figure 3. Assemble Sensor strip/Change sensor strip

After assembling of the Sensor Strip to the Transmitter, the Urine Sensor can be used for registration of urine on the allocated absorption product(s). For details on how to place and remove the Urine Sensor from the TENA absorbent products, see figure 4 and 5. Note, to initiate registration, [redacted] this study, the device will not be turned off by [redacted]

Figure 4. Place transmitter on absorbent area of the incontinence product

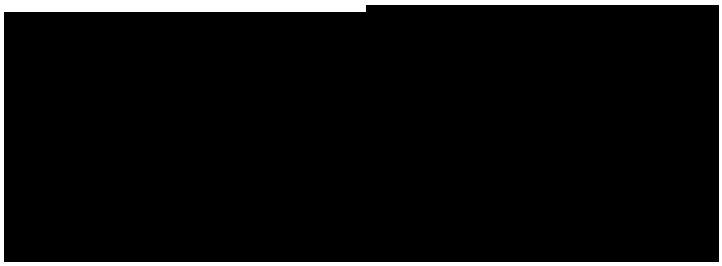

Figure 5. Change absorbent product

After changing of absorbent product, place the used product in the prepared plastic bag. Fill in the remaining sections of the label and hand over the plastic bag to the Sponsor's representative. Prepare a new plastic bag and document applicable information linked to the new absorbent product on the label, e.g. date and time of application, absorbent product type etc.

6.9 Cleaning

See figure 6 for cleaning instructions of the Urine Sensor and Gateway.

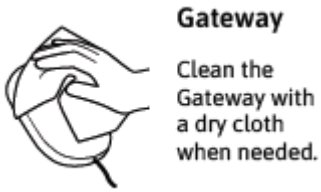

Figure 6. Cleaning instruction for Urine Sensor and Gateway.

6.10 Gateway Installation

Gateways will be installed [redacted] The installation will be performed by a Sponsor' representative well in time of the clinical investigation initiation. For details on the Gateway installation, see figure 7.

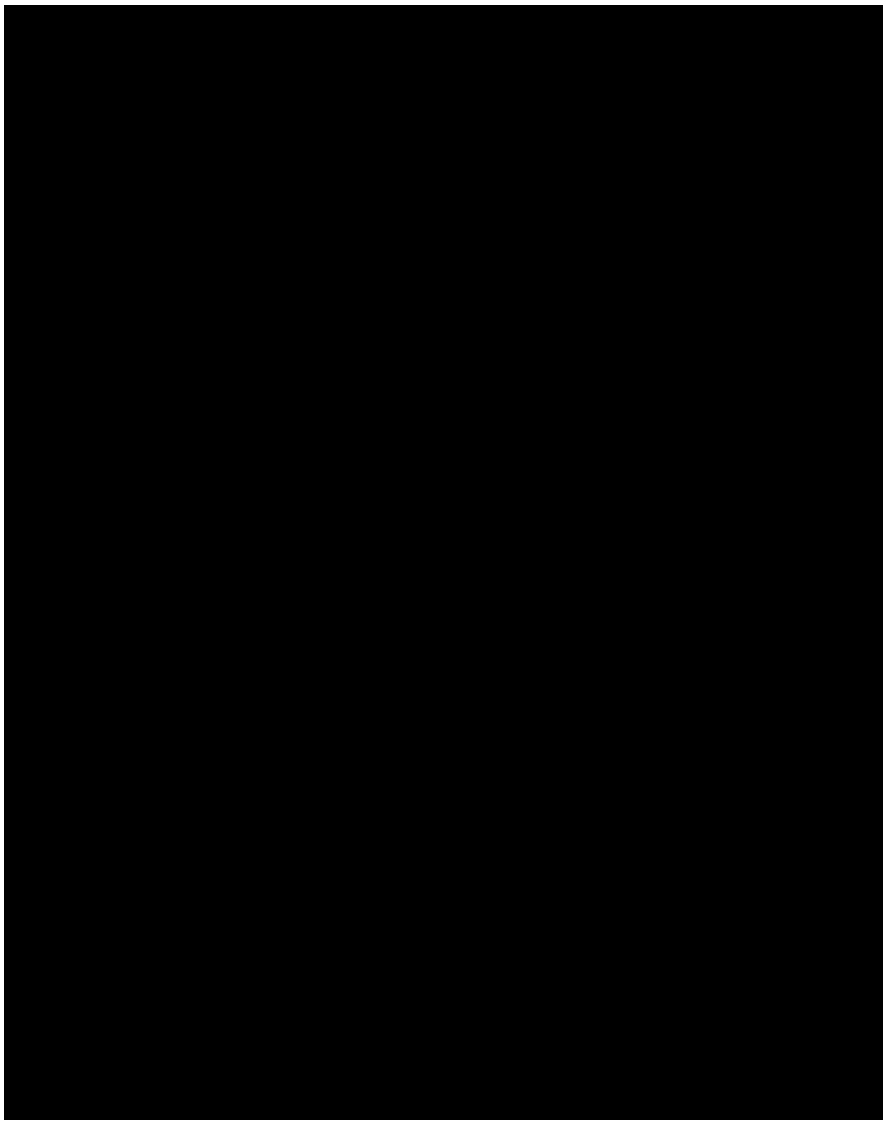

Figure 7. Gateway installation

6.11 Contraindications for Use

There are no contra indications for use as long as the absorbent product is suitable to be used according to normal procedures and intended use (15).

7 JUSTIFICATION OF CLINICAL INVESTIGATION DESIGN

During the ongoing marketing of the TENA product line of incontinence products the need for easy-to-use products and solutions to support caregivers were identified. Typically, an absorbing incontinence product is changed three to four times per day. Changing too early leads to unutilized products being discarded and changing too late implies a risk of leakages leading to a risk of reduced QoL for both the incontinent subject and the caregiver. To provide quality care and reassure that the incontinent individual is comfortable, a caregiver checks the saturation status of each pad on average 2-3 times between changes, including night-time. The saturation checking is a manual process involving touch-feel, looking, and/or asking that not only implies worry for the caregiver but also is an invasion of the privacy of the incontinent individual being cared for.

The purpose of this exploratory clinical investigation is to evaluate safety and to collect real-life measurement data using the TENA Urine Sensor and Gateway. The collected data will be used to assess the involved mathematical algorithms of the TENA SmartCare Change Indicator. The mathematical algorithms are key parts of the complete system. The Urine Sensor is capturing [redacted] values, [redacted] in the absorbent product. The physical [redacted] values are not in its captured form usable in the daily routine to judge the amount of urine in the incontinence product. The mathematical algorithms translate the captured physical [redacted] values into amount of urine values which can be used for assessing the saturation status of the incontinence product.

This exploratory clinical investigation will be conducted in a nursing home by professional and qualified nursing staff. By conducting this clinical investigation in a nursing home, sufficient number of suitable participants are estimated to be available and the measurements can be obtained under controlled conditions.

Data from this exploratory clinical investigation are necessary to continue the TENA SmartCare Change Indicator development. However, the clinical investigation will only involve TENA Urine Sensor and Gateway. No comparator device will be involved in this single-arm clinical investigation.

8 RISKS AND BENEFITS OF THE INVESTIGATIONAL DEVICE AND CLINICAL INVESTIGATION

When discussing risks and benefits of a new medical device, there are different aspects that have to be considered, including the potential risks and benefits for the subjects participating in the clinical investigation and for future subjects with clinical use of the new device.

Use of the device carries low risk. Risk management related to the device has been conducted in accordance with ISO 14971 and includes risk analysis and risk evaluation, risk control and pre-production and post-production review. The risk management process and the residual risks are further described in the IB (13).

8.1 Anticipated Clinical Benefits

There are no direct anticipated clinical benefits of the investigational device for the participating subjects. However, the intended use demonstrates a clear clinical need in the target population.

Anticipated benefits for the whole system (TENA SmartCare Change Indicator):

The TENA SmartCare Change Indicator is intended to facilitate the decision to change an incontinence product. The clinical benefit is that this can reduce the number of unnecessary manual checks of the incontinence product and reduce the time the resident spend in an incontinence product near saturation. The TENA SmartCare Change Indicator improves the residents' privacy and well-being by minimizing unnecessary disruptions of their daily activities and sleep as well as skin exposure to urine and undignified leakages.

8.2 Anticipated Adverse Device Effects

Use of the device is considered to be associated with low risk and there are no anticipated adverse device effects.

8.3 Residual Risks

After the risk assessment (16) were performed, there were five residual risks remaining. Most of these risks are related to severe misuse of the device due to impaired cognitive and/or physical function, see table 1. For the FUEL exploratory clinical investigation, the study will be supervised thus reducing the risk of severe misuse even further. Considering the controlled setting and applied inclusion/exclusion criterias these risks are deemed unlikey to occur. Additional risk control has not been conducted as further design changes will infringe on the intended use and reduce the clinical benefit of the device. All individual risks (except the residual risks) where accepted in the risk assessment. After the risk/benefit analysis the residual risks were also accepted as it was evaluated that the benefit of the device outweighs the risks (16).

8.4 Risks Associated with Participating in the Clinical Investigation

This clinical investigation will be conducted in line with applicable regulations and ethical principles designed to safeguard study subjects. The PI will ensure that appropriate training relevant to the investigation is provided to the staff involved.

According to the risk analysis report, if the device will not work or malfunction this will not pose a risk for the study subjects. Regular change of incontinence products will continue regardless of the functionality of the device. Furthermore, malfunctions will not be an issue for the clinical investigation as this will be part of the evaluation of the device within the scope of the investigation.

TENA SmartCare Change Indicator is a novel device system, designed as an accessory to the CE-marked TENA absorbent products (Class I) used in this clinical investigation.

The reporting of adverse events and monitoring described in section 11 and 19 respectively, will assure early detection of any increased risk or unanticipated subject safety concerns.

Except for the identified residual risks described above, no specific investigation related risk has been identified.

8.5 Possible Interactions with Concomitant Medical Treatments

No interactions with concomitant medication treatment have been identified.

8.6 Risk Control

A risk management plan has been implemented for the TENA SmartCare Change Indicator. Appropriate company procedures and systems are in place to obtain relevant production and post-production information. All risks have been reduced as far as possible, meaning that all safety principles have been applied where possible and where safety could be improved. See section 8.3 and the IB (13).

8.7 Risk-to-Benefit Rationale

The risks from all identified hazardous situations have been considered (17), for a summary of residual risks see table 1. It is concluded that the clinical benefit of using the device is greater than the residual risks, and the overall residual risk associated with the product are judged to be acceptable (16). Using the device adds no risk to the risk profile found for the absorbent incontinence products, which it is intended to be used in combination with, that have been on the market for many years.

The risk management activities are in line with the risk management plan (18), the risk management procedure (19) and the requirements of the EN ISO 14971:2012 standard.
The risk assessment (17) and the evaluation of the risk analysis (16) have been made with regard to the general safety and performance requirements of the Medical Device Regulation 2017/745.

Table 1: Summary of residual risks

Risk ID	Hazard	Hazardous situation	Risk/benefit analysis
4.1	Allergic reaction causing anaphylactic shock or other symptom with fatal outcome.	Urine sensor in contact with skin	The risk of having a hyper sensitive person among the users of the device are judged as very low.
39.1	Suffocation	The dependent end user may ingest the transmitter	The transmitter has been designed to be too large to easily ingest. This risk will also be present for dependent end users in a home or professional environment.
39.2	Suffocation	The dependent end user winds the sensor strip around the neck	The risks for the device are similar to that of any long thin object present in a home or professional environment. It is not possible to re-design the sensor strip without risking device performance.

Risk ID	Hazard	Hazardous situation	Risk/benefit analysis
39.4	Burns, Indigestion	The transmitter is opened and the battery swallowed	The battery type is common in electric appliances in society and the risks are well known. Design measures have been included to secure the battery, but the presence of the battery is necessary to achieve intended use.
39.7	Suffocation	Transmitter parts excluding battery may be ingested	It is not possible to design the components of the urine sensor to mitigate this risk without risking device performance and intended use.

9 OBJECTIVES AND HYPOTHESES OF THE CLINICAL INVESTIGATION

9.1 Primary Objective

The primary objective is to collect real-life measurement data using the Urine Sensor to assess the mathematical algorithms for wetness detection in TENA absorption products by urine volume quantification and [redacted] measurements.

9.2 Secondary Objectives

The secondary objective is to evaluate safety through analyzing device-related adverse events reported during the investigation.

9.3 Hypothesis

Not applicable. A statistical hypothesis has not been considered relevant due to the exploratory nature of this clinical investigation.

9.4 Claims and Intended Performance of the Investigational Device

Not applicable as this exploratory clinical investigation will be limited to the TENA Urine Sensor and Gateway.

9.5 Risks and Anticipated Device Effects

There are no identified adverse risks or anticipated device effects.

10 DESIGN OF THE CLINICAL INVESTIGATION

10.1 General

This is an exploratory clinical investigation to evaluate safety and to collect real-life measurement data using the TENA Urine Sensor and Gateway. The collected data will be used to evaluate and assess the device related algorithms. The primary algorithms have been established and evaluated in a laboratory environment. However, several parameters differ between real-life and laboratory settings and can be hard to predict. Consequently, real-life measurement data has been determined necessary to continue the product development.

To assess the mathematical algorithms the urine volume needs to be quantified (ml urine) and the [redacted] values from the Urine Sensor captured. Data such as; date and time of application, date and time of removal, Urine Sensor ID, absorbent product information (type, absorption level and size), leakage outside product, presence of feces, and the subject's main position since last absorbent product change will be recorded by the caregiver on a label located on a plastic bag. The absorbent product is thereafter placed in the plastic bag and provided to a Sponsor' representative. The plastic bag is weighed on a calibrated scale by the Sponsor' representative in the Essity lab and the weight documented in the eCRF. The urine spreading in the absorbent product is documented by taking a photo of the absorbent area of the product. The photo is uploaded in the eCRF system. All data documented by the caregiver on the plastic bag label are transferred to the eCRF by the Sponsor' representative, and the label is detached from the plastic bag and placed on a paper and returned to site. The paper is considered source data and will be stored in a study specific binder for quality assurance and archiving.

In total 9 types of absorbent products will be tested;

- TENA Slip
- TENA Flex
- TENA Pants

Each TENA absorbent product type exists in three different absorption levels, Plus, Super and Ultima, to meet different incontinence needs of the user. The lower absorption level is designed for users suffering from moderate incontinence needs and the higher absorption level is designed for users with higher incontinence need. In the FUEL clinical investigation, both absorption levels for each TENA absorbent product type will be included. The TENA absorbent products come in four different sizes; small, medium, large and extra large. All subjects will be allocated to the most appropriate size. Note, the size is not believed to affect the registrations and are not considered different product types.

Approximately 15 subjects diagnosed with UI will be recruited from the nursing home Tre Stiftelser in Gothenburg, Sweden.

The clinical investigation is designed to be conducted in a professional environment, for a duration of 8 weeks (approximately 6 weeks registration per subject + enrollment time). Two visits are planned for each subject during the duration of the clinical investigation; screening visit and follow-up visit. Absorption product registrations will be collected as specified above between these visits.

The overall duration of the investigation is estimated to 8 weeks, including a 2-week recruitment period.

10.1.1 Primary Endpoint

Summarize the individual differences (predicted urine volume* - true urine volume**) using descriptive statistics. The data*** will later be used to assess mathematical algorithms for the TENA SmartCare Change Indicator.

**Prediction calculated from urine sensor values*
*** Urine volume determined from absorbent product weights*
****Data is the combination of urine sensor values and absorbent product weights.*

10.1.2 Secondary Endpoints

Incidence of adverse events and device deficiencies; AEs, ADEs, SAEs, SADEs and DDs.

10.2 Investigational Device(s) and Comparator(s)

This is a single-arm clinical investigation. Thus, no comparator device will be used.

Each participating subject will be provided with one Urine Sensor, as well as absorbent products for the duration of the investigation. Eight types of absorbent products will be tested in the FUEL clinical investigation, and each participating subject will be allocated to the type(s) that are considered most suitable. What type(s) are most suitable will be decided during the screening visit depending on previous absorption product use and the subject's physiology.

Gateways will be placed [redacted] to enable full measurement registration.

Within the scope of this clinical investigation, no other additional medical device or medication is required.

10.3 Subjects

10.3.1 Inclusion Criteria

The subject must meet all of the following criteria to be eligible for this clinical investigation:

1. The subject is willing and able to provide informed consent and to participate in the clinical investigation.
2. The subject is ≥ 18 years of age.
3. The subject is diagnosed with urinary incontinence.
4. The subject is being cared for at Tre Stiftelser.

10.3.2 Exclusion Criteria

Subjects meeting any of the following criteria will not be permitted to participate in the clinical investigation:

1. The subject has ≥ 4 fecal "incidences" per week.
2. The subjecthas severe absorbent product related skin problems, as judged by the investigator.
3. The subject is hyper sensitive related to allergic reaction to any of the included materials, as judged by the investigator.
4. The subject has ≥ 2 intermittent urinary catheters per day.
5. The subject has a pacemaker or an implantable cardioverter-defibrillator.
6. The subject removes the incontinence product.
7. The subject demonstrates responsive behavior towards sensors.
8. The subject has any other condition that may make participation in the clinical investigation inappropriate, as judged by investigator.
9. The subject is not cared for at Tre Stiftelser.
10. The subject is pregnant or lactating.

10.3.3 Number of Subjects

The investigation population will be comprised of approximately 15 subjects suffering from UI, cared for at the nursing home Tre Stiftelser, and that are fulfilling all of the inclusion criteria and none of the exclusion criteria for the clinical investigation.

10.3.4 Methods of Assigning Subjects to the Different Treatment Arms

Not applicable as this is a non-randomized single-arm clinical investigation. For allocation to suitable incontinence products, see section 10.1.

10.3.5 Subject Withdrawal or Discontinuation

Subjects are free to discontinue participation in the clinical investigation at any time and are not required to give a reason for their decision. However, subjects who discontinue the investigation should always be asked about the reason(s) for their discontinuation and about the presence of any AE/ADE and, if possible, be assessed by an investigator. Discontinuation from the clinical investigation will not affect the future treatment/care of the subject.

If the subject withdraw his/her consent no further data will thereafter be recorded. Data collected up to the date of withdrawal of informed consent will be used in the data analysis and for the Clinical investigation Report (CIR), provided that the subject do not actively request all data to be removed.

Participants may be withdrawn from the clinical investigation and assessments at any time, if deemed necessary by the investigator.

Specific reasons for withdrawal of participants from this clinical investigation are:

- The decision of a subject to withdraw from the investigation.
- The investigator deems the subject unfit for the investigation or suspects poor CIP compliance.

In case of withdrawal, all AEs/ADEs should be followed up and applicable documentation should be returned to the Sponsor.

Incorrectly enrolled subjects will be withdrawn from further investigation and assessments. A subject may, however, continue the clinical investigation under exceptional circumstances (i.e. if continuation of investigation or follow-up are necessary for the subject's safety and well-being, or if only a follow-up period remain, and the continuation of the investigation is not expected to be associated with any risk or discomfort for the subject).

10.4 Clinical Investigation Duration

Table 2. Overview of clinical investigation duration.

Point of enrolment:	End Aug/beginning Sep 2019
Total expected duration of the clinical investigation:	8 weeks
Expected duration of each subject's participation:	6 weeks
Enrolment period:	2 weeks

10.5 Clinical Investigation Procedures

10.5.1 Schedule of Clinical Investigation Procedures/Assessments

The assessments and procedures that will be performed during the clinical investigation is illustrated in table 3 below. Further information is provided in the sections below.

Table 3. Clinical investigation schedule for assessments and procedures.

Clinical Investigation Visit:	Visit 1 – Screening	Visit 2 – Follow-up
Assessments and procedures:		
Subject information and informed consent	X	
Eligibility verification	X	
Enrollment	X	
Demography	X	
Concomitant medication review	X	X
Relevant medical and surgical history	X	
General health status	X	
Pregnancy test in subjects with childbearing potential	X	
Allocation to suitable absorbent product type(s) and size(s)	X	
Verification of eCRF completion		X
AE/ADE/SAE/SADE/DD documentation/Follow-up		X

10.5.1.1 Visit 1 – Screening, day 0

The screening visit is conducted by the PI. The PI will introduce the clinical investigation and explain the CIP, procedures and objectives to the potential subject. The PI will verbally inform the subject about the investigation and provide written subject information describing the clinical investigation, potential discomforts, risks and benefits of participation. Potential subjects will be given adequate time for review of the subject information and time to discuss the investigation and ask questions to the PI. Any queries that a potential subject may have regarding the investigation will be addressed appropriately by the PI. Potential subjects will be instructed that they are free to withdraw their consent and to discontinue their participation in the investigation at any time without prejudice. If the subject is willing to participate in the investigation, he/she needs to sign and date the ICF together with the investigator who gave the verbal and written information. The original ICF will be retained in the ISF and a copy provided to the subject. The investigator must obtain written informed consent before any clinical investigation related procedures are performed on the subject, for further details on the informed consent process please see section 18.

After written informed consent has been obtained the subject is considered to be enrolled in the clinical investigation. The subject will be allocated to the next available subject identification number, a unique number, used for the identification of the subject in the investigation. For FUEL clinical investigation the subject identification number will consist of the letter F (FUEL) and four digits. The first digit is the site number. As only one site is expected in the upcoming clinical investigation number 1 is currently the first number for all subjects. The remaining three digits are consecutive numbering. For example, the first subject will be allocated to subject No. F1001.

After enrollment, relevant medical/surgical history and relevant concomitant medication(s) will be collected and listed in the study specific eCRF. The general health status will be evaluated and for subjects with childbearing potential a urine pregnancy test obtained. Information on the subject's demographics will be documented in the eCRF and all inclusion and exclusion criteria reviewed (eligibility verification). If eligible, the subject will be allocated to the most suitable absorbent product type(s) to be tested (eight types in total) and size.

At visit 1, the following assessments/procedures will be performed:

- Subject information and informed consent

- Eligibility confirmation
- Enrollment
- Demographic data and baseline information; year of birth, gender, incontinence product(s) of use previous 6 months, bedridden/not bedridden
- Documentation of relevant concomitant medication(s)
- Documentation of relevant medical and surgical history
- Evaluation of general health status
- Urine pregnancy test in subjects with childbearing potential
- Allocation to suitable absorbent product type(s) and size

10.5.1.2 Visit 2 – Follow-up, after approximately 6 weeks of absorbent product registration

At the follow-up visit concomitant medications will be reviewed and completion of eCRF registrations confirmed. All AEs/ADEs/SAEs/SADEs and/or DDs will be documented and followed-up, as applicable. After completion of visit 2 the subject will be terminated from further participation in the clinical investigation.

At visit 2, the following assessment/procedures will be performed:

- Documentation and/or follow-up on AE/ADE/SAE/SADE/DD
- Concomitant medication review
- Verification of eCRF completion
- Study termination

10.5.1.3 Unscheduled Visits/Contacts

If deemed necessary for any reason, e.g. AE/ADE/SAE/SADE, unscheduled visits may be conducted within the course of the clinical investigation. All unscheduled visits shall be documented in the eCRF and medical notes, as applicable*.

** Any unscheduled examination between visit 1 and visit 2 will be considered an unscheduled visit.*

10.5.2 Demographic Data and Baseline Measurements

10.5.2.1 Demographic Data

At the screening visit the following demographic data are to be collected; year of birth, gender, incontinence product(s) of use the previous 6 months, bedridden/not bedridden.

The following information linked to incontinence product(s) of use the previous 6 months is expected to be recorded in the eCRF:

- Name/product type
- Absorption level
- Size
- Current/past use
- Night time use/day time use/both

10.5.2.2 Relevant Concomitant Medication

Relevant concomitant medication will be listed in the eCRF. At follow-up (visit 2) the listed concomitant medications will be reviewed, and eventual changes recorded.

10.5.2.3 Relevant Medical and Surgical History

During visit 1 relevant medical and surgical history will be elicited for each subject and listed in the eCRF. Relevant medical history will include specification whether the event is past or current. Relevant medical history will include date of surgical intervention. The medical history will assess the subject for any disqualifying medical conditions.

10.5.2.4 Evaluation of General Health Status

Based on available medical record data and recorded health status at screening, the PI will evaluate the general health status of the subject i.e.: poor, fair, good, or very good. Based on the above information the PI will determine whether the health status of the subject is sufficient for participation in the clinical investigation.

10.5.2.5 Urine Pregnancy Test

All women of childbearing potential will conduct a pregnancy test at visit 1. The following is to be recorded in the eCRF:

- Was a urine pregnancy test obtained? Yes/No/Not applicable
- If not applicable, reason.
- Result of conducted test? Positive/Negative

10.5.2.6 Allocation to Suitable Absorbent Products

The absorbent product allocation will be documented in the eCRF. The absorbent product type(s), absorbent level, size and time of use will be specified in a table.

10.5.3 Performance Variables and Measurements

10.5.3.1 Registration of Absorbent Product Information

Between visit 1 and visit 2 the following information are to be documented; date and time of application, date and time of removal, Urine Sensor ID, absorbent product information (type, absorption level and size), leakage outside product, presence of feces, and subject's main position since last absorbent product change will be recorded by the caregiver on a label located on a plastic bag. The absorbent product is thereafter placed in the plastic bag and provided to a Sponsor' representative. The plastic bag is weighed on a calibrated scale by the Sponsor' representative in the Essity lab and the weight documented in the eCRF. The urine spreading in the absorbent product is documented by taking a photo of the absorbent area of the product. The photo is uploaded in the eCRF system. All data documented by the caregiver on the plastic bag label are transferred to the eCRF by the Sponsor' representative. The label is thereafter detached from the plastic bag and placed on a paper and the paper is returned to site. The paper is considered source data and will be stored in a study specific binder for quality assurance and archiving.

10.5.4 Safety Variables and Measurements

All incidences of AEs and DDs will be documented and reported during the course of the clinical investigation. Adverse events will be documented as adverse events AE, ADE, SAE, and SADE. For details related to adverse event definitions or reporting see section 19.

All events will be followed up until resolved or judged as clinically stable according to the PI, if possible.

10.5.5 Activities Performed by Sponsor

- The Sponsor is responsible for device training of involved personnel. Device training will be documented in applicable training logs.
- The Sponsor is responsible for weighting and photographing absorbent products and transfer of data into eCRF according to section 10.5.3.
- The Sponsor is responsible for reporting of SAEs according to section 19.4.

10.5.6 Potential Confounding Factors

- Concomitant medications that could potentially affect urination.
- Subjects with regular fecal incidents.
- Illnesses occurring during the investigational period.

All the above identified potential confounding factors have been mitigated by study specific exclusion criterion.

11 MONITORING PLAN

A detailed description of the monitoring activities will be explained in investigation specific monitoring manual.

11.1 Subject Records and Source Data

Subject data recorded directly in the eCRF, and not into the medical record, will be considered as source data. It is the responsibility of the PI to record essential information in the medical records, in accordance with national regulations and requirements. The origin of the source data in this clinical investigation will be further specified in a separate document ("Origin of Source Data").
In general, the following information shall be recorded in the medical records:

- Clinical investigation code/title.
- Subject identification number.
- That informed consent for participating in the clinical investigation was obtained and date of consent.
- Diagnosis.
- All visits during the investigation period.
- All AEs/ADEs/SAEs/SADEs/DDs.
- Treatments and medications.

The PI is responsible for ensuring the accuracy; completeness, legibility and timeliness of the data recorded in the eCRFs. Completed sections of eCRFs will be monitored on a regular basis.

11.2 Access to Source Data and Documentation

The PI and site should guarantee access to source documents for the monitor and auditors as well as for inspection by appropriate Competent Authorities (CA), Regulatory Agencies, and the IEC, if required.

12 STATISTICAL CONSIDERATIONS

12.1 Statistical Design, Method and Analytical Procedures

As this is an exploratory clinical investigation results will be summarized using relevant descriptive statistics such as means, Standard Deviation (SD), median, minimum and maximum values and frequency tables. The data will later be used to assess the mathematical algorithms for the TENA SmartCare Change Indicator.

12.2 Sample Size

No formal sample size calculation has been performed. Instead, it has been assumed that [redacted] measurement points (absorptions product registrations) will be required per product type to be in an accuracy range similar to the lab verified urine sensor accuracy (20). Included in the assumptions for the [redacted] measurement points are also that each subject uses 3 absorbent products each day and that [redacted] absorbent products will be disregarded [redacted]

In total 9 product types will be evaluated [redacted]. It is estimated that at least 12 subjects are considered appropriate to adapt for individual spreading during the test. However, to compensate for drop-outs or non-compliance (see 12.4) 15 subjects are appropriate to include in the investigation. In the screening phase, a detailed product test plan will be made for each subject with the ambition to match test absorbent product type with the subject's current absorbent product type. However, it cannot be assumed that the subject is using the specific TENA absorbent products in scope of this clinical investigation for their incontinence need, so a different product type might be assigned each subject. Product absorption level as well as product size will however remain the same.

12.3 Level of Significance and Power

Not applicable as no formal statistical analyses will be performed for this clinical investigation.

12.4 Drop-out Rates

It is estimated that 20% of subjects will drop-out or not complete the investigation. See section 12.2 for further details.

12.5 Pass/fail Criteria

Not applicable as this clinical investigation does not contain a statistical hypothesis.

12.6 Interim Analysis

No interim analysis is currently planned.

12.7 Criteria for Termination on Statistical Grounds

Not applicable as no formal statistical analyses will be performed for this clinical investigation.

12.8 Reporting of Deviations from the Original Statistical Analysis Plan (SAP)

Any deviation(s) from the original SAP will be described and justified in a CIP Amendment and/or in a revised SAP and/or in the final report, as appropriate.

12.9 Subgroups for Analysis

No subgroup analyses are planned.

12.10 Procedures that Take into Account All the Data

Not applicable.

12.11 Missing, Unused or Spurious Data

Outliers will be included in summary tables and listings and will not be handled separately. Available data from prematurely withdrawn subjects will be included in the summaries as far as possible.

12.12 Exclusion of Particular Information from the Testing of the Hypothesis

Not applicable as this clinical investigation does not contain a statistical hypothesis.

13 DATA MANAGEMENT

The Data Management process includes all activities related to data handling, e.g.:

- Establishment of Data Management Plan (DMP)
- eCRF and database set-up
- Specification of on-line checks
- Data and database validation
- Export of data from Viedoc to Excel / SAS
- Creation of post-entry checks and listings
- Reconciliation of ADEs, SAEs, SADEs, and DDs
- Clean-file process including execution of post entry checks and listings
- Post clean-file tasks
- Establishment of Data Management Report (DMR)

Data management and handling will be conducted according to the investigation specific DMP in accordance with applicable guidelines and CRO's Standard Operating Procedures (SOPs). Any deviations, i.e. discrepancies and additions from the process defined in the DMP, will be described in an investigation specific DMR.

Data will be collected in an eCRF specifically designed for this clinical investigation. The PI or an authorized person (Essity employee or sponsor representative) will record and upload subject data in the eCRF in a precise and accurate manner. Abbreviations should not be used. The investigator is responsible for the data entered and sign off the eCRF at the end of the clinical investigation. The data should be recorded as soon as they are generated.

Data validation/ data cleaning procedures are designed to assure validity and accuracy of clinical data. These procedures consist of computerized edit checks and queries for identifying data values that are outside the allowed range, CIP deviations, incomplete or inconsistent. The Data Validation Plan (DVP) specifies the checks that are to be performed on subject data for the clinical investigation. All investigation-specific and standard data validation programming will be tested in a separate testing environment prior to use on production data.

When all data from all endpoints of all study participants have been entered, discrepancies solved and all reconciliation with the safety database is complete, the database will be locked, and the data will be analyzed.

13.1 Electronic Data Capture (EDC)

Viedoc a web-based EDC system, will be used to capture data in this investigation; eCRF. The EDC system complies with FDA Title 21 CFR part 11 (ER/ES) requirement and is validated according GAMP 5. eCRF training will be given to appropriate personnel before/at initiation of the investigation site(s). Data entry will be done by the PI and other authorized personnel (Essity employee or sponsor representative). For the FUEL clinical investigation authorized personnel for eCRF data entry will be both personnel at site and authorized Sponsor' representatives (absorbent product weight, photo and data entry of plastic bag label data). An Essity employee will enter the predicted value of each incontinence product into the eCRF. This person will not be able to see the actual weight of the product in the eCRF. To achieve this, a separate user will be created in the Viedoc database for this person. When entering data on-line checks are incorporated for consistency and validation. When data has been entered authorized personnel at Sponsor and CRO can immediately view the data, send queries if necessary and lock eCRF pages when they have been validated. The physical database will be stored using redundant enterprise level storage area networks (SAN) on separate data centers at separate geographic locations within the European Union. Programs for post-entry checks and data listings will be created and executed for validation of data. Completeness will be checked by authorized personnel at CRO so that there

are no unexplainable empty fields. This is done in order to prevent that data have been overlooked by personnel entering the data.

A clean-file meeting will be held prior to database lock. All decisions on the evaluability of the data from each individual subject for the statistical analysis and final definition of Intention To Treat (ITT), Per Protocol (PP) and safety populations must be made and documented before locking the database.

13.2 Data Retention

The medical files of clinical investigation subjects must be retained in accordance with local legislation and in accordance with the maximum period of time permitted by site practice.

The PI/investigational site shall retain all clinical investigation records during the investigation and for the period required by the applicable regulatory requirements or for at least 10 years after the premature termination or completion of the clinical investigation, whichever is the longer. The PI must take measures to prevent accidental or premature destruction of these documents. The PI should contact the Sponsor prior to destruction of any records or reports pertaining to the clinical investigation in order to ensure they no longer need to be retained. In addition, if the PI leaves the site, he/she should provide the Sponsor with the name and address of the person who will look after and be responsible for the clinical investigation-related records. If the records will be transferred to another person/party, the transfer will be documented at the investigation site and/or at the Sponsor.

As the Investigators do not normally work at Tre Stiftelser, a contact person at site will be appointed and documented in the delegation log located in the ISF.

13.3 Monitoring, Audits and Inspections

During the investigation, the monitor will have regular contacts with the investigation site. These contacts will include visits to confirm that the facilities remain adequate to specified standards and that the investigation team is carrying out the procedure stated in the CIP. All data must be accurately recorded in the eCRF. Source Data Verification (SDV), a comparison of data in the eCRF with the subject's medical records and other records at the investigation site, will also be performed. The source documents and records must be made accessible during the visit.

The monitor or other Sponsor personnel will be available between visits if the PI or other investigation staff at the site needs information and/or advise. Authorized representatives of the Sponsor and/or international Regulatory Agencies/CAs may visit the site to perform audits/inspections, including SDV.

14 AMENDMENTS TO THE CIP

Any change to the approved clinical investigation documents will be documented and include a written justification. Any effects of the implemented changes on other clinical investigation documents shall be evaluated and documented. If deemed necessary, affected documents shall be properly updated and relevant parties notified. The version number and date of amendments shall be documented.

Proposed amendments to the CIP shall be agreed upon between the Sponsor and the PI. The amendments to the CIP shall be notified to, or approved by, the IEC and CA, if required.

All amendments to the CIP will be documented in an amendment log and communicated to relevant parties.

15 DEVIATIONS FROM THE CIP

A CIP deviation is a failure to follow, intentionally or unintentionally, the requirements of the CIP. Every effort should be made to comply with the requirements of the CIP and the PI is not allowed to deviate from the CIP.

As required by national regulations or guidelines, requests for deviations and reports of deviations will be provided to the IEC if the deviation affects subject's rights, safety and well-being, or the scientific integrity of the clinical investigation.

Under emergency circumstances deviations from the CIP may proceed without prior approval by the Sponsor and favorable opinion of the IEC if the rights, safety and well being of human subjects need to be protected. Such deviations will be documented and reported to the Sponsor and IEC as soon as possible in accordance with national regulations.

When the monitor or Sponsor identifies that the PI is out of compliance, this will be notified to the PI in writing, with a request to correct the source of the deviation immediately. Corrective action will be implemented to avoid repeated non-compliance, which will usually include re-training and may include termination of the clinical investigation at the site.

The Sponsor is responsible for analyzing deviations and assessing their significance. Corrective actions will be implemented to avoid repeated deviations, which may include suspending the clinical investigation, or disqualifying the PI.

16 DEVICE ACCOUNTABILITY

The Sponsor and the PI will keep records documenting the location of all investigational devices from shipment of investigational devices to the investigation sites until return. This will be documented by a shipment log stored at the Sponsor and in a device accountability log at the investigation site. The device accountability log at site will include information on: date, device ID No no, list of delivered devices, date and subject identification for used devices, and date and device ID No of devices returned.

The monitor will verify the accountability process during the site monitoring visits.

17 STATEMENTS OF COMPLIANCE

This clinical investigation will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki (Appendix C). Furthermore, the clinical investigation will be conducted in compliance with ISO 14155:2011 and applicable regional or national regulations.

17.1 Institutional Ethics Review

The final CIP, including the final version of the ICF, must be approved or given favorable opinion in writing by an IEC, and CA, before enrolment of any subject into the clinical investigation. The PI is responsible for informing the IEC of any amendment to the CIP as per local requirements.

Any additional requirements imposed by the IEC or CA shall be followed.

17.1.1 IEC Submission

In Sweden, the IEC application is to be submitted to the Swedish Ethical Review Authority through the web portal Prisma. The application is to be submitted by the PI who needs a Prisma account.

17.1.2 CA Submission

In Sweden, the CA application is to be submitted to the Swedish Medical Products Agency through their e-portal. No specific account is needed to submit the application.

17.2 Insurance

The Sponsor will be responsible for ensuring adequate insurance covering any injuries to the subject caused by the investigational medical device. The nursing home have a private patient insurance through the insurance company Länsförsäkringar, the insurance is equivalent to the public insurance provided by the Swedish Patient Injury policy (LÖF).

18 INFORMED CONSENT PROCESS

All subjects will receive written and verbal information regarding the investigation prior to any investigation-related procedures. This information will emphasize that participation in the investigation is voluntary and that the subject may withdraw from the investigation at any time and for any reason. If any new important information occurs during the clinical investigation the subject will be informed both orally and in writing. All subjects will be given the opportunity to ask questions about the investigation and will be given sufficient time to decide whether to participate in the investigation or not.

The written subject information explains that the data will be stored in a computer database, maintaining confidentiality in accordance with national data legislation, and that authorized representatives of the Sponsor, international Regulatory Agencies, a Competent Authority or an IEC may require direct access to those parts of the medical records relevant to the investigation, including medical history, for verification of data. Additionally, the written subject information specifies that data will be recorded, collected, processed and may be transferred (to either EEA countries and/or non-EEA countries). In accordance with the General Data Protection Regulation (GDPR) 2016/679, the data will not identify any subjects taking part in the investigation.

Before any investigation-related procedures, the informed consent will be signed and dated by the subject (or their legally acceptable representative and/or witness, as applicable) and by the Investigator who gave the subject the verbal and written information.

19 ADVERSE EVENTS, ADVERSE DEVICE EFFECTS AND DEVICE DEFICIENCIES

The definitions and procedures for reporting Adverse Events (AE), Adverse Device Effects (ADE), Serious Adverse Events (SAE), Serious Adverse Device Effects (SADE) and Unanticipated Serious Adverse Device Effects (USADE) are presented in the subsections below. It is of utmost importance that all staff involved in the investigation is familiar with the definitions and procedures and it is the responsibility of the PI to ensure this.

19.1 Definitions

Adverse Event (AE)

Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons whether or not related to the investigational medical device.

Note 1: This definition includes events related to the investigational device or the comparator.

Note 2: This definition includes events related to the procedures involved.

Note 3: For users or other persons, this definition is restricted to events related to investigational medical devices.

Adverse Device Effect (ADE)

Adverse event related to the use of an investigational medical device.

Note 1: This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device.

Note 2: This includes any event that is a result of a use error or intentional abnormal use of the investigational medical device.

Device Deficiency (DD)

Inadequacy of an investigational medical device related to its identity, quality, durability, reliability, safety or performance. This may include malfunctions, use error, or inadequacy in the information supplied by the manufacturer.

Serious Adverse Event (SAE)

Adverse event that:

a) Led to a death, injury or permanent impairment to a body structure or a body function.
b) Led to a serious deterioration in health of the subject, that either resulted in:
   - A life-threatening illness or injury, or
   - A permanent impairment of a body structure or a body function, or
   - In-patient hospitalization or prolongation of existing hospitalization, or
   - In medical or surgical intervention to prevent life threatening illness.
c) Led to foetal distress, foetal death or a congenital abnormality or birth defect.

Note: Planned hospitalization for pre-existing condition, or a procedure required by the CIP, without a serious deterioration in health, is not considered a serious adverse event.

Serious Adverse Device Effect (SADE)

Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

Unanticipated Serious Adverse Device Effect (USADE)

Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.
Note: Anticipated SADE (ASADE): an effect which by its nature, incidence, severity or outcome has been previously identified in the risk analysis report.

19.2 Methods for Discovering and Documenting AE/ADE

All subjects will be carefully monitored for the occurrence of AEs throughout the clinical investigation, from enrollment to completion the clinical investigation. Events prior to enrollment will be considered medical history. The investigator will collect safety information using non-leading questions such as “have you experienced any new health problems or worsening of existing conditions?” Events directly observed or spontaneously volunteered by subjects will also be recorded throughout the clinical investigation.

Clearly related signs, symptoms and abnormal diagnostic procedure results should be grouped together and reported as a single diagnosis or syndrome whenever possible.

All AEs, including but not limited to events reported by the subject or reported in response to an open question by the PI or member of the investigation team, which fall into any of the previously defined definitions must be recorded as an AE in the eCRF and should include the following information:

- Brief description of the event (diagnosis).
- Date of event onset (and time, if relevant).
- Date of event resolution (and time, if relevant).
- Severity.
- Seriousness.
- Causality assessment (i.e. relationship to medical device and/or procedure).
- Event treatment.
- Event outcome.

If the AE meets seriousness criteria it should be subject to expedited reporting as described in section 19.4.

19.2.1 Severity

Severity describes the intensity of an AE and will be assessed as:

1. Mild: asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
2. Moderate: minimal, local or non-invasive intervention indicated, limiting age-appropriate instrumental activities of daily living.
3. Severe or medically significant but not immediately life-threatening: hospitalization or prolongation of hospitalization indicated; disabling; limiting self care activities of daily living.
4. Life-threatening consequences; urgent intervention indicated.
5. Death related to AE.

If an AE changes in severity, it should be reported as an AE of new severity but with the same description and identifier.

19.2.2 Causality

Causality is the relationship between the use of the medical device (including the investigational device and the medical – surgical procedure) and the occurrence of each AE.

During causality assessment activity, clinical judgment shall be used and the relevant documents, such as the Investigator Brochure (IB), the CIP or the risk analysis report shall be consulted, as all the foreseeable serious adverse events and the potential risks are listed and assessed there. The presence of confounding factors, such as concomitant medication/treatment, the natural history of the underlying disease, other concurrent illness or risk factors shall also be considered.

For the purpose of harmonizing reports, each SAE will be classified according to five different levels of causality. The sponsor and the investigator will use the following definitions to assess the relationship of the SAE to the investigational medical device or procedures:

a) Not related: relationship to the device or procedures can be excluded when:
   - The event is not a known side effect of the product category the device belongs to or of similar devices and procedures;
   - The event has no temporal relationship with the use of the investigational device or the procedures;
   - The serious event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible;
   - The discontinuation of medical device application or the reduction of the levels of activation/exposure – when clinically feasible – and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the serious event;
   - The event involves a body-site or an organ not expected to be affected by the device or procedure;
   - The serious event can be attributed to another cause (e.g. an underlying or concurrent illness/clinical condition, an effect of another device, drug, treatment or other risk factors);
   - The event does not depend on a false result given by the investigational device used for diagnosis when applicable;
   - Harms to the subject are not clearly due to use error;
   - In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.

b) Unlikely: the relationship with the use of the device seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.

c) Possible: the relationship with the use of the investigational device is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/clinical condition or/and an effect of another device, drug or treatment). Cases were relatedness cannot be assessed or no information has been obtained should also be classified as possible.

d) Probable: the relationship with the use of the investigational device seems relevant and/or the event cannot reasonably be explained by another cause, but additional information may be obtained.

e) Causal relationship: the serious event is associated with the investigational device or with procedures beyond reasonable doubt when:
   - The event is known side effect of the product category the device belongs to or of similar devices and procedures;
   - The event has a temporal relationship with investigational device use/application or procedures;
   - The event involved a body-site or organ that

f) The investigational device or procedures are applied to;

g) The investigational device or procedures have an effect on;
   - The serious event follows a known response pattern to the medical device (if the response pattern is previously known);

- The discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of activation/exposure), impact on the serious event (when a clinically feasible);
- Other possible causes (e.g. an underlying or concurrent illness/clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out;
- Harm to the subject is due to error in use;
- The event depends on a false result given by the investigational device used for diagnosis, when applicable;
- In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.

The Sponsor and the investigator will distinguish between the AEs related to the investigational device and those related to the procedures (any procedure specific to the clinical investigation). An AE can be related to both the procedures and the device. Complications of procedures are considered not related if the said procedures would have been applied to the subjects also in the absence of device use/application.

Particular attention shall be given to the causality evaluation of USADE, since the occurrence of USADE could suggest that the clinical investigation places subjects at increased risk of harm than was expected beforehand.

In case of disagreement between the Sponsor and the PI assessments of the AE, both opinions shall be communicated to concerned parties.

19.3 Methods for Discovering and Documenting Device Deficiencies

Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance shall be reported as a device deficiency without unnecessary delay to the Sponsor by using the device deficiency form. It is the PI's responsibility to record every observed device deficiency together with an assessment. The Sponsor shall review all DDs and determine and document in writing whether they could have led to a SADE. Device Deficiencies that are assessed to or have SADE potential should be subjected to expedited reporting as described in section 19.4.

19.4 Reporting of SAE/SADE and Device Deficiencies with SADE Potential

The following events are considered reportable events in according with the Medical Device Directive (MDD) 93/42/EEC, Medical Device Regulation (MDR) 2017/745, and ISO 14155:2011:

a) Any SAE,
b) Any Device Deficiency that might have led to a SAE if:
   - Suitable action had not been taken or,
   - Intervention had not been made or,
   - If circumstances had been less fortunate.
   - New findings/updates in relation to already reported events.

All SAEs/SADEs and DDs that could have led to a SADE must be reported to the Sponsor immediately, but not later than 3 calendar days according to MEDDEV 2.7/3 after investigational site investigation personnel's awareness of the event, regardless of the time that may have elapsed from the time the event occurred.

The initial report should contain as much information as possible, but as a minimum the following information:

- Subject identification.
- Site contact information.
- Date of procedure/first use.
- Date of event onset.

- Event type (i.e. SAE or DD with SADE potential).
- Description of event.
- Action/treatment/subject outcome.
- Relationship to investigation procedure.
- Relationship to medical device.
- Unanticipated SADE (Yes/No).
- Treatment Arm.
- Event status.

The Sponsor must also promptly receive a completed report. All SAEs have to be reported whether or not they are considered causally related to the investigational medical device.

SAE/SADE EMERGENCY CONTACT DETAILS
Name: Romana Stefek
Phone: +46 31 746 10 24
Email: romana.svensson@essity.com

In accordance with MEDDEV 2.7/3, the Sponsor must report to the CA where the clinical investigation has commenced:

- For all reportable events as described above, which indicate an imminent risk of death, serious injury, or serious illness and that requires prompt remedial action for other patients/subjects, users or other persons or a new finding to it: immediately, but not later than 2 calendar days after awareness by sponsor of a new reportable event or of new information in relation with an already reported event.
- Any other reportable events as described above or new finding/update to it: immediately, but not later than 7 calendar days following the date of awareness by the sponsor of the new reportable event or of new information in relation with an already reported event.

The Sponsor should inform the IEC and CA about reportable events as per local requirements. The summary tabulation featured in the appendix of MEDDEV 2.7/3 shall be used. The report format (excel) for reporting of all reportable events is also available on: http://ec.europa.eu/growth/sectors/medical-devices/guidance/index_en.htm

19.5 Data Monitoring Committee

Establishment of a Data Monitoring Committee (DMC) is not considered necessary for this clinical investigation. The reason is that the risk analysis indicates no need for a DMC. In case data retrieved during the clinical investigation contradicts the risk analysis and suggests a need, this decision might be reconsidered.

20 VULNERABLE POPULATION

No subjects considered vulnerable will be enrolled in the FUEL clinical investigation.

21 SUSPENSION OR EARLY TERMINATION OF THE CLINICAL INVESTIGATION

If the investigation is terminated early or suspended due to reasons of safety, the Sponsor will promptly inform the PI and the investigation site of the termination or suspension and the reason(s) thereof. The IEC will also be informed promptly and provided with the reason(s) for the termination or suspension by the Sponsor or by the PI/investigation site.

In addition, CIP violations may result in termination of the clinical investigation at a site. CIP violations are deviations made without permission as a result of error or fraud/misconduct. Where the monitor or Sponsor identifies that the PI is out of compliance, this will be noted to the PI in writing, with a request to correct the source of the deviation immediately. Corrective actions will be implemented to avoid repeated non-compliance, including re-training. However, in case of repeated non-compliance despite implemented corrective actions, the clinical investigation will be terminated at the site.

21.1 Criteria for Breaking the Blinding Code

Not applicable, as this is a non-randomized single-arm clinical investigation.

21.2 Subject Follow-up

If the clinical investigation is prematurely terminated, the Sponsor and the PI will assure that adequate consideration is given to the protection of subjects' interest, including subject follow-up, e.g. ongoing AEs/ADEs, or subjects becoming pregnant during the course of the clinical investigation (if applicable).

22 PUBLICATION POLICY

The clinical investigation will be registered in a publicly accessible database before recruitment of the first subject.

A final report of the investigation, a Clinical Investigation Report (CIR), will be completed, even if the investigation is prematurely terminated. The report will be prepared by the Sponsor according to the guideline presented in Annex D of ISO 14155:2011. All publications and presentations must be based upon the CIR.

All information supplied by the Sponsor in connection with this investigation will remain the sole property of the Sponsor and is to be considered confidential information. No confidential information will be disclosed to others without obtaining prior written consent from the Sponsor and will not be used except in the performance of this investigation.

The Sponsor may choose to publish or present data from this investigation. If a PI is offered first authorship, he/she will be asked to comment and approve the publication. The Sponsor has the right to use the results for registration and internal presentation and for promotion.

23 REFERENCES

1. *EAU Guidelines on Urinary Incontinence.* **Burkhard, F.C, et al.** Arnhem, The Netherlands. : EAU Guidelines Office, , 2019. EAU Guidelines. Edn. presented at the EAU Annual Congress Barcelona 2019.
2. *Absorbent products for moderate-heavy urinary and/or faecal incontinence in women and men.* **Fader, M, Cottenden, A.M and Getliffe, K.** 2008, The Cochrane Database of Systematic Reviews, p. (4).
3. *Prevalence of urinary incontinence among community-dwelling adults receiving home care.* **Du Moulin, M.F, et al.** 2008, Research in Nursing and Health, p. 31(6).
4. *Urinary incontinence in a community sample of older adults: prevalence and impact on quality of life.* **Sims, J, et al.** 2011, Disability and Rehabilitation, pp. 33(15-16).
5. *Clinical Burden and Nonpharmacologic Management of Nursing Facility Residents with Overactive Bladder and/or Urinary Incontinence.* **Zarowitz, B.J, et al.** 2015, The Consult Pharmacist, p. 30(9).
6. *Open retropubic colposuspension for urinary incontinence in women.* **Lapitan, M.C.M and Cody, J.D.** 2, 2016, Cochrane Database of Systematic Reviews.
7. *Laparoscopic colposuspension for urinary incontinence in women.* **Dean, N, et al.** 3, 2006, Cochrane Database of Systematic Reviews.
8. *Mid-urethral sling operations for stress urinaryincontinence in women.* **Ford, A.A, et al.** 7, 2015, Cochrane Database of Systematic Reviews.
9. *Traditional suburethral sling operations for urinary incontinence in women.* **Rehman, H, et al.** 1, 2011, Cochrane Database of Systematic Reviews.
10. *Bladder neck needle suspension for urinary incontinence in women.* **Glazener, C.M.A and Cooper, K.** 12, 2014, Cochrane Database of Systematic Reviews.
11. *Urethral injection therapy for urinary incontinence in women.* **Kirchin, V, Page, T and Keegan, P.E.** 2, 2012, Cochrane Database of Systematic Reviews.
12. *The current role of the artificial urinary sphincter in male and female urinary incontinence.* **Islah, M, Cho, S.Y and Son, H.** 1, 2013, The World Journal of Men's Health, Vol. 31.
13. (LUCY-054) FUEL Investigator Brochure.
14. (Lucy-019) System Description.
15. (Mary-003) IFU Smart Care change indicator Professional.
16. (Lucy-024) Risk Managment Report Lucy and Mary.
17. (Lucy-017) Risk Assessment Lucy and Mary.
18. (LUCY-047) Risk managment plan Lucy and Mary.
19. PRO-00122 Risk Managment Procedure.
20. (ENG-333) Sensor verification and wetness detection report.

24 APPENDICES

24.1 Appendix A – Clinical Investigation Plan Agreement Form

Investigation code: FUEL

CIP Version: A

I agree to the terms of this CIP. I will conduct the investigation according to the procedures specified herein.

Principal Investigator

Name: Ulla Molander

Signature: _____

Date (dd-Mmm-yyyy): _____

24.2 Appendix B – Clinical Investigation Contact List

PRINCIPAL INVESTIGATOR
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CLINICAL INVESTIGATION SITE(S)
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24.3 Appendix C – Declaration of Helsinki

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington, DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

PREAMBLE

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

   The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

GENERAL PRINCIPLES

3. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient's best interest when providing medical care.”
4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.
5. Medical progress is based on research that ultimately must include studies involving human subjects.
6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.
8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.
9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal

information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.
11. Medical research should be conducted in a manner that minimises possible harm to the environment.
12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.
13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.
14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

RISKS, BURDENS AND BENEFITS

16. In medical practice and in medical research, most interventions involve risks and burdens.

    Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

    Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

    When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

VULNERABLE GROUPS AND INDIVIDUALS

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

    All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research

SCIENTIFIC REQUIREMENTS AND RESEARCH PROTOCOLS

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

    The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

    In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions

RESEARCH ETHICS COMMITTEES

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

    The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

PRIVACY AND CONFIDENTIALITY

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

INFORMED CONSENT

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study

unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

    After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

    All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.
28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.
29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.
30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.
31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.
32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

USE OF PLACEBO

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

    Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

    Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

    and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

    Extreme care must be taken to avoid abuse of this option

POST-TRIAL PROVISIONS

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

RESEARCH REGISTRATION AND PUBLICATIONS AND DISSEMINATION OF RESULTS

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.
36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

UNPROVEN INTERVENTIONS IN CLINICAL PRACTICE

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.