Evaluation of a Wetness Sensing System for Continence Care

Protocol Number
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Version 2.0

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INVESTIGATOR ACKNOWLEDGMENT SIGNATURE

- I agree to conduct the study in accordance with the relevant, current protocol and will make changes in the protocol only after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of participants.
- I agree to personally conduct and supervise the investigation as described within.
- I agree to inform all participants that the device is being used for the purposes of an investigational study.
- I will ensure that requirements relating to obtaining informed consent in the guidelines for Good Clinical Practices (GCP), and 21 Code of Federal Regulations (CFR) Part 50 and Institutional Review Board (IRB) review and approval in 21 CFR Part 56 are met.
- I agree to report to the sponsor, IRB and/or Ethics Committee, according to the protocol, adverse experiences that occur during the course of the investigation in accordance with guidelines for GCP and 21 CFR 812.
- I have read and understood the information in the protocol, including the potential risks.
- I agree to maintain adequate and accurate records in accordance with guidelines for GCP and 21 CFR 812.140 and to make those records available for inspection.
- I will ensure that an IRB compliant with the requirements of guidelines for GCP and 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human participants or others.
- I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in the guidelines for GCP and the CFR.

I have received and reviewed this investigational plan. I will conduct the study as described.

Principal Investigator (Print name):
Principal Investigator (Signature):
Date (DD-MMM-YYYY):

DOCUMENT HISTORY

VERSION	DATE	DESCRIPTION
Version 1.0	25-APR-2022	Initial Release
Version 2.0	16-JUN-2022	Revision: The original protocol was written for waist sizes, but properly fitting briefs should be measured in hip sizes. Changed waist to hip dimension (circumference) in the Inclusion Criteria, Study Design, Application of the FitRight Wetness Sensing System, Additional clarification for re-wet test also included.

1. PROTOCOL SUMMARY

1.1. Synopsis

Title:	Evaluation of a Wetness Sensing System for Continence Care
Study Description:	The investigational product to be evaluated in this study is FitRight® Connect™ Wetness Sensing System which includes: the FitRight® Connect™ Pod, the FitRight® Connect™ App, the FitRight® Connect™ charger/adapter and the FitRight® Connect™ Sensing Brief- (Medline Industries, LP) henceforth, referred to as FitRight® System, Pod, App, Charger, Alert Indicator and Brief. The purpose of this study is to validate the FitRight System sensor's ability to detect when an adult brief has absorbed enough liquid (~90-360 milliliters (mL)) normal saline via simulated urinary void to trigger an alert to change the brief.
Phase:	This is a prospective single center post-marketing study investigating the performance and user acceptance of the FitRight ® System.
Objectives:	Primary Objective: To evaluate the FitRight® System sensor's ability to detect when an adult brief has absorbed enough liquid (~90-360 mL) normal saline via a simulated urinary void to trigger an alert to change the brief in the sitting, supine, and right or left side positions. Secondary Objective: To determine the FitRight® Brief's residual volume capacity. In a subset of 22 participants, evaluate the FitRight® Brief after the brief has absorbed the maximum amount of liquid normal saline via a simulated urinary void (360 mL) in the sitting position and then weighed via the rewet procedure.
Endpoints:	Primary Endpoint: The number of FitRight® System alerts when 90-360 mL normal saline has been absorbed into the brief in the sitting, supine, and right or left side positions. Secondary Endpoint: The weight of the filter paper after performing the rewet test with the FitRight® Brief after absorbing 360 mL of normal saline via a simulated void.
Study Population:	Fifty-six healthy, normal, adult volunteers

Inclusion criteria: Healthy individuals who meet all of the following criteria will participate in this study:

- Individuals ≥18 years of age
- Individual can dress and undress self with no assistance
- Individuals can ambulate without assistance
- Individual can sit unsupported in a chair or on bedside with no assistance
- Individual can lay supine and propel self up with no assistance
- Individual can lie left/right lateral and propel self up with no assistance
- Individuals who have hip dimensions between 32" and 70" (81– 178 cm)

Exclusion criteria*:* Individuals who meet any of the following criteria will not be allowed to participate in this study:

- Individual is sensitive to the components of the study product(s).
- Individual is considered inappropriate by the Principal Investigator (PI).
- Individual has self-reported current skin condition(s) or issues around the sacral or perineal areas, such as open sores, sacral pressure injuries, rash, burns, surgical wounds and/or compromise of skin integrity.
- Individuals who cannot complete all phases of the study requirements.
- Individual requires use of an absorbent undergarment or catheter as the primary incontinence management strategy
- Individuals who are pregnant

Description of Sites/Facilities Enrolling

Rochester Clinical Research located in Rochester, NY

Participants:

Fifty-Six Participants

Description of Study design:

Each participant will be provided with the FitRight ® System for the duration of the study. The study products will be used to collect real-life measurement data in order to assess the FitRight® System. Each participant will be asked to wear at least three briefs so that they are wearing each brief during the simulated voids performed by the site staff.

The site staff will perform the simulated void by addition of (90-360 mL normal saline to the brief. The FitRight® System will be assessed for alerts while participants are in the

following positions: supine, sitting, and laying on either left or right side. Each participant will be randomized to either the left or right side. Twenty-two of the fifty-six participants will perform rewet testing procedures. The study results will be used to assess the reliability of the device's absorption to trigger an alert.

Participant Duration: Approximate time will be two hours for each participant to complete the procedures.

1.2 Schedule of Activities (SOA)

Study Timeline of Events [a]	Pre-Study	During the Study	End of the Study
Informed Consent	X		
Verification of eligibility	X		
Randomization	X		
Participant applies first brief with tubing (study staff checks for correct application) and participant sits in sitting position.		X	
Study staff pours 90mL saline and starts timer for five minutes.		X	
After five minutes, staff records whether an alert was triggered. Staff pours an additional 150mL saline and starts a timer for five minutes. [b, c]		X	
After five minutes, staff records whether an alert was triggered. Staff pours an additional 120mL saline and starts a timer for five minutes. [b, c]		X	
After five minutes, staff records whether an alert was triggered. Staff pours an additional 120mL saline and starts a timer for five minutes. [b, c]		X	
After five minutes, staff records whether an alert was triggered. [d]		X	

Participant removes the first brief and applies second brief with new tubing (study staff checks for correct application) and participant lays in supine position.		X	
Study staff pours 90mL saline and starts timer for five minutes.		X	
After five minutes, staff records whether an alert was triggered. Staff pours an additional 150mL saline and starts a timer for five minutes. [b, c]		X	
After five minutes, staff records whether an alert was triggered. Staff pours an additional 120mL saline and starts a timer for five minutes. [b, c]		X	
After five minutes, staff records whether an alert was triggered. Staff pours an additional 120mL saline and starts a timer for five minutes. [b, c]		X	
After five minutes, staff records whether an alert was triggered. [d]		X	
Participant removes the second brief and applies third brief with new tubing (study staff checks for correct application) and participant lays in their randomized side position (either left or right side).		X	
Study staff pours 90mL saline and starts timer for five minutes.		X	
After five minutes, staff records whether an alert was triggered. Staff pours an additional 150mL saline and starts a timer for five minutes. [b, c]		X	
After five minutes, staff records whether an alert was triggered. Staff pours an additional 120mL saline and starts a timer for five minutes. [b, c]		X	
After five minutes, staff records whether an alert was triggered. Staff pours an additional 120mL saline and starts a timer for five minutes. [b, c]		X	
After five minutes, staff records whether an alert was triggered. Participant will remove brief [d]		X	
All participants will complete steps above. Only the first 22 participant will go on to complete the following steps.			

Participant applies new brief (study staff checks for correct application) and participant is in sitting position.[e]		X	
Study staff pours 360 mL saline into the brief and starts a timer for ten minutes. [e]		X	
After ten minutes, participant removes brief and gives it to the staff. [e]		X	
Staff weighs out at least 10.0 grams filter paper and records the weight. Staff places the filter paper centered on the wet brief and over the acquisition and dryness layer (ADL) places the calibrated weight on the filter paper and starts a timer for one minute.		X	
After one-minute, calibrated weight and filter paper is removed and the filter paper is weighed, and the weight is recorded.		X	
Study staff will complete steps below for all participants.			
Evaluation for adverse events	X	X	X
Participant dismissal			X

[a] Study activity will occur after informed consent has been signed and the participant has met all the inclusion criteria and none of the exclusion criteria.

[b] This pour will only occur if the previous pour(s) did not trigger an alert. If the previous pour did trigger an alert the participant will either move to the application of the next brief or the participant will be dismissed if they are at the end of their participation.

[c] If the Pod alerts prior to the fourth pour, it is considered a pass. If it doesn't alert after five minutes post the third pour, it is a failure. Note: There is no minimum pour volume for the first alert.

[d] Whether there was an alert triggered or not, participant will either move to the application of the next brief or the participant will be dismissed if they are at the end of their participation.

[e] This step is part of the rewet testing. Only the first 22 participants enrolled in the study will perform the rewet testing.

2 INTRODUCTION

2.1 Background & Rationale

Incontinence-Associated Dermatitis (IAD) is an inflammation of the skin that can occur when urine or feces come into contact with the perineal or perigenital skin.[1] The cause of IAD is incontinence of urine or bowel that results in a color change of the skin from pale to pink or deep red.[2] In addition. IAD is often associated with skin breakdown caused by pressure or shear.

According to the United States (US) Department of Human Services, the prevalence of a urinary and/or bowel incontinence among non-institutionalized persons aged 65 and over was 50.9%.[3] Among institutionalized persons aged 65 and over, 39.0% reported urinary and/or bowel incontinence. Urinary incontinence was approximately two times more likely than bowel incontinence. Women were 1.2 times more likely to have urinary incontinence compared to men, while there was no difference in bowel incontinence. Also, there were no significant differences for incontinence among age, race, or educational background.[3]

In a similar study of 5342 acute care facility residents the prevalence rate of urinary and/or fecal incontinence was 45.7% and the overall IAD prevalence rate was 21.3% among the same acute care facility residents.[4] In studies where prompted-voiding were encouraged, 30-66% percent of nursing home residents were able to reduce the episodes of incontinence to one episode per day.[5] In addition, residents who achieved successful prompted urinary voiding during a 3-day trial period tended to maintain continence over a longer period of time.[6]

In an attempt to keep residents dry and make their urinary incontinence more manageable, caregivers place residents in absorbent incontinence products also known as adult briefs, which they check periodically for wetness and change when appropriate. Each resident is unnecessarily woken more than once per night only to discover that they don't need to be changed. This inefficient process of checking and changing the residents exists due to a lack of real-time data of residents' urinary patterns. This lack of data results in residents spending hours at a time in a wet brief increasing their risk of developing dermatitis, and pressure ulcers. Sleep is also compromised when caregivers wake up and check the residents during the night only to find that they are dry.

The use of adult disposable incontinence management products, primarily adult briefs (diapers) are used almost exclusively in this population due to decline in strength, intellect and physical ability. Those suffering from incontinence may lie in soiled diapers for prolonged periods of time resulting in indignity, discomfort, skin breakdowns and bedsores. But timely diaper change is needed to avert the problems of staying in soiled diapers. Ideally, caregivers must know who is incontinent and attend to those with soiled diaper without delays. But incontinence episodes can occur at any time; there is no fixed or regular timing. The current practice requires caregivers to check diaper wetness from one patient to another and to perform these scheduled diaper checks at every specified interval. This approach is time consuming, expensive, and labor intensive.

So it is not feasible and effective to provide around the clock care to multiple incontinent residents in nursing homes. Management of incontinence is an essential component of care provided in hospitals, long-term care homes, assisted living, retirement homes, private homes, and geriatric institutions. A key aspect of treating and preventing skin damage is to protect the skin from irritant exposure (such as urine). In order to minimize a resident's time spent in a filled brief, care providers may adhere to toileting schedules for each resident. Alternatively, they may adopt a "check-and-change" system

whereby residents' containment briefs are checked periodically for wetness when appropriate or convenient, and subsequently changed if wet.

In order to provide a desirable level of continence management, one solution is the use of a device that is designed to notify caregivers when incontinence episodes take place.[7] There are products and devices available today, but none have been found to be a realistic, viable solution to aid caregivers with this daunting, time-consuming task of managing incontinence. In order to address this concern, we propose a solution using FitRight® System to aid caregivers of timely diaper changes. FitRight® System improves incontinence management by continuously monitoring incontinence episodes, empowering patient care staff in long-term care (LTC) settings with the data used to determine the appropriate continence care decisions.

The FitRight® System, aims to reduce or remove the "check" from check-and-change, using patent-pending technology to continuously monitor residents' briefs for wetness. The FitRight® System then wirelessly transmits this information to caregivers via a handheld device such as an iPod Touch. In doing so, the FitRight® System solution empowers caregivers to better manage their workflow while improving their residents' quality of life. The introduction of wearable technology into the set of tools used in incontinence management will reduce the time a resident is exposed to urine, thereby reducing the risk of associated (and costly) skin conditions. To institutions, this means indirect and direct cost savings and enhanced care compliance.

2.2 Study Product(s)

The investigational product being evaluated in this study is the FitRight® Connect™ Wetness Sensing System that includes the FitRight® Connect™ Pod, FitRight® Connect™ App, FitRight® Connect™ charger/adapter and FitRight® Connect™ Brief.

2.2.1. Product Overview:

The FitRight® Pod is a wearable sensor that monitors adult briefs for wetness and notifies caregivers when a resident becomes wet. In doing so, the FitRight® System may remove the need for caregivers to unnecessarily check residents while simultaneously ensuring residents are changed promptly as required. The FitRight® Pod is reusable and works by attaching to the outside of the FitRight® Brief. From the outside of the brief, the FitRight® Pod is able to monitor for and characterize moisture on the inside of the brief using a technique called impedance sensing.

The FitRight® Pod then transmits information wirelessly to a Wi-Fi enabled tablet. At a glance, caregivers can view the residents under their care, see who is wet and therefore requires immediate attention, and who is dry and shouldn't be disrupted.

2.2.2 Product Description:

The FitRight® System is used to help monitor and alert caregivers when it is appropriate to change the FitRight® Brief. The FitRight® System is composed of a wetness sensing brief, a pod that connects to Wi-Fi, and software that displays alerts on a display (FitRight® App). The FitRight® Brief is a wetness detection brief that is a non-sterile, disposable, single use device with a reusable wetness alert sensor (FitRight® Pod).

The FitRight® System alerts caregivers when a patient has micturated within the FitRight® Brief. An ink-based sensor is printed on the poly backsheet layer of the FitRight® Brief and when urine contacts the ink for a predetermined amount of time, it sends an alert to the FitRight® Pod that is attached on/secured to the outside of the FitRight® Brief. The FitRight® Pod translates that alert (via Wi-Fi) to the software application using a cloud-based server that is loaded on to a display device chosen by the user.

2.3 Risk/Benefit Profile

2.3.1 Potential Study Risks

This study entails minimal risk to the participants. The FitRight® System will be applied and operated according to the instructions for use (IFU). There is the possibility of minor skin irritation from the brief due to saline interaction, however, none is anticipated. In addition, the products will also be applied on the non-compromised skin of participants with no known skin conditions, which should impose less risk for study participants.

2.3.2 Potential Study Benefits

There may be no direct benefit to participants as a result of their participation in the study. The information gathered from this study may provide useful information to healthcare providers (HCP) on the efficacy of the FitRight® System. The knowledge gained as a result of this study may be used to identify novel approaches to improved incontinence care.

2.3.3 Assessment of Potential Risk/Benefit Profile

As this study entails minimal risk to the study participants and the results may identify novel approaches to improved incontinence care, the risk/benefit profile of this study is acceptable.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINT(S)
Primary Objective: To evaluate the FitRight® System sensor's ability to detect when an adult brief has absorbed enough liquid (~90-360 mL) normal saline via a simulated urinary void to trigger an alert to change the brief in the sitting, supine, and right or left side positions.	Primary Endpoint: The number of FitRight® System alerts when 90-360 mL normal saline has been absorbed into the brief in the sitting, supine, and right or left side positions.	To determine the wetness/absorbency efficacy of the FitRight® Alert indicator in three positions
Secondary Objective: To determine the brief's residual volume capacity . In a subset of 22 participants, evaluate the FitRight® Brief after the brief has absorbed the maximum amount of liquid normal saline via a simulated	Secondary Endpoint: The weight of the filter paper after performing the rewet test with the FitRight® Brief after absorbing 360 mL of normal saline via a simulated void.	To determine the brief's residual volume capacity for possible improvements to the FitRight® System.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINT(S)
urinary void (360 mL) in the sitting position and then weighed via the rewet procedure.		

4 STUDY DESIGN

4.1 Overall Design

The purpose of this study is to validate the FitRight® Sensor's ability to detect when an adult brief has absorbed enough liquid (90-360 mL normal saline via simulated urinary void) to trigger an alert to change the brief. Data will be collected from healthy, normal, adult volunteers and will be used to assess the device's absorption and ability to trigger an alert.

Each participant will be provided with the FitRight® System for the duration of the investigation. Briefs will be used to collect real-life measurement data in order to validate the FitRight® System algorithms and the FitRight® Alert Indicator.

Each participant will be measured for the appropriately sized briefs using the participant's hip dimension and will wear this size throughout the study. Three sized briefs will be worn in three different positions (sitting, laying supine, and laying on either left or right side) in order to determine the efficacy of the FitRight® Alert Indicator. Participants will apply the briefs themselves and study staff will confirm correct application. Tubing will be setup in order to apply normal saline directly to the center of the brief.

Study staff will pour 90mL normal saline (first pour) to the brief via the tubing and will start a timer for five minutes. After five minutes, study staff will record whether the FitRight® Alert Indicator triggered an alert. Note: there is no minimum volume for the alert. If the alert does trigger, participant will remove the brief and apply the next brief for the next position. If the alert did not trigger, study staff will apply 150mL normal saline (second pour) and will start a timer for five minutes. After five minutes, study staff will record whether the FitRight® Alert Indicator triggered an alert. If the alert does trigger, participant will remove the brief and apply the next brief for the next position. If the alert did not trigger, study staff will apply 120mL normal saline (third pour) and will start a timer for five minutes.

After five minutes, study staff will record whether the FitRight® Alert Indicator triggered an alert. If the alert does trigger, participant will remove the brief and apply the next brief for the next position. If the alert did not trigger, study staff will apply 120mL normal saline (fourth pour) and will start a timer for five minutes. After five minutes, study staff will record whether the FitRight® Alert Indicator triggered an alert. Whether the FitRight® Alert Indicator triggered an alert or not, the participant will remove the brief and apply the next brief for the next position. Study staff will record whether the brief passed or failed to indicate. If the brief triggered an alert within the five minutes after the first, second, or third saline pour and prior to the fourth pour, the brief passed. If the brief did not trigger an alert by five minutes after the third pour, the brief fails. The fourth pour, if required, will help to determine if more volume was needed to trigger the alert or if the brief was defective.

The first 22 participants enrolled in the study will perform the rewet procedures. Participants will apply the sized brief and study staff will confirm correct application. Tubing will be setup in order to apply normal saline directly to the center of the brief. Study staff will pour 360 mL normal saline to the brief via the tubing and will start a timer for ten minutes. After ten minutes, participants will remove the brief and give the brief to the study staff. Study staff will weigh out at least 10.0 grams(g) filter paper (and as close to 10.0g as possible) and record the weight. Study staff will apply the filter paper centered on the wet brief and over the ADL layer, , apply a calibrated weight to the top of the filter paper, and start a timer for one minute. After one minute, the study staff will remove the calibrated weight and filter paper and weigh the wetted filter paper and record the weight. If any leakage or fluid infusion related issues occur during rewet testing this will be considered an invalid test (test failure) and this case will not be counted toward the 22 cases needed for rewet testing The data will still be recorded.

4.2 End of Study Definition

The study will be complete when 56 participants have completed the simulated voiding procedure and 22 participants have completed the rewet testing. This study will be considered complete upon issuance of a Clinical Study Report that has been approved by the Clinical Affairs Director.

5 STUDY POPULATION

5.1 Inclusion Criteria

Individuals must meet the following requirements to be enrolled in the trial:

- Individuals >18 years of age
- Individual can dress and undress self with no assistance
- Individuals can ambulate without assistance
- Individual can sit unsupported in a chair or on bedside with no assistance
- Individual can lay supine and propel self up with no assistance
- Individual can lie left/right lateral and propel self up with no assistance
- Individuals who have hip circumference dimensions between 32” and 70” (81– 178 cm)

5.2 Exclusion Criteria

Individuals who meet any of the following criteria will not be allowed to participate in this study:

- Individual is sensitive to the components of the study product(s).
- Individual is considered inappropriate by the Principal Investigator (PI).
- Individual has self-reported pre-existing skin condition, such as open sores, sacral pressure injuries, rash and/or compromise of skin integrity.
- Individuals that cannot complete all phases of the study requirements.
- Individual has self-reported issues around the sacral or perineal areas and/or existing burns or surgical wounds
- Individual requires use of an absorbent undergarment or catheter as the primary incontinence management strategy
- Individuals who are pregnant

5.3 Strategies for Recruitment and Retention

Participants will be recruited from a database in which they have agreed to be contacted for studies or through IRB approved advertising. New participant(s) will be recruited if any participant withdraws from or is unable to complete the study, such that the total number of participants who complete the study are 56.

5.4 Early Withdrawal and Replacement

Each participant will remain on the study until they have completed up to four simulated urinary void cycles in each of the 3 positions: supine, sitting, and laying on either left or right side or they are withdrawn for any reason. Participants that withdraw or are withdrawn early will be replaced. Fifty-six participants are required to successfully complete the testing. Twenty-two of the 56 participants will also perform the rewet testing procedure.

6 STUDY PROCEDURES AND ASSESSMENTS

Pre-Visit Activities

6.1. FitRight® Wetness Sensing System Procedure Training

- The staff at the site will receive training by a Medline Industries, LP. Clinical Research Associate (CRA) and/or Clinical Product Specialist on the use of the FitRight® System products prior to the start of use.
- The training logistics will be coordinated between the Medline CRA and/or Clinical Product Specialist with the PI and site staff.
- The Medline CRA and/or Clinical Product Specialist will train a site staff member to be the ongoing trainer of other site staff members as needed.
- The trainer will be a delegated site staff member who will be able to identify staff who were not available at Site Initiation training that will be responsible for performing study activities. Training will be done using Medline provided materials and with any needed support from Medline CRA or Clinical Product Specialist.

6.2. Informed Consent

The study staff will obtain written informed consent from the participant. The written consent must be obtained from all participants and documented on an Informed Consent form (ICF) that has received approval by an IRB/Ethics Committee. The ICF must be written in adherence to GCP and must comply with all elements required by United States (U.S.) Food and Drug Administration (FDA) 21 CFR 50.25 and International Conference on Harmonization (ICH) 4.8, state and local regulations, and additional elements relevant to specific study situations (including a statement that Medline Industries, LP. and relevant authorities have access to participant records). A copy of the signed consent will be given to each participant.

6.3. Verification and Eligibility

Delegated study staff will verify the eligibility of the individual for the study, based on the inclusion and exclusion criteria that will be evaluated in the Participant Screening Form (PSF). Reasons for

participant exclusion will also be documented on the PSF. The participant will receive a unique screening number that will be recorded in the PSF. Demographic information of the participants will also be documented in the PSF.

Successfully enrolled participants will be assigned a unique participant identification number based on the order in which they enroll. Participants will be assigned a randomization sequence for right or left side position according to the Randomization Schedule. The Randomization Schedule, case report forms (CRFs), PSF, and other study-related documents will be provided separately to the study personnel.

6.4. Evaluation of Study Products

Rochester Clinical Research site staff will be responsible for recording participants name and participant identification number so that future identification of study participants can be made if necessary. PI/site staff will be responsible for providing Medline CRA with access to the records for all study participants. Prior to the start of the study, the Medline CRA, and product specialist will assist the study site with initial set-up of the technology/software components required. Refer to FitRight® System IFU.

6.4.1. Application of the FitRight Wetness Sensing System

Participants will be measured for their hip circumference. Participants will be given the brief for their size (available sizes are medium-2XL) that corresponds to the circumference measurement. Study staff will use their discretion to select the applicable size. Study staff will record on the CRF which size was provided to the participant. Following the IFU, participants will be given space to privately apply the FitRight® Brief and tubing. Once the brief is on and tubing is in place, study staff will apply exam gloves and assess the brief for correct application. If the brief or tubing needs to be adjusted, participants will be given more time to privately make adjustments. The tubing should be placed directly in the center of the bottom of the brief at the approximate location of urination.

Once the tubing is in place and the brief is applied correctly, participants will be instructed to sit on the bed in a sitting position. If the tubing moves, participants should again adjust the tubing to the correct position. Study staff will then apply the FitRight® Pod to the brief according to the IFU and make sure that the FitRight® App is indicating the Pod is connected. Once the FitRight® Pod and FitRight® App are properly setup, study staff will connect the tubing in the brief to the tubing connected to the funnel system.

6.4.2 Normal Saline Pours

Once the FitRight® System and tubing is properly setup on the participant, the study staff will pour 90 milliliters (mL) of normal saline (first pour) through the funnel system to enter the brief. Study staff will immediately start a calibrated timer for five minutes once the saline drains from the funnel system. After the five minutes, study staff will document whether the brief did or did not trigger an alert. If the brief triggers an alert, the brief passes and the participant is ready for the next brief. If the brief does not trigger an alert, study staff will pour an additional 150mL normal saline (second pour) through the funnel system and will immediately start a calibrated timer for five minutes once the saline drains from the funnel system.

After the five minutes, study staff will document whether the brief did or did not trigger an alert. If the brief triggers an alert, the brief passes and the participant is ready for the next brief. If the brief does not trigger an alert, study staff will pour an additional 120mL normal saline (third pour) through the filtration system and will immediately start a calibrated timer for five minutes once the saline drains from the funnel system.

After the five minutes, study staff will document whether the brief did or did not trigger an alert. If the brief triggers an alert, the brief passes and the participant is ready for the next brief. If the brief does not trigger an alert, the brief fails, and study staff will pour an additional 120mL normal saline (fourth pour) through the funnel system and will immediately start a calibrated timer for five minutes once the saline drains from the funnel system. After the five minutes, study staff will document whether the brief did or did not trigger an alert. No matter if the brief did or did not trigger an alert, the participant will move onto the next brief. The fourth pour, if required, will help to determine if more volume was needed to trigger the alert or if the system was defective.

Participants will remove the brief and apply a new brief (in their appropriate size) with new tubing as outlined in Section 6.4.1 Participants will be asked to lay in a supine position and study staff will perform the same steps as outlined in Section 6.4.2 above. Once participants and study staff have completed all steps in the supine position, participants will remove the brief and apply another new brief (in their appropriate size) with new tubing as outlined in Section 6.4.1. Study staff will refer to the Randomization Schedule to determine the next position the participant will be in (laying on either the left or right side). Study staff will then perform all of the same steps as outlined in Section 6.4.2.

6.4.3 Rewet Procedures

Twenty-two participants enrolled in the study will perform the rewet testing procedures. Participants will apply the sized FitRight® Brief and tubing as outlined in Section 6.4.1 above and study staff will confirm correct application. The FitRight® Pod will not be applied to the brief for this testing. Study staff will pour 360 mL normal saline through the funnel system to enter the brief. Study staff will immediately start a calibrated timer for ten minutes once the saline drains from the funnel system. After the ten minutes, participants will remove the brief and give the brief to the study staff. Study staff will weigh out at least 10.0g filter paper (and as close to 10.0g as possible) and record the weight (in grams). Study staff will apply the filter paper centered on the wet brief and over the ADL layer, apply a calibrated weight to the top of the filter paper, and immediately start a calibrated timer for one minute. After the one minute, the study staff will remove the calibrated weight and filter paper and weigh the wetted filter paper and record the weight in grams to the first decimal point (ie: tenth of a gram). If leakage or fluid related issues are noted, they will be recorded on the CRF. The re-wet test will be considered an invalid test (test failure) if leakage is noted. Additional participants will be tested until 22 valid re-wet tests are completed.

6.4.4 Rewet Procedure Measurement

After the participants have been dismissed from the study, the Medline Industries, LP. statistical team will calculate the rewet testing results using the weights collected during the rewet testing. The rewet measurement will be calculated as follows:

Rewet measurement = (weight of the wetted filter paper) - (weight of the dry filter paper)

6.4.5. FitRight® Pod Disinfection

The FitRight® Pods should be disinfected between participants. To disinfect the FitRight® Pods, study staff will don gloves and wipe all surfaces of the FitRight® Pod with EPA- registered 0.65% bleach concentration solution and allow for proper dry time. After disinfecting, study staff will remove and dispose of gloves and perform optimal hand hygiene. Study staff will record the number of times that the pod has been disinfected. Each pod has a maximum of 12 disinfections. Once a FitRight® Pod has been disinfected 12 times, the pod can no longer be used and will be returned to Medline Industries, LP.

7 ADVERSE DEVICE EVENTS (ADEs)

7.1 Definition of Adverse Device Event (ADE)

Any adverse event related to the use of an investigational medical device resulting from insufficiencies or inadequacies in the instructions for use, the deployment, installation, the operation, or any malfunction of the investigational medical device or from error use.

7.2 Definition of Serious Adverse Device Event (SADE)

Any adverse device events that have resulted in any of the consequences characteristic of a serious adverse event. The FDA definition of a SAE will be used in this study: An AE or suspected adverse reaction is considered "serious" if, in the view of either the PI or sponsor, it results in any of the following outcomes:

- Death,
- A life-threatening adverse event,
- Inpatient hospitalization or prolongation of existing hospitalization,
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or
- A congenital anomaly/birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. All SADEs will be reported to Medline, regardless of potential relationship to the study product(s). SADEs will be reported to the reviewing IRB as necessary according to their reporting requirements.

7.3 Definition of Unanticipated Adverse Device Effect (UADE)

Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants.

7.4 Severity of Adverse Device Event

The severity of all AEs will be graded on a scale of one through five according to the Common Terminology Criteria for AE guideline, where each grade represents a unique clinical description based on this general guideline:

- **Mild (1 = Grade 1):** Awareness of signs or symptoms, but easily tolerated; are of minor irritant type, causing no loss of time from normal activities; symptoms would not require medication or a medical evaluation; signs and symptoms are transient.
- **Moderate (2 = Grade 2):** Discomfort severe enough to cause interference with usual activities; requiring treatment but not extended hospitalization or intensive care for the participant.
- **Severe (3 = Grade 3):** Incapacitating with inability to do work or usual activities; signs and symptoms may be systemic in nature or require medical evaluation and/or treatment; requiring additional hospitalization or intensive care (prolonged hospitalization).
- **Life-threatening (4 = Grade 4**): At immediate risk of death in view of the investigator, or it is suspected that the use or continued use of the product would result in participant's death; urgent intervention indicated.
- **Death (5 = Grade 5):** Death related to adverse event.

7.5 Relatedness of Adverse Device Event and Serious Adverse Device Event

List the criteria for determining the probability that a given AE is related to participation in the study. A common rating system is provided below.

- **Unrelated:** This category applies to those AEs which, after careful consideration, are clearly and incontrovertibly due to extraneous causes (disease, environment, etc.)
- **Possible:** This category applies to those AEs for which, after careful medical consideration at the time they are evaluated, a connection with the Investigational Product administration appears unlikely but cannot be ruled out with certainty.
- **Probable:** This category applies to those AEs which, after careful medical consideration at the time they are evaluated, are felt with a high degree of certainty to be related to the study product(s).
- **Definite:** This category applies to those AEs which, after careful consideration, are clearly and incontrovertibly due to the study product(s).

7.6 Expectedness

The site PI will be responsible for determining whether an ADE or SADE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described.

Expected ADEs or SADEs may include any ADEs or SADEs that may occur as a result of using the FitRight Wetness Sensing System including but not limited to the following:

- **Skin irritation** or inflammation causing pain, discomfort and swelling.
- **Contact dermatitis:** Skin AEs potentially related to the brief and securement including itching, rash, blister, skin tear, bruising, and pressure areas

The PI will be responsible for determining whether an ADE or SADE is anticipated or unanticipated. An AE will be considered unanticipated if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

7.7 Adverse Device Event (ADE) Reporting

The ADEs will be recorded on the ADE Form (provided by Medline Industries, LP.) by the study staff and reviewed by the PI. Changes in the severity of an ADE will be documented to allow an assessment of the duration of the event at each level of severity. Changes in severity will necessitate a new ADE Form to document the new level of severity. ADEs characterized as intermittent require documentation of onset and duration of each episode.

Non-serious ADEs will be reported to the study sponsor on a monthly basis for review or as agreed upon with the study sponsor and reported to the IRB per IRB reporting requirements.

7.8 Serious Adverse Device Event and Unanticipated Adverse Device Effect Reporting

The PI shall complete an SADE Form (provided by Medline Industries, LP.) and submit to the study sponsor as soon as possible, but in no event later than 48 hours after the PI first learns of the effect. The PI will be responsible for reporting the event to the IRB, if applicable, per the IRB's reporting requirements. The study sponsor is responsible for conducting an evaluation of the SADE and shall report the results of such evaluation to the FDA and to all reviewing IRBs, if applicable, within 10 working days after the sponsor first receives notice of the effect. Thereafter, the sponsor shall submit such additional reports concerning the effect as FDA requests.

For questions regarding this process or the event, you may contact your Medline clinical designee or the Medline Director of Clinical Operations.

Name: Julie Miller, RN BSN CCRA
Phone: 630-418-6891
E-mail: clinicaloperations@medline.com

8 STATISTICAL CONSIDERATIONS

8.1 Sample Size Determination

A sample size of 56 was chosen to evaluate the 95% confidence interval on the proportion of successful wetness alerts. The NCSS PASS procedure "Confidence Intervals for One Proportion" was used to solve for "CI width or distance from P to limit". It was assumed that the proportion of successes would be around 90% (0.85, 0.90 and 0.95 entered into PASS). Because testing will occur in 8 subgroups, the largest sample size that was a multiple of 8 that provided the most narrow 95% confidence limits was selected (N=56).

Rewet testing sample size: A convenient subset of the first 22 completed patients will be recruited for the rewet procedure. Patients will be considered complete if they have all data, for all three of the brief tests.

8.2 Randomization

Patients were randomized into two equal groups of 28 by means of a SAS® software generated random seed number and randomization program (Copyright © 2013 SAS Institute Inc.) only for the side position. Twenty-eight patients will complete the test using their right side and 28 will complete the test using their left side. Practically, it will be impossible to blind the staff and patients to the left or right side, as it will be apparent. Thus, the randomization will only be blinded to the analyst to ensure an un bias analysis.

8.3 Populations for Analyses

The reliability analyses will be performed on the intent to treat (ITT) population which consists of all participants who participated in one full round of the study, meaning they have full data on all covariates as well as the volume of fluid administered, the position, and whether or not the sensor triggered. For the rewet testing all data collected will be analyzed.

A per protocol analysis is planned to examine the cases of rewet testing when leakage did not occur.

8.4 Protocol Deviations

The list of protocol deviations will be compiled prior to database lock. All deviations will be reviewed and decisions for handling each of the deviations will be made prior to the start of data analysis.

8.5 Endpoints

8.5.1. Primary Endpoint

FitRight® System alert value of pass (=1) or fail (=0), for each given value of fluid added (90, 150, 120, and 120 mL) and for each rotational position in the brief (sitting, laying supine, left side, and right side)

8.5.2. Secondary Endpoint

The weight of the filter paper (in grams) after performing the rewet test with the FitRight® Brief after absorbing 360 mL of normal saline via a simulated void.

8.5.3 Additional Endpoints

The percentage of pass alerts that were correctly triggered ((# passed/tests) x 100) and the percentage of failed alerts ((# fail/ # tests) x 100) will also be evaluated for the whole sample and stratified by volume of fluid and rotational position.

8.6 Demographics, Variables and Covariates

Age will be collected as a continuous measure, with all participants being ≥>=18 years of age. Age strata will be defined as stratum 1: 18-25 years old, stratum 2: 26-41 years old, stratum 3:

42-57 years old, stratum 4: 58-67 years old, stratum 5: 68-76 years old, stratum 6: 77-94 years old, 95+ years old. Age will be considered for secondary analysis.

Sex will be collected as a categorical equal to 0=male, 1=female, 2=other, or 3=decline to answer. Sex will be considered for secondary analysis.

Brief size will be recorded as a categorical measure and will be used as a proxy for participant weight for secondary analysis.

Rotational position of the participant during the procedure will be collected as a categorical measure equal to 1=sitting, 2=supine, 3=left side or 4=right side. Rotational position will be used in the primary analysis.

Volume of simulated urine added to the brief will be collected as a categorical measure of 90 mL, 150 mL, 120 mL, and 120 mL. The volume of fluid will be used in the primary analysis.

Nominal measures of data collected will include the participant ID, date of first brief application through removal.

8.7 Derived Variables

A variable will be created to indicate if a test should have passed for a given volume of fluid added to the brief. Correct pass =1 if a minimum of 90mL of fluid, else correct pass=0.

8.8 Handling of Missing Values

Listwise deletion of observations with missing data is necessary to correctly calculate Cronbach's coefficient alpha and for the chi-square test, therefore listwise deletion will be used for the reliability analysis and chi-square analysis. All missing data will be quantified in the final report and possible biases for any missing data will be reported.

8.9 Statistical Analysis

Statistical analyses will be conducted in SAS® software, Version 9.4 or higher of the SAS System for Windows (Copyright © 2013 SAS Institute Inc.) or other appropriate statistical software. $P<0.05$ will be considered statistically significant.

All continuous variables will be summarized using the following descriptive statistics: (non-missing sample size), mean, standard deviation, median, maximum and minimum. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical measures. 95% confidence intervals will be calculated for all means. In addition to summary statistics for the full sample and for each of the four positions with the key variable of interest being the percentage of tests that passed and those that failed for the full sample and for each of the four rotational positions will be calculated.

8.9.1 Analysis of Primary Endpoints

The primary goal of this research study is to assess the reliability of the FitRight® Alert Indicator for the full sample and stratified by the four rotational positions, the three different fluid amounts,

and the combination of rotational positions and fluid amounts. Cronbach's coefficient alpha estimate's reliability by determining the internal consistency of a test or the average correlation of items within a test. The pass/fail values from this set of test runs will be compared to the derived variable of whether or not the test should have triggered an alert. Since the variables of interest are dichotomous (pass/fail), the coefficient alpha is equivalent to the Kuder-Richardson 20 (KR-20) reliability measure. It produces a correlation measure between 0 where a high KR20 coefficient (e.g., >0.90) is indicative of a homogeneous test. A reliability of 0.70 or higher for an acceptable rating and 0.80 or higher for a good rating.

In addition, a chi-square analysis will be conducted to determine if any association between rotational position and test status (pass/fail) exists. This analysis will be repeated to examine any possible associations between fluid added and test status (pass/fail).

Spearman correlation analysis will be used to examine possible associations between the key variables of triggered alert value (pass/fail), rotational position (sitting, supine, left side, right side), and fluid volume of 90 mL, 150 mL, 120 mL, and 120 mL with covariates of age, sex, and brief size. Additional t-tests or non-parametric tests will be employed to further examine any significant associations found in the correlational analyses between key and covariate measures.

8.9.2 Analysis of Secondary Endpoints

The secondary goal is to determine the FitRight® Brief's residual volume capacity . In a subset of 22 participants, evaluate the FitRight® Brief after the brief has absorbed the maximum amount of liquid normal saline via a simulated urinary void (360 mL) in the sitting position. The wetted filter paper will -then be weighed. The rewet measurement will be calculated using the calculation shown below.

Rewet measurement = (weight of the wetted filter paper) - (weight of the dry filter paper)

9. Regulatory and Ethical Considerations

9.1. Confidentiality and Privacy

In all research involving human participants, confidentiality of identifiable information is presumed and must be maintained unless the investigator obtains the express permission of the participant to do otherwise. Participants have the rights to be protected against injury or illegal invasions of their privacy and to preservation of their personal dignity. The more sensitive the research material, the greater the care that must be exercised in obtaining, handling, and storing data.

In order to minimize the risk for loss of confidentiality, investigators should only collect personal information that is absolutely essential to the research activity. If personal data must be collected, it should be coded as early in the activity as possible and securely stored so that only the investigator and authorized staff may access it. Identities of individual participants must never be released without the express consent of the participant. In addition, if an investigator wishes to use data for a purpose other than the one for which it was originally collected and the data are still identifiable (e.g., a code list for the data still exists), the investigator may need to obtain consent from the participants for the new use of the data.

Participant confidentiality and privacy is strictly held in trust by the PI, the staff, and the sponsor. Therefore, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study, or the data will be released to any unauthorized third party without prior written approval of the sponsor. All study data and study records will be managed and stored in accordance with the site's policies on data storage and security. All electronic transmission of data will adhere to Health Insurance Portability and Accountability Act (HIPAA) and any local regulations.

The study monitor, other authorized representatives of the sponsor, representatives of the IRB, and regulatory agencies may inspect all documents and records required to be maintained by the PI, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

A master list linking participant numbers to patient name and medical record number will be maintained in a secure database by the PI or paper files in secure cabinet(s). The study participant's contact information will be securely stored at each clinical site for internal use during the study. The PI will agree to notify the sponsor of any intent to move or destroy these documents.

9.2 Safety Oversight

Safety oversight will consist of monitoring of visit activity ADEs and SADEs by the PI, who is suitably qualified and experienced to evaluate any ADEs or SADEs. The PI will review all ADEs and SADEs and make any necessary safety determinations or visit activity modification that are in the best interest of the participant as necessary. See also Section 7.0 ADEs for reporting and management requirements.

9.3 Study Discontinuation

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the PI, sponsor, and IRB. If the study is prematurely terminated or suspended, the PI, in collaboration with the sponsor, will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstance(s) that may warrant termination or suspension include, but are not limited to; determination of unexpected, significant, or unacceptable risk to participants as determined by ADE review, insufficient compliance to protocol requirements, and/or data that are not sufficiently complete and/or evaluable.

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and the sponsor and/or IRB satisfied.

9.4 Study Closeout

Upon completion of the study, Medline Industries, LP. and/or its designees will notify the site of closeout related procedures and will coordinate with the site the return of equipment and/or any unused product. Medline CRA will communicate closely with the PI at that time point and will review all close out steps and materials. All study data, related study documents, and unused study product, will be returned to the sponsor or as per agreement with the study contract. The site will also notify the IRB that the study has been completed.

9.5 Data Handling and Record Keeping

Data collection is the responsibility of the study staff at the site under the supervision of the PI. The PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported in the CRFs or any other study activity documentation as part of this study. All the documents should be completed in accordance with Good Documentation Practices (GDP) to ensure accurate interpretation of data.

Final storage of Medline data will be per ICH/GCP guidelines and kept stored in a protected access area for the length of the time required.

9.6 Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed.

9.7 Protocol Deviations

It is the responsibility of the PI and study staff to use continuous vigilance to identify and report deviations on a routine basis. All deviations must be reported to Medline Industries, LP. Protocol deviations must be sent to the reviewing IRB per reporting requirements and should be reported to the sponsor in a timely manner. The PI is responsible for knowing and adhering to the IRB requirements.

9.8 Abbreviations

ADE	Adverse Device Event
CFR	Code of Federal Regulations
CMP	Clinical Monitoring Plan
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
FDA	Food and Drug Administration

GCP	Good Clinical Practice
GDP	Good Documentation Practice
HCP	Health Care Provider
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IRB	Institutional Review Board
PI	Principal Investigator
PPE	Personal Protective Equipment
QA	Quality Assurance
SADE	Serious Adverse Device Events
SOA	Schedule of Activities
U.S.	United States

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