HidraWear AX HS Study

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Sponsor Name: HidraMed Solutions Ltd.

Sponsor Address: Business Innovation Centre, NUI, Galway, Galway, Ireland

Date:

Signed: _____ **Date:** _____

Chief Investigator

Signed: _____ **Date:** _____

HidraMed Solutions Ltd.

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Clinical Agreement Signature Log

I, the undersigned, have read and understand the Clinical Investigation Plan (CIP), and agree to conduct the investigation as stipulated.

The CIP, the Investigator Agreements and any additional information provided by the sponsor will serve as a basis for co-operation in the study.

I will provide copies of the CIP and all pertinent information to all individuals responsible to me who assist in the conduct of this study. I will discuss this material with them to ensure they are fully informed regarding the device and the conduct of the study.

I will use only the informed consent form approved by the Ethics Committee (EC) and will fulfil all responsibilities for submitting pertinent information to the EC.

Principal Investigator:

_____ _____

Signature Date

Name, address and professional position of Principal Investigator:

Prof Trevor Duffy. Consultant in Rheumatology and General Medicine.

Hermitage Medical Clinic, Old Lucan Road, Dublin 20

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Clinical Investigation Summary

Title	HidraWear AX Pilot Study
Investigational Product	HidraWear AX
Introduction	The product, HidraWear AX is and adhesive free wound dressing system for the every day home care of Hidradenitis Suppurativa (HS), a debilitating disease of the skin for which there are limited wound dressing products. This is a study to assess the use HidraWear Ax vs current product and method of use.
Study Objectives:	The objective is to evaluate the ease of use of Hidrawear AX compared to the subject's existing product use in 23 subjects with HS (Hidradenitis Suppurativa). Secondary objectives are to evaluate if Hidrawear AX: • Is comfortable • Improves quality of life • Faster to use than the subject's existing product • Reduces dressing related pain • Secure dressing retention
Study Design:	Sample size: 23 Female, over 18, presenting with HS of the axilla Study Duration: 9 months - from when the study opens to enrolment until completion of data analyses Subject participation duration: 3 weeks
Sample size and study duration:	Sample size: 23 Female, over 18, presenting with HS of the axilla Study Duration: 9 months - from when the study opens to enrolment until completion of data analyses Subject participation duration: 3 weeks

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Inclusion/Exclusion Criteria:	**Inclusion Criteria:** In order to be eligible to participate in this study, an individual must meet all of the following criteria: 1. Provision of signed and dated informed consent form in English. 2. Stated willingness to comply with all study procedures and availability for the duration of the study 3. Female, aged >18 4. Diagnosed with Hidradenitis Suppurativa 5. Hidradenitis Suppurativa affecting the axilla 6. Exuding lesion that requires wound dressings **Exclusion Criteria:** 1. Recent surgery <3 months in axilla 2. Psoriasis, Dermatitis or skin conditions/rash other than Hidradenitis Suppurativa on or near affected area 3. Pregnancy or lactation 4. Known allergic reactions to components of Hidrawear AX
Primary Performance Endpoints:	Primary outcome measure: Subjects own product use (Day 0) vs Hidramed (Day 21) • Ease of Use Day 21 vs Day 0
Secondary Performance Endpoints:	Secondary outcome measures: • Ease of Use Day 21 vs Day 0• Comfort, measured on a 5-point scale Day 21 vs Day 0 • Visual Pain Analogue Scale Day 21 vs Day 0 • Time Day 21 vs Day 0 • Additional equipment used – mirror, scissors etc • Could dressing be applied without raising arms over head • Necessity to stretch/contort body to apply dressing • Did subject need assistance
Duration of Investigation	9 months - from when the study opens to enrolment until completion of data analyses. Subject participation: 22 days, Visit day 0, and day 21.

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2 INTRODUCTION

Hidradenitis Suppurativa (HS) is a debilitating lifelong condition characterized by painful nodules and lesions localized mainly in the inverse body areas, such as the axillae and groin [1]. These lesions are typically fluid filled and require regular wound dressings. People with HS live in dressings and bandages.

Hidradenitis Suppurativa

- Presents after puberty with an average diagnosis pathway of 8 years [2]
- Is frequently misdiagnosed due to lack of clinical awareness [3]
- Causes deep seated, painful skin lesions, tunneling tracts and wounds
- Affects the armpits, groin, thigh and buttocks
- Causes irreversible skin damage
- Causes high levels of subject pain, distress and despair [4]
- Subjects at higher risk of anxiety, depression and suicide [5]

People living with HS are tending to their lesions widely unaided. The majority of subjects, unless referred to a wound clinic, are self-managing. [6]

There are no recommended products or guidelines on how to manage HS lesions and there are no wound dressings that are suitable for use on the armpit. Current dressings often leak, move or fall off and the constant application and removal of adhesives to the skin further irritates and damages the affected area. Subjects are doing on average 3-4 dressing changes per day, using products that are not fit for purpose.

2.1 Description of the Investigational Device

HidraMed Solutions has developed an adhesive free wound dressing fixation device for people living with Hidradenitis Suppurativa (HS), a chronic and debilitating disease which causes non-healing lesions of the skin, mainly in the armpit, groin, thigh and buttocks - Hidrawear AX, designed to make dressing changes quick and easy for subjects.

The Hidrawear AX is designed to improve the wound care management for HS and chronic wound subjects. The unique features of the product completely remove the use of adhesives on the skin. Designed by a patient, for patients, Hidrawear AX provides comfort, ease of use and effective care for the every-day management of HS lesions.

The 3- part system is comprised of

1. The investigational device: the Hidrawear AX: A washable garment
2. An off-the-shelf dressing
3. An off-the-shelf mechanism to attach the dressing to the Hidrawear AX, such as a fastener supplied with the dressing or medical tape

The body conforming garment acts as a second skin and incorporates largely perforated panels over wound affected areas, minimising skin contact and aerating the area. The main function of the perforated is to act as a retaining device for the wound pads.

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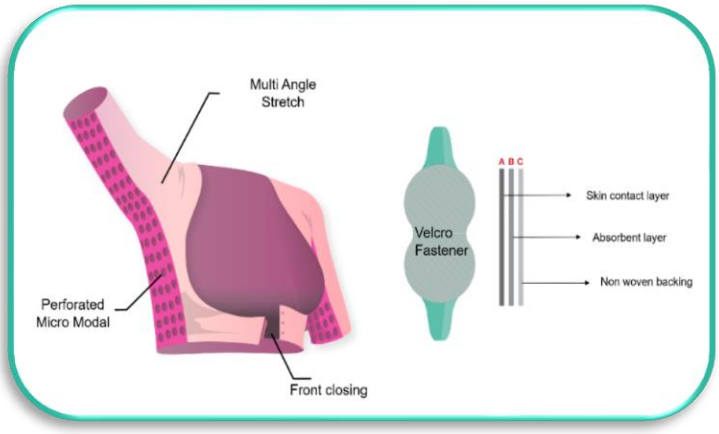
The garment facilitates easy insertion, removal, precise positioning and adjustment of a non-adhesive wound dressing onto the effected wound space. The perforated section of the garment sits on the outer surface of the dressing providing provisional fixation. Next, an outer patch is placed on the outside of the garment on the footprint of the dressing. Through a hook and loop mechanism the dressing is now fully secured in place. It is designed so that quick, precise and pain free dressing changes can be achieved.in less than 15 seconds



2.2 Manufacturer of the Investigational Device: Hidrawear AX

Name:

Hidramed Solutions Limited

Address:

Business Innovation Centre, NUI, Galway Galway City, Ireland

2.3 Intended Purpose

Is intended for the retention of a dressing in the axilla area.

2.4 Contraindications and Warnings

A full list of contraindications and warnings are provided in the IFU supplied with the device.

Contraindications: Known allergies to materials specified

Warnings: Do not use if you have known allergies to materials specified.

Warnings

1. The garment is not a wound dressing – wound(s) should be fully covered by dressing(s).
2. If any unexpected discomfort or wound irritation occurs, please consult your doctor or nurse.
3. Do not use, if you have a known allergy or sensitivity to materials listed.

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Potential side effects: Dermatitis, infection and skin irritation or skin abrasion.

2.5 Summary of Required Experience/Training

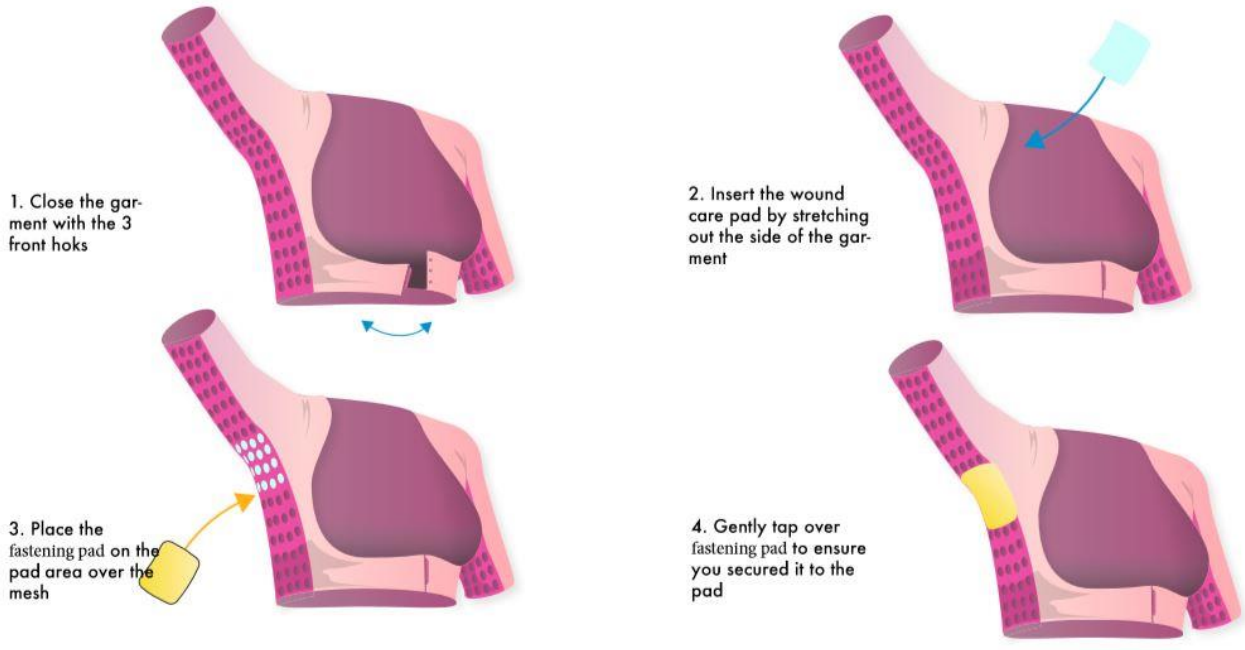
The research nurse will be trained to

- Use the device and to demonstrate correct use of the device to subjects
- Determine if the subject can be included or excluded

The research nurse will train the subject:

- how to use Hidrawear AX
- how to record their temperature.

2.6 Description of Specific Procedures for the Use of the Investigational Device



2.7 Traceability

The dressing and fastener packaging will have a part number and batch number.

The Hidrawear AX garment will have a washing label with a part number.

Hidrawear AX garment packaging will have the Hidrawear AX garment lot number. The lot number will contain a unique identifier code.

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3 JUSTIFICATION FOR STUDY DESIGN

3.1 Justification for the Design of the Clinical Investigation

There is no standard of care for HS wound care globally. Subjects rely on existing non-specific wound care products. The anatomical locations of the disease are high sweat areas. The locations have hair and the skin is compromised with deep seated, painful skin lesions, tunnelling tracts and wounds. As the skin is compromised by the disease, the use of adhesive wound pads is not optimal. There is pain and discomfort involved. Subjects spend time changing dressings which has an impact on the quality aspects of their lives.[7]

The Hidrawear AX's is designed to allow quick and easy wound dressing, comfortable method of retaining the dressing that avoids use of skin damaging adhesive, resulting in better wound management that will allow the subject to have an improved quality of life.

This study will compare the product HidraWear with current methods used to manage HS wounds in the home setting. Comparison will be made:

- Between the patient's experience with existing standard dressings used on Day 0
- Between the patient's experience and the data collected in the survey

There are no studies found that capture the impact of HS wound care to the patient. This study will inform the researchers what areas of wound care should be further researched and whether quality of life is a tangible measurement in terms of HS wound care.

There is limited data available regarding the best choice of dressing in HS subjects. There is no perfect single dressing for HS and current literature suffers a lack of evidence regarding the choice of dressings in these patients.

There is a huge need for more studies evaluating topical therapies and dressings in order to improve quality of evidence and subject care. Current literature remains focused on post-surgical wound healing after an HS subject has had either minor surgery or excisional surgery [7]

Research shows that there is a significant effect on HS subjects' Quality of Life. Matusiak's literature review assesses DLQI scores from seven HS DLQI studies against studies of other dermatoses. Other dermatosis includes Skin Tumours, Atopic Dermatitis, Vascular anomalies of the face, Darier Disease, Hailey-Hailey Disease, Psoriasis, Acne Vulgaris, Alopecia and Chronic Idiopathic Urticaria. The DLQI questions the symptoms and feelings, daily activities, leisure, work or school, personal relationships and treatment of a person with HS. "The burden of disease of HS is usually greater than that reported for other common dermatoses, with mean Dermatology Life Quality Index scores indicating a moderate-to-large effect on subjects' lives." [8].

Use of the DLQI questionnaire is standard practice in the assessment of quality of life for subjects with HS. The DLQI questionnaire is a validated questionnaire. [9], [10] and [11].

Braunberger assess available dressings to HS subjects. Dressing are not specific to HS subjects. There are a range of non-active and active dressing available on the market. Braunberger 's assessment summary is "As an important component of wound healing, large, randomized controlled trials that compare dressing options for the management of wounds in hidradenitis suppurativa subjects are needed." [12]

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Hidramed's ease of use assessment and comfort is directly related to the performance of the Hidrawear AX device.

3.2 Prevalence of Disease/Condition (Background)

In recent years researchers have investigated the prevalence of HS in the general population. However, it is difficult to get an accurate estimate of the true prevalence of HS as such studies have used different methodologies and sample sizes for estimation. In general, three types of studies have been used to estimate the prevalence: (i) registry-based studies (RBS), (ii) prospective examination of subjects (PEP), and (iii) self-reported data from larger groups (SRS). These different designs each have their strengths and weaknesses. However, the most reliable prevalence estimates come from cross-sectional, general SRS using validated screening questions and/or clinical assessment [13].

At the lower end of the HS prevalence range, most RBS from the USA estimate HS prevalence to be 0.05%–0.20%. However, Jemec and Kimball (2015) argue that these studies underestimate the true prevalence of HS as they mainly used RBS methods. RBS methods rely on a sequence of events: the subject must present for treatment, be given a correct diagnosis, and be coded appropriately. Such methods consistently give the lowest prevalence estimates. Furthermore, as the condition is frequently misdiagnosed, and the average diagnostic delay is ~ 7 years [14], there may be many undiagnosed people with HS who were excluded from these studies. It is noteworthy that some of the more recent RBS [15] that used large sample sizes estimate HS prevalence to be ~1% of the general population.

PEPs involve examination of specific groups. Such group-based studies are attractive in that they are highly specific but are limited in the numbers of subjects involved in such studies are typically small restricting the statistical significance of the data generated. The exact diagnostic criteria used in these studies have not been specified [16].

SRS are thought to offer the highest sensitivity in prevalence studies and have produced consistent results. A French SRS indicated that the prevalence of HS may be ~1% of the general population [17]. Several more recent population-based studies involving cross-sectional, general SRS using validated screening questions and/or clinical assessment estimate the prevalence of HS in Australian, Brazilian, and European populations to be ~1% [18,19,20,21]. Jemec and Kimball (2015) argue that more SRS are needed to gain an accurate picture of the true prevalence of HS.

There is significant variation in figures examining the prevalence of HS in different populations. Most European-based studies estimate the prevalence to be ~1% of the general population, while several USA and other countries using RBS estimate HS prevalence to be 0.05%–0.20%. The large variation (~250-fold) may be due to different methodologies used by researchers in estimating HS prevalence but may also reflect differences in the respective populations. There is a growing body of evidence to support the 1% figure estimated using SRS and some RBS.

3.3 Impact of Disease/Condition

HS has a massively under recognized impact on the subject's quality of life, limiting them from socialising, working, exercising and intimacy.

HS subjects see up to 5 clinicians and attend 17 appointments over the course of 8 years before a correct diagnosis is made.[2]. Many subjects live with chronic pain, become sedentary, obese and have a high risk of developing anxiety and depression. HS subjects miss an average of 3 days per

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month from work, with many losing the confidence and ability to sustain full time employment as a result. [4]

Current HS treatments include topical, pharmaceutical and surgical intervention. However, the cause of the disease remains unknown, and none of the treatment pathways offered to subjects lead to successful healing. There is no clinical standard for the every-day care of HS wounds in the home setting, yet subjects are left to deal with these life altering lesions with little direction from healthcare professionals.

While the prevalence of HS may approach that of Psoriasis, quality of life scores indicate that subjects with moderate to severe HS are substantially worse off than subjects with moderate to severe Psoriasis. These parallels are worth considering given the cost of the impact of Psoriasis is estimated to be $35.2 billion annually in the United States [22]. High drug costs and cost settings, such as emergency department and in subject care are used more frequently for subjects with HS than other dermatological disease. Further, HS is widely misdiagnosed due to lack of awareness among the general practitioner and general population. This results in many wasted resources in the diagnosis of the condition.

3.4 Clinical Evaluation

This pilot study will evaluate usability - the safety, efficacy and performance of HidraWear AX in the home setting. Quality of life, ease of use and comfort of Hidrawear AX will be assessed.

The clinical effect of the wound pad will not be assessed. HIdraWear AX does not claim wound healing but is a quicker and easier way to dress wounds.

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4 RISKS AND BENEFITS

4.1.1 Risk Analysis

- *Hidradenitis Suppurativa wounds can sometimes be colonised by non-pathogenic bacteria, and may appear to be infected. This is not a true infection. However, subjects will examined by research nurse to assess the wound and will be asked to record their temperature during the study to monitor for signs of infection. There will be a registered nurse overseeing all subject interactions and demonstrations to ensure the safety of subjects*
- *Garment could cause discomfort to the subject. In the case of any discomfort the subject is requested to remove the wound care product*
- *There is also a minor concern re allergies to certain materials and this will be included in the PIL and will be an exclusion criteria*

***Risk assessment for Hidramed vs Standard Adhesive dressing**.*

Risk level and likelihood rated 1-5, 1 being the lowest and 5 being the highest.

Hidrawear AX Garment

Risk	Cause	Level of Risk	Likelihood of Risk	Control
Skin Irritation	Allergic to garment	1	1	Discontinue use immediately
Unnecessary Pain	Difficult dressing site	3	1	Use product as instructed exactly. Discontinue use immediately
Subject distress and embarrassment	Dressing leaking or falling off.	1	1	Use product as instructed exactly
Physical contamination of wound	Thread or fibres from product retained in wound	1	1	Selected bonded fabric that does not fray/produce fibres. Users instructed to carry out daily visual inspection of wound. Discontinue use immediately

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Dressing Supplied During Study

Risk	Cause	Level of Risk	Likelihood of Risk	Control
Skin Irritation	Allergic to dressings	1	1	Discontinue use immediately
Localised infection	Misuse of dressings	3	1	Follow user instructions exactly. Discontinue use immediately
Septicemia	Misuse of dressings	5	1	Follow user instructions exactly. Discontinue use immediately Monitor temperature twice daily during pilot period.
Subject distress and embarrassment	Dressing leaking or falling off.	1	1	Use product as instructed exactly

Standard Adhesive Dressing

Risk	Cause	Level of Risk	Likelihood of risk	Control
Skin Irritation	Allergic to or reaction to adhesive in dressing	1	3	Discontinue Use immediately
Localised infection	Misuse of dressings	3	3	N/A user instructions do not specify
Septicemia	Misuse of dressings	5	1	N/A user instructions do not specify
Unnecessary pain	Difficult dressing site, Adhesive damage to skin	5	4	N/A
Subject distress and embarrassment	Dressing leaking or falling off. Ineffective product for use on Armpit (sweaty, moist, mobile area of body)	3	5	N/A
Physical contamination of wound	Thread or fibres from product retained in wound	1	1	N/A

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4.2 Anticipated Clinical Benefits

- *Participating in the study may give subjects a sense of control and empowerment to be involved in the evolution of a product developed for their specific needs.*
- *The product may provide a superior method of applying, retaining and changing a wound dressing, providing comfort and security to subjects*
- *Subjects may see a reduction in dressing related pain*
- *Subjects will get to interact daily with researcher and share their experiences of living with HS*

4.3 Adverse Device Effects

Materials selected are designed for contact with the skin and all use of adhesives on the skin have been removed so the likelihood of adverse effects due to using the device is low. However, there is a slight possibility of skin irritation, infection and pain due to misuse of the device. See table in section 4.1.1

In all instances of adverse effects, subjects must cease using the device immediately and make contact with research nurse for further instruction.

4.4 Risks Associated with Participation in the Clinical Investigation

On Day 0, the subject will be asked to demonstrate or explain dressing their axilla using their usual methods and products. These products may use adhesives and in turn cause discomfort to subjects during demonstration.

4.5 Possible Interactions with Concomitant Medical Treatments

None expected as this is an assessment of the HidraWear AX garment.

4.6 Steps to be Taken to Control or Mitigate Risks

Users will be assessed by a Research Team member to establish that no infection is present in the wound site on enrolment and assessment.

Subjects will be asked to measure and record their temperature daily and to contact nurse support if there is an elevation in temperature.

If subjects record a pyrexia greater than 38 degrees. The Subject will contact the Research team where it will be recorded. Subject will be asked to recheck temperature following 1 hour without temperature reducing medication (paracetamol ibuprofen et). If pyrexia persists, subject will be directed to attend GP for immediate follow up and the use of the study device will be stopped.

Research nurse to assess whether pyrexia is device related.

If it is not device related, a telephone contact log is to be filled in and reported to the sponsor.

If it is device related, an adverse is to be recorded and reported to sponsor

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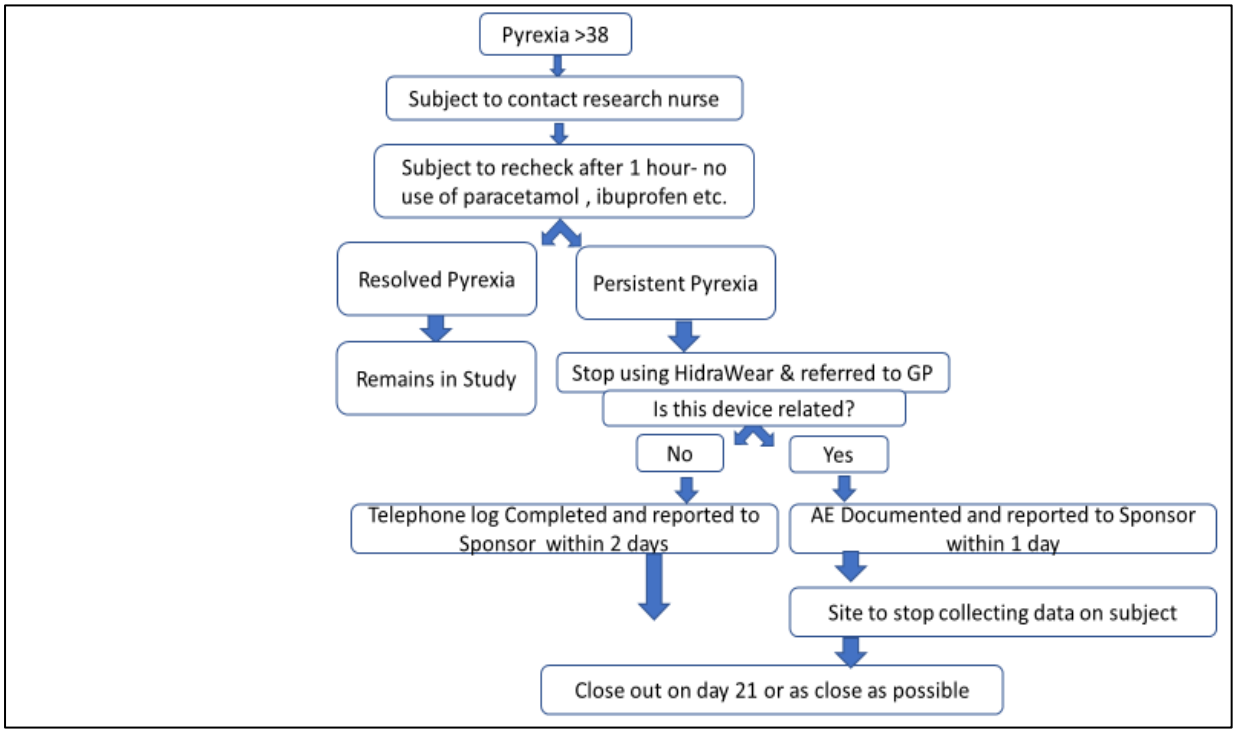

Process Flow for Pyrexia >38 Degrees

The dressing used in this study is provided sterile.

The fastener used in this study is used externally and does not touch the skin during use. Material base and Velcro is medical grade.

The dressing and fastener will be CE marked by the legal manufacturer (Planet Medical Products Co. Ltd., China). The manufacturer is ISO13485 certified.

Hidramed AX fabric is an OEKO-TEX® certified material. The Hidramed AX full produced garment has been evaluated in accordance with ISO 10993 and it is biocompatible for its intended use. Verification and validation testing will be performed to evaluate the design of the garment. Hidramed Solutions will CE mark the device in accordance with the medical device directive 93/42/EEC.

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5 OBJECTIVES AND HYPOTHESIS OF THE CLINICAL INVESTIGATION

5.1 Objectives

The objective is to evaluate the ease of use of Hidrawear AX compared to the subject's existing product use in 20 subjects with HS (Hidradenitis Suppurativa).

Secondary objectives are:

To establish the impact of wound care to patients using online survey.

To evaluate if Hidrawear AX:

- Is comfortable
- Improves quality of life
- Faster to use than the subject's existing product
- Reduces dressing related pain
- Secure dressing retention

5.2 Hypothesis

When compared to standard methods of dressing the axilla, Hidrawear AX will be equivalent to or superior in terms of:

Ease of use

Comfort (wearing) to user

Time to apply

Dressing related pain and discomfort

Secure Dressing retention

And in turn will have a positive impact on the patient's quality of life.

5.3 Claims of Performance

Easy to use.

Comfortable.

Faster than existing products used.

Reduces pain.

Secure dressing retention

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6 DESIGN OF THE CLINICAL INVESTIGATION

6.1 General

6.1.1 Description

Questionnaire, Pilot Trial, Single-arm, unblinded study of Hidrawear AX

6.1.2 Measures to Minimise Bias

The sponsor will not be involved in the study processes or day to day management. The sponsor has agreed to work with the Clinical Research Platform, (CRP) an independent research organisation who will conduct an independent trial. A research nurse will record the data. The Clinical Operations Manager of the CRP is Shane Brennan with an address at 110 Lower Baggott Street Dublin 2.

6.1.3 Primary and Secondary Endpoints

Primary Endpoint

- The change in the ease of use at week 3 compared to Day 0

Secondary Endpoints – Subject Assessment

- Ease of use W2 vs W1
- Comfort measured on a 10 point scale D21 vs D0
- Pain measured on a 10 point scale D21 vs D0
- Time measured on a 10 point scale D21 vs D0
- Dressing retention confidence measured on a 10 point scale D21 vs D0

Secondary Endpoints – Nurse Assessment

- Necessity to stretch/contort the body to apply dressing
- Did subject need assistance
- Could dressing be applied without raising arms over head
- Additional equipment used- mirror, scissors etc.

Outcome selection rationale:

- Assessment of ease of use as primary outcome was selected as most users have voiced frustration
- Comfort was selected as we wish to learn if Hidrawear AX is comfortable to use.
- Dressing retention confidence was selected as user have voiced frustration
- Dressing related pain was selected as HidraWear AX may reduce unnecessary patient distress due to dressing/adhesive related pain
- Time was selected as regular wound dressing changes are time consuming (6)

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DLQI was selected as it a validated tool that has been commonly used for assessment of quality of life for HS subjects. will assess if Hidrawear AX is better than the current products used by HS subjects.

6.1.4 Methodology

Before the study commences on site, a survey will be shared into select closed patient groups online, to capture the patient experience of living with Hidradenitis Suppurativa (HS) in terms of self-managing wound care and the impact that HS wound care has on patients' day to day life, physically, financially and emotionally.

A secure and confidential survey tool (Typeform) will be used. This is governed under EU data legislation and encrypted to ensure privacy. The survey will not collect any identifying information and is a precursor to the HidraWear AX Pilot Study.

Day 0

Subjects will visit trial site or have a home visit from research nurse.

Following consent and enrolment, Subjects will be asked to demonstrate or explain their usual method of dressing their wound using their usual wound dressing products.

Subjects will assess this activity based on ease of use, comfort, experienced pain, confidence in dressing retention and time, using a 10 point visual analogue scale. (see appendix 2)

The subjects will complete a Dermatology Quality of Life Index Survey. (see appendix 5)

The research nurse will assess the activity based on whether the subject needs assistance, uses additional equipment, contorts or stretches their body, can dress the wound without raising their arms above their head. (See appendix 4)

Day 1-21

Daily Check in with Subjects:

Each day, at 1pm, subjects will receive an email requesting them to check in with the researcher by answering 3 questions.

1. What is your temperature?
2. How many dressings did you use in the last 24 hours?
3. Any comments?

This check in should take less than 5 minutes to complete.

Subjects will be required to respond by 5pm each evening. If subject has not responded by 5pm, a reminder text message will be sent to them.

If subject does not respond within 24 hours, the research nurse will call the subject to check in and take answers over the phone.

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Weekly Check in with Subjects:

On day 7 and 14 subjects will be asked to complete the Dermatology Quality of life survey and questions on Ease of use, comfort, pain and confidence, at home. A link to the surveys will be emailed to them at 1pm in the afternoon with their daily check in.

Subjects will be required to respond by 5pm each evening. If subject has not responded by 5pm, a reminder text message will be sent to them.

If subject does not respond within 24 hours, the research nurse will call the subject to check in and take answers over the phone.

Day 21

Subjects will return to site or be visited by research nurse for review.

Subjects will be asked to demonstrate how they dress their wound using HidraWear AX.

Subjects will assess this activity based on ease of use, comfort, experienced pain, confidence in dressing retention and time, using a 10 point visual analogue scale. (see appendix 3)

The subjects will complete a Dermatology Quality of Life Index Survey. (see appendix 5)

The research nurse will assess the activity based on whether the subject needs assistance, uses additional equipment, contorts or stretches their body, can dress the wound without raising their arms above their head. (See appendix 4)

6.1.5 Equipment

Calibrated thermometer for each subject. Maintenance will constitute in the form of thermometer replacement if required. Calibration is not necessary for the duration of the study

6.2 Investigational Device(s) and Comparator(s)

The comparator used is the subject's own product use which is assessed at W0.

6.3 Participants

6.3.1 Recruitment

A dedicated email address and phone number will be assigned to the study.

Subjects will be recruited through several channels:

1. The Clinical Research Platform will inform its network of GP's in Dublin and surrounding areas of the study. GP's will inform relevant patients and give them the Subject Information Leaflet/Invitation to participate

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2. HS specialist dermatologists in Dublin and surrounding areas will be notified of the study and can inform patients.
3. An invitation will be shared with a closed patient support group online.

Candidates can call or email to express interest in the study. Candidates will be screened based on the inclusion/exclusion criteria below.

6.3.2 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form in English
2. Stated willingness and ability to comply with all study procedures (in English) and availability for the duration of the study
3. Female, aged >18
4. Diagnosed with Hidradenitis Suppurativa
5. Hidradenitis Suppurativa affecting the axilla
6. Exuding lesion that requires wound dressings

6.3.3 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Recent surgery <3 months in axilla
2. Psoriasis, Dermatitis or skin conditions/rash other than Hidradenitis Suppurativa on or near affected area
3. Pregnancy or lactation
4. Known allergic reactions to components of Hidrawear AX

6.3.4 Criteria for Withdrawal or Discontinuation

Subjects may withdraw from the study at any time without any rationale and without compromising their future medical care.

The subject may also be removed from the study by their physician or the consultant if they feel it is the best interest of the subject.

The use of the Hidrawear garment will be suspended if the patient presents with pyrexia and/or infection.

6.3.5 Enrolment

Subjects will be enrolled on Day 0

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Subjects with Hidradenitis Suppurativa of the axilla are candidates for enrolment into this pilot study. Following review of the inclusion and exclusion criteria, eligible subjects will be invited to participate in the study.

A Subject information leaflet will be provided to each subject in the study. Information non the study, the fact that it involves research, the purpose of the study, the potential risks/benefits will be given to all subject.

All subjects will sign an informed consent form before they can be enrolled into the study and begin proceedings

The subject's participation is completely voluntary, and they can withdraw from the study at any time throughout. Their withdrawal will have no impact on any services / treatment they are currently receiving or the relationship with their doctor.

6.3.6 Replacement of Subjects

Drop-out rates of up to 6 subjects (25%) are anticipated.

A cohort of 23 subjects will be selected from pre-screened applicants.

Applicants not selected will have the option to join a waiting list in the instance of a drop out or excluded subject.

Applicants on the waiting list will be contacted and invited to consent and enrol into the study subject to approval from the PI.

Subjects will be replaced by recommencing the enrolment process as detailed in 6.3.4.

6.3.7 Duration of the Clinical Investigation

Planning, CIP and essential documents – 3 months

6 weeks expected recruitment and 22 days subject participation.

Data analysis and Reporting – 3 months

6.3.8 Expected Study Duration for Participants

From the time of enrolment, subjects with participate for 22 days: 2 days on site or home visit, 20 days in the home setting.

6.3.9 Number of Subjects

23 subjects

6.3.10 Time to Select all Subjects

The recruitment period will remain open until 23 subjects are enrolled. Estimated time required is 6 weeks.

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6.4 Procedures

6.4.1 Pilot Study Procedures

Procedures & Assessments	Day 0 Enrolment Assessment	Day 1 - 6	Day 7	Day 8 - 13	Day 14	Day 15 - 20	V2; End of Intervention Day 21
Informed Consent	X						
Medical / HS History	X						
Armpit Clinical assessment	X						X
Inclusion/exclusion criteria	X						
Observe Subject using usual method of dressing wound	X						
Dermatology Quality or life index survey, Ease of Use, Comfort, Time, Pain scale.	X		X		X		X
Subject trained on use of HidraWear Ax	X						
Subject trained on use of Thermometer	X						
Subject daily use of Hidrawear AX		X	X	X	X	X	X
Temperature Record	X	X	X	X	X	X	X
Observe Subject using Hidrawear AX							X
Daily Survey		X	X	X	X	X	X
Checkup phone call			X		X		
Researcher Data Entry	X	X	X	X	X	X	X
Adverse Events	X	X	X	X	X	X	X

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6.4.2 Factors with Potential to Compromise the Outcome/Interpretation of the Results

Subjects are living with a debilitating disease and are often affected in more than one anatomical location.

This study is capturing/measuring quality of life based on an improved method and product indicated for use in dressing an axillary wound only. While an improvement in ease of use, comfort, time, secure dressing retention may be captured, an improvement in quality of life scores may be compromised due to other affected areas impacting negatively on the subject's daily life.

6.4.3 Follow-up Medical Care

Subjects will remain under the care of their GP throughout the study.

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7 STATISTICAL CONSIDERATIONS

7.1 Statistical Design

This pilot study is a small-scale preliminary investigation to evaluate feasibility, time, cost, adverse events and improve upon the study design prior to performance of a full-scale investigation. The data collected will provide the estimates needed of the potential treatment effect and the likely variability in the response at baseline and over time.

7.2 Sample Size

A sample size of 23 subjects, chosen based on feasibility, will be investigated. The sample corresponds to an estimated margin error of 0.18 in the primary response.

7.3 Level of Significance and Power of the Clinical Investigation

This is a post-market clinical follow-up. The size of the study was not determined based on a power calculation.

7.4 Expected Drop-out Rates

Drop-out rates of up to 6 subjects (25%) are anticipated.

7.5 Criteria for Stopping Clinical Investigation

There are no stopping rules on statistical grounds

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8 DATA MANAGEMENT

8.1 Procedures for Data Review, Database Cleaning, and Issuing/Resolving Queries

All data will be collected on paper.

Surveys at The Hermitage Clinic will be completed on paper by subjects and transcribed in to Typeform by research nurse

Typeform account will be held by the sponsor and access will be available only to the research nurse and sponsor.

Data will be sent electronically for data analysis to Prof Newell at NUIG through secure intranet server.

Subject personal information will be encrypted, accessible only by the study nurse with the use of an inscription key for the duration of the study. This will mean that subject information will be identifiable by only by a subject number, rather than personal information.

All investigation data will be stored electronically for a period of 7 years following study completion on a password protected file.

Data analysis shall be conducted by Prof John Newell, NUI Galway.

8.2 Other Aspects of Clinical Quality Assurance

The study will be performed in accordance with this protocol, regulations (21 Code of Federal ICH guidelines for Good Clinical Practice (GCP), the regulations on electronic records and electronic signature (21 CFR 11), and the most recent guidelines of the Declaration of Helsinki (Section 19.2).

The study will also be performed in accordance with any laws and regulations in force in the country in which the research is carried out.

Participants should be informed that they may withdraw from the study at any time. They will receive all information that is required by local regulations and ICH guidelines. The principal investigator or a designated representative will provide the sponsor or its representative with a copy of the IRB/IEC-approved ICF before the start of the study. This Study will be conducted according to ICH GCP and strict adherence to the protocol.

Monitoring visit will be conducted by external organization which will provide quality assurance during the study.

Monitoring will include personal visits and telephone communication to assure that the investigation is conducted according to the protocol, standard operating procedures, GCP guidelines, and applicable regulatory requirements. Quality control procedures will be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

By signing this protocol, the investigator grants permission to personnel from the sponsor, its representatives, and appropriate regulatory authorities, for on-site monitoring of all appropriate study documentation, as well as on-site review of the procedures employed in eCRF generation, where clinically appropriate

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9 AMENDMENTS TO THE CLINICAL INVESTIGATION PLAN

The Clinical Investigation Plan may require an amendment during the conduct of a clinical investigation. Any amendment to the clinical investigation plan will be agreed between the Sponsor and the Principal Investigator. The amendments will be notified to, or approved by, the Ethics Committee as appropriate.

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10 CLINICAL INVESTIGATION PLAN COMPLIANCE

The study will be carried out in accordance with ISO 14155.

The protocol, informed consent form(s), recruitment materials, and all subject materials will be submitted to the Research Ethics Committee (REC) for review and approval. Approval of both the protocol and the consent form must be obtained before any subject is enrolled. Any amendment to the protocol will require review and approval by the REC before the changes are implemented to the study. In addition, all changes to the consent form will be REC-approved; a determination will be made regarding whether a new consent needs to be obtained from subjects who provided consent, using a previously approved consent form.

The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor, funding agency and documented approval from the REC except where necessary to eliminate an immediate hazard(s) to the trial subjects. All personnel involved in the conduct of this study have completed ICH GCP and relevant training.

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11.1 Procedures for Recording and Reporting CIP Deviations

The process for recording deviations for the clinical investigation plan, for reporting of the deviations, development of Corrective and Preventative Actions (CAPA) and analysis of deviations shall be carried out in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and as per ISO14155 requirements

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12 PRODUCT ACCOUNTABILITY

Prior to the study commencement date, the product will be shipped from Hidramed Solutions Galway and bonded stock will be shipped to and stored at the Hermitage Clinic, Lucan, Dublin.

3 garments will be supplied to subjects.

A 3 week supply of dressings will be provided to subjects.

Device packaging will be labelled “For Clinical Investigation Use Only” and will display the following information:

Packet contents

Part Number, Batch Number and Lot Number

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13 STATEMENTS OF COMPLIANCE

13.1 Statement of Compliance: ISO 14155 and National Regulations

The study will be carried out in accordance with ISO 14155

The protocol, informed consent form(s), recruitment materials, and all subject materials will be submitted to the Research Ethics Committee (REC) for review and approval. Approval of both the protocol and the consent form must be obtained before any subject is enrolled. Any amendment to the protocol will require review and approval by the REC before the changes are implemented to the study. In addition, all changes to the consent form will be REC-approved; a determination will be made regarding whether a new consent needs to be obtained from subjects who provided consent, using a previously approved consent form.

The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor, funding agency and documented approval from the REC except where necessary to eliminate an immediate hazard(s) to the trial subjects. All personnel involved in the conduct of this study have completed ICH GCP and relevant training. The investigation will be performed to the standards set out in the ISO 14155 standard.

13.2 Statement Regarding Ethical Approval

The Study shall not commence until written approval/favourable opinion from the Ethics Committee.

13.3 Statement of Insurance Cover

The sponsor has insurance in place for the clinical investigation.

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14 INFORMED CONSENT PROCESS

14.1 General Informed Consent

All documents below will be provided in English only.

Informed consent will be obtained in writing by the PI or a delegate from the subject prior to any procedures specific to the clinical investigation being applied to the subject.

The Subject Information Leaflet (SIL) and Informed Consent Form (ICF)

SIL and ICF will be prepared in accordance with ISO 14155 Good Clinical Practice

Subjects will be invited to participate in the study and will be given the SIL to review.

Subjects will be given adequate time to read the SIL and ICF and ask questions before signing the consent form.

14.2 Informed Consent in Special Circumstances

Informed consent will not be sought from infants, children, juveniles, seriously ill, mentally incapacitated or unconscious subjects.

14.3 Subjects unable to read or write:

Informed consent will not be sought from subjects unable to read or write.

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15 ADVERSE EVENTS, ADVERSE DEVICE EVENTS AND DEVICE DEFICIENCIES

15.1 Definition: Adverse Event (AE)

An Adverse Event (AE) is defined as any untoward medical occurrence, unintended disease or injury, or any untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device.

This includes:

- Events related to the investigational medical device
- Events related to procedures involved (any procedure in the clinical investigation plan)
- For users and other persons, this definition is restricted to events related to the investigational medical device.

15.2 Definition: Adverse Device Effect (ADE)

An Adverse Device Effect (ADE) is defined as an adverse event related to the use of an investigational medical device resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, operation, any malfunction, user error, or intentional misuse of the investigational medical device

Subjects will be fully trained on how to use the device and be provided with instructions for use. Subjects can contact research nurse at any time if unsure, and can send daily comments to the researcher through daily check ins.

15.3 Definition: Device Deficiency

An Adverse Device Effect (ADE) is defined as an adverse event related to the use of an investigational medical device resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, operation, any malfunction, user error, or intentional misuse of the investigational medical device

15.4 Serious Adverse Event

A Serious Adverse Event (SAE) is any event (whether or not associated with the investigational device) that:

- Results in death
- Leads to serious deterioration in the health of the subject, that either resulted in
- Life threatening illness or injury, or
- Permanent impairment of a body structure or a body function, or
- In-subject or prolonged hospitalization, or
- Medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or body function.
- Leads to foetal distress, foetal death or a congenital abnormality or birth defect

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This includes device deficiencies that might have led to a serious adverse event if a) suitable action had not been taken or b) intervention had not been made or, c) if the circumstances had been less fortunate. These are handled under the SAE reporting system.

Planned hospitalisation for a pre-existing condition, without serious deterioration in health, is not considered a serious adverse event.

Subjects who experience and adverse will be released to their primary care provider/GP and excluded from the study.

15.5 Definition: Unanticipated Serious Device Effect (USADE)

A Serious Adverse Device Event (SADE) is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

15.6 Reporting Adverse Events

Any and all adverse events shall be captured by our independent trial implementation partner, The Clinical Research Platform Ireland.

Adverse events will be reported in accordance with MEDDEV 2.12-1 GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM and QP025 Clinical Evaluation procedure.

When an event/incident occurs, a report is necessary; the event is recorded within the records outlined in QP025 Clinical Evaluation procedure, Appendix 1: Clinical Operations Document Listing by either the SMO, Research Coordinator or Investigator and returned to HidraMed Solutions within the timelines outlined in QP025 Clinical Evaluation procedure.

15.7 Reporting Device Deficiencies

Any device deficiencies observed during the investigations shall be documented and controlled and processed by Hidramed Solutions.

A root cause analysis shall be undertaken by Hidramed Solutions Design & Development and Quality Assurance teams, with appropriate steps taken to remove risk of future reoccurrence.

15.8 Emergency Contact Details for Reporting SAEs and SADEs

A dedicated email address has been allocated to the study:
hsresearch@clinicalresearchplatform.com

A dedicated phone number has been allocated to the study: 01 662 47 30

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16 STUDY SUSPENSION OR PREMATURE TERMINATION

16.1 Criteria for suspension of whole clinical investigation or in one or more sites

The study may be terminated by the Sponsor or the Investigator at any time. Criteria for suspension or premature termination of the whole clinical investigation include, but is not limited to:

- Occurrence of Unanticipated Adverse Event(s)
- Occurrence of Unanticipated Device Effect(s)
- Any other clinical reasons as identified by the Sponsor or Investigator
- Business decisions of the sponsor. This is not expected.

In the case of temporary suspension documented justification for recommencing the study, signed by the PI, will be required.

16.2 Requirements for subject follow up

In the event of suspension of whole clinical investigation, subjects shall be contacted by our independent trial implementation partner, The Clinical Research Platform Ireland to inform the subject of the premature suspension of the investigation.

A day 21 nurse visit shall be conducted whether the investigation runs to completion or not.

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17 PUBLICATION POLICY

Commitment to Publish Results

The results of the clinical investigation may be submitted for publication in clinically relevant publications

A summary of the results will be provided to subjects in lay terms.

The trial will be registered on clinicaltrials.gov

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19 APPENDIX 1. STUDY SCHEMATIC

Procedures & Assessments	V1; Baseline Day 0	Day 1 - 6	Day 7	Day 8 - 13	Day 14	Day 15 - 20	V2; End of Treatment Day 21
Informed Consent	X						
Medical / HS History	X						
Armpit Clinical assessment	X						X
Inclusion/exclusion criteria	X						
Observe Subject using usual method of dressing wound	X						
Dermatology Quality or life index survey, Ease of Use, Comfort, Time, Pain scale.	X		X		X		X
Subject trained on use of Hidrawear AX	X						
Subject trained on use of Thermometer	X						
Subject daily use of Hidrawear AX		X	X	X	X	X	X
Temperature Record	X	X	X	X	X	X	X
Observe Subject using Hidrawear AX							X
Daily Survey		X	X	X	X	X	X
Checkup phone call			X		X		
Data Entry	X	X	X	X	X	X	X
Adverse Events	X	X	X	X	X	X	X

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20 APPENDIX 2 – ONLINE SURVEY

Section 1: Background Information

1. Please select which age bracket you belong to :

18-24	25-34	35-44	45-54	55-64	65+

2. What country do you live in? Please select.
Drop down menu of countries.

3. Are you male, female, or other? Please select
Male / Female/prefer not to say

4. Are you living with HS?
Yes/No

Section 2: Current Care

1. Where on your body are you affected by HS? Please select all that apply to you.

Armpit	Groin/Bikini line/thigh	Perineum/ perianal skin	genitals	Buttocks	Breasts	Other(please specify in comments)

2. What stage is your HS? Please select

Stage 1	Stage2	Stage3	Don't Know

3. Are your HS lesions oozing?

No – Dry/scarring	Yes-light	Yes-Moderate	Yes-Heavy	Yes-Very heavy	Variable(if variable please elaborate in comments)

4. Do your lesions smell unpleasant?

Yes I am worried people will notice	Yes But I am not worried people will notice	Sometimes there is an unpleasant odour	There is an unpleasant odour on rare occasions	There is no odour

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Section 3 Dressings:

1. Do your HS lesions require dressings? Yes/No

2. Do you need assistance to apply your dressings? Yes/No/Sometimes

3. What do you currently use for dressing your lesions?

Adhesive dressing	Non-adhesive dressing with tape	Non-adhesive dressing with bandage	Improvising with kitchen roll/kitchen roll/other	Other (Please elaborate in comments)

4. How many dressings do you use on a typical day?

1	2	3	4	5+

5. How do you acquire your dressings?

Purchase myself - pharmacy	Purchase myself- online	Purchase myself – other (please specify in comments)	I get them on prescription. (no out of pocket expense)	I get them on prescription but still have to purchase more	Insurance pays for them	Nurse/Clinic Provides them at no cost

6. How much per week do you pay for dressings/bandages/tape/gauze

0	<5	6-10	11-15	16-20	21-25	26-30	31-35	36-40	41-45	>45

7. How many months out of the year do you usually require dressings?

1-2	3-4	5-6	7-8	9-10	11-12

8. Do you find it painful when tending to your lesions/changing dressings?

Yes. Very Painful	Yes. Painful	Neither painful or unpainful	No. Moderate discomfort	No. Not painful at all

9. Do you experience sensitivity to adhesive? Yes/No

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10. Have you ever had a dressing leak/move or fall off? Yes/No

11. How long do you typically spend doing dressing changes and tending to your lesions on a daily basis?

0-5 minutes	6-10 minutes	11-15 minutes	16-20 minutes	21-25 minutes	26-30 minutes	31-35 minutes	36-40 minutes	41-45 minutes	Over 45 minutes

12. Do you think that your wound care needs are being met by current dressing options? Yes/no/maybe (please elaborate)
13. How satisfied are you with current dressings in terms of
    Comfort - scale 0-10
    Ease of application, adjustment and removal (a full dressing change) – scale 0-10
    Confidence it won't leak, move or fall off scale 0-10

14. Do you believe that wound care / dressing changes are a contributing factor to a reduced quality of life for you? Yes/No/Don't Know

15. Does managing your wounds / dressings impact negatively on:
    Work life yes/no
    Social life and hobbies yes/no
    Sex and relationships yes/no
    Day to day activities yes/no
    Mental health yes/no
    Financial well being yes/no
    General wellbeing yes/no

16. Please tell us, in your own words about your experiences of home management/ dressings for HS. How does it make you feel?
    For example- What is your biggest frustration with dressings? Does it impact your daily life? Any problems you experience when doing your dressing changes. Do you need a mirror, extra equipment, assistance? What is the worst part about it and how do you manage on a daily basis?

Section 4: HS information and Support

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1. Where do you find your information on HS?

Doctors/ Healthcare	Information Websites	Online patient forums/groups	Meeting other patients	Other (please specify in comment)

2. What do you think would help you feel more supported in managing your HS? What would you like to see? Please elaborate in comments.

Thank you for participating in our survey. Your time and effort will directly contribute to the publication that highlights the daily impact of HS wounds and wound care on the patient's life.

If some of the questions have made you feel upset about your HS, please visit the following sites for information and support:

https://irishskin.ie/ask-our-dermatology-nurse/

https://hopeforhs.org/

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21 APPENDIX 3 – SUBJECT ASSESSMENT FORM DAY 0

Subject Assessment Day 0

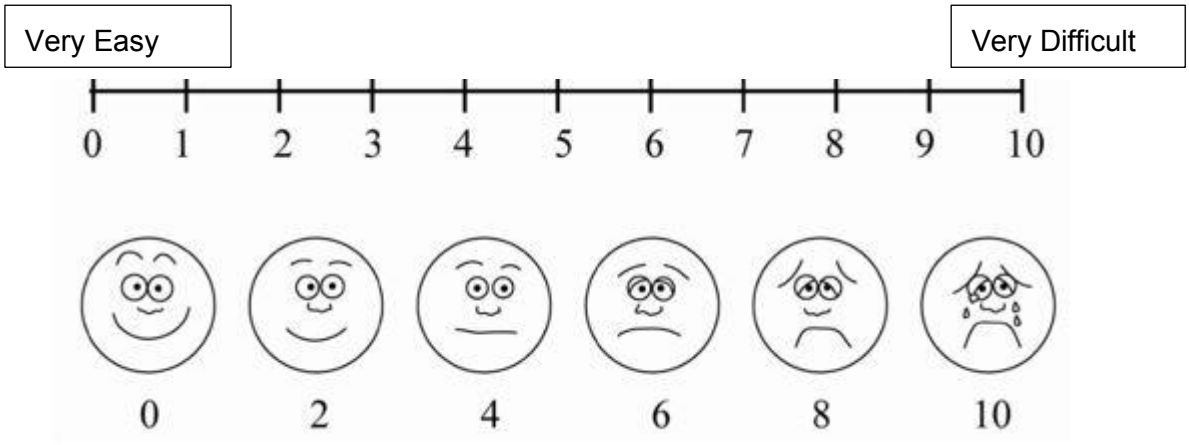
Please dress your wound using your usual product and method.

While you are dressing your wound, please pay close attention to the following:

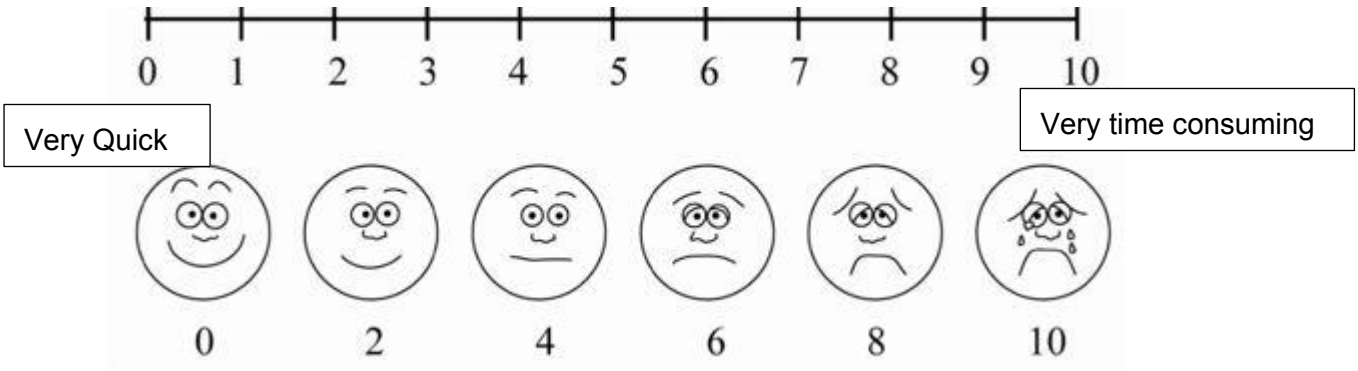
- How easy/difficult it is
- Is it time consuming for a full dressing change
- How comfortable/uncomfortable is a dressing change
- Do you experience dressing related pain
- How confident are you that your dressing will not leak or move.

Once the dressing change is complete, please answer the following:

1. **Is it easy/difficult to change your dressing using your current product and method? Please indicate the level of difficulty involved.**



2. **How time consuming is a dressing change using your current product and method?**



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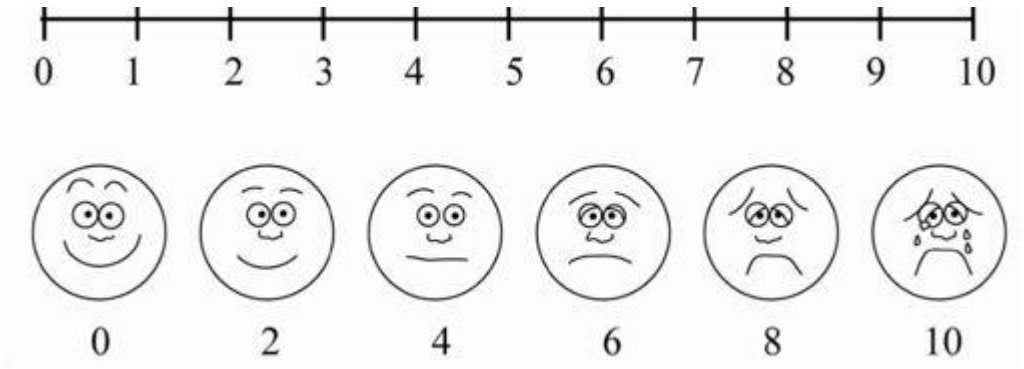
3. How Comfortable is it to use and wear your current dressing?

Very Comfortable

Very Uncomfortable



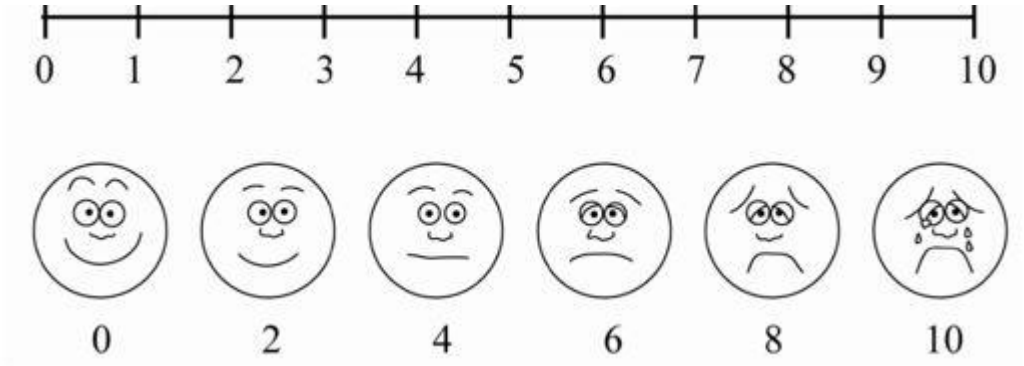
4. Do you require pain killers before a dressing change? Please tick

Yes	No

5. Do you experience dressing related pain using current product?

Pain Free

Extreme Pain



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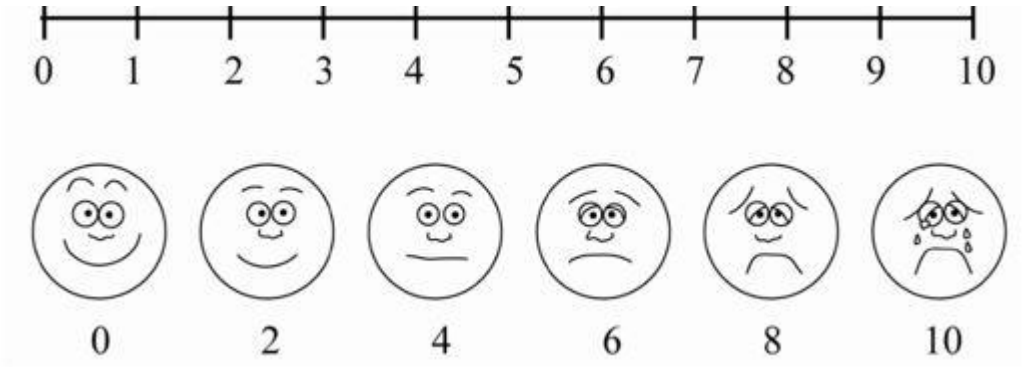
6. How confident are you that your current dressing will not leak or move?

Very Confident

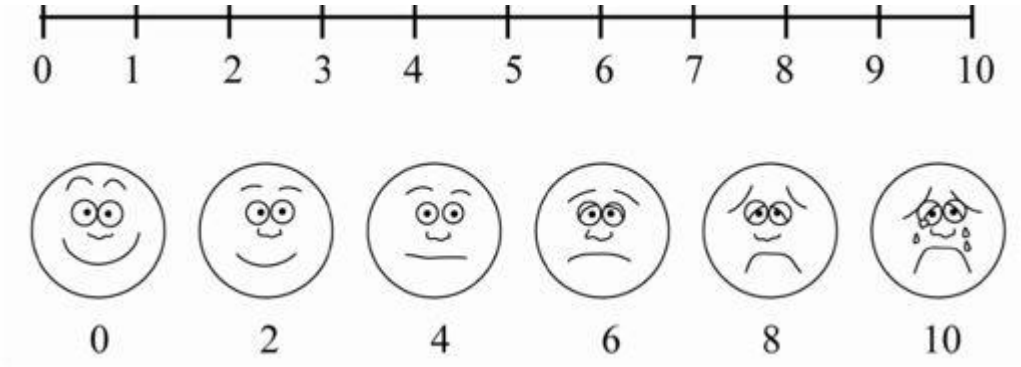
Not Confident



7. How confident do you feel in yourself about your body image – self confidence/self esteem?

Very Confident

Not Confident



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22 APPENDIX 4 – SUBJECT ASSESSMENT FORM DAY 21

Please dress your wound using HidraWear AX

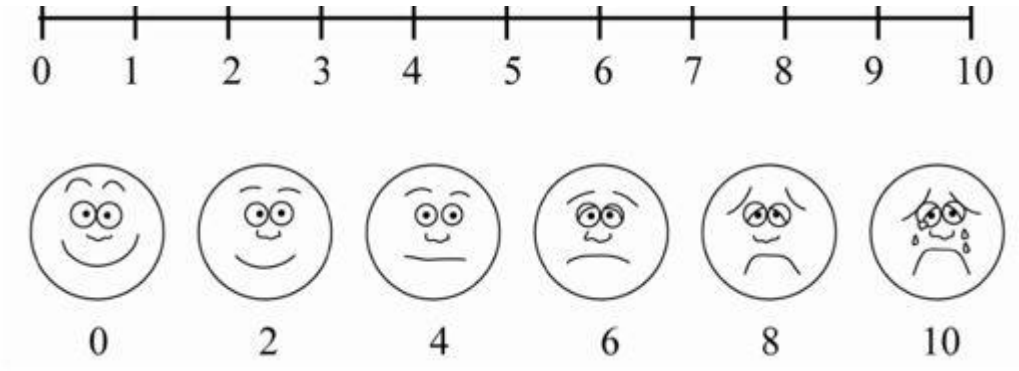
While you are dressing your wound, please pay close attention to the following:

- How easy/difficult it is
- Is it time consuming for a full dressing change
- How comfortable/uncomfortable is a dressing change
- Do you experience dressing related pain
- How confident are you that your dressing will not leak or move.

Once the dressing change is complete, please answer the following:

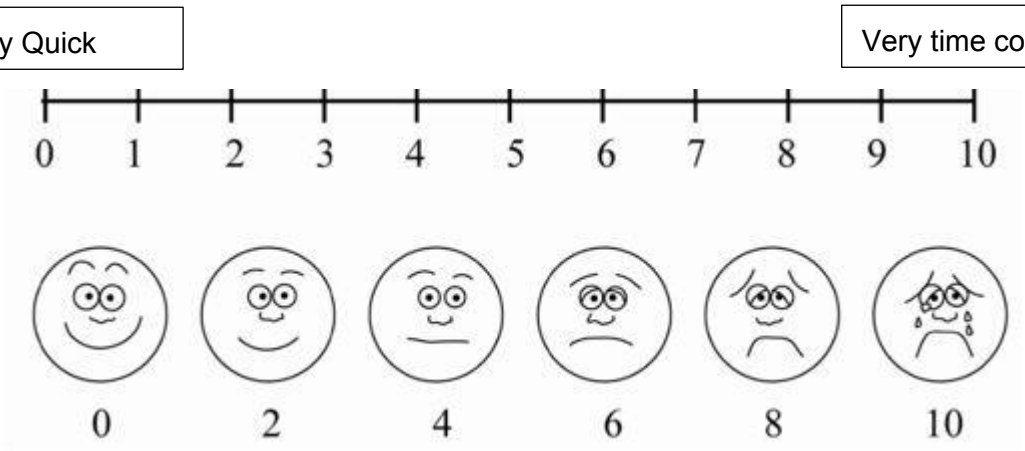
8. **Is it easy/difficult to change your dressing using HidraWear AX? Please indicate the level of difficulty involved.**

Very Easy — Very Difficult



9. **How time consuming is a dressing change using HidraWear AX?**

Very Quick — Very time consuming



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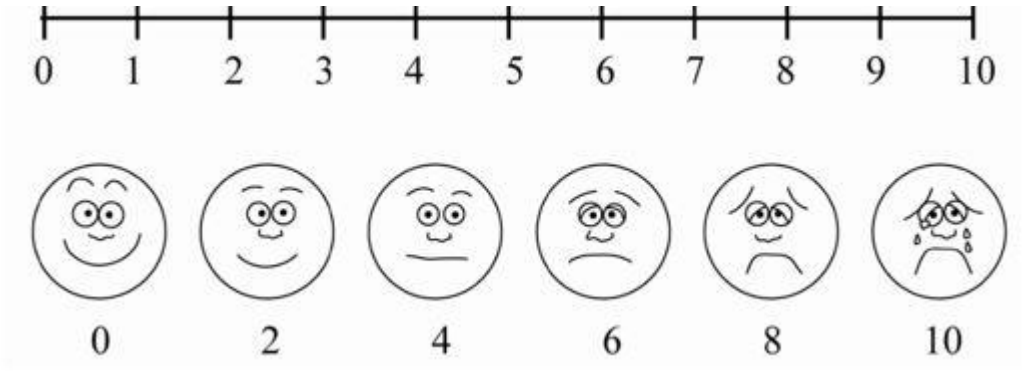
10. How Comfortable is it to use and wear HidraWear AX?

Very Comfortable — Very Uncomfortable



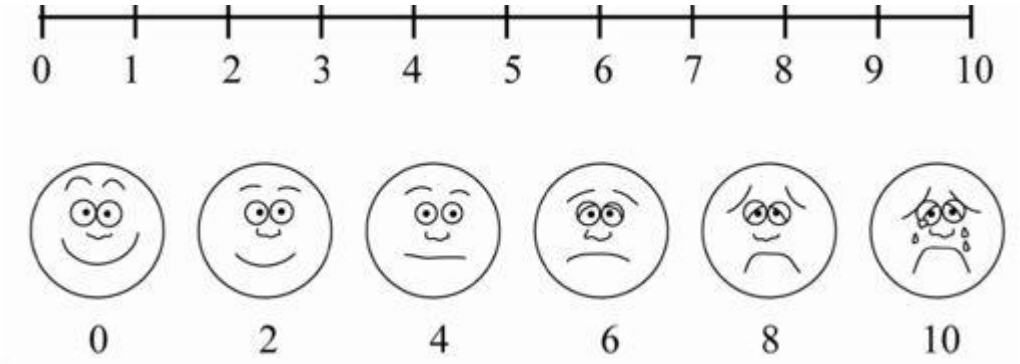
11. Do you require pain killers before a dressing change? Please tick

Yes	No

12.

Do you experience dressing related pain using HidraWear AX?

Pain Free — Extreme Pain



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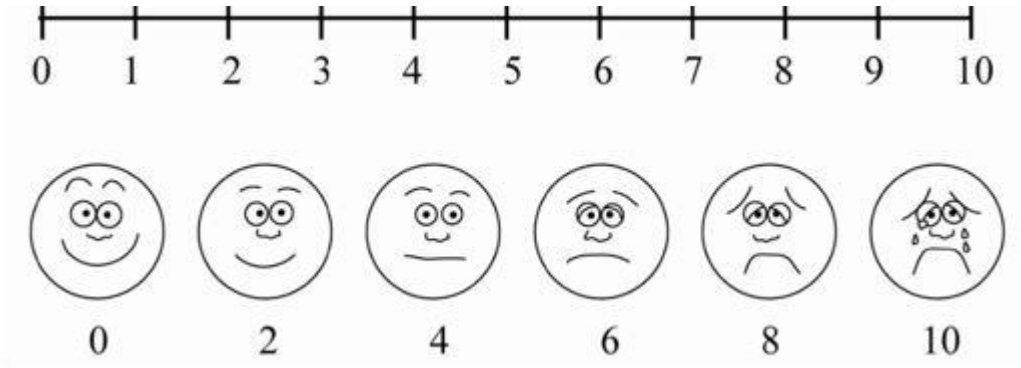
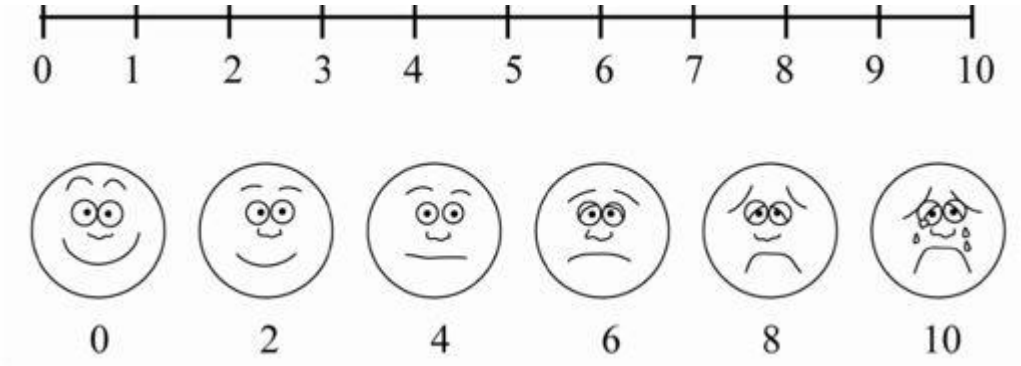
13. How confident are you that HidaWear AX will not leak or move?

Very Confident — Not Confident



14. How confident do you feel in yourself about your body image – self confidence/self esteem?

Very Confident — Not Confident



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23 APPENDIX 5 – NURSE ASSESSMENT FORMS

Nurse Assessment Day 0

Subject Number:	

Subjects use of usual product and method for dressing a wound.		
What dressings did subject use?		
	Yes	**No**
Did subject contort/ stretch to apply dressing?		
Did Subject need assistance?		
Could subject apply dressing without raising arms over their head?		
Did subject use additional equipment to dress their wound? eg. Scissors, pins, tape, mirror		
If yes, please specify		

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Nurse Assessment Day 21

Subject Number:	

Subjects use of HidraWear AX for dressing a wound.	**Yes**	**No**
Did subject contort/ stretch to apply dressing?		
Did Subject need assistance?		
Could subject apply dressing without raising arms over their head?		
Did subject use additional equipment to dress their wound? eg. Scissors, pins, tape, mirror		
If yes, please specify		

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24 APPENDIX 6 DERMATOLOGY QUALITY OF LIFE INDEX

1.	Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been?	Very much A lot A little Not at all	☐ ☐ ☐ ☐		
2.	Over the last week, how **embarrassed** or **self conscious** have you been because of your skin?	Very much A lot A little Not at all	☐ ☐ ☐ ☐		
3.	Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden**?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	Not relevant	☐
4.	Over the last week, how much has your skin influenced the **clothes** you wear?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	Not relevant	☐
5.	Over the last week, how much has your skin affected any **social** or **leisure** activities?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	Not relevant	☐
6.	Over the last week, how much has your skin made it difficult for you to do any **sport**?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	Not relevant	☐
7.	Over the last week, has your skin prevented you from **working** or **studying**?	Yes No	☐ ☐	Not relevant	☐
	If "No", over the last week how much has your skin been a problem at **work** or **studying**?	A lot A little Not at all	☐ ☐ ☐		
8.	Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	Not relevant	☐
9.	Over the last week, how much has your skin caused any **sexual difficulties**?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	Not relevant	☐
10.	Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	Not relevant	☐

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DERMATOLOGY LIFE QUALITY INDEX (DLQI) - INSTRUCTIONS FOR USE

The Dermatology Life Quality Index questionnaire is designed for use in adults, i.e. subjects over the age of

16. It is self-explanatory and can be simply handed to the subject who is asked to fill it in without the need for detailed explanation. It is usually completed in one or two minutes.

SCORING

The scoring of each question is as follows:

Very much scored 3

A lot scored 2

A little scored 1

Not at all scored 0

Not relevant scored 0

Question 7, 'prevented work or studying' scored 3

The DLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired.

HOW TO INTERPRET MEANING OF DLQI SCORES

0 – 1 no effect at all on subject's life 2 – 5 small effect on subject's life

6 – 10 moderate effect on subject's life 11 – 20 very large effect on subject's life

21 – 30 extremely large effect on subject's life

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25 APPENDIX 7 – SUBJECT CHECK INS

Daily Check in with Subjects:

Each day, at 1pm, subjects will receive an email requesting them to check in with the researcher by answering 3 questions.

1. What is your temperature?
2. How many dressings did you use in the last 24 hours?
3. Any comments?

This check in should take less than 5 minutes to complete.

Subjects will be required to respond by 5pm each evening. If subject has not responded by 5pm, a reminder text message will be sent to them.

If subject does not respond within 24 hours, the research nurse will call the subject to check in and take answers over the phone.

Weekly Check in with Subjects:

On day 7 and 14 subjects will be asked to complete the Dermatology Quality of life survey and questions on Ease of use, comfort, pain and confidence, at home. A link to the surveys will be emailed to them at 1pm in the afternoon with their daily check in.

Subjects will be required to respond by 5pm each evening. If subject has not responded by 5pm, a reminder text message will be sent to them.

If subject does not respond within 24 hours, the research nurse will call the subject to check in and take answers over the phone.

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26 REVISION HISTORY

Version history is managed and controlled by HidraMed Solutions' internal quality system.

Version	Reason for change	Changed by	Date
1.0	Initial Release	Conan Cavanagh	18 Oct 2019
2.0	New subject matter added detailing Reporting Guidelines for Serious Adverse Events, Adverse Events and Incidents per QP025 Clinical Evaluation Procedure and MEDDEV 2.12-1 GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM. Removal of the requirement to Return Product.	Laura Garvey-Trill	26 Feb 2020
3.0	Section 4.6 updated to include a more detailed process flow and information relating to Subjects presenting with Pyrexia >38 Degrees.	Suzanne Moloney	09 Mar 2020
4.0	Protocol updated with changes to include a home visit for subjects when they cannot attend the clinic. Revision History section added to track changes throughout document life cycle	Suzanne Moloney	18 Mar 2020

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