STATISTICAL ANALYSIS PLAN
STUDY KCE-16012

THE USE OF A SILICONE ADHESIVE MULTILAYER FOAM DRESSING AS AN ADJUVANT PROPHYLACTIC THERAPY FOR PRESSURE ULCER PREVENTION: A MULTICENTRE RANDOMISED OPEN LABEL PARALLEL GROUP MEDICAL DEVICE TRIAL IN HOSPITALISED PATIENTS AT RISK OF PRESSURE ULCER DEVELOPMENT

This document is based on the statistical section of the protocol.
Any deviations from this plan will be described in the final clinical study report.

Version FINAL
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ClinicalTrials.gov NCT03442777

TABLE OF CONTENTS

1 INTRODUCTION

This document gives a detailed statistical analysis plan for the Pressure Ulcer Prevention study (KCE-16012), and should be read in conjunction with the current protocol.

2 BACKGROUND

A pressure ulcer is defined as a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear (National Pressure Ulcer Advisory Panel, 2014). To prevent the development of pressure ulcers, the KCE clinical practice guideline recommends to reduce both the amount and the duration of pressure and shear (Beeckman, Matheï, Van Lancker, Van Houdt, Vanwalleghem et al., 2013). Currently, interest is growing in the application of multilayer foam dressings (initially being used for wound treatment) as an adjuvant prophylactic therapy for pressure ulcer prevention. The clinical effectiveness of a multilayer foam dressing as a preventative intervention for pressure ulcers has been summarized in three systematic reviews (Clark et al., 2014; Davies, 2016; Moore & Webster, 2013). The three reviews concluded at the lack of a large randomized study to ascertain the most appropriate patient populations, and anatomical locations for the use of multilayer foam dressings as a preventative intervention for pressure ulcers. The smaller trials on the prevention of pressure ulcers, providing some proof of concept, were limited to the ICU setting. The study aims to confirm the effectiveness of such intervention in ICU and non-ICU settings.

3 TRIAL OBJECTIVES AND DESIGN

The Pressure Ulcer Prevention trial is a multicentre, randomised, open-label trial with the following objective:

Primary objective

The objective of this study is to determine if silicone adhesive multilayer foam dressings applied to the sacrum, heels and greater trochanter in addition to standard prevention reduce pressure ulcer incidence category II, III, IV, Unstageable and Deep Tissue Injury (DTI) compared to standard pressure ulcer prevention alone, in at risk hospitalised patients. In particular, this trial extends previous trial results obtained in ICU setting.

No secondary objectives have been formulated for this trial.

3.1 Study design

This is a randomised, open label, parallel group, superiority, multicentre post-marketing study. There are two intervention groups (Allevyn® and Mepilex®) and one control group (standard of care). Patients have been randomised in a 1:1:1 ratio to the Allevyn®, Mepilex® and control group and stratified by hospital and the type of ward (ICU vs non- ICU). The duration of the intervention period is maximum 14 days (see Figure 1). There is no follow-up after the end of the intervention period.

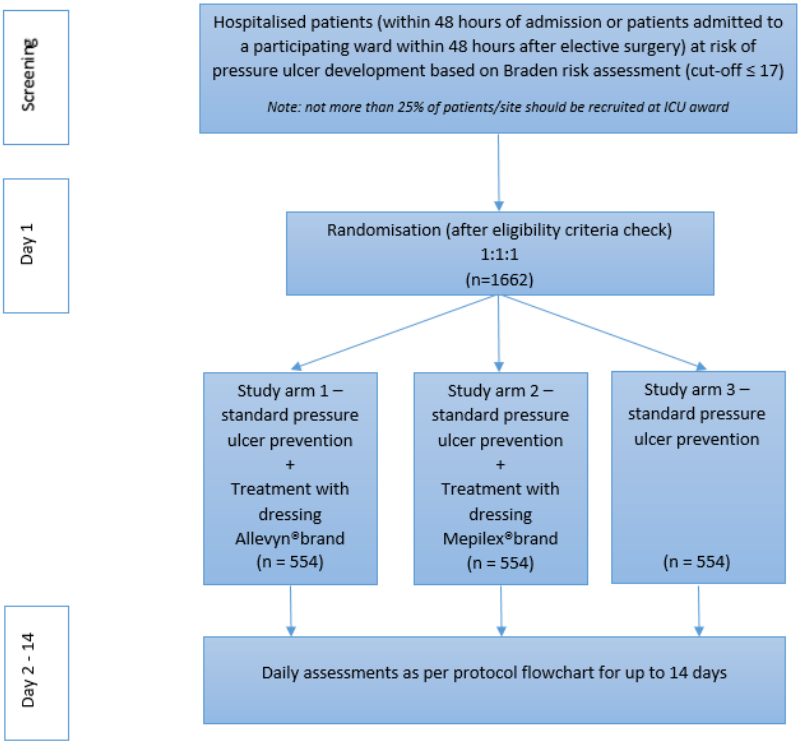

Figure 1: Study design.

3.2 Patient Eligibility criteria

3.2.1 Inclusion criteria

Following inclusion criteria will be applied:

1. At risk for pressure ulcer development based on Braden risk assessment (Braden score ≤17).

2. Admitted to hospital within the previous 48 hours.

   Note: Not more than 25% of patients per site should be recruited at ICU wards.

3. Skin at sacrum is assessable and there is no clinically relevant incontinence- associated dermatitis (IAD) or another skin condition that would be a contra-indication for the application of the devices under study, and there is no pressure ulcer category II or worse present.
   **clinically relevant IAD is defined as any of the 4 categories described in the publication http://users.ugent.be/~dibeeckm/globiadnl/nlv1.0.pdf*

4. for at least 3 of the following 4 skin sites (heel left, heel right, greater trochanter left, greater trochanter right) one of the following two conditions should apply:

   - A study dressing can be applied as prevention of a pressure ulcer category II or worse at that skin site (there is no contra-indication)

OR

- There is already a pressure ulcer category II or worse at that skin site.

5. Written informed consent by the patient or his/her legal representative.

3.2.2 Exclusion criteria

Following exclusion criteria will be applied:

1. Aged < 18 years.
2. The length of stay counting from first day of admission in one or (if the patient is transferred to another ward) more participating wards is < 7 days.
3. Both heels amputated
4. Previously known/documented allergy for substances used in the devices under study.
5. A clinical condition not allowing participation in a clinical study.
6. Participation in another interventional clinical trial.
7. Patients who exceptionally receive or are planned to receive a dressing for the prevention of pressure ulcers at sacrum, heels and trochanters based on best medical judgment and outside of the surgery setting.

3.3 Sample size calculation

For all analyses, both treatment groups will be pooled into one group unless specified otherwise. The sample size calculation is based on this assumption.

The primary objective is to compare the incidence rate of occurrence of at least one new pressure ulcer category II, III, IV, Unstageable, and DTI pressure ulcer at sacrum, heels and greater trochanter in both treatment arms versus the control arm.

The primary hypothesis is that the incidence rate of new pressure ulcer category II, III, IV, Unstageable, and DTI at sacrum, heels and greater trochanter will be lower in the treatment groups compared to the standard of care group. Superiority will be concluded if the primary variable is significantly different in the treatment groups compared to the standard of care group, based on a two sided test at 5% level of significance.

The sample size calculation is based on the results of a number of randomised trials with data about pressure ulcer category II, III, IV, Unstageable, and DTI incidence.

- The pressure ulcer category II, III, IV, Unstageable, and DTI incidence rate on sacrum, greater trochanter and heels is 6% in the standard of care group (Schoonhoven et al., 2007)
- The treatment groups will have a 50% reduction in pressure ulcer incidence category II, III, IV, Unstageable, and DTI incidence on sacrum, greater trochanter and heels. (Demarré et al., 2012; Nixon et al., 2006)

In order to have 80% power to show superiority, data should be available for 1578 patients in total of which 526 are allocated to the control group and 1052 are allocated to the treatment group.

Considering approximately 5% drop a total of 1662 patients are to be randomised to ensure that sufficient patients complete the study without compromising the power of the study.

Exploratory efficacy analysis will compare the effectiveness of the two treatments: Allevyn® and Mepilex®. The null hypothesis is that there is no difference between Allevyn® and Mepilex®. The alternative hypothesis is that there is a difference between the treatment groups. The difference will be tested two- sided at 5 % level of significance.

4 DATABASE

The database comprises of the following 9 datasets:

Clinical Database

1. GEN (GENERAL): general datasets with all demographics and inclusion and exclusion criteria, 1 line per patient (contains all patients who consented to the study)
2. ASS (ASSESSMENTS): all the assessments data, 1 line per patient per day.
3. PHO (PHOTOS): central blinded review of the pictures (the pictures will also be transferred).
4. ADE (ADVERSE EVENT DEVICE): 1 line per reported case. All descriptions are in free text.
5. DD (DEVICE DEFICIENCY): one line per reported case.
6. COM (COMMENTS in e-CRF) - one line per comment

Data Management and Monitoring Database

7. DCR (DATA CLARIFICATIONS REQUEST), 3 types of requests (Monitor; automatic edits checks; Data management). 1 line per DCR.
8. MONITORING: information on whether the page has been monitored or not on site.

Audit Trail

9. A_TRAIL (AUDIT TRAIL): audit trial of whole eCRF. It contains all the creation of records and the changes that have been made to it, when and by whom.

The annotated e-CRF describes all variables present in the database (see appendix 1).

All datasets are in SAS format (extension .sas7bdat).

5 ANALYSES

5.1 Endpoints

The following endpoints will be analysed:

Clinical endpoints

1. Occurrence of a new Pressure Ulcer category II or worse (i.e. a Pressure Ulcer Category II, III, IV, Unstageable, and Deep Tissue Injury) at any site during the observation period, as reported by site.

2. Occurrence of a new Pressure Ulcer category II or worse (ie Pressure Ulcer Category II, III, IV, Unstageable, and DTI) on sacrum, right greater trochanter, left greater trochanter, right heel, left heel during the observation period, as reported by site.

3. Occurrence of a new Pressure Ulcer category II or worse (i.e. a Pressure Ulcer Category II, III, IV, Unstageable, and Deep Tissue Injury) at any site and by body site, during the observation period, as confirmed by central review of pressure ulcer pictures.

For all those endpoints, a patient with a PU (cat II or above) already present at baseline for the specific site assessed will be excluded for the analysis of that specific site. For patients with a specific site not assessable at baseline, the first day where this site is assessed will be used as baseline information.

Health Economics endpoints

4. Area under the curve for utilities derived from EQ-5D-5L Quality of Life score at Day 3 and Day 14 or end of study day.
5. Number of dressing applied during intervention period (by body site and in total), for patients versus pressure ulcers prevented overall and by body site.

Safety endpoints (only for patients in the intervention group)

6. Occurrence of any Adverse Device Effect (ADE)
7. Occurrence of any Serious Adverse Device Effect (SADE)
8. Occurrence of any Device Deficiency (DD)

5.2 Analysis populations (ITT and PP)

The following analysis sets will be considered:

1. **Total Set**: all patients who consented to participate in the study and who did not explicitly ask to have their data excluded from the analysis.
2. **Intent-to-treat (ITT) Population**: All patients of the Total set who were randomised.
3. **Per Protocol (PP) Population**: all patients of the ITT Population who received the study treatment according to the protocol, without any major protocol deviation impacting the primary efficacy assessment.
4. **Safety Population**: all patients of the ITT population who entered into the observation period and who were applied at least once dressing.

For the ITT Population patients will be considered in the treatment group as randomised (as foreseen by the attributed randomisation number). For the other analysis sets patients will be considered in the treatment group as treated.

The efficacy analyses will primarily be performed for the ITT Population and supportively for the PP Population

For the PP analyses, patients will be excluded:

1. If they were non-eligible for the study (if they did not meet all inclusion criteria, or they met one of the exclusion criteria)
2. who received the intervention of another group (not the one allocated using randomisation)
3. patients who were not applied any dressing during the intervention period on the specific site assessed
4. who discontinued the intervention for any reason before day 3 (as pressure ulcer incidence is likely highest on day 3)

5.3 Statistical analyses

5.3.1 General considerations

The statistical analysis will be performed using the SAS statistical package, version 9.2.

Descriptive statistics

Unless otherwise stated, summary statistics for quantitative variables will include the mean, standard deviation, minimum, 1st quartile, median, 3rd quartile, maximum, number of observations, and number of missing values. For categorical variables absolute counts (n) and percentages (%) of patients with data will be presented.

P-values

Unless otherwise specified, all p-values will be from two-sided test. No corrections for multiple testing will be made.

Missing data

Patients without any assessment of the primary endpoint after randomization will be excluded from the ITT population.

5.3.2 Demographics and baseline characteristics.

A description will be given of key patient characteristics recorded at the baseline visits, for all patients and broken down by treatment group. See appendix 2 for templates of tables' results.

The following conventions will be taken take

- Age: is the age at the date of written informed consent.
- Time spent is hospital: is the time from data of hospital admission to the date of written informed consent (maximum 48 hours per protocol)
- Time since surgery: is the time from data of surgery to the date of written informed consent
- BMI will be categorized following usual international standards
- Braden Score at baseline will be categorised as mild risk (17), moderate risk (12-16), low risk (11 and lower)

5.3.3 Efficacy evaluation

Primary efficacy variable

For the primary efficacy variable:

- Comparison of the treatment group (Allevyn® & Mepilex® pooled) versus the control group (incidence rate is frequency at which patients develop one or more such new pressure ulcers over the study period as judged on site) by means of the CMH test controlled for type of ward (ICU/Non-ICU).

Patients in study arms 1 and 2 will be pooled as the treatment group and the incidence rate of pressure ulcers category II or worse as judged on site will be compared between the treatment group and the usual care group as per randomisation scheme, by means of the CMH test controlled for type of ward (ICU/Non-ICU).

The primary endpoint of this study is the incidence rate during the study period of the patient (during maximum 14 days) of at least one new pressure ulcer category II, III, IV, Unstageable, Deep Tissue Injury (DTI) (briefly referred to as pressure ulcers category II or worse) on sacrum, heels and greater trochanter as judged on site. The primary analysis of the primary efficacy variable is a superiority analysis that compares the incidence rate in the pooled treatment groups versus the control group, on the ITT population by means of the CMH test controlled for type of ward (ICU/Non-ICU). Superiority will be concluded if the estimated impact of the treatment (Allevyn® and Mepilex® versus standard of care) is significant based on a 2 sided test at 5% significance level.

Subgroup analyses of primary endpoint

<u>All sites</u>
Subgroup analyses will be performed on the following variables:

- Age (<60, 60-69, 70-79, 80+)
- Gender
- Ward (ICU, non-ICU)
- Surgery (yes/no)
- BMI (categories)
- Diabetes (yes/no)
- By Braden Scale Score at baseline (17, 12-16, 11 or less) , and by Braden score specific dimensions:
  - Nutrition (very poor or probably inadequate *versus* adequate or excellent)
  - Sensory perception (completely limited or very limited *versus* slightly limited or no impairment)
  - Activity (bedfast or chairfast *versus* walks occasionally or walks frequently)
  - Mobility (completely immobile or very limited *versus* slightly limited or no limitations)
- Hospital

<u>In addition, for the analysis of the sacrum and the trochanters</u>
By Braden score for

- Moisture (constantly moist or very moist or occasionally moist *versus* rarely moist)

<u>In addition, for the analysis of the heels</u>
By Braden score for

- Friction and shear (problem or potential problem *versus* no apparent problem)

These exploratory subgroup analyses will be undertaken, appropriately cautiously, to investigate any influence of the prognostic factors.

See appendix 3 for templates of tables' results on clinical endpoints.

Sensitivity analysis

- A sensitivity analysis will be conducted in the ITT populations based on the reviewed photographs of the PU, based on the review by the CI team.

Exploratory analyses

- Comparison (ITT and PP) of incidence rates (primary endpoint) between the experimental investigational devices (arms 1 and 2).

Exploratory efficacy variables: logistic regression

A sensitivity analysis will be done using logistic regression. The model of the logistic will have the following variables: intervention group, hospital, age, sex, type of ward and Braden score category. A comparison between the efficacy of the two treatments will be made by defining a contrast in the logistic model. A difference between the two treatments will be concluded if there is a significant difference between the two treatments based on 2 sided testing at the 5% significance level.

5.3.4 Health economics evaluation

Health economic analyses will be performed on the basis of the ITT population.

Because no Belgian values for the EQ5D utilities[a] are currently available (this is an undergoing project at KCE), values from The Netherlands will be used (with a sensitivity analysis based on values from England).

Statistical comparisons on the impact of the intervention on the QOL will be for exploratory purposes only.

No statistical comparison will be performed on the number of dressings applied.

See appendix 4 for templates of tables' results on health economics endpoints.

5.3.5 Safety evaluation

Safety analyses will be performed on the basis of the Safety Population and will be descriptive.

The description of safety findings will be provided as entered in the e-CRF (as a free text in Dutch).

No statistical comparisons will be performed on the safety endpoints.

See appendix 5 for templates of tables' results on safety endpoints.

6 CLINICAL STUDY REPORT

The clinical study report will be written by the Chief Investigator. After database lock, all tables described in appendices 2 to 5 will be provided in RTF format to him.

■ APPENDICES

The appendices of this SAP are in a separate document.

[a] https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/valuation-standard-value-sets/

APPENDICES

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This document contains the appendices of the statistical analysis plan.

Version FINAL
Date 08 10 2019

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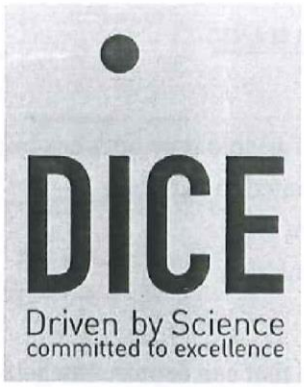
■ TABLE OF CONTENTS

The tables templates presented in this SAP are based on the analysis of a mock database of 10 patients. The tables in the final clinical study report may look slightly different in function of the analysis of the complete database.

APPENDICES

APPENDIX 1. ANNOTATED E-CRF



Annotated CRF for

THE USE OF A SILICONE ADHESIVE MULTILAYER FOAM DRESSING AS AN ADJUVANT PROPHYLACTIC THERAPY FOR PRESSURE ULCER PREVENTION: A MULTICENTRE RANDOMISED OPEN LABEL PARALLEL GROUP MEDICAL DEVICE TRIAL IN HOSPITALISED PATIENTS AT RISK OF PRESSURE ULCER DEVELOPMENT.

Protocol KCE-16012 (KCE2)

Version	Date	Status
1.0	14 December 2017	Final
2.0	12 February 2018	Amendment 1
3.0	23 March 2018	Amendment 2

ANNOTATION OF ECRF DATABASE

Color code:

- Red = Variable name, with variable type between brackets
- Green = Format/codes attributed to variables
- Blue = Panel names / content
- Black = Additional documentation

Variable type:

- Ax: Refers to text variables that can capture integers (e.g. numerical variables without decimals) with x digits, and predefined text codes such as 'NA', 'ND', etc.

  Example: A2

  - Allows entering numeric values between -9 and 99
  - Allows entering text codes 'NA', 'ND', etc.
  - Refuses the entry of -10.

- Ax.y: Refers to text variables that can capture numeric values, with x the width of the field (including the decimal field separator '.') and y the maximum number of digits to the right of the decimal point in the numeric value, as well as predefined text codes such as 'NA', 'ND', etc.. The entry of at least one number before the decimal field separator is mandatory, the entry of the decimal field separator or of decimals is not mandatory. Information is stored as entered. When using this format for variables calculated by the system, results are always rounded to and displayed on screen with y decimals.

  Example: A4.1

  - Allows entering numeric values between -9.0 and 99.9
  - Allows entering text codes 'NA', 'ND', etc.
  - Accepts the entry of an integer value (values between 0 and 9999) and stores the information without adding a decimal to the value e.g. 4 is stored as '4'
  - Refuses the entry of '4.12' and of ' .1'.

- AFx.y: Refers to text variables that can capture numeric values, with x the width of the field (including the decimal field separator '.') and y the fixed number of digits to the right of the decimal point in the numeric value, as well as predefined text codes such as 'NA', 'ND', etc.. The entry of the at least one number before the decimal field separator is mandatory, and the entry of the y decimals is mandatory.

  Example: AF4.1

  - Allows entering numeric values between -9.0 and 99.9
  - Allows entering text codes 'NA', 'ND', etc.
  - Refuses the entry of values with more/less than 1 decimal (e.g. 4, 4.12)

- Refuses the entry of ' .1'.

- Cx: Refers to text variables of length x. Can consist of letters (lower and upper case), numbers or any combination of these. While exporting the data, special characters (ASCII characters 8, 9, 10, 11 and 13) are replaced by a space.

  Example: C255:

  - Allows entering any text string of maximum 255 characters.

- Nx: Refers to integers (e.g. numerical variables without decimals) with x digits

  Example: N2:

  - Allows entering numeric values between -9 and 99.
  - Refuses the entry of text codes 'NA', 'ND', etc.
  - Refuses the entry of -10.

- Nx.y: Refers to numerical variables, with x the width of the field (including the decimal field separator '.') and y the maximum number of digits to the right of the decimal point in the numeric value. The entry of at least one number before the decimal field separator is mandatory, the entry of the decimal field separator or of decimals is not mandatory. Information is stored as entered. When using this format for variables calculated by the system, results are always rounded to and displayed on screen with y decimals.

  Example: N4.1:

  - Allows entering numeric values between -9.0 and 99.9.
  - Allows the entry of an integer value (values between 0 and 9999) and stores the information without adding a decimal to the value e.g. 4 is stored as '4'; Refuses the entry of '4.12' and of '.1'
  - Refuses the entry of text codes 'NA', 'ND', etc..

- NFx.y: Refers to numerical variables, with x the width of the field (including the decimal field separator '.') and y the number of digits to the right of the decimal point in the numeric value. The entry of at least one number before the decimal field separator is mandatory, and the entry of the y decimals is mandatory.

  Example: NF4.1:

  - Allows entering numeric values between -9.0 and 99.9.
  - Refuses the entry of Text codes 'NA', 'ND', etc.
  - Refuses the entry of values with more/less than 1 decimal (e.g. 4, 4.12)
  - Refuses the entry of ' .1'.

Notes:

- For variables of type A and N:
  - If decimal parts are allowed, the point ('.') should be used as decimal field indicator. The use of a thousand field indicator is not allowed.
- For variables of type A:
  - When entering leading zero's, these will be retained and considered when verifying whether the entry fits in the maximal width allowed for the variable.
  - Leading zero's may be entered, but are not mandatory to be entered, except if otherwise documented in the screen or edit check plan document.
- For variables of type N:
  - When entering leading zero's, these will be removed and not considered when verifying whether the entry fits in the maximal width allowed for the variable.

DOCUMENT HISTORY

Amendment 1:

- 1.7 Inclusion / Exclusion Criteria:

  - New variable ECT7 added
  - Text of ICT3 and ICT4 has changed
  - Changed IC1-IC5 into ICT1-ICT5 and EC1-EC7 into ECT1-ECT7
  - Changed ARM[C1] into ARM[C16]
  - Added variables for date of randomisation and time of randomisation

- 1.9 Daily assessment:

  - Section Study Intervention: Variables for 'Dressing type applied' changed from tickboxes to numerical fields
  - Corrected the length for SUPSURFT, FREQREPT, COMPIDT

- 1.10 Termination:

  - 'Date of end of study intervention on ALL body sites' changed from N to A

- 1.11 Adverse Device Effects (ADE) Log:

  - Corrected the length for ADEOUTT

- 1.14 Device Deficiency (DD) Log:

  - Corrected the length for DDNAT

Amendment 2:

- 1.13 Photographs Log: annotation added
- Photographs Log for Blind Review: annotation added
- 1.9: format of Day changed from [N1] into [C3]

FLOW OF THE E-CRF SCREENS

Creation of patient

	Screen
1.4	Informed Consent

Day 1 (Baseline)

	Screen
1.5	Patient Profile
1.6	Pre-Randomisation Assessment (Day 1)
1.7	Inclusion / Exclusion Criteria
1.8	Day 1 – Study Intervention

Day 2 until Day 14

	Screen
1.9	Daily Assessment

Log Screens

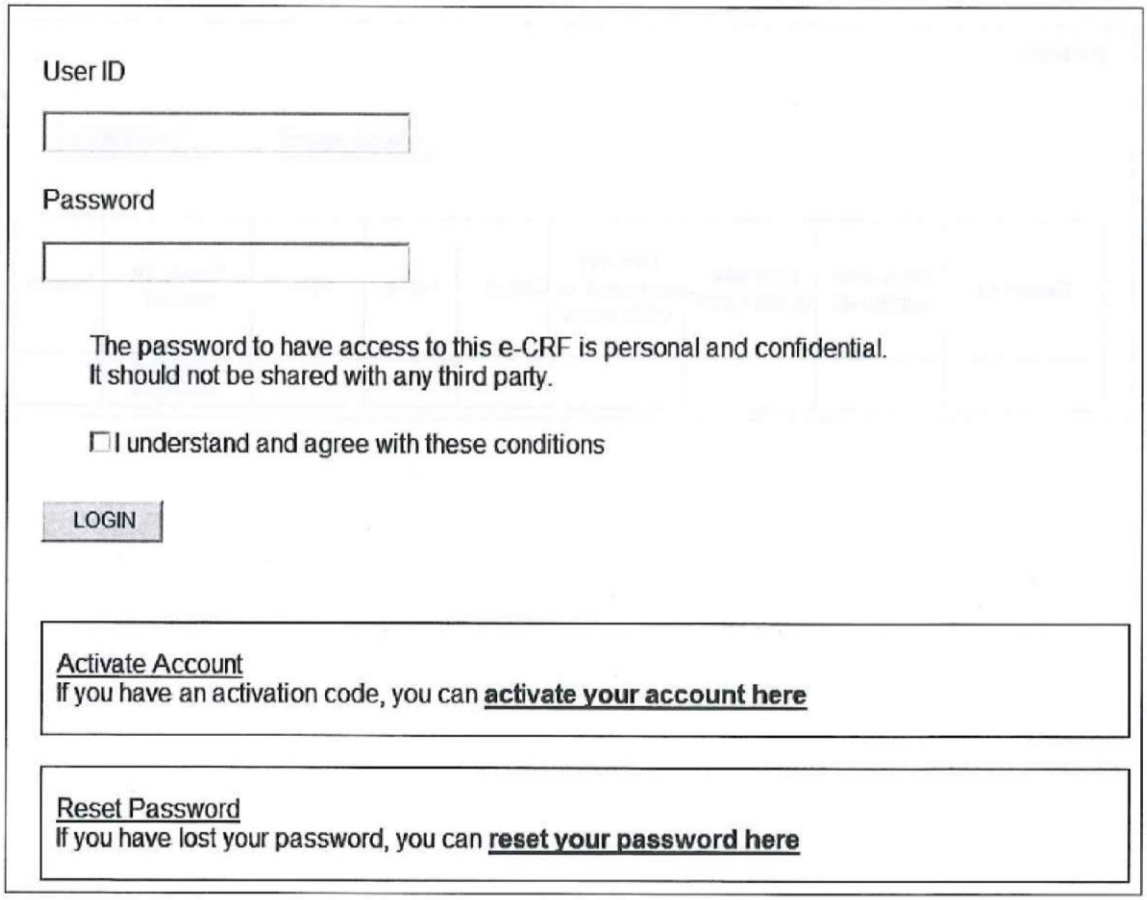
	Screen
1.10	Termination
1.11	Adverse Device Effects (ADE) Log
1.12	Comments Log
1.13	Photograph Log
1.14	Device Deficiency (DD) Log
1.15	Investigator Statement

Reviewer Screen

	Screen
	Photographs Log for Blind Review

1.1. Log-on to the System

1.1.1. Screen



1.2. Patients Overview

1.2.1. Screen

Patients

Add new patient | Search

Patient ID	Ward upon enrollment	User who randomised	Last day assessed or EOS status	Status	Active	PDF	Ready for sign-off	Details
							Ready	

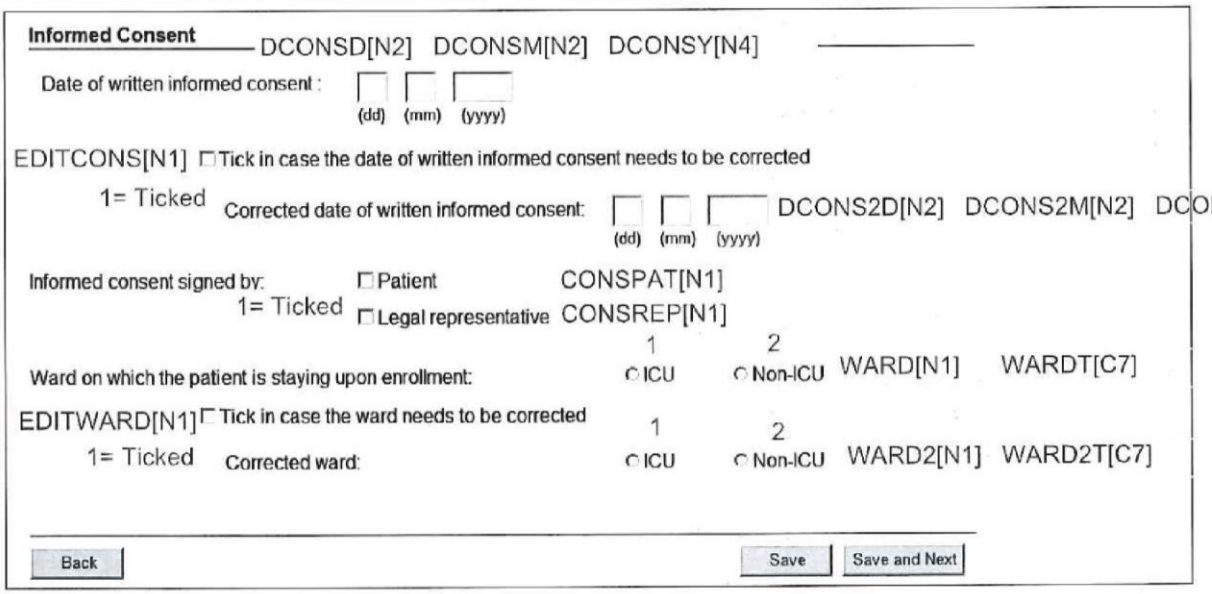
1.3. Patient Summary

PATIENT_ID = SUBJID[C7]

1.4. Informed Consent

PANEL = GEN

1.4.1. Screen



1.5. Patient Profile

PANEL = GEN

1.5.1. Screen

Patient Profile

Date of birth: ☐ ☐ ☐ DDBD[A2] DDBM[A2] DDBY[N4]
(dd) (mm) (yyyy)

Gender: 1 ○ Male 2 ○ Female SEX[N1] SEXT[C6]

Height: ☐ cm HEIGHT[A3]

Weight: ☐ kg WEIGHT[A5.1]

Body Mass Index (BMI): ☐ BMI [N4.1]

Does the patient have diabetes? ○ Yes ○ No DIABETE[N1] DIABETET[C3]
1 2

Back | Save | Save and Next

1.6. Pre- Randomisation Assessment (Day 1)

1.6.1. Screen

PANEL = GEN

Pre - Randomisation Assessment (Day 1)

Date ☐☐ (dd) ☐☐ (mm) ☐☐☐☐ (yyyy) DRANDD[N2] DRANDM[N2] DRANDY[N4]

1. Admission information DADMD[N2] DADMM[N2] DADMY[N4]

Date admission to hospital: ☐☐ (dd) ☐☐ (mm) ☐☐☐☐ (yyyy) Time: ☐ (hh on 24 hour clock) TADMH[N2]

Expected length of stay on participating wards since date of admission to hospital: 1 ○ Less than 7 days STAY[N1]
2 ○ 7 days or more STAYT[C16]

Did the patient have surgery since admission? ○ Yes 1 ○ No 2 SURG[N1] SURGT[C3]

Date of start of surgery: ☐☐ (dd) ☐☐ (mm) ☐☐☐☐ (yyyy)
DSURD[N2] DSURM[N2] DSURY[N4]

Type of surgery: 1 ○ Elective 2 ○ Non-elective SURTYPE[N1] SURTYPET[C12]

Anaesthesia 1 ○ General 2 ○ Local SURANAE[N1] SURANAET[C7]

2. Braden scale assessment DAY[N2] = 1 REFER TO SCREEN 1.9 **PANEL = ASS**

Sensory perception ❗ ☐ (1-4) Moisture ❗ ☐ (1-4) Activity ❗ ☐ (1-4) Mobility ❗ ☐ (1-4) Nutrition ❗ ☐ (1-4) Friction & shear ❗ ☐ (1-3) Braden score ☐☐ (6-23)

1=Sacrum
2=Heel right
3=Heel left
4=Greater trochanter right
5=Greater trochanter left

PANEL = ASS

3. Body sites evaluation

	1 Sacrum	2 Patient's right heel	3 Patient's left heel	4 Patient's right greater trochanter	5 Patient's left greater trochanter
Body site assessable? ASSESS1[N1] ASSESS1T[C34]	1 ○ Yes, likely to remain assessable 2 ○ Yes, unlikely to remain assessable 3 ○ No				
Existing pressure ulcer on Day 1?	○ Yes ○ No Category:		REFER TO SCREEN 1.9		
Is the body site dry?	○ Yes ○ No Type of moisture: ☐ Sweat ☐ Urine ☐ Diarrhea ☐ Other				
Is the body site intact?	○ Yes ○ No				
Are there dermatological contra-indications to apply dressing?	○ Yes ○ No Skin condition: ☐ Incontinence-associated dermatitis ☐ Skin infection ☐ Other				
Is there any other contra-indication to apply dressing?	1 ○ Yes ○ No 2 OTHCI1[N1] OTHCI1T[C3]				

Identification in audit trail:
List: 1 to 5
Variable: VARNAME

Identification in export:
Variable: VARNAMEx

PANEL = ASS

4. Support information

Support surface in bed:
- ○ Active support surface (such as alternating or low-air loss)
- ○ Reactive support surface (such as visco-elastic foam or air-filled)
- ○ No specific mattress to prevent pressure ulcers (standard foam, not pressure redistributing)

Heel(s) elevated from the bed? ○ Yes ○ No

Frequency of repositioning:
- ○ At least every 2 hours
- ○ Every 3 - 4 hours
- ○ Every 5 - 6 hours
- ○ Every 7 hours or more

REFER TO SCREEN 1.9

5. EQ - 5D - 5L Quality of Life Questionnaire

Patient status: ○ Conscious ○ Unconscious

Has the EQ - 5D - 5L Quality of Life Questionnaire been completed? ○ Yes ○ No

Completed by:
- ○ Patient
- ○ Relative
- ○ Ward staff
- ○ Other

Mobiliteit / Mobilité

Zelfzorg / Autonomie de la personne

Dagelijkse activiteiten / Activités courantes

Pijn, ongemak / Douleurs, gêne

Angst, somberheid / Anxiété, dépression

Gezondheidsheidstoestand / Santé: (0 - 100)

Reason:

Back | Save | Save and Next

PANEL = ASS

1.6.2. Droplists

Mobiliteit / Mobilité

Dagelijkse activiteiten / Activités courantes

REFER TO SCREEN 1.9

Pijn, ongemak / Douleurs, gêne

Angst, somberheid / Anxiété, dépression

Zelfzorg / Autonomie de la personne

Category

I - Nonblanchable Erythema
II - Partial Thickness Skin Loss
III - Full Thickness Skin Loss
IV - Full Thickness Tissue Loss
Unstageable: Depth unknown
Suspected Deep Tissue Injury: Dept Unknown

1.7.1. Screen

Inclusion / Exclusion Criteria

PANEL = GEN

All answers must be checked "Yes" in order to be eligible for study participation

	Yes	No	
1. At risk for pressure ulcer development based on Braden risk assessment (Braden score ≤17).	○	○	ICT1[C3]
2. Admitted to hospital within the previous 48 hours. *Note: Not more than 25% of patients per site should be recruited at ICU wards.*	○	○	ICT2[C3]
3. Skin at sacrum is assessable and there is no clinically relevant incontinence-associated dermatitis (IAD*) or another skin condition that would be a contra-indication for the application of the devices under study, and there is no pressure ulcer category II or worse present.	○	○	ICT3[C3]
**clinically relevant IAD is defined as any of the 4 categories described in the publication http://users.ugent.be/~dibeeckm/globiadnl/nlv1.0.pdf*			
4. For at least 3 of the following 4 body sites (heel left, heel right, greater trochanter left, greater trochanter right) one of the following two conditions should apply: - A study dressing can be applied as prevention of a pressure ulcer category II or worse at that body site (there is no contra-indication) OR - There is already a pressure ulcer category II or worse at that body site.	○	○	ICT4[C3]
5. Written informed consent by the patient or his/her legal representative.	○	○	ICT5[C3]

Exclusion criteria

All answers must be checked "No" in order to be eligible for study participation

	Yes	No	
1. Aged < 18 years.	○	○	ECT1[C3]
2. The length of stay counting from first day of admission in one or (if the patient is transferred to another ward) more participating wards is < 7 days.	○	○	ECT2[C3]
3. Both heels amputated	○	○	ECT3[C3]
4. Previously known/documented allergy for substances used in the devices under study.	○	○	ECT4[C3]
5. A clinical condition not allowing participation in a clinical study.	○	○	ECT5[C3]
6. Participation in another interventional clinical trial.	○	○	ECT6[C3]
7. Patients who exceptionally receive or are planned to receive a dressing for the prevention of pressure ulcers at sacrum, heels and trochanters based on best medical judgment and outside of the surgery setting.	○	○	ECT7[C3]

Randomisation

Patient is randomised in arm: [ ] ARM[C16]

Back | Save | Save and Next

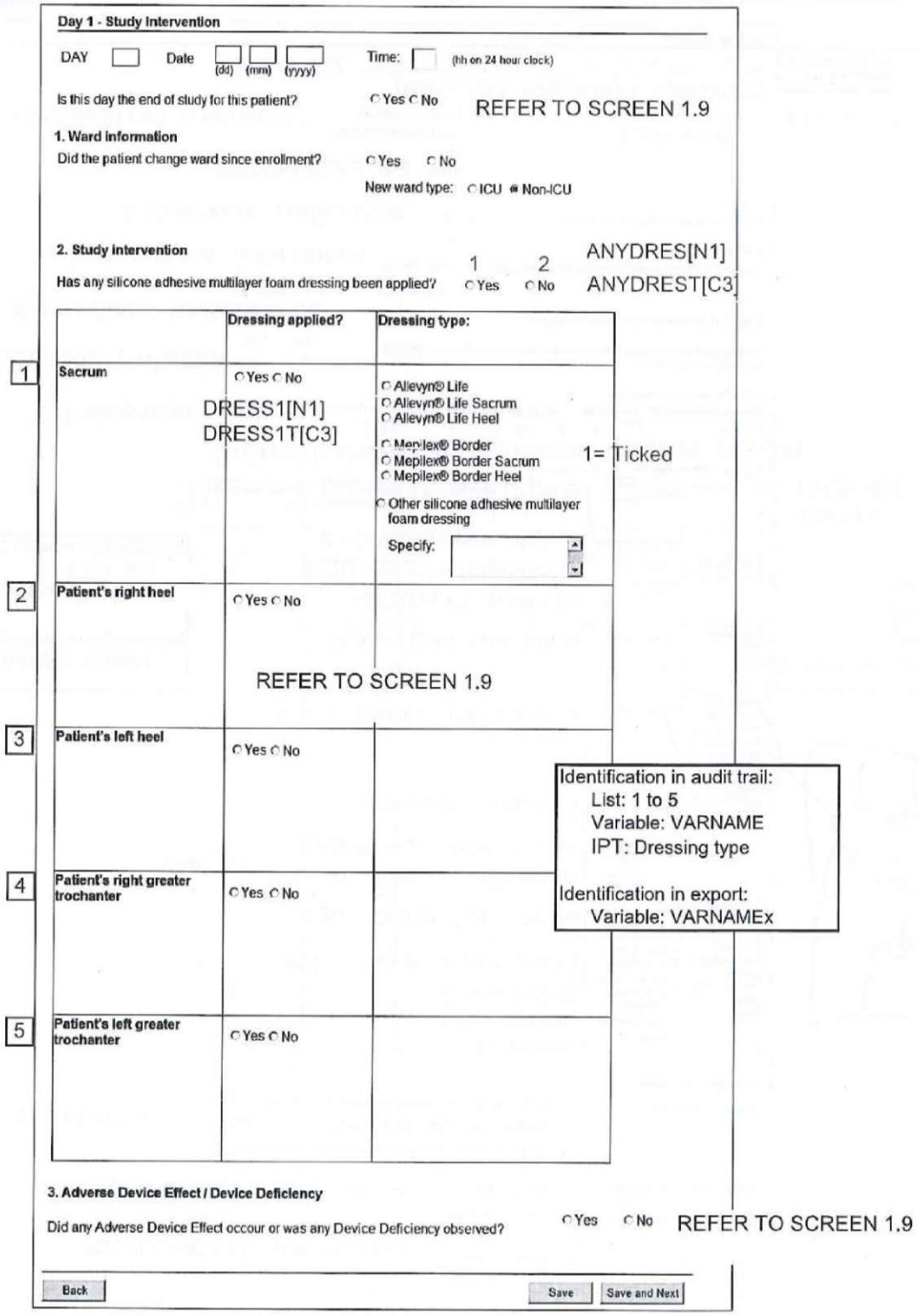
Date of randomisation DENTRD[N2] DENTRM[N2] DENTRY[N4]

Time of randomisation TENTRH[N2] TENTRM[N2]

1.8. Day 1 - Study Intervention

1.8.1. Screen

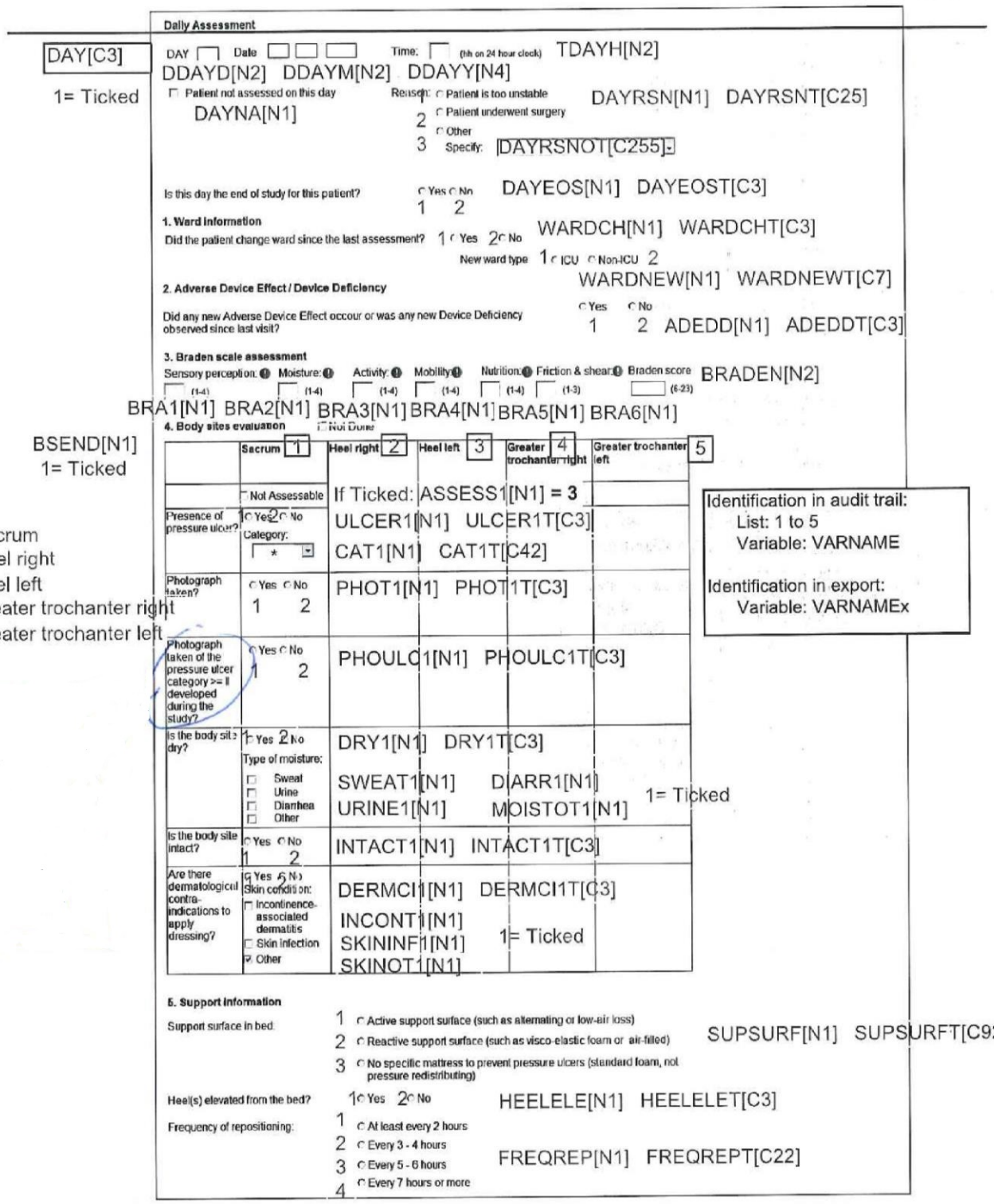
PANEL = ASS



1.9. Daily Assessment

1.9.1. Screen

PANEL = ASS



PANEL = ASS

6. Study intervention

Has there been a change of silicone adhesive multilayer foam dressing since previous assessment? ○ Yes 1 ◉ No 2 CHDRES[N1] CHDREST[C3]

		Has there been removal or replacement or placement at this body site?	Reason why dressing was removed and not replaced:	Reason why dressing was replaced:	Reason why dressing was newly applied:	Dressing type applied (enter the number applied of each type):	
1	**Sacrum**	1 ○ No 2 ○ Yes: Previous dressing removed 1 ○ Replaced 2 ○ Not replaced 3 ○ Yes: Dressing applied to the previously untreated body site CHANGE1[N1] CHANGE1T[C59]	☐ End of study ☐ Ulcer category >= 2 ☐ Other dermatological contra-indication ☐ Body site no longer assessable (bandage / plaster / other medical device, etc.) ☐ Other REMEOS1[N1] REMULC1[N1] REMDERM1[N1]	☐ Saturated ☐ No longer fully adheres ☐ Dislodged ☐ Rolled at the edges ☐ Wrinkled ☐ Creased/damaged ☐ Soiled ☐ As per manufacturer's instructions ☐ Other REPSAT1[N1] REPNLA1[N1] REPDISL1[N1]	☐ No contra-indications anymore ☐ Body site became treatable ☐ Other NAPNCI1[N1] NAPTREA1[N1] NAPOTH1[N1] 1= Ticked	☐ Allevyn® Life ☐ Allevyn® Life Sacrum ☐ Allevyn® Life Heel ☐ Mepilex® Border ☐ Mepilex® Border Sacrum ☐ Mepilex® Border Heel ☐ Other silicone adhesive multilayer foam dressing Specify: DRESOTS1[C255]	AL1[N1] ALS1[N1] ALH1[N1] MB1[N1] MBS1[N1] MBH1[N1] DRESOTH1[N1]
2	**Heel right**		REMNLA1[N1] REMOTH1[N1]	REPROLL1[N1] REPWRIN1[N1] REPCREA1[N1] REPSOIL1[N1] REPMAN1[N1] REPOTH1[N1]			
3	**Heel left**		1= Ticked	1= Ticked			
4	**Greater trochanter right**						
5	**Greater trochanter left**						

Identification in audit trail:
List: 1 to 5
Variable: VARNAME

Identification in export:
Variable: VARNAMEx

7. EQ - 5D - 5L Quality of Life Questionnaire (Day 3 and End of Study only)

Patient status: 1 ○ Conscious 2 ○ Unconscious STATUS[N1] STATUST[C11]

Has the EQ - 5D - 5L Quality of Life Questionnaire been completed? 1 ○ Yes 2 ○ No QOLCOMP[N1] QOLCOMPT[C3]

Completed by: 1 ○ Patient 2 ○ Relative 3 ○ Ward staff 4 ○ Other COMPID[N1] COMPIDT[C31]

Mobiliteit / Mobilité		MOBIL[N1] MOBILT[C255]
Zelfzorg / Autonomie de la personne		AUTONOM[N1] AUTONOMT[C255]
Dagelijkse activiteiten / Activités courantes		ACTIVIT[N1] ACTIVITT[C255]
Pijn, ongemak / Douleurs, gêne		PAIN[N1] PAINT[C255]
Angst, somberheid / Anxiété, dépression		DEPRES[N1] DEPREST[C255]
Gezondheidsheidstoestand / Santé:	(0 - 100)	HEALTH[A3]

Reason: QOLRSN[C255]

Back Save Save and Next

1.9.2. Droplists

Category *

1 I - Nonblanchable Erythema
2 II - Partial Thickness Skin Loss
3 III - Full Thickness Skin Loss
4 IV - Full Thickness Tissue Loss
5 Unstageable: Depth unknown
6 Suspected Deep Tissue Injury: Dept Unknown
8 II or higher - classification unknown

Mobiliteit / Mobilité

Dagelijkse activiteiten / Activités courantes

Pijn, ongemak / Douleurs, gêne

Angst, somberheid / Anxiété, dépression

Zelfzorg / Autonomie de la personne

1.10. Termination

1.10.1. Screen

PANEL = GEN

Termination

Discontinuation of Study Intervention on ALL body sites

Date of end of study intervention on ALL body sites: (dd) (mm) (yyyy)

DENDD[A2] DENDM[A2] DENDY[A4]

1 = TICKED

Please indicate the reason for discontinuation of study intervention on ALL body sites (check all that apply):

ENDDISC1[N1] ☐ Non-compliance with study procedures

ENDDISC2[N1] ☐ Life- threatening AE or Serious Adverse Event (SAE) that places the patient at immediate risk if the study intervention would be continued

ENDDISC3[N1] ☐ Patient shows a worsening of his/her medical condition, which in the investigator's opinion requires a discontinuation of the study intervention

ENDDISC4[N1] ☐ Patient's best interest

ENDDISC5[N1] ☐ Contra-indications / inability to apply dressing on ALL body sites

ENDDISC6[N1] ☐ Other

Specify: ENDEXP6[C255]

End of Study

End of study date: (dd) (mm) (yyyy)

DEOSD[N2] DEOSM[N2] DEOSY[N4]

1 = TICKED

Please indicate the reason for End of Study (check all that apply):

EOSDISC1[N1] ☐ Patient is no longer at risk of pressure ulcer development according to the Braden scale (Braden score >17)

EOSDISC2[N1] ☐ Day 14 reached

EOSDISC3[N1] ☐ Patient withdrawal

1 2

Can collected data be kept in the study and used for the analysis? ○ Yes ○ No

USEDATA[N1]

USEDATAT[C3]

EOSDISC4[N1] ☐ Discharged from the hospital

EOSDISC5[N1] ☐ Moved to a non-participating ward

EOSDISC6[N1] ☐ Death Date of death: (dd) (mm) (yyyy)

DDTHD[N2] DDTHM[N2] DDTHY[N4]

EOSDISC7[N1] ☐ Study closure by sponsor

EOSDISC8[N1] ☐ Other

Specify: EOSEXP8[C255]

Back Save Save and Next

1.11. Adverse Device Effects (ADE) Log

1.11.1. Screen

Adverse Device Effects (ADE) Log PANEL = ADE

Add

Nr	ADE description	Start Date (dd/mm/yyyy)	Outcome	Date resolved (dd/mm/yyyy)	Serious ADE	Alerts	Monitor	
								X

ADE number: ☐ ADENR[N3]

ADE description: ADENAME[C100]

Severity: 1 ○ Mild 2 ○ Moderate 3 ○ Severe 4 ○ NA/UK ADESEV[N1] ADESEVT[C8]

Start Date: ☐☐☐☐ DADESD[N2] DADESM[N2] DADESY[N4]

Outcome: 1 ○ Resolved 2 ○ Fatal 3 ○ Ongoing 4 ○ Unknown ADEOUT[N1] ADEOUTT[C8]

Date resolved: ☐☐☐☐ DADEED[A2] DADEEM[N2] DADEEY[N4]

Date of death: ☐☐☐☐ (dd) (mm) (yyyy) DADEDTHD[N2] DADEDTHM[N2] DADEDTHY[N4]

Date of last assessment: ☐☐☐☐ (dd) (mm) (yyyy) DADELASD[N2] DADELASM[N2] DADELASY[N4]

Serious ADE: 1 ○ Yes 2 ○ No ADESER[N1] ADESERT[C3]

Event considered as: 1 ○ Expected 2 ○ Unexpected ADEEXP[N1] ADEEXPT[C10]

Action taken: 1 ○ Yes 2 ○ No ADEACT[N1] ADEACTT[C3]

1 = TICKED

ADEACT1[N1] ☐ Discontinuation of study intervention at the affected/selected body site(s)

ADEACT2[N1] ☐ Discontinuation of study intervention on ALL body sites

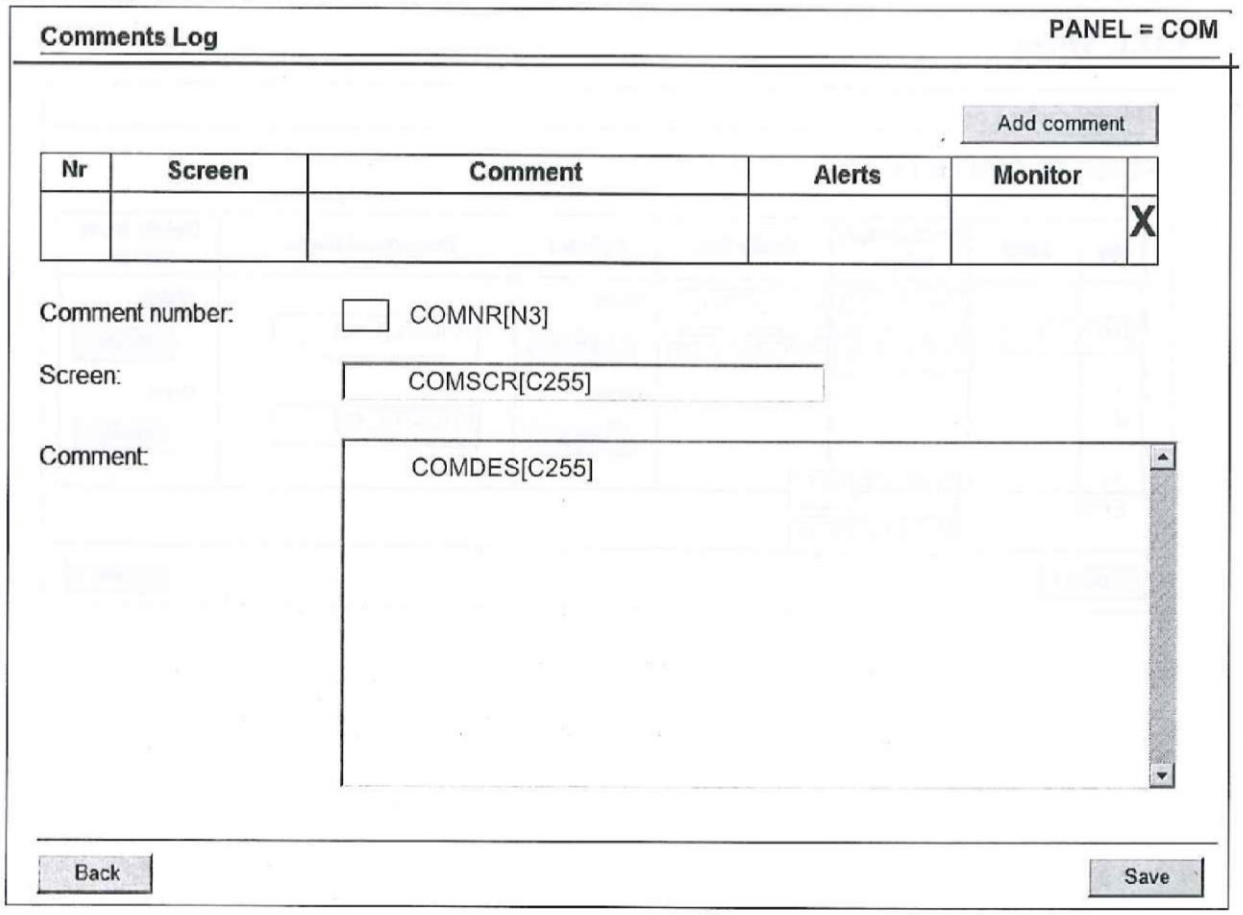
ADEACT3[N1] ☐ Medication / Therapy Specify: ADEACT3S[C255]

ADEACT4[N1] ☐ Other Specify: ADEACT4S[C255]

Back Save Save and Next

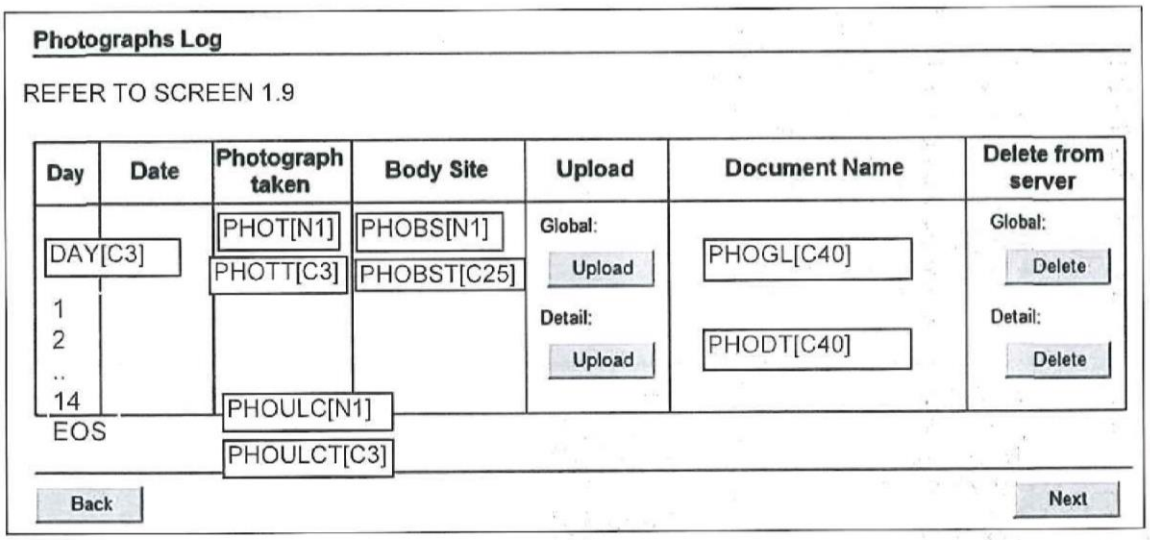
1.12. Comments Log

1.12.1. Screen



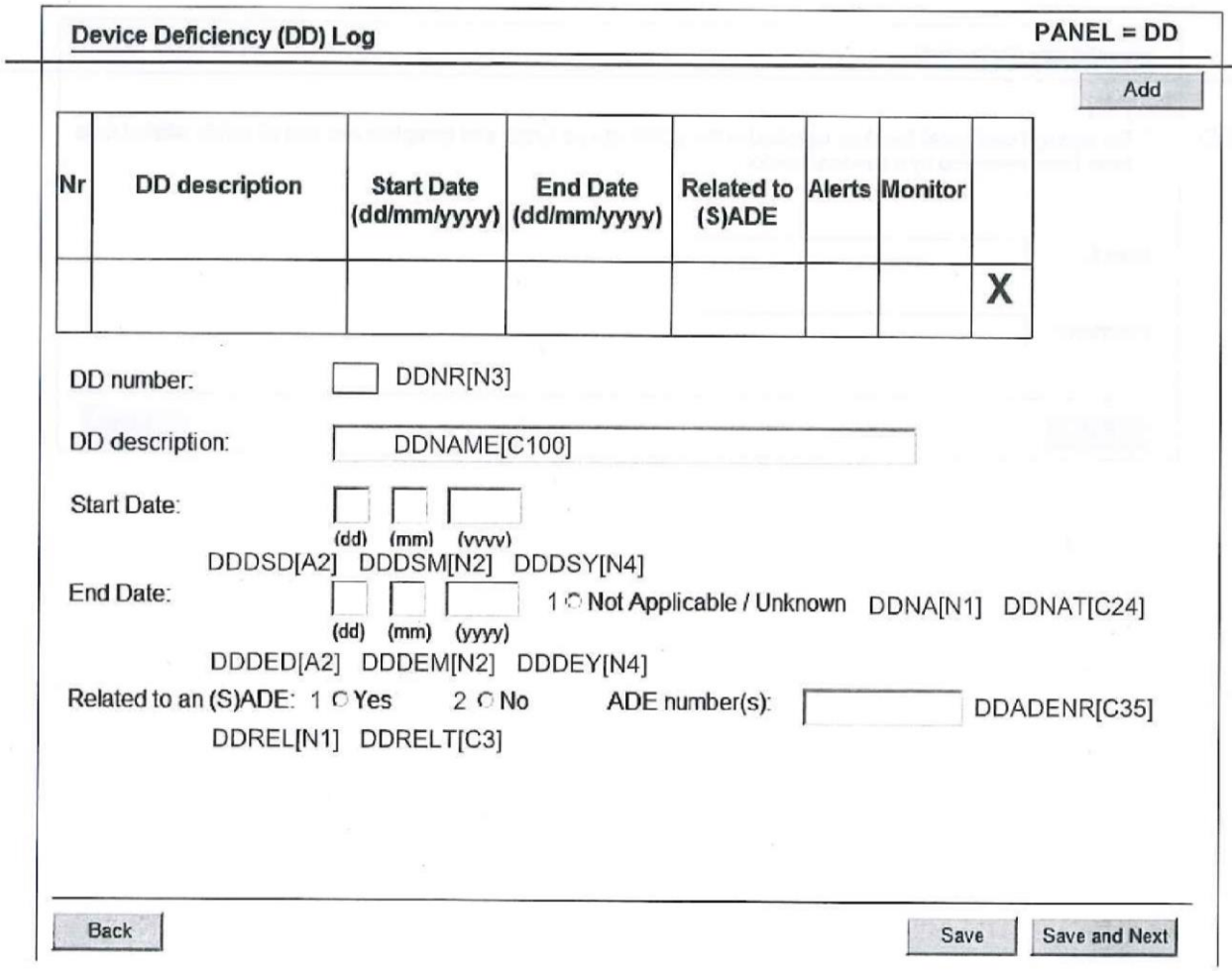
1.13 Photographs Log

1.13.1. Screen



1.14. Device Deficiency (DD) Log

1.14.1. Screen



Device Deficiency (DD) Log PANEL = DD

Add

Nr	DD description	Start Date (dd/mm/yyyy)	End Date (dd/mm/yyyy)	Related to (S)ADE	Alerts	Monitor	
							X

DD number: ☐ DDNR[N3]

DD description: DDNAME[C100]

Start Date: ☐ (dd) ☐ (mm) ☐ (yyyy)
DDDSD[A2] DDDSM[N2] DDDSY[N4]

End Date: ☐ (dd) ☐ (mm) ☐ (yyyy) 1 ○ Not Applicable / Unknown DDNA[N1] DDNAT[C24]
DDDED[A2] DDDEM[N2] DDDEY[N4]

Related to an (S)ADE: 1 ○ Yes 2 ○ No ADE number(s): ☐ DDADENR[C35]
DDREL[N1] DDRELT[C3]

Back Save Save and Next

1.15. Investigator Statement

1.15.1. Screen

Investigator Statement PANEL = GEN

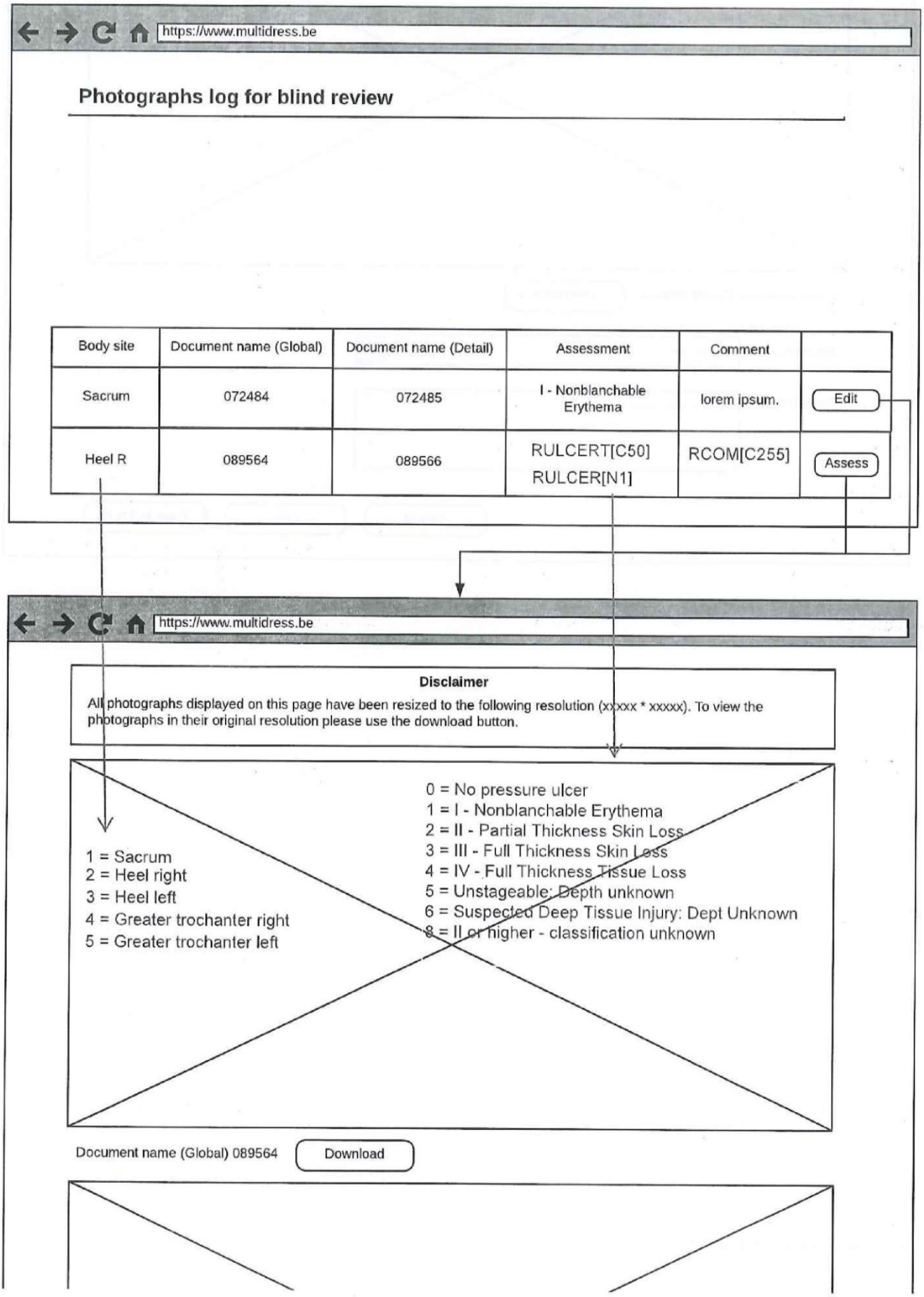
INV[N1]

1 = TICKED ☐ By signing I certify that the data reported in the eCRF are accurate and complete and that all safety related data have been reviewed by a medical doctor.

User ID:

Password:

Back Save


https://www.multidress.be
Photographs log for blind review
Body site
Document name (Global)
Document name (Detail)
Assessment
Comment
Sacrum
072484
072485
I - Nonblanchable Erythema
lorem ipsum.
Edit
Heel R
089564
089566
RULCERT[C50]
RULCER[N1]
RCOM[C255]
Assess
https://www.multidress.be
Disclaimer
All photographs displayed on this page have been resized to the following resolution (xxxxx * xxxxx). To view the photographs in their original resolution please use the download button.
1 = Sacrum
2 = Heel right
3 = Heel left
4 = Greater trochanter right
5 = Greater trochanter left
0 = No pressure ulcer
1 = I - Nonblanchable Erythema
2 = II - Partial Thickness Skin Loss
3 = III - Full Thickness Skin Loss
4 = IV - Full Thickness Tissue Loss
5 = Unstageable: Depth unknown
6 = Suspected Deep Tissue Injury: Dept Unknown
8 = II or higher - classification unknown
Document name (Global) 089564
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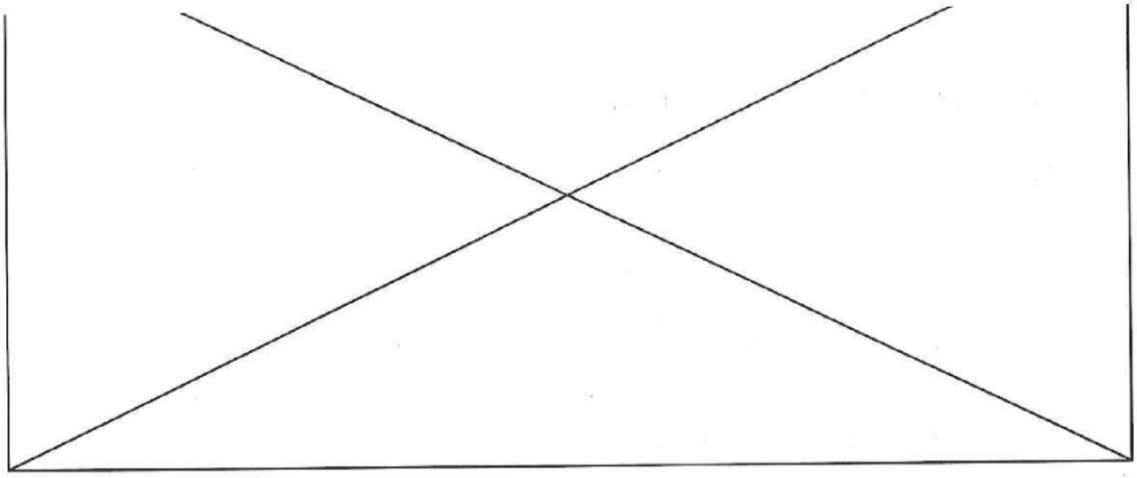

Document name (Detail) 089564 Download

Assessment Please select ...

Comment Write a comment...

Cancel Save Save and next

APPENDIX 2. TEMPLATE TABLES RESULTS (1) PATIENT INFO

Table 1. Patient's baseline demographics (categorical variables), by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Total	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Consent signed by								
Patient	1	25.0 %	2	40.0 %	1	100.0 %	4	40.0 %
Legal representative	3	75.0 %	3	60.0 %	0	0	6	60.0 %
Ward type on which patient is staying (corrected)								
ICU	0	0	1	20.0 %	0	0	1	10.0 %
Non-ICU	4	100.0 %	4	80.0 %	1	100.0 %	9	90.0 %
Age (years)								
<60	0	0	1	20.0 %	0	0	1	10.0 %
60-69	0	0	1	20.0 %	0	0	1	10.0 %
70-79	0	0	2	40.0 %	0	0	2	20.0 %
>=80	4	100.0 %	1	20.0 %	1	100.0 %	6	60.0 %
Gender type								
Female	4	100.0 %	4	80.0 %	1	100.0 %	9	90.0 %
Male	0	0	1	20.0 %	0	0	1	10.0 %
BMI_cat								
Normal weigh	4	100.0 %	2	40.0 %	1	100.0 %	7	70.0 %
Overweight	0	0	2	40.0 %	0	0	2	20.0 %
Obesity	0	0	1	20.0 %	0	0	1	10.0 %
[illegible] type								
No	4	100.0 %	2	40.0 %	1	100.0 %	7	70.0 %
Yes	0	0	3	60.0 %	0	0	3	30.0 %
Expected stay								
7 days or more	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Surgery type								
No	3	75.0 %	5	100.0 %	1	100.0 %	9	90.0 %
Yes	1	25.0 %	0	0	0	0	1	10.0 %
Type of surgery								
	3	75.0 %	5	100.0 %	1	100.0 %	9	90.0 %
Non-elective	1	25.0 %	0	0	0	0	1	10.0 %
Anaesthesia type								
	3	75.0 %	5	100.0 %	1	100.0 %	9	90.0 %
General	1	25.0 %	0	0	0	0	1	10.0 %

Table 2. Inclusion and Exclusion Criteria, by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Total	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Inclusion criteria 1								
Yes	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Inclusion criteria 2								
Yes	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Inclusion criteria 3								
Yes	4	100.0 %	5	100.0 %			10	100.0 %
Inclusion criteria 4								
Yes	4	100.0 %	5	10	1	100.0 %		100.0 %
Inclusion criteria 5								
Yes	4	100.0 %	5	100.	1	10	10	100.0 %
Exclusion criteria 1								
No	4	100.0 %	5	100.0 %		0.0 %	10	100.0 %
Exclusion criteria 2								
No	4	%		%	1	100.	10	100.0 %
Exclusion criteria 3								
No	4	100.	5	%		%	10	100.0 %
Exclusion criteria 4								
No	4	100.0 %		100.0 %	1	100.0 %	10	100.0 %
sion criteria 5								
		0.0 %		100.0 %	1	100.0 %	10	100.0 %
clusion cri								
	4	100	5	100.0 %	1	100.0 %	10	100.0 %
Exclusion criteria 7								
No	4	%	5	100.0 %	1	100.0 %	10	100.0 %

Table 3. Patient's baseline demographics (continuous variables), by Randomised Arm, ITT population

		Randomised arm			
		Allevyn Life®	Mepilex Border®	Standard of Care	Total
Age (years)	**N**	4	5	1	10
	Mean	84.2	73.1	91.2	79.3
	Std	3.2	9.4	0	9.5
	Min	80.5	59.2	91.2	59.2
	Q1	82.0	69.6	91.2	74.3
	Median	84.2	74.3	91.2	82.0
	Q3	[illegible]	78.1	91.2	84.8
	[illegible]	[illegible]	84.0	91.2	91.2
	NMiss	0	0	0	0
Braden score (code)	**N**	4	5	1	10
	[illegible]**ean**	[illegible]	12.6	17.0	12.4
	[illegible]	0.8	2.3	0	2.4
	Min	10.0	11.0	17.0	10.0
	Q1	[illegible]	11.0	17.0	11.0
	Median	[illegible]	11.0	17.0	11.0
	[illegible]	11.5	14.0	17.0	14.0
	Max	12.0	16.0	17.0	17.0
	NMiss	0	0	0	0
Time (days) betwe[illegible]rgery and informed conse	**N**	1	0	0	1
	Mean	2.0	0	0	2.0
	Std	0	0	0	0
	Min	2.0	0	0	2.0
	Q1	2.0	0	0	2.0
	Median	2.0	0	0	2.0
	Q3	2.0	0	0	2.0
	Max	2.0	0	0	2.0
	NMiss	3	5	1	9

Table 3. Patient's baseline demographics (continuous variables), by Randomised Arm, ITT population

		Randomised arm			
		Allevyn Life®	Mepilex Border®	Standard of Care	Total
Time (days) between hosp admission and informed consent	N	4	5	1	10
	Mean	2.0	1.8	2.0	1.9
	Std	0.8	0.4	0	0.6
	Min	1.0	1.0	2.0	1.0
	Q1	1.5	2.0	2.0	2.0
	Median	2.0	2.0	2.0	2.0
	Q3	[illegible]	2.0	2.0	2.0
	[illegible]	[illegible]	2.0	2.0	3.0
	[illegible]Miss	0	0	0	0
Time (days) between informed consent and randomisat[illegible]	N	[illegible]	5	1	10
	[illegible]ean	[illegible]	1.0	1.0	1.0
	[illegible]	0.0	0.0	0	0.0
	Min	1.0	1.0	1.0	1.0
	Q1	[illegible]	1.0	1.0	1.0
	Median	[illegible]	1.0	1.0	1.0
	[illegible]	1.0	1.0	1.0	1.0
	Max	1.0	1.0	1.0	1.0
	NMiss	0	0	0	0
Time (days) betwe[illegible]ndomisation and terminati[illegible]	N	4	5	0	9
	Mean	13.3	9.2	0	11.0
	Std	1.5	3.1	0	3.2
	Min	12.0	6.0	0	6.0
	Q1	12.0	7.0	0	9.0
	Median	13.0	9.0	0	12.0
	Q3	14.5	10.0	0	14.0
	Max	15.0	14.0	0	15.0
	NMiss	0	0	1	1

Table 3. Patient's baseline demographics (continuous variables), by Randomised Arm, ITT population

		Randomised arm			
		Allevyn Life®	Mepilex Border®	Standard of Care	Total
Time (days) between randomisation and end of study	**N**	4	5	1	10
	Mean	13.3	9.2	8.0	10.7
	Std	1.5	3.1	0	3.2
	Min	12.0	6.0	8.0	6.0
	Q1	12.0	7.0	8.0	8.0
	Median	13.0	9.0	8.0	11.0
	Q3	[illegible]	10.0	8.0	14.0
	[illegible]	[illegible]	14.0	8.0	15.0
	NMiss	0	0	0	0
Body Mass Index	**N**	4	5	1	10
	Mean	[illegible]	28.7	24.6	25.5
	[illegible]	1.4	9.8	0	7.5
	Min	20.3	23.4	24.6	20.3
	Q1	[illegible]	23.4	24.6	22.0
	Median	[illegible]	25.0	24.6	23.4
	[illegible]	22.7	25.6	24.6	25.0
	Max	23.4	46.1	24.6	46.1
	NMiss	0	0	0	0
Height (cm)	**N**	4	5	1	10
	Mean	159.3	158.2	165.0	159.3
	Std	8.6	2.0	0	5.6
	Min	149.0	155.0	165.0	149.0
	Q1	153.5	158.0	165.0	158.0
	Median	159.0	158.0	165.0	159.0
	Q3	165.0	160.0	165.0	160.0
	Max	170.0	160.0	165.0	170.0
	NMiss	0	0	0	0

Table 3. Patient's baseline demographics (continuous variables), by Randomised Arm, ITT population

		Randomised arm			
		Allevyn Life®	Mepilex Border®	Standard of Care	Total
Weight (kg)	**N**	4	5	1	10
	Mean	54.8	71.8	67.0	64.5
	Std	3.8	24.2	0	18.4
	Min	52.0	60.0	67.0	52.0
	Q1	52.0	60.0	67.0	55.0
	Median	53.5	60.0	67.0	60.0
	Q3	[illegible]	64.0	67.0	64.0
	[illegible]	60	115.0	67.0	115.0
	[illegible]Miss	0	0	0	0

Table 4. Braden scale at Day 1, by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Total	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
BRADEN_cat								
10-14	4	100.0 %	4	80.0 %	0	0	8	80.0 %
15-19	0	0	1	20.0 %	1	100.0 %	2	20.0 %
Braden scale assessement - Sensory (code)								
2	2	50.0 %	2	40.0 %	0	0	4	40.0 %
3	2	50.0 %	1			0	3	30.0 %
4	0	0		40.0 %		100.0 %	3	30.0 %
Braden scale assessement - Moisture (code)								
1	0		1	20.0 %		0	1	10.0 %
2	3	75.0 %		40.0 %		0	5	50.0 %
3	1	25.0 %			1	100.0 %	4	40.0 %
Braden scale assessement - Activity (code)								
1		75.0 %	2	40.	0	0	5	50.0 %
2			3	60.0 %		100.0 %	5	50.0 %
Braden scale assessement - Mobility (cod								
1		25.0	0		0	0	1	10.0 %
2		%	4	80.0 %	0	0	7	70.0 %
3		0	1	20.0 %	1	100.0 %	2	20.0 %
Braden scale assessement - Nutrition (code)								
1	1	0 %	0	0	0	0	1	10.0 %
2	3	%	4	80.0 %	0	0	7	70.0 %
3	0	0	1	20.0 %	1	100.0 %	2	20.0 %
Braden scale assessement - Friction (code								
1	2	50.0 %	3	60.0 %	0	0	5	50.0 %
2	2	50.0 %	2	40.0 %	1	100.0 %	5	50.0 %

Table 5a. Sacrum evaluation at Day 1, by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Total	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Body site assessable type - Sacrum								
Yes, likely to remain assessable	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Presence of pressure ulcer - Sacrum								
No	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Category - Sacrum (code)								
	4	100.0 %			1	100.0 %	10	100.0 %
Photograph taken - Sacrum								
	4		5	100.0 %	1	100.0 %	10	100.0 %
Photo taken category >= II - Sacrum								
	4		5		1	100.0 %	10	100.0 %
Is the body site dry - Sacrum								
No	1	25.0 %		20.0 %	0	0	2	20.0 %
Yes	3	75.0 %	4	%	1	100.0 %	8	80.0 %
Type of moisture - Sweat - Sacrum (co								
.	4		5	100.0 %	1	100.0 %	10	100.0 %
Type of moisture - Urine - Sacrum (code)								
.		75.0 %	5	100.0 %	1	100.0 %	9	90.0 %
1	1	25.0 %	0	0	0	0	1	10.0 %
Type of moi - Diarrhea - Sacrum (code)								
.		100.0 %	4	80.0 %	1	100.0 %	9	90.0 %
1		0	1	20.0 %	0	0	1	10.0 %
Type of mo Sacrum (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Is body site intact - Sacrum								
Yes	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Dermatologic contra-indications - Sacrum								
No	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - incontience-associated - Sacrum (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - Skin infection - Sacrum (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - Other - Sacrum								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %

Table 5a. Sacrum evaluation at Day 1, by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Is there other contra-indication - Sacrum								
No	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %

Table 5b. Heel right evaluation at Day 1, by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Total	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Body site assessable type - Heel right								
Yes, likely to remain assessable	3	75.0 %	5	100.0 %	1	100.0 %	9	90.0 %
Yes, unlikely to remain assessable	1	25.0 %	0	0	0	0	1	10.0 %
Presence of pressure ulcer - Heel right								
	1	25.0 %	0	0	0	0	1	10.0 %
No	3	75.0 %			1	100.0 %	8	80.0 %
Yes	0		1	20.0	0	0	1	10.0 %
Category - Heel right (code)								
	4	.0 %	4	80.	1	100.0 %	9	90.0 %
III - Full Thickness Skin Loss	0		1	%	0	0	1	10.0 %
Photograph taken - Heel right								
	4	100.0 %		100.0 %	1	100.0 %	10	100.0 %
Photo taken category >= II - Heel rig								
		00.0 %	5		1	100.0 %	10	100.0 %
Is the body site dry - Heel right								
	1	.0 %		0	0	0	1	10.0 %
No		0	1	20.0 %	0	0	1	10.0 %
Yes	3	75.0 %	4	80.0 %	1	100.0 %	8	80.0 %
Type of moi - Sweat - Heel right (code)								
.		100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Type of m ure - Urine ht (cod								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Type of moisture - Diarrhea - Heel right (cod								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Type of moisture - Oth de)								
.	4	100.0 %	4	80.0 %	1	100.0 %	9	90.0 %
1	0	0	1	20.0 %	0	0	1	10.0 %
Is body site intact - Heel right								
	1	25.0 %	0	0	0	0	1	10.0 %
No	0	0	1	20.0 %	0	0	1	10.0 %
Yes	3	75.0 %	4	80.0 %	1	100.0 %	8	80.0 %
Dermatologic contra-indications - Heel right								
	1	25.0 %	0	0	0	0	1	10.0 %
No	3	75.0 %	5	100.0 %	1	100.0 %	9	90.0 %

Table 5b. Heel right evaluation at Day 1, by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Skin condition - incontience-associated - Heel right (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - Skin infection - Heel right (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - Other - Heel right								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Is there other contra-indication - Heel right								
	1	25.0	0	0	0	0	1	10.0 %
No	3	%	5	100.0	1	100.0 %	9	90.0 %

Table 5c. Heel left evaluation at Day 1, by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Total	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Body site assessable type - Heel left								
Yes, likely to remain assessable	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Presence of pressure ulcer - Heel left								
No	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Category - Heel left (code)								
	4	100.0 %			1	100.0 %	10	100.0 %
Photograph taken - Heel left								
	4		5	100.0 %	1	100.0 %	10	100.0 %
Photo taken category >= II - Heel left								
	4		5		1	100.0 %	10	100.0 %
Is the body site dry - Heel left								
Yes	4	100.0 %		100.0 %	1	100.0 %	10	100.0 %
Type of moisture - Sweat - Heel left (c								
.		00.0 %	5	10	1	100.0 %	10	100.0 %
Type of moisture - Urine - Heel left (code)								
.	4	.0 %		.0 %	1	100.0 %	10	100.0 %
Type of moisture - Diarrhea - Heel left (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Type of mo - Other - Heel left (code)								
.		100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Is y site intact ft								
Yes	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Dermatologic contra-indications - Heel lef								
No	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - incontience-a eft (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - Skin infection - Heel left (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - Other - Heel left								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Is there other contra-indication - Heel left								
No	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %

Table 5d. Greater trochanter right evaluation at Day 1, by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Total	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Body site assessable type - Greater trochanter right								
Yes, likely to remain assessable	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Presence of pressure ulcer - Greater trochanter right								
No	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Category - Greater trochanter right (code)								
	4	1		100.0 %	1	100.0 %	10	100.0 %
Photograph taken - Greater trochanter right								
		100.0 %	5	.0 %	1	100.0 %	10	100.0 %
Photo taken category >= II - Greater trochanter right								
		100.0 %		100.0 %	1	100.0 %	10	100.0 %
Is the body site dry - Greater trochanter right								
Yes	4	10	5	100.0 %	1	100.0 %	10	100.0 %
Type of moisture - Sweat - Greater trochanter								
.	4	100.0 %		100.0 %	1	100.0 %	10	100.0 %
Type of moisture - Urine - Greater trochanter rig de)								
.	4	10	5	100.0 %	1	100.0 %	10	100.0 %
Type of moisture - Diarrhea - Greater trochanter right (e)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Type of moisture - - Greater trochanter right (code								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Is body si tact - Great nter rig								
Yes	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Dermatologic contra-indications - Greater trochan ght								
No	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - incontience-associat anter right (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - Skin infection - Greater trochanter right (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - Other - Greater trochanter right								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Is there other contra-indication - Greater trochanter right								
No	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %

Table 5e. Greater trochanter left evaluation at Day 1, by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Total	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Body site assessable type - Greater trochanter left								
No	1	25.0 %	0	0	0	0	1	10.0 %
Yes, likely to remain assessable	3	75.0 %	4	80.0 %	1	100.0 %	8	80.0 %
Yes, unlikely to remain assessable	0	0	1	20.0 %	0	0	1	10.0 %
Presence of pressure ulcer - Greater trochanter left								
	1	2		20.0 %	0	0	2	20.0 %
No	3	.0 %	4	0 %	1	100.0 %	8	80.0 %
Category - Greater trochanter left (code)								
	4	100.0 %	5	0.0 %	1	100.0 %	10	100.0 %
Photograph taken - Greater trochanter left								
	4		5	100.0 %	1	100.0 %	10	100.0 %
Photo taken category >= II - Greater trochanter left								
	4	100.0 %		100.0 %	1	100.0 %	10	100.0 %
Is the body site dry - Greater trochanter								
		.0 %	1	20.0 %	0	0	2	20.0 %
Yes	3	75.	4	80.0 %	1	100.0 %	8	80.0 %
Type of moisture - Sweat - Greater trochanter left (c								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Type of moisture - Greater trochanter left (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Type of moisture rrhea - Gre anter ode)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Type of moisture - Other - Greater trochanter lef e)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Is body site intact - Gr ft								
	1	25.0 %	1	20.0 %	0	0	2	20.0 %
Yes	3	75.0 %	4	80.0 %	1	100.0 %	8	80.0 %
Dermatologic contra-indications - Greater trochanter left								
	1	25.0 %	1	20.0 %	0	0	2	20.0 %
No	3	75.0 %	4	80.0 %	1	100.0 %	8	80.0 %
Skin condition - incontience-associated - Greater trochanter left (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Skin condition - Skin infection - Greater trochanter left (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %

Table 5e. Greater trochanter left evaluation at Day 1, by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Skin condition - Other - Greater trochanter left								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Is there other contra-indication - Greater trochanter left								
	1	25.0 %	1	20.0 %	0	0	2	20.0 %
No	3	75.0 %	4	80.0 %	1	100.0 %	8	80.0 %

Table 6. Support information at Day 1, by Randomised Arm, ITT population

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Total	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Support information type								
Active support surface (such as alternating or low-air loss)	0	0	1	20.0 %	1	100.0 %	2	20.0 %
No specific mattress to prevent pressure ulcers (standard foam, not pressure redistributing)	0	0	1	20.0 %	0	0	1	10.0 %
Reactive support surface (such as visco-elastic foam or air-filled)	4	100.0	3	60.0 %	0	0	7	70.0 %
Heels elevated from bed								
No	3	75.0 %		60.0 %	0	0	6	60.0 %
Yes	1	25.0 %	2	40.0 %	1	100.0 %	4	40.0 %
Frequency of repositioning type								
Every 3-4 hours		0 %	1	20.0 %	1	100.0 %	4	40.0 %
Every 5-6 hours	2	0 %	2	40.0 %	0	0	4	40.0 %
Every 7 hours or more	0		2	40.0 %	0	0	2	20.0 %

Table 2. Pressure Ulcer and Randomised Arm, by anatomic site

	Randomised arm						Total	
	Allevyn Life®		Mepilex Border®		Standard of Care			
	N	Col %	N	Col %	N	Col %	N	Col %
Total	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Reason for discontinuation-Non compliance (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Reason for discontinuation-Life threatening AE or SAE (code)								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Reason for discontinuation-Worsening medical condition (code)								
.	4	100.0		0 %	1	100.0 %	10	100.0 %
Reason for discontinuation-Patient's best interest (code)								
.	4	0.0 %	5	10	1	100.0 %	10	100.0 %
Reason for discontinuation-Contra indications (code)								
.	4	0 %	5	0.0 %	1	100.0 %	10	100.0 %
Other reasons for discontinuation (code)								
.	0	0		0	1	100.0 %	1	10.0 %
1	4	100.0 %		100.0 %	0	0	9	90.0 %
Other reasons to discontinue								
	0		0	0	1	100.0 %	1	10.0 %
DAY 14 REACHED		0		20.0 %	0	0	1	10.0 %
Discharged from the hospital	2	50.0 %	0	0	0	0	2	20.0 %
EOS (day 14 reached)	1	25.0 %	0	0	0	0	1	10.0 %
End of study (day 14 re d)	1	25.0 %	0	0	0	0	1	10.0 %
death	0	0	1	20.0 %	0	0	1	10.0 %
discharged	0	0	1	20.0 %	0	0	1	10.0 %
no longer at risk	0	0	1	20.0 %	0	0	1	10.0 %
ontslag uit ziekenhuis	0	0	1	20.0 %	0	0	1	10.0 %
Reason for end of study - no risk of pressu er								
.	4	100.0 %	4	80.0 %	0	0	8	80.0 %
1	0	0	1	20.0 %	1	100.0 %	2	20.0 %
Reason for end of study - Day 14 reached								
.	2	50.0 %	4	80.0 %	1	100.0 %	7	70.0 %
1	2	50.0 %	1	20.0 %	0	0	3	30.0 %
Reason for end of study - Patient withdraw								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Reason for end of study - Discharged from hospital								
.	2	50.0 %	3	60.0 %	1	100.0 %	6	60.0 %
1	2	50.0 %	2	40.0 %	0	0	4	40.0 %

Table 2. Pressure Ulcer and Randomised Arm, by anatomic site

	Randomised arm							
	Allevyn Life®		Mepilex Border®		Standard of Care		Total	
	N	Col %	N	Col %	N	Col %	N	Col %
Reason for end of study - Moving to non-participating ward								
.	4	100.0 %	5	100.0 %	1	100.0 %	10	100.0 %
Reason for end of study - Death								
.	4	100.0 %	4	80.0 %	1	100.0 %	9	90.0 %
1	0	0	1	20.0 %	0	0	1	10.0 %
Reason for end of study - Study closure by sponsor (code)								
.	4	100.0		0 %	1	100.0 %	10	100.0 %
Reason for end of study - Other (code)								
.	4	0.0 %	5	10	1	100.0 %	10	100.0 %
Collected data can be used for the analysis type								
	4	0 %	5	0.0 %	1	100.0 %	10	100.0 %
Reason for end of study - Other								
	4	100.0		100.0 %	1	100.0 %	10	100.0 %

Table 2. Pressure Ulcer and Randomised Arm, by anatomic site

APPENDIX 3. TEMPLATE TABLES RESULTS (2) CLINICAL OUTCOMES

Table 1. Patient's characteristics, by Pressure Ulcer

	Pressure ulcer					
	Yes		No		Total	
	N	%	N	%	N	%
Total	2	20.0	8	80.0	10	100.0
Site						
AZ Groeninge		0.0		00.0	4	100.0
UZ Brussel	0	0.0	1	0.0	1	100.0
Aalst	1	50.0	1	0.0	2	100.0
AZ Zottegem	0	0.0		100.0	1	100.0
UZ Leuven		1	0	0.0	1	100.0
OLV Waregem	0		1	100.0	1	100.0
Age (yea						
<60	0	0.0		00.0	1	100.0
60-69		0.0	1	100.0	1	100.0
70-79	0		2	100.0	2	100.0
>=80	2	33.3	4	66.7	6	100.0
Gender type						
Fema	2	22.2	7	77.8	9	100.0
Male	0	0.0	1	100.0	1	100.0
BMI_cat						
Normal weight	2	28.6	5	71.4	7	100.0
Overweight	0	0.0	2	100.0	2	100.0
Obesity	0	0.0	1	100.0	1	100.0
Diabete type						
No	2	28.6	5	71.4	7	100.0
Yes	0	0.0	3	100.0	3	100.0
Ward type on which patient is staying (corrected)						
ICU	0	0.0	1	100.0	1	100.0
Non-ICU	2	22.2	7	77.8	9	100.0

Table 2. Pressure Ulcer and Randomised Arm, by anatomic site

	Pressure ulcer				Total	
	Yes		No			
	N	%	N	%	N	%
BRADEN_cat						
10-14	2	25.0	6	75.0	8	100.0
15-19	0	0.0	2	100.0	2	100.0

	Randomised arm				Total	
	Treatment		Standard of Care			
	N	Col	N	Col	N	Col
Total	9	100.00	1	100.00	10	100
PU All sites						
Yes	2	22.22	0	0.00		0.00
No	7	77.78	1	100.00	8	
PU Sacrum						
Yes	2	22.22		0.00	2	20.00
No	7	77.78			8	80.00
PU Heel R						
.	1	11.11	0	0.00	1	
Yes	0	0.00	0	00		0.00
No		.89	1		9	90.00
PU H						
Yes	0	0.0		0.0	0	0.00
No	9	.00	1	100.00	10	100.00
PU Tro						
Yes	0	0.00	0	0.00	0	0.00
No	9	100.00		100.00	10	100.00
PU Troch L						
Yes	0	0.00	0	0.00	0	0.00
No	9	100.00	1	100.00	10	100.00

Table 2. Pressure Ulcer and Randomised Arm, by anatomic site

	Randomised arm						Total	
	Allevyn Life®		Mepilex Border®		Standard of Care			
	N	Col	N	Col	N	Col	N	Col
Total	4	100.00	5	100.00	1	100.00	10	100.00
PU All sites								
Yes	2	50.00	0	0.00	0	0.00	2	20.00
No	2	50.00	5	100.00	1	100.00	8	80.00
PU Sacrum								
Yes	2	50.00	0	0.00	0			20.00
No	2	50.00	5	100.00		100.00		80.00
PU Heel R								
.	0	0.00	1	2	0	0.00		10.00
Yes	0	0.00	0	0.00		0.0	0	0.00
No	4	100.00	4	80.00		0	9	90.00
PU Heel L								
Yes	0			0.00	0	0.0	0	0.00
No	4	100	5		1	100.00		100.00
PU Troch R								
Yes	0	0.00	0		0	0.00	0	0.00
N	4	100.00		100.00	1	100.00	10	100.00
Troch L								
Yes	0		0	.00	0	0.00	0	0.00
No		100.	5	0.00	1	100.00	10	100.00

Table 3. Pressure Ulcer and Randomised Arm - stratified by patient characteristics

		Randomised arm				Total	
		Treatment		Standard of Care			
		N	%	N	%	N	%
All	Pressure ulcer						
	Yes	2	22.2	0	0.0	2	20.0
	No	7	77.8	1	100.0	8	80.0
Site	Pressure ulcer						
AZ Groeninge	Yes	0	0.0	0	0.0	0	0.0
	No	3	100.0	1	100.0	4	100.0
UZ Brussel	Yes	0	[illegible]	0	0	0	0.0
	No	1	[illegible]	0	0	1	100.0
Aalst	Yes	1	[illegible]	0	0	1	50.0
	No	1	50.0	0	0	1	50.0
AZ Zottegem	Yes	[illegible]	0.0	0	0	0	0.0
	No	[illegible]	100.0	0	0	1	100.0
UZ Leuven	Yes	[illegible]	100.0	0	0	1	100.0
	[illegible]	0	[illegible]	0	0	0	0.0
OLV Waregem	Yes	[illegible]	0.0	0	0	0	0.0
	[illegible]	1	100.0	0	0	1	100.0
A[illegible]	Pressure ulcer						
<60	Yes	0	0.0	0	0	0	0.0
	[illegible]	1	100.0	0	0	1	100.0
60-69	[illegible]	0	0.0	0	0	0	0.0
	No	1	100.0	0	0	1	100.0
70-79	Yes	0	0.0	0	0	0	0.0
	No	2	100.0	0	0	2	100.0
>=80	Yes	2	40.0	0	0.0	2	33.3
	No	3	60.0	1	100.0	4	66.7
Gender type	Pressure ulcer						
Female	Yes	2	25.0	0	0.0	2	22.2
	No	6	75.0	1	100.0	7	77.8
Male	Yes	0	0.0	0	0	0	0.0
	No	1	100.0	0	0	1	100.0

Table 3. Pressure Ulcer and Randomised Arm - stratified by patient characteristics

		Randomised arm				Total	
		Treatment		Standard of Care			
		N	%	N	%	N	%
Ward type on which patient is staying (corrected)	Pressure ulcer						
ICU	Yes	0	0.0	0	0	0	0.0
	No	1	100.0	0	0	1	100.0
Non-ICU	Yes	2	25.0	0	0.0	2	22.2
	No	6	75.0	1	100.0	7	77.8

		Randomised arm							
		Allevyn Life®		Mepilex Border®		Standard of Care		Total	
		N	%	N	%	N	%	N	%
All	Pressure ulcer								
	Yes	2	50.0	0	0.0	0	0.0	2	20.0
	No	2	50.0	5	100.0	1	100.0	8	80.0
Site	Pressure ulcer								
AZ Groeninge	Yes	0	0	0	0.0	0	0.0	0	0.0
	No	0	0	3	100.0	1	100.0	4	100.0
UZ Brussel	Yes	0	0.0	0	0	0	0	0	0.0
	No	1	[illegible]	0	0	0	0	1	100.0
Aalst	Yes	[illegible]	[illegible]	[illegible]	0	0	0	1	50.0
	No	1	50.0	[illegible]	0	0	0	1	50.0
AZ Zottegem	Yes	0	0	[illegible]	0.0	0	0	0	0.0
	No	0	[illegible]	1	100.0	0	0	1	100.0
UZ Leuven	Yes	[illegible]	[illegible].0	0	0	0	0	1	100.0
	No	[illegible]	0.0	0	0	0	0	0	0.0
OLV Waregem	[illegible]	0	[illegible]	0	0.0	0	0	0	0.0
	No	0	0	[illegible]	100.0	0	0	1	100.0
Age (years)	Pressure [illegible]								
<60	[illegible]es	0	0	0	0.0	0	0	0	0.0
	[illegible]	0	0	1	100.0	0	0	1	100.0
60-69	[illegible]	0	0	0	0.0	0	0	0	0.0
	No	0	0	1	100.0	0	0	1	100.0
70-79	Yes	0	0	0	0.0	0	0	0	0.0
	No	0	0	2	100.0	0	0	2	100.0
>=80	Yes	2	50.0	0	0.0	0	0.0	2	33.3
	No	2	50.0	1	100.0	1	100.0	4	66.7
Gender type	Pressure ulcer								
Female	Yes	2	50.0	0	0.0	0	0.0	2	22.2
	No	2	50.0	4	100.0	1	100.0	7	77.8
Male	Yes	0	0	0	0.0	0	0	0	0.0
	No	0	0	1	100.0	0	0	1	100.0
Ward type on which patient is staying (corrected)	Pressure ulcer								
ICU	Yes	0	0	0	0.0	0	0	0	0.0
	No	0	0	1	100.0	0	0	1	100.0
Non-ICU	Yes	2	50.0	0	0.0	0	0.0	2	22.2
	No	2	50.0	4	100.0	1	100.0	7	77.8

APPENDIX 4. TEMPLATE TABLES RESULTS (3) HEALTH ECONOMIC OUTCOMES

		Randomised arm			
		Allevyn Life®	Mepilex Border®	Standard of Care	All
Dressing applied - All	**N**	4	5	1	10
	Mean	16.50	12.40	0.00	12.80
	Std	9.47	6.11	0	8.42
	Min	9.00	5.00	0.00	0.00
	Q1	10.00	[illegible]	[illegible].00	9.00
	Median	13.5[illegible]	12.00	[illegible]00	11.50
	Q3	[illegible]	12.00	[illegible]00	16.00
	Max	3[illegible]	22.00	0.00	30.00
	NMiss	0	[illegible]	0	0
Dressing applied - Sacrum	**N**	4	[illegible]	1	10
	[illegible]	4.00	3.0[illegible]	0.00	3.10
	Std	[illegible]	2.83	[illegible]0	2.28
	[illegible]in	3[illegible]	[illegible].00	0.00	0.00
	[illegible]	[illegible]50	2.0[illegible]	0.00	2.00
	M[illegible]	4.00	2.00	0.00	2.50
	Q3	4.50	2.00	0.00	4.00
	Max	5.00	8.00	0.00	8.00
	[illegible]Miss	0	0	0	0
D[illegible]ied - Heel R		4	5	1	10
	[illegible]ean	4.75	1.80	0.00	2.80
	Std	4.57	1.48	0	3.33
	Min	0.00	0.00	0.00	0.00
	Q1	1.00	1.00	0.00	0.00
	Median	4.50	2.00	0.00	2.00
	Q3	8.50	2.00	0.00	4.00
	Max	10.00	4.00	0.00	10.00
	NMiss	0	0	0	0

		Randomised arm			
		Allevyn Life®	Mepilex Border®	Standard of Care	All
Dressing applied - Heel L	**N**	4	5	1	10
	Mean	4.25	2.20	0.00	2.80
	Std	4.03	0.84	0	2.78
	Min	1.00	1.00	0.00	0.00
	Q1	1.50	2.00	0.00	1.00
	Median	3.00	2.00	0.00	2.00
	Q3	7.00	3.00	0.00	3.00
	Max	10.00	3.[illegible]	0.00	10.00
	NMiss	0	[illegible]	[illegible]0	0
Dressing applied - Troch R	**N**	4	5		10
	Mean	[illegible]	2.80	[illegible].00	2.00
	Std	0.[illegible]	1.48	0	1.41
	Min	1.00	[illegible]	0.00	0.00
	Q1	1.00	[illegible]	0.00	1.00
	[illegible]	1.50	3.00	0.00	2.00
	Q3	[illegible]	3.00	[illegible].00	3.00
	[illegible]ax	[illegible]	[illegible]	0.00	5.00
	[illegible]ss	0	0	0	0
Dressi[illegible]Troch L	**N**	4	5	1	10
	Mea[illegible]	2.00	2.60	0.00	2.10
	Std	1.83	2.70	0	2.23
	[illegible]n	0.00	0.00	0.00	0.00
	[illegible]	0.50	1.00	0.00	0.00
	[illegible]edian	2.00	2.00	0.00	1.50
	Q3	3.50	3.00	0.00	3.00
	Max	4.00	7.00	0.00	7.00
	NMiss	0	0	0	0

APPENDIX 5. TEMPLATE TABLES RESULTS (4) SAFETY OUTCOMES

		Intervention group					
		Allevyn Life®		Mepilex Border®		Total	
		N	%	N	%	N	%
All	Adverse devise effect						
	Yes						
	No						
Site	Adverse devise effect						
UZ Gent	Yes						
	No						
AZ Groeninge	Yes						
	No						
UZ Brussel	Yes						
	No						
Aalst	Yes						
	No						
AZ Zottegem	Yes						
	No						
UZ Leuven	Yes						
	No						
Ma[illegible]iddelares	Yes						
	[illegible]						
OL[illegible]arec[illegible]	Yes						
	No						

		Intervention group					
		Allevyn Life®		Mepilex Border®		Total	
		N	%	N	%	N	%
All	Devise deficiency						
	Yes	65	12.0	32	5.9	97	8.9
	No	478	88.0	513	94.1	991	91.1
Site	Devise deficiency						
UZ Gent	Yes						
	No						
AZ Groeninge	Yes						
	No						
UZ Brussel	Yes						
	No						
Aalst	Yes						
	No						
AZ Zottegem	Yes						
	No						
UZ Leuven	Yes						
	No						
Mari[illegible]	Yes						
	No						
[illegible]V Waregem							
	No						