

Subject Case Report Forms

Production Germany 14. Jan. 2020 - Primary matrix

Signature Prompt: As investigator I certify that the information submitted within the application is true, complete, and accurate to the best of my knowledge.

Production Germany 14. Jan. 2020: Primary matrix
Form: Subject
Generated On: 30 Sep 2020 12:31:31

Investigator Name _____ ①

Site Number _____ ②

Subject Number _____ ③

Production Germany 14. Jan. 2020: Primary matrix
Form: Subject
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① INVNAM	\$30				INVNAM
② SITE	\$5				SITE
③ SUBJECT	4				SUBJECT

Production Germany 14. Jan. 2020: Primary matrix
Folder: Visit 0
Form: Subject Informed Consent
Generated On: 30 Sep 2020 12:31:31

Please enter date of signed Informed Consent

_____ **1**

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 0

Form: Subject Informed Consent

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① ICDAT	dd MMM YYYY				ICDAT

Production Germany 14. Jan. 2020: Primary matrix
Folder: Visit 0
Form: Visit Date
Generated On: 30 Sep 2020 12:31:31

Please enter visit date

①

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 0

Form: Visit Date

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① VISITDAT	dd MMM YYYY				VISITDAT

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 0

Form: Inclusion Criteria

Generated On: 30 Sep 2020 12:31:31

All fields on the Inclusion Criteria Form are required. The Subject must be able to answer 'Yes' to the following criteria:

Has given written consent to participate by signing the Informed Consent Signature Form

No ②
Yes

Has an ileostomy or colostomy with liquid output*
*Definition of liquid output: Six-Seven in the Bristol scale
(Appendix 5 - Bristol scale)

No ③
Yes

Currently using a flat product

No ④
Yes

Be at least 18 years of age and have full legal capacity

No ⑤
Yes

Have had their stoma for at least three months (90 days)

No ⑥
Yes

Can use a product with a max cut size of 40 mm

No ⑦
Yes

Has experienced leakage under the baseplate at least three times within the last fourteen days.
Leakage defined as output seeping under the baseplate

No ⑧
Yes

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Folder: Visit 0

Form: Inclusion Criteria

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Has symptoms of peristomal skin complications or has peristomal skin complications defined by at least one of the below.

No **9**
Yes

a)=Has experienced symptoms of skin complications (itching, burning, pain) within the last fourteen days.

b)=Has experienced red skin in the inner circle (within three cm from stoma edge) within the last fourteen days.

c)=Has skin complication (assessed by Principal Investigator, or delegate) in the inner circle (within three cm from stoma edge) of the peristomal area.

Is able to handle the electronic diary (questionnaire/photo) themselves

No **10**
Yes

Is able to handle (apply, remove, cut etc.) the product themselves

No **11**
Yes

Is willing to not use barrier film or barrier cream during the investigation

No **12**
Yes

Is willing and suitable (determined by Principal Investigator, or delegate) to use a flat custom cut one-piece open or a two-piece open product during the investigation

No **13**
Yes

Is willing to change the product (1pc) or baseplate (2pc) at least every fourth days

No **14**
Yes

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Folder: Visit 0

Form: Inclusion Criteria

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Inclusion no. 1	1		0 = No 1 = Yes		ITEST1
③ Inclusion no. 2	1		0 = No 1 = Yes		ITEST2
④ Inclusion no. 3	1		0 = No 1 = Yes		ITEST3
⑤ Inclusion no. 4	1		0 = No 1 = Yes		ITEST4
⑥ Inclusion no. 5	1		0 = No 1 = Yes		ITEST5
⑦ Inclusion no. 6	1		0 = No 1 = Yes		ITEST6
⑧ Inclusion no. 7	1		0 = No 1 = Yes		ITEST7
⑨ Inclusion no. 8	1		0 = No 1 = Yes		ITEST8
⑩ Inclusion no. 9	1		0 = No 1 = Yes		ITEST9
⑪ Inclusion no. 10	1		0 = No 1 = Yes		ITEST10

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Folder: Visit 0
Form: Inclusion Criteria
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 Inclusion no. 11	1		0 = No 1 = Yes		ITEST11
 Inclusion no. 12	1		0 = No 1 = Yes		ITEST12
 Inclusion no. 13	1		0 = No 1 = Yes		ITEST13

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Folder: Visit 0

Form: Exclusion criteria

Generated On: 30 Sep 2020 12:31:31

All fields on the Exclusion Criteria Form are required. The Subject must be able to answer 'No' to the following criteria:

Is currently receiving or have within the past 60 days received radio-and/or chemotherapy
- = low doses chemotherapy (assessed by Principal Investigator) is allowed for indications other than cancer

No ②
Yes

Is currently receiving or have within the past month received topical steroid treatment in the peristomal skin area, e.g. lotion or spray.
- = Low dose systemic steroid treatment (e.g. inhalation) assessed by the Principal Investigator are allowed.
- = Other systemic steroid treatment (e.g. injection, or tablet) are not allowed

No ③
Yes

Is breastfeeding

No ④
Yes
Not applicable

Is pregnant (based on pregnancy test - urine)

No ⑤
Yes
Not applicable

Has known hypersensitivity towards any of the products used in the investigation

No ⑥
Yes

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Folder: Visit 0

Form: Exclusion criteria

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Exclusion no. 1	1		0 = No 1 = Yes		ETEST1
③ Exclusion no. 2	1		0 = No 1 = Yes		ETEST2
④ Exclusion no. 3	1		0 = No 1 = Yes 2 = Not applicable		ETEST3
⑤ Exclusion no. 4	1		0 = No 1 = Yes 2 = Not applicable		ETEST4
⑥ Exclusion no. 5	1		0 = No 1 = Yes		ETEST5

Production Germany 14. Jan. 2020: Primary matrix
Folder: Randomisation
Form: Randomisation Details
Generated On: 30 Sep 2020 12:31:31

Is the subject eligible for inclusion in the study?

No ①
Yes

Which product type does the subject use?

One piece product ②
Two piece product

Is the subject ready to be randomized?

_____ ③

Regime Name

_____ ④

Regime Ratio

_____ ⑤

Regime Description

_____ ⑥

Date and time of randomization
(time in UTC)

_____ ⑦

Stratum Name

_____ ⑧

Blinded

_____ ⑨

Reason for Unblinding

_____ ⑩

Error Marking Group

_____ ⑪

Production Germany 14. Jan. 2020: Primary matrix



Folder: Randomisation

Form: Randomisation Details

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Eligibility	1		0 = No 1 = Yes		ELIGIBLE_Y N
② PRODUCT_ TYPE	1		1 = One piece product 2 = Two piece product		PRODUCT_ TYPE
③ RANDTRIG	1				RANDTRIG
④ REGIME_NA\$200 ME					REGIME_NA ME
⑤ REGIME_RA 2 TIO					REGIME_RA TIO
⑥ REGIME_DE \$1999 SCRIPTION					REGIME_DE SCRIPTION
⑦ RANDOMIZ ED_AT	dd MMM yyyy HH:nn:ss				RANDOMIZ ED_AT
⑧ STRATUM_ NAME	\$50				STRATUM_ NAME
⑨ BLINDED	\$6				BLINDED

Production Germany 14. Jan. 2020: Primary matrix
Folder: Randomisation
Form: Randomisation Details
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 UNBLIND_R\$1999 EASON					UNBLIND_R EASON
 SYS_ERROR1 _MARKING_ GROUP			1		SYS_ERROR _MARKING_ GROUP

Production Germany 14. Jan. 2020: Primary matrix
Folder: Visit 1
Form: Visit Date
Generated On: 30 Sep 2020 12:31:31

Please enter visit date

①

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 1

Form: Visit Date

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① VISITDAT	dd MMM YYYY				VISITDAT

Production Germany 14. Jan. 2020: Primary matrix
Folder: Visit 1
Form: Demographics
Generated On: 30 Sep 2020 12:31:31

Demographics

Date of birth _____ ②

Derived age _____ ③

Gender Female ④
Male

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Folder: Visit 1

Form: Demographics

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Date of birth	dd MMM YYYY				BRTHDAT
③ Derived age 2					AGE
④ Gender	1		1 = Female 2 = Male		GENDER

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Folder: Visit 1

Form: Vital signs

Generated On: 30 Sep 2020 12:31:31

Height and weight

Height (xxx)

cm ②
in

Weight (xxx)

kg ③
lb

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Folder: Visit 1

Form: Vital signs

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Height	3	cm = cm IN = in			VSHT
③ Weight	3	kg = kg LB = lb			VSWT

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Folder: Visit 1

Form: Stoma

Generated On: 30 Sep 2020 12:31:31

Information about the stoma

When was the stoma created / month; (if applicable; e.g Jan) _____ **2**

When was the stoma created / Year _____ **3**

Type of stoma Ileostomy **4**
Colostomy

What was the reason for creation of the stoma? (you may tick more than 1 box)

Morbus Crohn _____ **6**

Colitis Ulcerosa _____ **7**

Cancer _____ **8**

Other _____ **9**

What is the diameter of the stoma on the widest place? Fixed Unit: mm **10**

What is the height of the stoma? Fixed Unit: mm **11**

What is the shape of the stoma / intestine? Round **12**
Oval

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Folder: Visit 1

Form: Stoma

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Irregular

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Folder: Visit 1

Form: Stoma

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Stoma operation month	\$3				STOMA_OP MONTH
③ Stoma operation - Year	4				STOMA_OP YEAR
④ Stoma type 1			1 = Ileostomy 2 = Colostomy		STOMA_TY PE
⑥ Stoma reason 1	1				MULTI_STO MAREASON _1
⑦ Stoma reason 2	1				MULTI_STO MAREASON _2
⑧ Stoma reason 3	1				MULTI_STO MAREASON _3
⑨ Stoma reason 4	1				MULTI_STO MAREASON _4
⑩ Stoma diameter	2				STOMA_DIA METER

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Folder: Visit 1

Form: Stoma

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 Stoma height	2				STOMA_HEI GHT
 Stoma shape	1		1 = Round 2 = Oval 3 = Irregular		STOMA_SH APE

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Folder: Visit 1

Form: Output

Generated On: 30 Sep 2020 12:31:31

Leakage / output

What is the frequency of the output?

All the time (continuous) ②

With regular intervals

With irregular intervals

What is the consistency of the output evaluated on the Bristol scale?

Type 1 ③

Type 2

Type 3

Type 4

Type 5

Type 6

Type 7

Does the subject experience the bag becoming overfilled with air during use (ballooning)?

No ④

Yes

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Folder: Visit 1

Form: Output

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Output frequency	1		1 = All the time (continuous) 2 = With regular intervals 3 = With irregular intervals		OUTPUT_FR Q
③ Bristol scale 1			1 = Type 1 2 = Type 2 3 = Type 3 4 = Type 4 5 = Type 5 6 = Type 6 7 = Type 7		BRISTOL_S CALE
④ Ballooning	1		0 = No 1 = Yes		BALLOONIN G

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Folder: Visit 1

Form: Normal device

Generated On: 30 Sep 2020 12:31:31

Information about the stoma product normally used

What brand of stoma product is normally used? (you may tick more than 1 box)

Coloplast _____ 3

ConvaTec _____ 4

Hollister _____ 5

Dansac _____ 6

Salts _____ 7

Other _____ 8

If 'Other', please specify _____ 9

What is the product name? _____ 10

What is the product number / item number? _____ 11

What is the product size (base plate size)? _____ 12

Is the subject used to cutting the product / baseplate? No 13
Yes

If Yes, how much is cut off - minimum value? Fixed Unit: mm 14

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Folder: Visit 1

Form: Normal device

Generated On: 30 Sep 2020 12:31:31

If Yes, how much is cut off - maximum value?

Fixed Unit: mm 15

On average, how often is the product/baseplate normally changed?

- Once a day or more frequent 16
- Every 2nd day
- Every 3rd day
- Every 4th day
- Every 5th day
- Every 6th day
- Once a week or less frequent
-

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Folder: Visit 1

Form: Normal device

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Brand 1	1				MULTI_BRAND_1
④ Brand 2	1				MULTI_BRAND_2
⑤ Brand 3	1				MULTI_BRAND_3
⑥ Brand 4	1				MULTI_BRAND_4
⑦ Brand 5	1				MULTI_BRAND_5
⑧ Brand 6	1				MULTI_BRAND_6
⑨ Brand other	\$50				MULTI_BRAND_OTHER
⑩ Product name	\$100				PRODUCT_NAME
⑪ Product number	\$50				PRODUCT_NUMBER
⑫ Product size	\$30				PRODUCT_SIZE

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Folder: Visit 1

Form: Normal device

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 Cutting YN	1		0 = No 1 = Yes		CUTTING_Y N
 Cutting min	2				CUTTING_M IN
 Cutting max2					CUTTING_M AX
 Frequency of change	1		1 = Once a day or more frequent 2 = Every 2nd day 3 = Every 3rd day 4 = Every 4th day 5 = Every 5th day 6 = Every 6th day 7 = Once a week or less frequent		CHANGE_F REQ

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Folder: Visit 1

Form: Accessories

Generated On: 30 Sep 2020 12:31:31

Use of accessories

Which stoma accessories are normally used? (you may tick more than one box)

None _____ **3**

Adhesive remover _____ **4**

Paste _____ **5**

Rings _____ **6**

Ostomy tape _____ **7**

Ostomy belt _____ **8**

Hernia belt _____ **9**

Stoma powder _____ **10**

Barrier lotion _____ **11**

Barrier cream _____ **12**

Barrier spray _____ **13**

Barrier wipes _____ **14**

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Folder: Visit 1

Form: Accessories

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Cleansing wipes/cleansing spray _____ 15

Odour remover _____ 16

Other accessories _____ 17

If 'Other' please specify _____ 18

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Folder: Visit 1

Form: Accessories

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Accessories 1 1					MULTI_ACC _1
④ Accessories 1 2					MULTI_ACC _2
⑤ Accessories 1 3					MULTI_ACC _3
⑥ Accessories 1 4					MULTI_ACC _4
⑦ Accessories 1 5					MULTI_ACC _5
⑧ Accessories 1 6					MULTI_ACC _6
⑨ Accessories 1 7					MULTI_ACC _7
⑩ Accessories 1 8					MULTI_ACC _8
⑪ Accessories 1 9					MULTI_ACC _9
⑫ Accessories 1 10					MULTI_ACC _10

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Folder: Visit 1

Form: Accessories

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
13 Accessories 1 11					MULTI_ACC _11
14 Accessories 1 12					MULTI_ACC _12
15 Accessories 1 13					MULTI_ACC _13
16 Accessories 1 14					MULTI_ACC _14
17 Accessories 1 15					MULTI_ACC _15
18 Accessories \$50 other					MULTI_ACC _OTHER

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Folder: Visit 1

Form: Body Profile

Generated On: 30 Sep 2020 12:31:31

Body Profile

Please refer to the Body Profile Guide in the Site File and describe the area that is usually covered by the base plate with regard to the following parameters

The form around the stoma (picture in box 1)

Regular ③
Inward
Outward

Selected form being uniform or variable (picture in box 2)

Uniform ④
Variable

Soft or firm abdomen (pictures in box 3)

Soft ⑤
Firm

Superficial creases or deep folds (pictures in box 4)

No creases or superficial creases ⑥
Deep folds

Location of stoma (pictures in box 5)

Above bending line ⑦
At bending line
Below bending line

Level of stoma opening in relation to skin surface (pictures in box 6)

Above skin surface ⑧
In level with skin surface
Below skin surface

Consistency of output

Thick stool ⑨

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Folder: Visit 1

Form: Body Profile

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Liquid stool

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 1

Form: Body Profile

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Body Profile 1 1			1 = Regular 2 = Inward 3 = Outward		PROFILE_1
④ Body Profile 1 2			1 = Uniform 2 = Variable		PROFILE_2
⑤ Body Profile 1 3			1 = Soft 2 = Firm		PROFILE_3
⑥ Body Profile 1 4			1 = No creases or superficial creases 2 = Deep folds		PROFILE_4
⑦ Body Profile 1 5			1 = Above bending line 2 = At bending line 3 = Below bending line		PROFILE_5
⑧ Body Profile 1 6			1 = Above skin surface 2 = In level with skin surface		PROFILE_6

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Folder: Visit 1

Form: Body Profile

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Below skin surface		
 Body Profile 1 7			1 = Thick stool 2 = Liquid stool		PROFILE_7

Peristomal skin area

Please ask the subject the following questions:

How often do you experience skin complications around the stoma (itching, burning, red or discoloured skin, pain, bleeding, moist or broken skin)?

- Daily ②
Every 2-3 days
Every 4-6 days
Once a week
Every second week
More rarely

How many times in the last year have you had a peristomal skin complication where you had to seek consultation and/or treatment from a health care professional? _____

③

Which peristomal skin complication/symptom do you experience most often? (you may tick more than one box)

Itching _____ ⑤

Burning _____ ⑥

Red/discoloured skin _____ ⑦

Pain _____ ⑧

Bleeding skin _____ ⑨

Moist skin _____ ⑩

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Folder: Visit 1

Form: Skin area visit 1

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Broken skin **11**

Do you have any skin complications around your stoma today? No **12**
Yes

How would you describe the skin complications around your stoma today? No skin complications **13**
Very mild
Mild
Moderate
Severe
Very severe

Peristomal skin area

Please evaluate the peristomal skin - for site personnel to evaluate

Does the subject have any peristomal skin complications today? No **15**
Yes

Overall, how would you describe the severity of the subjects peristomal skin complications today? Very mild **16**
Mild
Moderate
Severe
Very severe

Does the subject have any discoloration on the peristomal skin today? No **17**
Yes

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Folder: Visit 1

Form: Skin area visit 1

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Overall, how would you describe the severity of the subject's discoloration on their peristomal skin today?

- Very mild 18
Mild
Moderate
Severe
Very severe

Does the subject have any erosion on the peristomal skin today?

- No 19
Yes

Overall, how would you describe the severity of the subject's erosion on their peristomal skin complications today?

- Very mild 20
Mild
Moderate
Severe
Very severe

Is there discoloration of peristomal skin with complications (pain, shiny, indurated, hot, itching, burning)?

- No 21
Yes

Is there damage to the lower layers of the skin with complications (moisture, bleeding or ulceration)?

- No 22
Yes

Is there raised tissue above skin level with complications (bleeding, pain or moisture)?

- No 23
Yes

Please remember to check for adverse events, device deficiencies and concomitant medication

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Folder: Visit 1

Form: Skin area visit 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Frequency of complications	1		1 = Daily 2 = Every 2-3 days 3 = Every 4-6 days 4 = Once a week 5 = Every second week 6 = More rarely		COMP_FRQ
③ Number of consultations	\$5				COMP_CONSULT
⑤ Skin complication 1	1				MULTI_COMPTYPE_1
⑥ Skin complication 2	1				MULTI_COMPTYPE_2
⑦ Skin complication 3	1				MULTI_COMPTYPE_3
⑧ Skin complication 4	1				MULTI_COMPTYPE_4

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Folder: Visit 1

Form: Skin area visit 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 Skin complication 5	1				MULTI_CO MPTYPE_5
10 Skin complication 6	1				MULTI_CO MPTYPE_6
11 Skin complication 7	1				MULTI_CO MPTYPE_7
12 Complications today	1		0 = No 1 = Yes		COMP_TOD AY
13 Severity of complications	1		0 = No skin complications 1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		COMP_IF_Y ES
15 Skin complications	1		0 = No 1 = Yes		COMPLICAT ION_YN

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Folder: Visit 1

Form: Skin area visit 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
16 Skin complications severity	1		1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		COMPLICATION_IF_YES
17 Discolouration	1		0 = No 1 = Yes		DISCOLOUR_YN
18 Discolouration severity	1		1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		DISCOLOUR_IF_YES
19 Erosion	1		0 = No 1 = Yes		EROSION_YN
20 Erosion severity	1		1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		EROSION_IF_YES

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Folder: Visit 1

Form: Skin area visit 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
21 Discolouration complications	1		0 = No 1 = Yes		DISCOLOUR_COMP_YN
22 Erosion complications	1		0 = No 1 = Yes		EROSION_COMP_YN
23 Tissue complications	1		0 = No 1 = Yes		TISSUE_COMP_YN

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Folder: Visit 1

Form: Study supplies visit 1

Generated On: 30 Sep 2020 12:31:31

Administration of study supplies

Please register the supplies handed out to this subject at this visit

Please enter the name of the product handed out at this visit _____

②

Please enter the number of boxes handed out _____

③

Please enter the subject number from the phone that is handed out. PLEASE NOTE: it is extremely important that the subject number in Rave and on the phone is identical. Please also take the first photo at the visit. _____

④

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Folder: Visit 1

Form: Study supplies visit 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Product supplied	\$100				SUPPLIES_1
③ Boxes supplied	2				SUPPLIES_2
④ Phone supplied	4				SUPPLIES_3

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Folder: Phone call week 2
Form: Phone call
Generated On: 30 Sep 2020 12:31:31

Registration of phone call

Date of the call _____

②

Please check the subject's well-being and make sure to ask the subject the following questions

Have you seen a change in the skin condition since the last visit/call?

No ④
Yes

If yes, please describe _____

⑤

Did the stoma behave differently from normal since the last visit/call?

No ⑥
Yes

If the stoma behaved differently, please describe _____

⑦

Please remember to check for adverse events, device deficiencies and concomitant medication

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Folder: Phone call week 2

Form: Phone call

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Date of call	dd MMM YYYY				VISITDAT
④ Check of skin	1		0 = No 1 = Yes		SKINCHECK
⑤ If yes, please describe	\$300				SKINCHECK_IF_YES
⑥ Check of stoma	1		0 = No 1 = Yes		STOMA_CHECK
⑦ If yes please describe	\$300				STOMACHECK_IF_YES

Production Germany 14. Jan. 2020: Primary matrix
Folder: Phone call week 4
Form: Phone call
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Registration of phone call

Date of the call _____

②

Please check the subject's well-being and make sure to ask the subject the following questions

Have you seen a change in the skin condition since the last visit/call?

No ④
Yes

If yes, please describe _____

⑤

Did the stoma behave differently from normal since the last visit/call?

No ⑥
Yes

If the stoma behaved differently, please describe _____

⑦

Please remember to check for adverse events, device deficiencies and concomitant medication

Production Germany 14. Jan. 2020: Primary matrix

Folder: Phone call week 4

Form: Phone call

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Date of call	dd MMM YYYY				VISITDAT
④ Check of skin	1		0 = No 1 = Yes		SKINCHECK
⑤ If yes, please describe	\$300				SKINCHECK_IF_YES
⑥ Check of stoma	1		0 = No 1 = Yes		STOMA_CHECK
⑦ If yes please describe	\$300				STOMACHECK_IF_YES

Production Germany 14. Jan. 2020: Primary matrix
Folder: Visit 2
Form: Visit Date
Generated On: 30 Sep 2020 12:31:31

Please enter visit date

①

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 2

Form: Visit Date

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① VISITDAT	dd MMM YYYY				VISITDAT

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 2

Form: Skin area visit 2

Generated On: 30 Sep 2020 12:31:31

Peristomal skin area

Please evaluate the peristomal skin

Does the subject have any peristomal skin complications today?

No ②
Yes

Overall, how would you describe the severity of the subject's peristomal skin complications today?

Very mild ③
Mild
Moderate
Severe
Very severe

Does the subject have any discoloration on the peristomal skin today?

No ④
Yes

Overall, how would you describe the severity of the subject's discoloration on their peristomal skin today?

Very mild ⑤
Mild
Moderate
Severe
Very severe

Does the subject have any erosion on the peristomal skin today?

No ⑥
Yes

Overall, how would you describe the severity of the subject's erosion on their peristomal skin complications today?

Very mild ⑦
Mild
Moderate
Severe
Very severe

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 2

Form: Skin area visit 2

Generated On: 30 Sep 2020 12:31:31

Is there discoloration of peristomal skin with complications (pain, shiny, indurated, hot, itching, burning)?

No **8**
Yes

Is there damage to the lower layers of the skin with complications (moisture, bleeding or ulceration)?

No **9**
Yes

Is there raised tissue above skin level with complications (bleeding, pain or moisture)?

No **10**
Yes

Compared to the beginning of this test period (Test Period 1) how have the subject's peristomal skin complications changed during the study? (based on photo from visit 1 and the skin at visit 2)

Very much improved **11**
Much improved
A little improved
No change
A little worse
Much worse
Very much worse

Compared to the beginning of this test period (test period 1) how has the discolouration of the subject's skin around the stoma changed during the study? (based on photo from visit 1 and the skin at visit 2)

Very much improved **12**
Much improved
A little improved
No change
A little worse
Much worse
Very much worse

Compared to the beginning of this test period (test period 1) how has the erosion of the subject's skin around the stoma changed during the study? (based on photo from visit 1 and the skin at visit 2)

Very much improved **13**
Much improved
A little improved

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 2

Form: Skin area visit 2

Generated On: 30 Sep 2020 12:31:31

-
- No change
 - A little worse
 - Much worse
 - Very much worse

Please remember to check for adverse events, device deficiencies and concomitant medication

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 2

Form: Skin area visit 2

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Skin complications	1		0 = No 1 = Yes		COMPLICAT ION_YN
③ Skin complications severity	1		1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		COMPLICAT ION_IF_YE S
④ Discolouration	1		0 = No 1 = Yes		DISCOLOUR _YN
⑤ Discolouration severity	1		1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		DISCOLOUR _IF_YES
⑥ Erosion	1		0 = No 1 = Yes		EROSION_Y N
⑦ Erosion severity	1		1 = Very mild 2 = Mild 3 = Moderate		EROSION_I F_YES

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 2

Form: Skin area visit 2

Generated On: 30 Sep 2020 12:31:31



Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Severe 5 = Very severe		
8 Discolouration complications	1		0 = No 1 = Yes		DISCOLOUR_COMP_YN
9 Erosion complications	1		0 = No 1 = Yes		EROSION_COMP_YN
10 Tissue complications	1		0 = No 1 = Yes		TISSUE_COMP_YN
11 Comparison of skin	1		1 = Very much improved 2 = Much improved 3 = A little improved 4 = No change 5 = A little worse 6 = Much worse 7 = Very much worse		COMPARE_SKIN

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 2

Form: Skin area visit 2

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 Comparison 1 of discolouration			1 = Very much improved 2 = Much improved 3 = A little improved 4 = No change 5 = A little worse 6 = Much worse 7 = Very much worse		COMPARE_DISCOLOUR
 Comparison 1 of erosion			1 = Very much improved 2 = Much improved 3 = A little improved 4 = No change 5 = A little worse 6 = Much worse 7 = Very much worse		COMPARE_EROSION

Production Germany 14. Jan. 2020: Primary matrix
Folder: Visit 2
Form: Study supplies visit 2
Generated On: 30 Sep 2020 12:31:31

Administration of study supplies
Please register the supplies handed out to this subject at this visit

_____ ②

_____ ③

Please confirm that the phone has been configured, so the app is pushed forward to test period 2. Please also take the first photo at the visit.

No ④
Yes

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 2

Form: Study supplies visit 2

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Product supplied	\$100				SUPPLIES_1
③ Boxes supplied	2				SUPPLIES_2
④ Phone configured	1		0 = No 1 = Yes		SUPPLIES_4

Production Germany 14. Jan. 2020: Primary matrix
Folder: Phone call week 8
Form: Phone call
Generated On: 30 Sep 2020 12:31:31

Registration of phone call

Date of the call _____

②

Please check the subject's well-being and make sure to ask the subject the following questions

Have you seen a change in the skin condition since the last visit/call?

No ④
Yes

If yes, please describe _____

⑤

Did the stoma behave differently from normal since the last visit/call?

No ⑥
Yes

If the stoma behaved differently, please describe _____

⑦

Please remember to check for adverse events, device deficiencies and concomitant medication

Production Germany 14. Jan. 2020: Primary matrix

Folder: Phone call week 8

Form: Phone call

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Date of call	dd MMM YYYY				VISITDAT
④ Check of skin	1		0 = No 1 = Yes		SKINCHECK
⑤ If yes, please describe	\$300				SKINCHECK_IF_YES
⑥ Check of stoma	1		0 = No 1 = Yes		STOMA_CHECK
⑦ If yes please describe	\$300				STOMACHECK_IF_YES

Production Germany 14. Jan. 2020: Primary matrix
Folder: Phone call week 10
Form: Phone call
Generated On: 30 Sep 2020 12:31:31

Registration of phone call

Date of the call _____

②

Please check the subject's well-being and make sure to ask the subject the following questions

Have you seen a change in the skin condition since the last visit/call?

No ④
Yes

If yes, please describe _____

⑤

Did the stoma behave differently from normal since the last visit/call?

No ⑥
Yes

If the stoma behaved differently, please describe _____

⑦

Please remember to check for adverse events, device deficiencies and concomitant medication

Production Germany 14. Jan. 2020: Primary matrix

Folder: Phone call week 10

Form: Phone call

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Date of call	dd MMM YYYY				VISITDAT
④ Check of skin	1		0 = No 1 = Yes		SKINCHECK
⑤ If yes, please describe	\$300				SKINCHECK_IF_YES
⑥ Check of stoma	1		0 = No 1 = Yes		STOMA_CHECK
⑦ If yes please describe	\$300				STOMACHECK_IF_YES

Production Germany 14. Jan. 2020: Primary matrix
Folder: Visit 3
Form: Visit Date
Generated On: 30 Sep 2020 12:31:31

Please enter visit date

①

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 3

Form: Visit Date

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① VISITDAT	dd MMM YYYY				VISITDAT

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 3

Form: Skin area visit 3

Generated On: 30 Sep 2020 12:31:31

Peristomal skin area
Please evaluate the peristomal skin

Does the subject have any peristomal skin complications today? No **2**
Yes

Overall, how would you describe the severity of the subjects peristomal skin complications today? Very mild **3**
Mild
Moderate
Severe
Very severe

Does the subject have any discoloration on the peristomal skin today? No **4**
Yes

Overall, how would you describe the severity of the subject's discoloration on their peristomal skin today? Very mild **5**
Mild
Moderate
Severe
Very severe

Does the subject have any erosion on the peristomal skin today? No **6**
Yes

Overall, how would you describe the severity of the subject's erosion on their peristomal skin complications today? Very mild **7**
Mild
Moderate
Severe
Very severe

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 3

Form: Skin area visit 3

Generated On: 30 Sep 2020 12:31:31

Is there discoloration of peristomal skin with complications (pain, shiny, indurated, hot, itching, burning)?

No **8**
Yes

Is there damage to the lower layers of the skin with complications (moisture, bleeding or ulceration)?

No **9**
Yes

Is there raised tissue above skin level with complications (bleeding, pain or moisture)?

No **10**
Yes

Compared to the beginning of this test period (Test Period 2) how have the subject's peristomal skin complications changed during the study? (based on photo from visit 2 and the skin at visit 3)

Very much improved **11**
Much improved
A little improved
No change
A little worse
Much worse
Very much worse

Compared to the beginning of this test period (test period 2) how has the discolouration of the subject's skin around the stoma changed during the study? (based on photo from visit 2 and the skin at visit 3)

Very much improved **12**
Much improved
A little improved
No change
A little worse
Much worse
Very much worse

Compared to the beginning of this test period (test period 2) how has the erosion of the subject's skin around the stoma changed during the study? (based on photo from visit 2 and the skin at visit 3)

Very much improved **13**
Much improved
A little improved

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 3

Form: Skin area visit 3

Generated On: 30 Sep 2020 12:31:31

No change

A little worse

Much worse

Very much worse

Please remember to check for adverse events, device deficiencies and concomitant medication

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 3

Form: Skin area visit 3

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Skin complications	1		0 = No 1 = Yes		COMPLICAT ION_YN
③ Skin complications severity	1		1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		COMPLICAT ION_IF_YE S
④ Discolouration	1		0 = No 1 = Yes		DISCOLOUR _YN
⑤ Discolouration severity	1		1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		DISCOLOUR _IF_YES
⑥ Erosion	1		0 = No 1 = Yes		EROSION_Y N
⑦ Erosion severity	1		1 = Very mild 2 = Mild 3 = Moderate		EROSION_I F_YES

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 3

Form: Skin area visit 3

Generated On: 30 Sep 2020 12:31:31



Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Severe 5 = Very severe		
8 Discolouration complications	1		0 = No 1 = Yes		DISCOLOUR_COMP_YN
9 Erosion complications	1		0 = No 1 = Yes		EROSION_COMP_YN
10 Tissue complications	1		0 = No 1 = Yes		TISSUE_COMP_YN
11 Comparison of skin	1		1 = Very much improved 2 = Much improved 3 = A little improved 4 = No change 5 = A little worse 6 = Much worse 7 = Very much worse		COMPARE_SKIN

Production Germany 14. Jan. 2020: Primary matrix

Folder: Visit 3

Form: Skin area visit 3

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 Comparison 1 of discolouration			1 = Very much improved 2 = Much improved 3 = A little improved 4 = No change 5 = A little worse 6 = Much worse 7 = Very much worse		COMPARE_DISCOLOUR
 Comparison 1 of erosion			1 = Very much improved 2 = Much improved 3 = A little improved 4 = No change 5 = A little worse 6 = Much worse 7 = Very much worse		COMPARE_EROSION

Production Germany 14. Jan. 2020: Primary matrix
Folder: Unscheduled call
Form: Phone call
Generated On: 30 Sep 2020 12:31:31

Registration of phone call

Date of the call _____

②

Please check the subject's well-being and make sure to ask the subject the following questions

Have you seen a change in the skin condition since the last visit/call?

No ④
Yes

If yes, please describe _____

⑤

Did the stoma behave differently from normal since the last visit/call?

No ⑥
Yes

If the stoma behaved differently, please describe _____

⑦

Please remember to check for adverse events, device deficiencies and concomitant medication

Production Germany 14. Jan. 2020: Primary matrix

Folder: Unscheduled call

Form: Phone call

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Date of call	dd MMM YYYY				VISITDAT
④ Check of skin	1		0 = No 1 = Yes		SKINCHECK
⑤ If yes, please describe	\$300				SKINCHECK_IF_YES
⑥ Check of stoma	1		0 = No 1 = Yes		STOMA_CHECK
⑦ If yes please describe	\$300				STOMACHECK_IF_YES

Production Germany 14. Jan. 2020: Primary matrix

Folder: Deviations

Form: Deviation Form

Generated On: 30 Sep 2020 12:31:31

Protocol Deviation Form

This form is used for deviations related to data. In case of several deviations, please fill in one form for each deviation

Please state the date the deviation took place _____ ②

Please state what the deviation is related to:

Informed consent ③

Inclusion / exclusion criteria

Study procedures

Safety registrations

Randomisation

Other

If 'Other', please describe _____ ④

Please provide any supplementary description of the deviation if applicable _____ ⑤

Please describe any actions taken with regards to the deviation _____ ⑥

Production Germany 14. Jan. 2020: Primary matrix

Folder: Deviations

Form: Deviation Form

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② Date	dd MMM YYYY				DATE
③ Type of deviation	2		1 = Informed consent 2 = Inclusion / exclusion criteria 3 = Study procedures 4 = Safety registration s 5 = Randomisation 6 = Other		DEVIATION _TYPE
④ Other deviation type	\$100				DEV_OTHE R
⑤ Description of deviation	\$500				DEV_TERM
⑥ Action after deviation	\$200				DEV_ACTIO N

Production Germany 14. Jan. 2020: Primary matrix
Folder: Adverse event summary
Form: Adverse/Serious Events Summary
Generated On: 30 Sep 2020 12:31:31

Did the subject experience any adverse events since last visit / call?

No 1
Yes

Production Germany 14. Jan. 2020: Primary matrix
Folder: Adverse event summary
Form: Adverse/Serious Events Summary
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① AEYN	1		0 = No 1 = Yes		AEYN

Production Germany 14. Jan. 2020: Primary matrix
Folder: Device deficiency summary
Form: Device Deficiency Summary
Generated On: 30 Sep 2020 12:31:31

Did the subject experience any device deficiencies since
last visit / call?

No 1
Yes

Production Germany 14. Jan. 2020: Primary matrix
Folder: Device deficiency summary
Form: Device Deficiency Summary
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① DDYN	1		0 = No 1 = Yes		DDYN

Production Germany 14. Jan. 2020: Primary matrix
Folder: Con medication summary
Form: Concomitant Medication Summary
Generated On: 30 Sep 2020 12:31:31

Does the subject use any concomitant medication or did
the subject change concomitant medications since last
visit / call?

No 1
Yes

Production Germany 14. Jan. 2020: Primary matrix
Folder: Con medication summary
Form: Concomitant Medication Summary
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① CMYN	1		0 = No 1 = Yes		CMYN

Production Germany 14. Jan. 2020: Primary matrix
Folder: Termination
Form: Termination Form
Generated On: 30 Sep 2020 12:31:31

Termination Form

Date of completion/discontinuation of the study: _____ ②

Did the subject complete the study as planned? No ③
Yes

Please select the primary reason for the discontinuation:

- Adverse Event ④
- Device deficiency, which led to an Adverse Event
- Device deficiency, which DID NOT lead to an Adverse Event
- Lack of effectiveness
- Subject wishes to discontinue
- Protocol deviation
- Screening failure
- Withdrawal of Consent
- Lost to Follow-Up
- Other

If Protocol Deviation, please specify: _____ ⑤

If Other, please specify: _____ ⑥

Production Germany 14. Jan. 2020: Primary matrix

Folder: Termination

Form: Termination Form

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② DSSTDAT	dd MMM YYYY				DSSTDAT
③ DSDECOD	1		0 = No 1 = Yes		DSDECOD
④ DSTERM	\$35		1 = Adverse Event 2 = Device deficiency, which led to an Adverse Event 3 = Device deficiency, which DID NOT lead to an Adverse Event 4 = Lack of effectivenes s 5 = Subject wishes to discontinue 6 = Protocol deviation 9 = Screening failure 10 = Withdrawal of Consent		DSTERM

Production Germany 14. Jan. 2020: Primary matrix
Folder: Termination
Form: Termination Form
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Lost to Follow-Up 8 = Other		
⑤ DSPD	\$100				DSPD
⑥ DSOTH	\$100				DSOTH

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Do you have any skin complications around your stoma today?

No ①
Yes

If yes, how would you describe the skin complications around your stoma today?

No skin complications ②
Very mild
Mild
Moderate
Severe
Very severe

In the last seven days, due to leakage or worry about leakage...

③

I felt panic

All of the time ④
Often
Sometimes
Rarely or never

I felt stressed out

All of the time ⑤
Often
Sometimes
Rarely or never

I felt more afraid about leaks in the future

All of the time ⑥
Often
Sometimes
Rarely or never

I felt worry

All of the time ⑦

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Often
Sometimes
Rarely or never

I felt frustrated

All of the time 8
Often
Sometimes
Rarely or never

I felt embarrassed

All of the time 9
Often
Sometimes
Rarely or never

I felt worried that I might leak

All of the time 10
Often
Sometimes
Rarely or never

I couldn't sleep

All of the time 11
Often
Sometimes
Rarely or never

I kept waking up at night to check my stoma

All of the time 12
Often
Sometimes
Rarely or never

I kept checking my ostomy bag to see if I have leaked

All of the time 13
Often
Sometimes
Rarely or never

Usual and Social activities
In the last seven days due to leakage or worry about leakage...

14

I decided to stay at home

All of the time 15
Often
Sometimes
Rarely or never
Not applicable

I couldn't do light activities

All of the time 16
Often
Sometimes
Rarely or never
Not applicable

I changed my plans

All of the time 17
Often
Sometimes
Rarely or never
Not applicable

I was unable to go out and meet family and friends

All of the time 18
Often

Sometimes
Rarely or never
Not applicable

I avoided close physical contact with family and friends

All of the time 19
Often
Sometimes
Rarely or never
Not applicable

I did not want to see people

All of the time 20
Often
Sometimes
Rarely or never
Not applicable

I avoided people

All of the time 21
Often
Sometimes
Rarely or never
Not applicable

I tried to avoid meeting new people

All of the time 22
Often
Sometimes
Rarely or never
Not applicable

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Coping and in control
In the last 7 days, due to leakage or worry about
leakage...

23

I felt in control

All of the time 24
Often
Sometimes
Rarely or never

I was able to cope

All of the time 25
Often
Sometimes
Rarely or never

I felt calm

All of the time 26
Often
Sometimes
Rarely or never

I saw my friends as I usually do

All of the time 27
Often
Sometimes
Rarely or never

Discreetness
In the last seven days...

28

It was difficult to hide the stoma appliance under
clothing

Strongly agree 29
Slightly agree

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Neither agree nor disagree
Slightly disagree
Strongly disagree

I was self-conscious about the appearance of the stoma appliance

Strongly agree 30
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The stoma appliance limited the choice of clothes that I could wear

Strongly agree 31
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The stoma appliance was obvious to other people

Strongly agree 32
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The color of the stoma appliance was discreet

Strongly agree 33
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

It was difficult to hide the stoma appliance because of ballooning

Strongly agree 34
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

Comfort
In the last seven days...

35

The stoma appliance was comfortable to wear

Strongly agree 36
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

I was not concerned about skin irritation under the stoma appliance (for example feelings of burning, itching, pinching or pain)

Strongly agree 37
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

It was uncomfortable to remove the stoma appliance from my body

Strongly agree 38
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

I often forgot that I was wearing the stoma appliance

Strongly agree 39
Slightly agree

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Neither agree nor disagree

Slightly disagree

Strongly disagree

The stoma appliance was comfortable as it fitted well to my body movements

Strongly agree 40

Slightly agree

Neither agree nor disagree

Slightly disagree

Strongly disagree

The stoma appliance disrupted my sleep during the night

Strongly agree 41

Slightly agree

Neither agree nor disagree

Slightly disagree

Strongly disagree

Confidence
In the last seven days...

42

I was confident that the stoma appliance would not leak

Strongly agree 43

Slightly agree

Neither agree nor disagree

Slightly disagree

Strongly disagree

I worried that the stoma appliance would become loose from my body

Strongly agree 44

Slightly agree

Neither agree nor disagree

Slightly disagree

Strongly disagree

I felt confident that I could spend the night away from home despite wearing the stoma appliance

Strongly agree 45
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

I was confident the stoma appliance would not cause any problems for me

Strongly agree 46
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

I felt confident to take part in physical activities (for example, sports) whilst wearing the stoma appliance

Strongly agree 47
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

I worried that the stoma appliance would make a rustling noise

Strongly agree 48
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

Social life and relationships
In the last seven days...

49

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

I worried that my family and friends felt awkward around me because of the stoma appliance

- Strongly agree 50
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I felt my social life had been restricted because of the stoma appliance

- Strongly agree 51
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I avoided close physical contact with family and friends because of the stoma appliance

- Strongly agree 52
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I worried about whether I could have a relationship because of my stoma appliance

- Strongly agree 53
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I worried about whether the stoma appliance would affect my sex life

- Strongly agree 54
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Complications today	1		0 = No 1 = Yes		COMP_TODAY
② Severity of complications	1		0 = No skin complications 1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		COMP_IFYES
③ LEAKAGE_H1EADER					LEAKAGE_H1EADER
④ LEAKAGE_Q1S_1			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q1S_1
⑤ LEAKAGE_Q1S_2			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q1S_2

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑥ LEAKAGE_Q1 S_3			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_3
⑦ LEAKAGE_Q1 S_4			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_4
⑧ LEAKAGE_Q1 S_5			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_5
⑨ LEAKAGE_Q1 S_6			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_6
⑩ LEAKAGE_Q1 S_7			0 = All of the time		LEAKAGE_Q S_7

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			1 = Often 2 = Sometimes 3 = Rarely or never		
11 LEAKAGE_Q1 S_8			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_8
12 LEAKAGE_Q1 S_9			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_9
13 LEAKAGE_Q1 S_10			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_10
14 LEAKAGE_H1 EADER2					LEAKAGE_H EADER2

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15 LEAKAGE_Q1 S_11			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_11
16 LEAKAGE_Q1 S_12			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_12
17 LEAKAGE_Q1 S_13			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_13
18 LEAKAGE_Q1 S_14			0 = All of the time 1 = Often 2 = Sometimes		LEAKAGE_Q S_14

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Rarely or never 9 = Not applicable		
19 LEAKAGE_Q1 S_15			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_15
20 LEAKAGE_Q1 S_16			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_16
21 LEAKAGE_Q1 S_17			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_17

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
22 LEAKAGE_Q1 S_18			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_18
23 LEAKAGE_H1 EADER3					LEAKAGE_H EADER3
24 LEAKAGE_Q1 S_19			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_19
25 LEAKAGE_Q1 S_20			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_20
26 LEAKAGE_Q1 S_21			0 = All of the time 1 = Often 2 = Sometimes		LEAKAGE_Q S_21

Production Germany 14. Jan. 2020: Primary matrix
Folder: Paper CRF data
Form: Paper Evaluation visit 1
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Rarely or never		
27 LEAKAGE_Q1 S_22			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_22
28 QOLH1	1				QOLH1
29 QOL_QS_1	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_1
30 QOL_QS_2	1		1 = Strongly agree 2 = Slightly agree		QOL_QS_2

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		
31 QOL_QS_3	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_3
32 QOL_QS_4	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_4

Production Germany 14. Jan. 2020: Primary matrix
Folder: Paper CRF data
Form: Paper Evaluation visit 1
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
33 QOL_QS_5	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_5
34 QOL_QS_6	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_6
35 QOLH2	1				QOLH2
36 QOL_QS_7	1		1 = Strongly agree		QOL_QS_7

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		
37 QOL_QS_8	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_8
38 QOL_QS_9	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree		QOL_QS_9

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Strongly disagree		
39 QOL_QS_101			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_10
40 QOL_QS_111			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_11

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
41 QOL_QS_121			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_12
42 QOLH3	1				QOLH3
43 QOL_QS_131			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_13
44 QOL_QS_141			1 = Strongly agree		QOL_QS_14

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		
45 QOL_QS_151			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_15
46 QOL_QS_161			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree		QOL_QS_16

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Strongly disagree		
47 QOL_QS_171			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_17
48 QOL_QS_181			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_18
49 QOLH4	1				QOLH4

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31



Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
50 QOL_QS_191			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_19
51 QOL_QS_201			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_20
52 QOL_QS_211			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree		QOL_QS_21

Production Germany 14. Jan. 2020: Primary matrix

Folder: Paper CRF data

Form: Paper Evaluation visit 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Slightly disagree 5 = Strongly disagree		
 QOL_QS_221			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_22
 QOL_QS_231			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_23

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Type of change
Generated On: 30 Sep 2020 12:31:31

Product sequence number _____ ①

What type of change do you want to register? Bag change ②
Baseplate change

_____ ③

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Type of change

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Product sequence number	3				PRODSEQUENCE
② Type of change	\$3		BAG = Bag change BP = Baseplate change		CNG_TYPE
③ HIDDEN	\$100		{ "Change_ty pe": { "BAG": "CHANGETI ME_BP", "BP": "CHANGETI ME_BP" } }	1: { "Change_ty pe": { "BAG": "CHANGETI ME_BP", "BP": "CHANGETI ME_BP" } }	HIDDEN

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Time for performing change of bag
Generated On: 30 Sep 2020 12:31:31

Product sequence number _____

①

Are you going to change now or have you changed
previously without using the app?

I am going to change now ②

I have changed previously
without using the app (e.g.
during the night)

{ "CNGnowprev": { "N": ③
"BAGCNG", "P":
"BAGCNGPREV" } }

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Time for performing change of bag

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Product sequence number	3				PRODSEQUENCE
② Time for performing change of bag	\$1		N = I am going to change now P = I have changed previously without using the app (e.g. during the night)		CHANGETIME_BAG
③ HIDDEN	\$100		{ "CNGnowpr ev": { "N": "BAGCNG", "P": "BAGCNGPR EV" } }		HIDDEN

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Bag change previously
Generated On: 30 Sep 2020 12:31:31

Product sequence number

①

When did you change the bag (approximately)?

②

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Bag change previously
Generated On: 30 Sep 2020 12:31:31

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	Product sequence number	3				PRODSEQUENCE
②	When did you change the bag	dd MMM yyyy HH:nn				CNGPREVDT

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Bag change
Generated On: 30 Sep 2020 12:31:31

Product sequence number _____ ①

Photo of the baseplate on the skin _____ ②

Baseplate on skin photo file name _____ ③

Baseplate on skin photo date and time _____ ④

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Bag change

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Product sequence number	3				PRODSEQUENCE
② Photo of the1 baseplate on the skin					PHOTO_BP ONSKIN
③ Photo file name	\$100				BPONSKIN_ PHOTO
④ Baseplate on skin photo	dd MMM yyyy HH:nn				PHT03DTC

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Time for performing change of BP
Generated On: 30 Sep 2020 12:31:31

Product sequence number _____

①

Are you going to change now or have you changed previously?

I am going to change now ②

I have changed previously
without using the app (e.g.
during the night)

③

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Time for performing change of BP

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Product sequence number	3				PRODSEQUENCE
② Time for performing change of baseplate	\$1		N = I am going to change now P = I have changed previously without using the app (e.g. during the night)		CHANGETIME_BP
③ HIDDEN	\$100		{ "CNGnowpr ev": { "N": "BPCNG", "P": "BPCNGPRE V" } }	1: { "CNGnowpr ev": { "N": "BPCNG", "P": "BPCNGPRE V" } }	HIDDEN

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Baseplate change previously
Generated On: 30 Sep 2020 12:31:31

Product sequence number

①

When did you change the product (approximately)?

②

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Baseplate change previously
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Product sequence number	3				PRODSEQUENCE
② Product change previously	dd MMM yyyy HH:nn				CNGPREVDTTC

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Baseplate change TP 1

Generated On: 30 Sep 2020 12:31:31

Product sequence number _____ ①

Photo of the stoma _____ ②

Stoma photo file name _____ ③

Stoma photo date and time _____ ④

Photo of the product _____ ⑤

Product photo file name _____ ⑥

Product photo date and time _____ ⑦

Do you experience any bleeding from the skin around your stoma right now when changing your product? Not experiencing ⑧
Experiencing

Once you have cleaned and dried the skin, do you still experience any weeping or moisture on the skin around your stoma right now when changing your product? Not experiencing ⑨
Experiencing

Are you experiencing any ulcers or sores around your stoma right now when changing your product? Not experiencing ⑩
Experiencing

How much of the time have you experienced any itching around your stoma since you last changed your product? None of the time ⑪
A little of the time
Some of the time
A lot of the time
All of the time

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Baseplate change TP 1
Generated On: 30 Sep 2020 12:31:31

Please rate on a scale from 0-10 how itchy the skin around your stoma has been at its worst since you last changed your product

- 0 No itch 12
 - 1 Very mild itch
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10 Worst possible peristomal skin itch
-

How much of the time have you experienced any pain around your stoma since you last changed your product?

- None of the time 13
 - A little of the time
 - Some of the time
 - A lot of the time
 - All of the time
-

Please rate on a scale from 0-10 how painful the skin around your stoma has been at its worst since you last changed your product

- 0 No pain 14
 - 1 Very mild pain
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10 Worst possible peristomal skin pain
-

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Baseplate change TP 1
Generated On: 30 Sep 2020 12:31:31

How much of the time have you experienced any burning feelings from the skin around your stoma since you last changed your product?

- None of the time 15
 - A little of the time
 - Some of the time
 - A lot of the time
 - All of the time
-

Please rate on a scale from 0-10 any burning feelings from the skin around your stoma at its worst since you last changed your product

- 0 No burning 16
 - 1 Very mild burning
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10 Worst possible peristomal skin burning
-

How would you rate on a scale of 0-10 your overall physical discomfort from the skin around your stoma since you last changed your product?

- 0 No discomfort 17
 - 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10 A lot of discomfort
-

On a scale of 0-10, how much have skin complications around your stoma caused you difficulty in your overall ability to move around since you last changed your product? For example, bending or walking

No skin complications 18

0 No difficulty

1

2

3

4

5

6

7

8

9

10 A lot of difficulty

On a scale of 0-10, how much have skin complications around your stoma caused you difficulty in your overall ability to stick the stoma bag adhesive to your skin since you last changed your product?

No skin complications 19

0 No difficulty

1

2

3

4

5

6

7

8

9

10 A lot of difficulty

What was the main reason for change of the baseplate? _____ 20

I followed my usual changing pattern _____ 21

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Baseplate change TP 1
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I thought it would be nice with a clean product _____ (22)

In preparation of an activity (i.e. going out, doing sports, travelling) _____ (23)

The entire baseplate had become detached _____ (24)

The outer edge of the baseplate had become detached _____ (25)

The center of the baseplate had become detached _____ (26)

I was afraid the baseplate would become detached _____ (27)

The area around the stoma was itching _____ (28)

The area around the stoma was painful _____ (29)

There was leakage underneath and outside the baseplate _____ (30)

There was leakage underneath the baseplate (but not outside the baseplate) _____ (31)

The bag was full of air (ballooning) _____ (32)

There was a vacuum in the bag (pancaking) _____ (33)

Due to visit in the investigation _____ (34)

Other reason _____ (35)

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Baseplate change TP 1
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If other reason for change is selected, please specify _____ **36**

Did you experience leakage outside the baseplate (i.e. soiling the clothes)?

No **37**
Yes

Did you experience the bag becoming overfilled with air during use (ballooning)?

Not at all **38**
A little
Some
Much
Very much

Which stoma accessories did you use?

None _____ **40**

Adhesive remover _____ **41**

Paste _____ **42**

Rings _____ **43**

Ostomy tape _____ **44**

Ostomy belt _____ **45**

Hernia belt _____ **46**

Stoma powder _____ **47**

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Baseplate change TP 1
Generated On: 30 Sep 2020 12:31:31

Barrier lotion	_____	48
Barrier cream	_____	49
Barrier spray	_____	50
Barrier wipes	_____	51
Cleansing wipes/cleansing spray	_____	52
Odour remover	_____	53
Other accessories	_____	54
If 'Other' please specify:	_____	55

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Baseplate change TP 1

Generated On: 30 Sep 2020 12:31:31

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	Product sequence number	3				PRODSEQUENCE
②	Photo of the stoma	1				PHOTO_SKIN
③	Stoma photo name	\$100				PHT0101
④	Stoma photo date and time	dd MMM yyyy HH:nn				PHT01DTC
⑤	Photo of the product	1				PHOTO_PRODUCT
⑥	Product photo name	\$100				PROD_PHOTO
⑦	Product photo date and time	dd MMM yyyy HH:nn				PHT02DTC
⑧	Ostomy Skin Tool 1	1		0 = Not experiencing 1 = Experiencing		OST_1

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Baseplate change TP 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 Ostomy Skin Tool 2	1		0 = Not experiencing 1 = Experiencing		OST_2
10 Ostomy Skin Tool 3	1		0 = Not experiencing 1 = Experiencing		OST_3
11 Ostomy Skin Tool 4	1		1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time 5 = All of the time		OST_4
12 Ostomy Skin Tool 5	2		0 = 0 No itch 1 = 1 Very mild itch 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7		LONGSCALE_OST_5

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Baseplate change TP 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = 8 9 = 9 10 = 10 Worst possible peristomal skin itch		
 Ostomy Skin Tool 6		1	1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time 5 = All of the time		OST_6
 Ostomy Skin Tool 7		2	0 = 0 No pain 1 = 1 Very mild pain 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 Worst possible peristomal skin pain		LONGSCALE_OST_7

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Baseplate change TP 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15 Ostomy Skin Tool 8	1		1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time 5 = All of the time		OST_8
16 Ostomy Skin Tool 9	2		0 = 0 No burning 1 = 1 Very mild burning 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 Worst possible peristomal skin burning		LONGSCALE_OST_9
17 Ostomy Skin Tool 10	2		0 = 0 No discomfort 1 = 1 2 = 2 3 = 3 4 = 4		LONGSCALE_OST_10

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Baseplate change TP 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 A lot of discomfort		
 Ostomy Skin Tool 11	2		99 = No skin complications 0 = 0 No difficulty 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 A lot of difficulty		LONGSCALE _OST_11
 Ostomy Skin Tool 12	2		99 = No skin complications 0 = 0 No difficulty 1 = 1 2 = 2		LONGSCALE _OST_12

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Baseplate change TP 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 A lot of difficulty		
20	MULTI_CNG1_HEADER				MULTI_CNG_HEADER
21	Reason for change no. 1	1			MULTI_CNG_1
22	Reason for change no. 2	2			MULTI_CNG_2
23	Reason for change no. 3	3			MULTI_CNG_3
24	Reason for change no. 4	4			MULTI_CNG_4

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Baseplate change TP 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
25 Reason for change no. 5	1				MULTI_CNG_5
26 Reason for change no. 6	1				MULTI_CNG_6
27 Reason for change no. 7	1				MULTI_CNG_7
28 Reason for change no. 8	1				MULTI_CNG_8
29 Reason for change no. 9	1				MULTI_CNG_9
30 Reason for change no. 10	1				MULTI_CNG_10
31 Reason for change no. 11	1				MULTI_CNG_11
32 Reason for change no. 12	1				MULTI_CNG_12

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP1

Form: Baseplate change TP 1

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
33 Reason for change no. 13	1				MULTI_CNG_13
34 Reason for change no. 14	1				MULTI_CNG_14
35 Reason for change no. 15	1				MULTI_CNG_15
36 Description of other reason for change	\$100				MULTI_CNG_OTHER
37 Leakage outside	1		0 = No 1 = Yes		LEAKAGE_OUTSIDE
38 Degree of ballooning	1		1 = Not at all 2 = A little 3 = Some 4 = Much 5 = Very much		BALLOONING_DEGREE
40 Accessories 1	1				MULTI_ACC_1

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Baseplate change TP 1
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
41 Accessories 1 2					MULTI_ACC _2
42 Accessories 1 3					MULTI_ACC _3
43 Accessories 1 4					MULTI_ACC _4
44 Accessories 1 5					MULTI_ACC _5
45 Accessories 1 6					MULTI_ACC _6
46 Accessories 1 7					MULTI_ACC _7
47 Accessories 1 8					MULTI_ACC _8
48 Accessories 1 9					MULTI_ACC _9
49 Accessories 1 10					MULTI_ACC _10
50 Accessories 1 11					MULTI_ACC _11

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP1
Form: Baseplate change TP 1
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
51 Accessories 1 12					MULTI_ACC _12
52 Accessories 1 13					MULTI_ACC _13
53 Accessories 1 14					MULTI_ACC _14
54 Accessories 1 15					MULTI_ACC _15
55 Accessories \$50 other					MULTI_ACC _OTHER

Do you have any skin complications around your stoma today?

No ①
Yes

If yes, how would you describe the skin complications around your stoma today?

No skin complications ②
Very mild
Mild
Moderate
Severe
Very severe

How often have you experienced itchy skin around your stoma in the past 14 days?

None of the time ③
A little of the time
Some of the time
A lot of the time
All of the time

How often have you experienced any pain in the skin around the stoma in the past 14 days?

None of the time ④
A little of the time
Some of the time
A lot of the time
All of the time

How often have you experienced burning feelings in the skin around your stoma in the past 14 days?

None of the time ⑤
A little of the time
Some of the time
A lot of the time
All of the time

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Compared to the beginning of this test period (Test Period 1) how have any skin complications around your stoma changed?

- Very much improved **6**
- Much improved
- A little improved
- No change
- A little worse
- Much worse
- Very much worse

Did your stoma behave differently from normal since your last visit/call?

- No **7**
- Yes

If yes, please describe _____ **8**

Emotional impact. In the last seven days, due to leakage or worry about leakage... (please tick the box to continue) _____ **9**

I felt panic

- All of the time **10**
- Often
- Sometimes
- Rarely or never

I felt stressed out

- All of the time **11**
- Often
- Sometimes
- Rarely or never

I felt more afraid about leaks in the future

- All of the time **12**
- Often

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Sometimes

Rarely or never

I felt worry

All of the time 13

Often

Sometimes

Rarely or never

I felt frustrated

All of the time 14

Often

Sometimes

Rarely or never

I felt embarrassed

All of the time 15

Often

Sometimes

Rarely or never

I felt worried that I might leak

All of the time 16

Often

Sometimes

Rarely or never

I couldn't sleep

All of the time 17

Often

Sometimes

Rarely or never

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I kept waking up at night to check my stoma

- All of the time 18
Often
Sometimes
Rarely or never

I kept checking my ostomy bag to see if I have leaked

- All of the time 19
Often
Sometimes
Rarely or never

Usual and social activities.
In the last seven days due to leakage or worry about
leakage... (please tick to continue)

20

I decided to stay at home

- All of the time 21
Often
Sometimes
Rarely or never
Not applicable

I couldn't do light activities

- All of the time 22
Often
Sometimes
Rarely or never
Not applicable

I changed my plans

- All of the time 23
Often
Sometimes

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Rarely or never

Not applicable

I was unable to go out and meet family and friends

All of the time 24

Often

Sometimes

Rarely or never

Not applicable

I avoided close physical contact with family and friends

All of the time 25

Often

Sometimes

Rarely or never

Not applicable

I did not want to see people

All of the time 26

Often

Sometimes

Rarely or never

Not applicable

I avoided people

All of the time 27

Often

Sometimes

Rarely or never

Not applicable

I tried to avoid meeting new people

All of the time 28

Often

Sometimes
Rarely or never
Not applicable

Coping and in control.
In the last 7 days, due to leakage or worry about
leakage...

29

I felt in control

All of the time 30
Often
Sometimes
Rarely or never

I was able to cope

All of the time 31
Often
Sometimes
Rarely or never

I felt calm

All of the time 32
Often
Sometimes
Rarely or never

I saw my friends as I usually do

All of the time 33
Often
Sometimes
Rarely or never

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Discreetness.

In the last seven days...

34

It was difficult to hide the stoma appliance under clothing

Strongly agree 35
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

I was self-conscious about the appearance of the stoma appliance

Strongly agree 36
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The stoma appliance limited the choice of clothes that I could wear

Strongly agree 37
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The stoma appliance was obvious to other people

Strongly agree 38
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The color of the stoma appliance was discreet

Strongly agree 39
Slightly agree

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Neither agree nor disagree

Slightly disagree

Strongly disagree

It was difficult to hide the stoma appliance because of ballooning

Strongly agree 40

Slightly agree

Neither agree nor disagree

Slightly disagree

Strongly disagree

Comfort.
In the last seven days...

41

The stoma appliance was comfortable to wear

Strongly agree 42

Slightly agree

Neither agree nor disagree

Slightly disagree

Strongly disagree

I was not concerned about skin irritation under the stoma appliance (for example feelings of burning, itching, pinching or pain)

Strongly agree 43

Slightly agree

Neither agree nor disagree

Slightly disagree

Strongly disagree

It was uncomfortable to remove the stoma appliance from my body

Strongly agree 44

Slightly agree

Neither agree nor disagree

Slightly disagree

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Strongly disagree

I often forgot that I was wearing the stoma appliance

Strongly agree 45
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The stoma appliance was comfortable as it fitted well to my body movements

Strongly agree 46
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The stoma appliance disrupted my sleep during the night

Strongly agree 47
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

Confidence.
In the last seven days...

48

I was confident that the stoma appliance would not leak

Strongly agree 49
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

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I worried that the stoma appliance would become loose from my body

- Strongly agree 50
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I felt confident that I could spend the night away from home despite wearing the stoma appliance

- Strongly agree 51
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I was confident the stoma appliance would not cause any problems for me

- Strongly agree 52
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I felt confident to take part in physical activities (for example, sports) whilst wearing the stoma appliance

- Strongly agree 53
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I worried that the stoma appliance would make a rustling noise

- Strongly agree 54
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

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Social life and relationships.
In the last seven days...

55

I worried that my family and friends felt awkward around
me because of the stoma appliance

- Strongly agree 56
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree

I felt my social life had been restricted because of the
stoma appliance

- Strongly agree 57
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree

I avoided close physical contact with family and friends
because of the stoma appliance

- Strongly agree 58
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree

I worried about whether I could have a relationship
because of my stoma appliance

- Strongly agree 59
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree

I worried about whether the stoma appliance would
affect my sex life

- Strongly agree 60
- Slightly agree

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-
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree

How was the feeling of security while wearing the product?

- Very poor 61
- Poor
- Neither poor nor good
- Good
- Very good

How did you find cutting the baseplate?

- Very difficult 62
- Difficult
- Neither difficult nor easy
- Easy
- Very easy

How did you find applying the baseplate?

- Very difficult 63
- Difficult
- Neither difficult nor easy
- Easy
- Very easy

How did you find removing the baseplate?

- Very difficult 64
- Difficult
- Neither difficult nor easy
- Easy
- Very easy

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Complications today	1		0 = No 1 = Yes		COMP_TODAY
② Severity of complications	1		0 = No skin complications 1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		COMP_IF_YES
③ Itching in 14 days	1		1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time 5 = All of the time		ITCHING_14DAYS
④ Pain in 14 days	1		1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time		PAIN_14DAYS

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = All of the time		
⑤ Burning in 14 days	1		1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time 5 = All of the time		BURNING_14DAYS
⑥ Own comparison of skin	1		1 = Very much improved 2 = Much improved 3 = A little improved 4 = No change 5 = A little worse 6 = Much worse 7 = Very much worse		COMPARE_OWN
⑦ Stoma behaviour	1		0 = No 1 = Yes		STOMABEHAVE_YN

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 Different stoma behaviour	\$200				BEHAVE_IF_YES
9 LEAKAGE_H1 EADER					LEAKAGE_H EADER
10 LEAKAGE_Q1 S_1			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_1
11 LEAKAGE_Q1 S_2			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_2
12 LEAKAGE_Q1 S_3			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_3
13 LEAKAGE_Q1 S_4			0 = All of the time		LEAKAGE_Q S_4

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			1 = Often 2 = Sometimes 3 = Rarely or never		
14 LEAKAGE_Q1 S_5			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_5
15 LEAKAGE_Q1 S_6			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_6
16 LEAKAGE_Q1 S_7			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_7
17 LEAKAGE_Q1 S_8			0 = All of the time 1 = Often		LEAKAGE_Q S_8

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Sometimes 3 = Rarely or never		
18 LEAKAGE_Q1 S_9			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_9
19 LEAKAGE_Q1 S_10			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_10
20 LEAKAGE_H1 EADER2					LEAKAGE_H EADER2
21 LEAKAGE_Q1 S_11			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_11

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Form: Final evaluation TP 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
22 LEAKAGE_Q1 S_12			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_12
23 LEAKAGE_Q1 S_13			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_13
24 LEAKAGE_Q1 S_14			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_14
25 LEAKAGE_Q1 S_15			0 = All of the time 1 = Often 2 = Sometimes		LEAKAGE_Q S_15

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Rarely or never 9 = Not applicable		
26 LEAKAGE_Q1 S_16			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_16
27 LEAKAGE_Q1 S_17			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_17
28 LEAKAGE_Q1 S_18			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_18

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
30 LEAKAGE_H1 EADER3					LEAKAGE_H EADER3
30 LEAKAGE_Q1 S_19			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_19
31 LEAKAGE_Q1 S_20			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_20
32 LEAKAGE_Q1 S_21			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_21
33 LEAKAGE_Q1 S_22			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_22

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
34 QOLH1	1				QOLH1
35 QOL_QS_1	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_1
36 QOL_QS_2	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_2
37 QOL_QS_3	1		1 = Strongly agree		QOL_QS_3

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP1
Form: Final evaluation TP 1
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		
38 QOL_QS_4	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_4
39 QOL_QS_5	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree		QOL_QS_5

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Folder: Final evaluation TP1
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Strongly disagree		
40 QOL_QS_6	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_6
41 QOLH2	1				QOLH2
42 QOL_QS_7	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_7

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
43 QOL_QS_8	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_8
44 QOL_QS_9	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_9
45 QOL_QS_101			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree		QOL_QS_10

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Slightly disagree 5 = Strongly disagree		
46 QOL_QS_111			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_11
47 QOL_QS_121			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_12

Production Germany 14. Jan. 2020: Primary matrix
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
48 QOLH3	1				QOLH3
49 QOL_QS_131			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_13
50 QOL_QS_141			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_14
51 QOL_QS_151			1 = Strongly agree		QOL_QS_15

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		
 QOL_QS_161			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_16
 QOL_QS_171			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree		QOL_QS_17

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Strongly disagree		
54 QOL_QS_181			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_18
55 QOLH4	1				QOLH4
56 QOL_QS_191			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_19

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 QOL_QS_201			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_20
 QOL_QS_211			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_21
 QOL_QS_221			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree		QOL_QS_22

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Form: Final evaluation TP 1
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Slightly disagree 5 = Strongly disagree		
60 QOL_QS_231			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_23
61 Feeling of security	1		1 = Very poor 2 = Poor 3 = Neither poor nor good 4 = Good 5 = Very good		SECURITY
62 Cutting difficulty	1		1 = Very difficult 2 = Difficult		CUTTING_D IFF

Production Germany 14. Jan. 2020: Primary matrix

Folder: Final evaluation TP1

Form: Final evaluation TP 1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Neither difficult nor easy 4 = Easy 5 = Very easy		
63	Application of product	1	1 = Very difficult 2 = Difficult 3 = Neither difficult nor easy 4 = Easy 5 = Very easy		APPLICATION
64	Removal of baseplate	1	1 = Very difficult 2 = Difficult 3 = Neither difficult nor easy 4 = Easy 5 = Very easy		REMOVAL

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP2
Form: Type of change
Generated On: 30 Sep 2020 12:31:31

Product sequence number _____

①

What type of change do you want to register?

Bag change ②
Baseplate change

③

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP2
Form: Type of change
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Product sequence number	3				PRODSEQUENCE
② Type of change	\$3		BAG = Bag change BP = Baseplate change		CNG_TYPE
③ HIDDEN	\$100		{ "Change_ty pe": { "BAG": "CHANGETI ME_BP", "BP": "CHANGETI ME_BP" } }	1: { "Change_ty pe": { "BAG": "CHANGETI ME_BP", "BP": "CHANGETI ME_BP" } }	HIDDEN

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP2
Form: Time for performing change of bag
Generated On: 30 Sep 2020 12:31:31

Product sequence number _____

①

Are you going to change now or have you changed
previously without using the app?

I am going to change now ②
I have changed previously
without using the app (e.g.
during the night)

{ "CNGnowprev": { "N": ③
"BAGCNG", "P":
"BAGCNGPREV" } }

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP2

Form: Time for performing change of bag

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Product sequence number	3				PRODSEQUENCE
② Time for performing chance of bag	\$1		N = I am going to change now P = I have changed previously without using the app (e.g. during the night)		CHANGETIME_BAG
③ HIDDEN	\$100		{ "CNGnowpr ev": { "N": "BAGCNG", "P": "BAGCNGPR EV" } }		HIDDEN

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Folder: Product change TP2
Form: Bag change previously
Generated On: 30 Sep 2020 12:31:31

Product sequence number

①

When did you change the bag (approximately)?

②

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP2
Form: Bag change previously
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Product sequence number	3				PRODSEQUENCE
② When did you change the bag	dd MMM yyyy HH:nn				CNGPREVDT

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP2
Form: Bag change
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Product sequence number _____ ①

Photo of the baseplate on the skin _____ ②

Baseplate on skin photo file name _____ ③

Baseplate on skin photo date and time _____ ④

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP2

Form: Bag change

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Product sequence number	3				PRODSEQUENCE
② Photo of the1 baseplate on the skin					PHOTO_BP ONSKIN
③ Photo file name	\$100				BPONSKIN_ PHOTO
④ Baseplate on skin photo	dd MMM yyyy HH:nn				PHT03DTC

Production Germany 14. Jan. 2020: Primary matrix
Folder: Product change TP2
Form: Time for performing change of BP
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Product sequence number

_____ **1**

Are you going to change now or have you changed previously?

I am going to change now **2**

I have changed previously
without using the app (e.g.
during the night)

_____ **3**

Production Germany 14. Jan. 2020: Primary matrix

Folder: Product change TP2

Form: Time for performing change of BP

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	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	Product sequence number	3				PRODSEQUENCE
②	Time for performing change of baseplate	\$1		N = I am going to change now P = I have changed previously without using the app (e.g. during the night)		CHANGETIME_BP
③	HIDDEN	\$100		{ "CNGnowpr ev": { "N": "BPCNG", "P": "BPCNGPRE V" } }	1: { "CNGnowpr ev": { "N": "BPCNG", "P": "BPCNGPRE V" } }	HIDDEN

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Product sequence number _____ ①

When did you change the product (approximately)? _____ ②

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Product sequence number	3				PRODSEQUENCE
② Product change previously	dd MMM yyyy HH:nn				CNGPREVDTTC

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Product sequence number _____ ①

Photo of the stoma _____ ②

Stoma photo file name _____ ③

Stoma photo date and time _____ ④

Photo of the product _____ ⑤

Product photo file name _____ ⑥

Product photo date and time _____ ⑦

Do you experience any bleeding from the skin around your stoma right now when changing your product? Not experiencing ⑧
Experiencing

Once you have cleaned and dried the skin, do you still experience any weeping or moisture on the skin around your stoma right now when changing your product? Not experiencing ⑨
Experiencing

Are you experiencing any ulcers or sores around your stoma right now when changing your product? Not experiencing ⑩
Experiencing

How much of the time have you experienced any itching around your stoma since you last changed your product? None of the time ⑪
A little of the time
Some of the time
A lot of the time
All of the time

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Please rate on a scale from 0-10 how itchy the skin around your stoma has been at its worst since you last changed your product

- 0 No itchy 12
 - 1 Very mild itchy
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10 Worst possible peristomal skin itchy
-

How much of the time have you experienced any pain around your stoma since you last changed your product?

- None of the time 13
 - A little of the time
 - Some of the time
 - A lot of the time
 - All of the time
-

Please rate on a scale from 0-10 how painful the skin around your stoma has been at its worst since you last changed your product

- 0 No pain 14
 - 1 Very mild pain
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10 Worst possible peristomal skin pain
-

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How much of the time have you experienced any burning feelings from the skin around your stoma since you last changed your product?

- None of the time 15
 - A little of the time
 - Some of the time
 - A lot of the time
 - All of the time
-

Please rate on a scale from 0-10 any burning feelings from the skin around your stoma at its worst since you last changed your product

- 0 No burning 16
 - 1 Very mild burning
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10 Worst possible peristomal skin burning
-

How would you rate on a scale of 0-10 your overall physical discomfort from the skin around your stoma since you last changed your product?

- 0 No discomfort 17
 - 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10 A lot of discomfort
-

On a scale of 0-10, how much have skin complications around your stoma caused you difficulty in your overall ability to move around since you last changed your product? For example, bending or walking

No skin complications 18

0 No difficulty

1

2

3

4

5

6

7

8

9

10 A lot of difficulty

On a scale of 0-10, how much have skin complications around your stoma caused you difficulty in your overall ability to stick the stoma bag adhesive to your skin since you last changed your product?

No skin complications 19

0 No difficulty

1

2

3

4

5

6

7

8

9

10 A lot of difficulty

What was the main reason for change of the baseplate? _____ 20

I followed my usual changing pattern _____ 21

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-
- I thought it would be nice with a clean product _____ (22)
-
- In preparation of an activity (i.e. going out, doing sports, travelling) _____ (23)
-
- The entire baseplate had become detached _____ (24)
-
- The outer edge of the baseplate had become detached _____ (25)
-
- The center of the baseplate had become detached _____ (26)
-
- I was afraid the baseplate would become detached _____ (27)
-
- The area around the stoma was itching _____ (28)
-
- The area around the stoma was painful _____ (29)
-
- There was leakage underneath and outside the baseplate _____ (30)
-
- There was leakage underneath the baseplate (but not outside the baseplate) _____ (31)
-
- The bag was full of air (ballooning) _____ (32)
-
- There was a vacuum in the bag (pancaking) _____ (33)
-
- Due to visit in the investigation _____ (34)
-
- Other reason _____ (35)
-
-

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If other reason for change is selected, please specify _____ **36**

Did you experience leakage outside the baseplate (i.e. soiling the clothes)?

No **37**
Yes

Did you experience the bag becoming overfilled with air during use (ballooning)?

Not at all **38**
A little
Some
Much
Very much

Which stoma accessories did you use?

None _____ **40**

Adhesive remover _____ **41**

Paste _____ **42**

Rings _____ **43**

Ostomy tape _____ **44**

Ostomy belt _____ **45**

Hernia belt _____ **46**

Stoma powder _____ **47**

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Barrier lotion	_____	48
Barrier cream	_____	49
Barrier spray	_____	50
Barrier wipes	_____	51
Cleansing wipes/cleansing spray	_____	52
Odour remover	_____	53
Other accessories	_____	54
If 'Other' please specify:	_____	55

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	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	Product sequence number	3				PRODSEQUENCE
②	Photo of the stoma	1				PHOTO_SKIN
③	Stoma photo name	\$100				PHT0101
④	Stoma photo date and time	dd MMM yyyy HH:nn				PHT01DTC
⑤	Photo of the product	1				PHOTO_PRODUCT
⑥	Product photo name	\$100				PROD_PHOTO
⑦	Product photo date and time	dd MMM yyyy HH:nn				PHT02DTC
⑧	Ostomy Skin Tool 1	1		0 = Not experiencing 1 = Experiencing		OST_1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 Ostomy Skin Tool 2	1		0 = Not experiencing 1 = Experiencing		OST_2
10 Ostomy Skin Tool 3	1		0 = Not experiencing 1 = Experiencing		OST_3
11 Ostomy Skin Tool 4	1		1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time 5 = All of the time		OST_4
12 Ostomy Skin Tool 5	2		0 = 0 No itch 1 = 1 Very mild itch 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7		LONGSCALE_OST_5

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = 8 9 = 9 10 = 10 Worst possible peristomal skin itch		
 Ostomy Skin Tool 6		1	1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time 5 = All of the time		OST_6
 Ostomy Skin Tool 7		2	0 = 0 No pain 1 = 1 Very mild pain 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 Worst possible peristomal skin pain		LONGSCALE_OST_7

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15 Ostomy Skin Tool 8	1		1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time 5 = All of the time		OST_8
16 Ostomy Skin Tool 9	2		0 = 0 No burning 1 = 1 Very mild burning 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 Worst possible peristomal skin burning		LONGSCALE_OST_9
17 Ostomy Skin Tool 10	2		0 = 0 No discomfort 1 = 1 2 = 2 3 = 3 4 = 4		LONGSCALE_OST_10

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 A lot of discomfort		
 Ostomy Skin Tool 11	2		99 = No skin complications 0 = 0 No difficulty 1 = 1 2 = 2 3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 A lot of difficulty		LONGSCALE _OST_11
 Ostomy Skin Tool 12	2		99 = No skin complications 0 = 0 No difficulty 1 = 1 2 = 2		LONGSCALE _OST_12

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = 3 4 = 4 5 = 5 6 = 6 7 = 7 8 = 8 9 = 9 10 = 10 A lot of difficulty		
20	MULTI_CNG1_HEADER				MULTI_CNG_HEADER
21	Reason for change no. 1	1			MULTI_CNG_1
22	Reason for change no. 2	2			MULTI_CNG_2
23	Reason for change no. 3	3			MULTI_CNG_3
24	Reason for change no. 4	4			MULTI_CNG_4

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
25 Reason for change no. 5	1				MULTI_CNG_5
26 Reason for change no. 6	1				MULTI_CNG_6
27 Reason for change no. 7	1				MULTI_CNG_7
28 Reason for change no. 8	1				MULTI_CNG_8
29 Reason for change no. 9	1				MULTI_CNG_9
30 Reason for change no. 10	1				MULTI_CNG_10
31 Reason for change no. 11	1				MULTI_CNG_11
32 Reason for change no. 12	1				MULTI_CNG_12

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
33 Reason for change no. 13	1				MULTI_CNG_13
34 Reason for change no. 14	1				MULTI_CNG_14
35 Reason for change no. 15	1				MULTI_CNG_15
36 Description of other reason for change	\$100				MULTI_CNG_OTHER
37 Leakage outside	1		0 = No 1 = Yes		LEAKAGE_OUTSIDE
38 Degree of ballooning	1		1 = Not at all 2 = A little 3 = Some 4 = Much 5 = Very much		BALLOONING_DEGREE
40 Accessories 1	1				MULTI_ACC_1

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
41 Accessories 1 2					MULTI_ACC _2
42 Accessories 1 3					MULTI_ACC _3
43 Accessories 1 4					MULTI_ACC _4
44 Accessories 1 5					MULTI_ACC _5
45 Accessories 1 6					MULTI_ACC _6
46 Accessories 1 7					MULTI_ACC _7
47 Accessories 1 8					MULTI_ACC _8
48 Accessories 1 9					MULTI_ACC _9
49 Accessories 1 10					MULTI_ACC _10
50 Accessories 1 11					MULTI_ACC _11

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
51 Accessories 1 12					MULTI_ACC _12
52 Accessories 1 13					MULTI_ACC _13
53 Accessories 1 14					MULTI_ACC _14
54 Accessories 1 15					MULTI_ACC _15
55 Accessories \$50 other					MULTI_ACC _OTHER

Do you have any skin complications around your stoma today?

No ①
Yes

If yes, how would you describe the skin complications around your stoma today?

No skin complications ②
Very mild
Mild
Moderate
Severe
Very severe

How often have you experienced itchy skin around your stoma in the past 14 days?

None of the time ③
A little of the time
Some of the time
A lot of the time
All of the time

How often have you experienced any pain in the skin around the stoma in the past 14 days?

None of the time ④
A little of the time
Some of the time
A lot of the time
All of the time

How often have you experienced burning feelings in the skin around your stoma in the past 14 days?

None of the time ⑤
A little of the time
Some of the time
A lot of the time
All of the time

Compared to the beginning of this test period (Test Period 2) how have any skin complications around your stoma changed?

- Very much improved 6
Much improved
A little improved
No change
A little worse
Much worse
Very much worse
-

Did your stoma behave differently from normal since your last visit/call?

- No 7
Yes
-

If yes, please describe _____ 8

Emotional impact. In the last seven days, due to leakage or worry about leakage... (please tick the box to continue) _____ 9

I felt panic

- All of the time 10
Often
Sometimes
Rarely or never
-

I felt stressed out

- All of the time 11
Often
Sometimes
Rarely or never
-

I felt more afraid about leaks in the future

- All of the time 12
Often
-

Sometimes
Rarely or never

I felt worry

All of the time 13
Often
Sometimes
Rarely or never

I felt frustrated

All of the time 14
Often
Sometimes
Rarely or never

I felt embarrassed

All of the time 15
Often
Sometimes
Rarely or never

I felt worried that I might leak

All of the time 16
Often
Sometimes
Rarely or never

I couldn't sleep

All of the time 17
Often
Sometimes
Rarely or never

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I kept waking up at night to check my stoma

All of the time 18
Often
Sometimes
Rarely or never

I kept checking my ostomy bag to see if I have leaked

All of the time 19
Often
Sometimes
Rarely or never

Usual and social activities.
In the last seven days due to leakage or worry about
leakage...

20

I decided to stay at home

All of the time 21
Often
Sometimes
Rarely or never
Not applicable

I couldn't do light activities

All of the time 22
Often
Sometimes
Rarely or never
Not applicable

I changed my plans

All of the time 23
Often
Sometimes

Rarely or never
Not applicable

I was unable to go out and meet family and friends

All of the time 24
Often
Sometimes
Rarely or never
Not applicable

I avoided close physical contact with family and friends

All of the time 25
Often
Sometimes
Rarely or never
Not applicable

I did not want to see people

All of the time 26
Often
Sometimes
Rarely or never
Not applicable

I avoided people

All of the time 27
Often
Sometimes
Rarely or never
Not applicable

I tried to avoid meeting new people

All of the time 28
Often

Sometimes
Rarely or never
Not applicable

Coping and in control.
In the last 7 days, due to leakage or worry about
leakage...

29

I felt in control

All of the time 30
Often
Sometimes
Rarely or never

I was able to cope

All of the time 31
Often
Sometimes
Rarely or never

I felt calm

All of the time 32
Often
Sometimes
Rarely or never

I saw my friends as I usually do

All of the time 33
Often
Sometimes
Rarely or never

Discreetness. 34
In the last seven days...

It was difficult to hide the stoma appliance under clothing 35

Strongly agree
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

I was self-conscious about the appearance of the stoma appliance 36

Strongly agree
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The stoma appliance limited the choice of clothes that I could wear 37

Strongly agree
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The stoma appliance was obvious to other people 38

Strongly agree
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The color of the stoma appliance was discreet 39

Strongly agree
Slightly agree

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Neither agree nor disagree

Slightly disagree

Strongly disagree

It was difficult to hide the stoma appliance because of ballooning

Strongly agree 40

Slightly agree

Neither agree nor disagree

Slightly disagree

Strongly disagree

Comfort.
In the last seven days...

41

The stoma appliance was comfortable to wear

Strongly agree 42

Slightly agree

Neither agree nor disagree

Slightly disagree

Strongly disagree

I was not concerned about skin irritation under the stoma appliance (for example feelings of burning, itching, pinching or pain)

Strongly agree 43

Slightly agree

Neither agree nor disagree

Slightly disagree

Strongly disagree

It was uncomfortable to remove the stoma appliance from my body

Strongly agree 44

Slightly agree

Neither agree nor disagree

Slightly disagree

Strongly disagree

I often forgot that I was wearing the stoma appliance

Strongly agree 45
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The stoma appliance was comfortable as it fitted well to my body movements

Strongly agree 46
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

The stoma appliance disrupted my sleep during the night

Strongly agree 47
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

Confidence.
In the last seven days...

48

I was confident that the stoma appliance would not leak

Strongly agree 49
Slightly agree
Neither agree nor disagree
Slightly disagree
Strongly disagree

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I worried that the stoma appliance would become loose from my body

- Strongly agree 50
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I felt confident that I could spend the night away from home despite wearing the stoma appliance

- Strongly agree 51
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I was confident the stoma appliance would not cause any problems for me

- Strongly agree 52
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I felt confident to take part in physical activities (for example, sports) whilst wearing the stoma appliance

- Strongly agree 53
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

I worried that the stoma appliance would make a rustling noise

- Strongly agree 54
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree
-

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Social life and relationships.
In the last seven days...

55

I worried that my family and friends felt awkward around
me because of the stoma appliance

- Strongly agree 56
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree

I felt my social life had been restricted because of the
stoma appliance

- Strongly agree 57
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree

I avoided close physical contact with family and friends
because of the stoma appliance

- Strongly agree 58
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree

I worried about whether I could have a relationship
because of my stoma appliance

- Strongly agree 59
- Slightly agree
- Neither agree nor disagree
- Slightly disagree
- Strongly disagree

I worried about whether the stoma appliance would
affect my sex life

- Strongly agree 60
- Slightly agree

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-
- Neither agree nor disagree
 - Slightly disagree
 - Strongly disagree

How was the feeling of security while wearing the product?

- Very poor 61
- Poor
- Neither poor nor good
- Good
- Very good

How did you find cutting the baseplate?

- Very difficult 62
- Difficult
- Neither difficult nor easy
- Easy
- Very easy

How did you find applying the baseplate?

- Very difficult 63
- Difficult
- Neither difficult nor easy
- Easy
- Very easy

How did you find removing the baseplate?

- Very difficult 64
- Difficult
- Neither difficult nor easy
- Easy
- Very easy

Which product do you prefer?

65

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The product from the first test period

The product from the second test period

Why do you prefer this product over the other? (you may tick more than one box)

Less leakage _____ **67**

Better feeling of security _____ **68**

Better comfort _____ **69**

Better discretion _____ **70**

Less pancaking _____ **71**

Less ballooning _____ **72**

Better skin condition _____ **73**

Better ability to fit and follow the body _____ **74**

Other reason _____ **75**

Which product do you prefer? _____ **76**

The product from the first test period

The product from the second test period

Your own product

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Why do you prefer this product over the other? (you may tick more than one box)

Less leakage _____ (78)

Better feeling of security _____ (79)

Better comfort _____ (80)

Better discretion _____ (81)

Less pancaking _____ (82)

Less ballooning _____ (83)

Better skin condition _____ (84)

Better ability to fit and follow the body _____ (85)

Other reason _____ (86)

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Complications today	1		0 = No 1 = Yes		COMP_TODAY
② Severity of complications	1		0 = No skin complications 1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		COMP_IF_YES
③ Itching in 14 days	1		1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time 5 = All of the time		ITCHING_14DAYS
④ Pain in 14 days	1		1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time		PAIN_14DAYS

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = All of the time		
⑤ Burning in 14 days	1		1 = None of the time 2 = A little of the time 3 = Some of the time 4 = A lot of the time 5 = All of the time		BURNING_14DAYS
⑥ Own comparison of skin	1		1 = Very much improved 2 = Much improved 3 = A little improved 4 = No change 5 = A little worse 6 = Much worse 7 = Very much worse		COMPARE_OWN
⑦ Stoma behaviour	1		0 = No 1 = Yes		STOMABEHAVE_YN

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 Different stoma behaviour	\$200				BEHAVE_IF_YES
9 LEAKAGE_H1 EADER					LEAKAGE_H EADER
10 LEAKAGE_Q1 S_1			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_1
11 LEAKAGE_Q1 S_2			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_2
12 LEAKAGE_Q1 S_3			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_3
13 LEAKAGE_Q1 S_4			0 = All of the time		LEAKAGE_Q S_4

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			1 = Often 2 = Sometimes 3 = Rarely or never		
14 LEAKAGE_Q1 S_5			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_5
15 LEAKAGE_Q1 S_6			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_6
16 LEAKAGE_Q1 S_7			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_7
17 LEAKAGE_Q1 S_8			0 = All of the time 1 = Often		LEAKAGE_Q S_8

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Sometimes 3 = Rarely or never		
18 LEAKAGE_Q1 S_9			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_9
19 LEAKAGE_Q1 S_10			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_10
20 LEAKAGE_H1 EADER2					LEAKAGE_H EADER2
21 LEAKAGE_Q1 S_11			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_11

Production Germany 14. Jan. 2020: Primary matrix

Folder: Final evaluation TP2

Form: Final evaluation TP 2

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
22 LEAKAGE_Q1 S_12			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_12
23 LEAKAGE_Q1 S_13			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_13
24 LEAKAGE_Q1 S_14			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_14
25 LEAKAGE_Q1 S_15			0 = All of the time 1 = Often 2 = Sometimes		LEAKAGE_Q S_15

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Rarely or never 9 = Not applicable		
26 LEAKAGE_Q1 S_16			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_16
27 LEAKAGE_Q1 S_17			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_17
28 LEAKAGE_Q1 S_18			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never 9 = Not applicable		LEAKAGE_Q S_18

Production Germany 14. Jan. 2020: Primary matrix

Folder: Final evaluation TP2

Form: Final evaluation TP 2

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
39 LEAKAGE_H1 EADER3					LEAKAGE_H EADER3
30 LEAKAGE_Q1 S_19			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_19
31 LEAKAGE_Q1 S_20			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_20
32 LEAKAGE_Q1 S_21			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_21
33 LEAKAGE_Q1 S_22			0 = All of the time 1 = Often 2 = Sometimes 3 = Rarely or never		LEAKAGE_Q S_22

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
34 QOLH1	1				QOLH1
35 QOL_QS_1	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_1
36 QOL_QS_2	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_2
37 QOL_QS_3	1		1 = Strongly agree		QOL_QS_3

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		
38 QOL_QS_4	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_4
39 QOL_QS_5	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree		QOL_QS_5

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Strongly disagree		
40 QOL_QS_6	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_6
41 QOLH2	1				QOLH2
42 QOL_QS_7	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_7

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
43 QOL_QS_8	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_8
44 QOL_QS_9	1		1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_9
45 QOL_QS_101			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree		QOL_QS_10

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Slightly disagree 5 = Strongly disagree		
46 QOL_QS_111			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_11
47 QOL_QS_121			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_12

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
48 QOLH3	1				QOLH3
49 QOL_QS_131			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_13
50 QOL_QS_141			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_14
51 QOL_QS_151			1 = Strongly agree		QOL_QS_15

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		
52 QOL_QS_161			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_16
53 QOL_QS_171			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree		QOL_QS_17

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Strongly disagree		
54 QOL_QS_181			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_18
55 QOLH4	1				QOLH4
56 QOL_QS_191			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_19

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
57 QOL_QS_201			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_20
58 QOL_QS_211			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_21
59 QOL_QS_221			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree		QOL_QS_22

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Slightly disagree 5 = Strongly disagree		
60 QOL_QS_231			1 = Strongly agree 2 = Slightly agree 3 = Neither agree nor disagree 4 = Slightly disagree 5 = Strongly disagree		QOL_QS_23
61 Feeling of security	1		1 = Very poor 2 = Poor 3 = Neither poor nor good 4 = Good 5 = Very good		SECURITY
62 Cutting difficulty	1		1 = Very difficult 2 = Difficult		CUTTING_D IFF

Production Germany 14. Jan. 2020: Primary matrix

Folder: Final evaluation TP2

Form: Final evaluation TP 2

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Neither difficult nor easy 4 = Easy 5 = Very easy		
63 Application of product	1		1 = Very difficult 2 = Difficult 3 = Neither difficult nor easy 4 = Easy 5 = Very easy		APPLICATION
64 Removal of baseplate	1		1 = Very difficult 2 = Difficult 3 = Neither difficult nor easy 4 = Easy 5 = Very easy		REMOVAL
65 Preference 1	1		1 = The product from the first test period		PREFERENC E_1

Production Germany 14. Jan. 2020: Primary matrix

Folder: Final evaluation TP2

Form: Final evaluation TP 2

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = The product from the second test period		
67 Preference no. 1	1				MULTI_PRE F_1
68 Preference no. 2	1				MULTI_PRE F_2
69 Preference no. 3	1				MULTI_PRE F_3
70 Preference no. 4	1				MULTI_PRE F_4
71 Preference no. 5	1				MULTI_PRE F_5
72 Preference no. 6	1				MULTI_PRE F_6
73 Preference no. 7	1				MULTI_PRE F_7
74 Preference no. 8	1				MULTI_PRE F_8

Production Germany 14. Jan. 2020: Primary matrix

Folder: Final evaluation TP2

Form: Final evaluation TP 2

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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
75 Preference no. 9	1				MULTI_PRE F_9
76 Preference 2	1		1 = The product from the first test period 2 = The product from the second test period 3 = Your own product		PREFERENC E_2
78 Preference no. 21	1				MULTI_PRE F2_1
79 Preference no. 22	1				MULTI_PRE F2_2
80 Preference no. 23	1				MULTI_PRE F2_3
81 Preference no. 24	1				MULTI_PRE F2_4
82 Preference no. 25	1				MULTI_PRE F2_5

Production Germany 14. Jan. 2020: Primary matrix
Folder: Final evaluation TP2
Form: Final evaluation TP 2
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
83 Preference no. 26	1				MULTI_PRE F2_6
84 Preference no. 27	1				MULTI_PRE F2_7
85 Preference no. 28	1				MULTI_PRE F2_28
86 Preference no. 29	1				MULTI_PRE F2_9

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements
Form: Skin discolouration
Generated On: 30 Sep 2020 12:31:31

STUDY ID	_____	①
SITE ID	_____	②
SUBJECT ID	_____	③
Photo date	_____	④
Photo time	_____	⑤
Sequence no.	_____	⑥
PHOTO ID	_____	⑦
Total discoloration area (cm2)	_____	⑧
Discoloration area_Inner zone 3 cm (cm2)	_____	⑨
Discoloration area_Outer zone 3 cm (cm2)	_____	⑩
Total Intensity 0-10% (cm2)	_____	⑪
Total Intensity 11-20% (cm2)	_____	⑫
Total Intensity 21-30% (cm2)	_____	⑬

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements
Form: Skin discolouration
Generated On: 30 Sep 2020 12:31:31

Total Intensity
31-40% (cm2) _____ **14**

Total Intensity
41-50% (cm2) _____ **15**

Total Intensity
51-60% (cm2) _____ **16**

Total Intensity
61-70% (cm2) _____ **17**

Total Intensity
71-80% (cm2) _____ **18**

Total Intensity
81-90% (cm2) _____ **19**

Total Intensity
91-100% (cm2) _____ **20**

Intensity_Inner zone (3 cm)
0-10% (cm2) _____ **21**

Intensity_Inner zone (3 cm)
11-20% (cm2) _____ **22**

Intensity_Inner zone (3 cm)
21-30% (cm2) _____ **23**

Intensity_Inner zone (3 cm)
31-40% (cm2) _____ **24**

Production Germany 14. Jan. 2020: Primary matrix

Folder: Measurements

Form: Skin discolouration

Generated On: 30 Sep 2020 12:31:31

Intensity_Inner zone (3 cm) 25
41-50% (cm2) _____

Intensity_Inner zone (3 cm) 26
51-60% (cm2) _____

Intensity_Inner zone (3 cm) 27
61-70% (cm2) _____

Intensity_Inner zone (3 cm) 28
71-80% (cm2) _____

Intensity_Inner zone (3 cm) 29
81-90% (cm2) _____

Intensity_Inner zone (3 cm) 30
91-100% (cm2) _____

Intensity_outer zone (3 cm) 31
0-10% (cm2) _____

Intensity_outer zone (3 cm) 32
11-20% (cm2) _____

Intensity_outer zone (3 cm) 33
21-30% (cm2) _____

Intensity_outer zone (3 cm) 34
31-40% (cm2) _____

Intensity_outer zone (3 cm) 35
41-50% (cm2) _____

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements
Form: Skin discolouration
Generated On: 30 Sep 2020 12:31:31

Intensity_outer zone (3 cm) 36
51-60% (cm2) _____

Intensity_outer zone (3 cm) 37
61-70% (cm2) _____

Intensity_outer zone (3 cm) 38
71-80% (cm2) _____

Intensity_outer zone (3 cm) 39
81-90% (cm2) _____

Intensity_outer zone (3 cm) 40
91-100% (cm2) _____

Production Germany 14. Jan. 2020: Primary matrix

Folder: Measurements

Form: Skin discolouration

Generated On: 30 Sep 2020 12:31:31

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	STUDY ID	\$50				STUDY_ID
②	SITE ID	\$50				SITE_ID
③	SUBJECT ID	\$5				SUBJECT_ID
④	Photo date	dd MMM YYYY				PHOTODAT
⑤	Photo time	\$12				PHOTOTM
⑥	Sequence no.	5				SEQUENCE
⑦	PHOTO ID	\$70				PHOTO_ID
⑧	Total discolouration	3.3				DISCOLOURATION_TOTAL
⑨	Inner discolouration	3.3				DISCOLOURATION_INNER
⑩	Outer discolouration	3.3				DISCOLOURATION_OUTER

Production Germany 14. Jan. 2020: Primary matrix

Folder: Measurements

Form: Skin discolouration

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
11 Total intensity 0	3.3				INTENSITY_TOTAL_0
12 Total intensity 1	3.3				INTENSITY_TOTAL_1
13 Total intensity 2	3.3				INTENSITY_TOTAL_2
14 Total intensity 3	3.3				INTENSITY_TOTAL_3
15 Total intensity 4	3.3				INTENSITY_TOTAL_4
16 Total intensity 5	3.3				INTENSITY_TOTAL_5
17 Total intensity 6	3.3				INTENSITY_TOTAL_6
18 Total intensity 7	3.3				INTENSITY_TOTAL_7
19 Total intensity 8	3.3				INTENSITY_TOTAL_8
20 Total intensity 9	3.3				INTENSITY_TOTAL_9

Production Germany 14. Jan. 2020: Primary matrix

Folder: Measurements

Form: Skin discolouration

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
21 Inner intensity 0	3.3				INTENSITY_INNER_0
22 Inner intensity 1	3.3				INTENSITY_INNER_1
23 Inner intensity 2	3.3				INTENSITY_INNER_2
24 Inner intensity 3	3.3				INTENSITY_INNER_3
25 Inner intensity 4	3.3				INTENSITY_INNER_4
26 Inner intensity 5	3.3				INTENSITY_INNER_5
27 Inner intensity 6	3.3				INTENSITY_INNER_6
28 Inner intensity 7	3.3				INTENSITY_INNER_7
29 Inner intensity 8	3.3				INTENSITY_INNER_8
30 Inner intensity 9	3.3				INTENSITY_INNER_9

Production Germany 14. Jan. 2020: Primary matrix

Folder: Measurements

Form: Skin discolouration

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
31 Outer intensity 0	3.3				INTENSITY_OUTER_0
32 Outer intensity 1	3.3				INTENSITY_OUTER_1
33 Outer intensity 2	3.3				INTENSITY_OUTER_2
34 Outer intensity 3	3.3				INTENSITY_OUTER_3
35 Outer intensity 4	3.3				INTENSITY_OUTER_4
36 Outer intensity 5	3.3				INTENSITY_OUTER_5
37 Outer intensity 6	3.3				INTENSITY_OUTER_6
38 Outer intensity 7	3.3				INTENSITY_OUTER_7
39 Outer intensity 8	3.3				INTENSITY_OUTER_8
40 Outer intensity 9	3.3				INTENSITY_OUTER_9

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements
Form: Leakage measurements
Generated On: 30 Sep 2020 12:31:31

STUDY ID	_____	①
SITE ID	_____	②
SUBJECT ID	_____	③
Photo date	_____	④
Photo time	_____	⑤
Sequence no.	_____	⑥
PHOTO ID	_____	⑦
Leakage area (cm ²)	_____	⑧
Shortest distance to edge (cm)	_____	⑨
Area center hole	_____	⑩
Area baseplate	_____	⑪

Production Germany 14. Jan. 2020: Primary matrix

Folder: Measurements

Form: Leakage measurements

Generated On: 30 Sep 2020 12:31:31

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	STUDY ID	\$50				STUDY_ID
②	SITE ID	\$50				SITE_ID
③	SUBJECT ID	\$5				SUBJECT_ID
④	Photo date	dd MMM YYYY				PHOTODAT
⑤	Photo time	\$12				PHOTOTM
⑥	Sequence no.	5				SEQUENCE
⑦	PHOTO ID	\$70				PHOTO_ID
⑧	Area of leakage	3.3				AREA_LEAKAGE
⑨	Shortest distance	3.3				DISTANCE
⑩	Area of center hole	3.3				AREA_CENTERHOLE
⑪	Area of baseplate	3.3				AREA_BASEPLATE

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score CA visit 1
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Please evaluate the skin on the photo using the DET score

Domain 1: Discolouration

Area of discolouration

0 3
1
2
3

Severity of discolouration

1 4
2

Domain 2: Erosion

Area of erosion

0 6
1
2
3

Severity of erosion

1 7
2

Domain 3: Tissue overgrowth

Area of tissue overgrowth

0 9
1
2
3

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score CA visit 1
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Severity of tissue overgrowth

1 10
2

Total DET score

11

Production Germany 14. Jan. 2020: Primary matrix

Folder: Measurements >> DET score CA visit 1

Form: DET score by external nurse

Generated On: 30 Sep 2020 12:31:31

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③	Area of discolouration	1		0 = 0 1 = 1 2 = 2 3 = 3		DISCOLOUR_AREA
④	Severity of discolouration	1		1 = 1 2 = 2		DISCOLOUR_SEVERITY
⑥	Area of erosion	1		0 = 0 1 = 1 2 = 2 3 = 3		EROSION_AREA
⑦	Severity of erosion	1		1 = 1 2 = 2		EROSION_SEVERITY
⑨	Area of tissue overgrowth	1		0 = 0 1 = 1 2 = 2 3 = 3		OVERGROWTH_AREA
⑩	Severity of tissue overgrowth	1		1 = 1 2 = 2		OVERGROWTH_SEVERITY
⑪	Total DET score	2				DETSORE_TOTAL

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score CA visit 2
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Please evaluate the skin on the photo using the DET score

Domain 1: Discolouration

Area of discolouration

0 3
1
2
3

Severity of discolouration

1 4
2

Domain 2: Erosion

Area of erosion

0 6
1
2
3

Severity of erosion

1 7
2

Domain 3: Tissue overgrowth

Area of tissue overgrowth

0 9
1
2
3

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score CA visit 2
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Severity of tissue overgrowth

1 10
2

Total DET score

11

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score CA visit 2
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Area of discolouration	1		0 = 0 1 = 1 2 = 2 3 = 3		DISCOLOUR_AREA
④ Severity of discolouration	1		1 = 1 2 = 2		DISCOLOUR_SEVERITY
⑥ Area of erosion	1		0 = 0 1 = 1 2 = 2 3 = 3		EROSION_AREA
⑦ Severity of erosion	1		1 = 1 2 = 2		EROSION_SEVERITY
⑨ Area of tissue overgrowth	1		0 = 0 1 = 1 2 = 2 3 = 3		OVERGROWTH_AREA
⑩ Severity of tissue overgrowth	1		1 = 1 2 = 2		OVERGROWTH_SEVERITY
⑪ Total DET score	2				DETSORE_TOTAL

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score CA visit 3
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Please evaluate the skin on the photo using the DET score

Domain 1: Discolouration

Area of discolouration

0 3
1
2
3

Severity of discolouration

1 4
2

Domain 2: Erosion

Area of erosion

0 6
1
2
3

Severity of erosion

1 7
2

Domain 3: Tissue overgrowth

Area of tissue overgrowth

0 9
1
2
3

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score CA visit 3
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Severity of tissue overgrowth

1 10
2

Total DET score

11

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score CA visit 3
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Area of discolouration	1		0 = 0 1 = 1 2 = 2 3 = 3		DISCOLOUR_AREA
④ Severity of discolouration	1		1 = 1 2 = 2		DISCOLOUR_SEVERITY
⑥ Area of erosion	1		0 = 0 1 = 1 2 = 2 3 = 3		EROSION_AREA
⑦ Severity of erosion	1		1 = 1 2 = 2		EROSION_SEVERITY
⑨ Area of tissue overgrowth	1		0 = 0 1 = 1 2 = 2 3 = 3		OVERGROWTH_AREA
⑩ Severity of tissue overgrowth	1		1 = 1 2 = 2		OVERGROWTH_SEVERITY
⑪ Total DET score	2				DETSORE_TOTAL

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score DK visit 1
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Please evaluate the skin on the photo using the DET score

Domain 1: Discolouration

Area of discolouration

0 3
1
2
3

Severity of discolouration

1 4
2

Domain 2: Erosion

Area of erosion

0 6
1
2
3

Severity of erosion

1 7
2

Domain 3: Tissue overgrowth

Area of tissue overgrowth

0 9
1
2
3

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score DK visit 1
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Severity of tissue overgrowth

1 10
2

Total DET score

11

Production Germany 14. Jan. 2020: Primary matrix

Folder: Measurements >> DET score DK visit 1

Form: DET score by external nurse

Generated On: 30 Sep 2020 12:31:31

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③	Area of discolouration	1		0 = 0 1 = 1 2 = 2 3 = 3		DISCOLOUR_AREA
④	Severity of discolouration	1		1 = 1 2 = 2		DISCOLOUR_SEVERITY
⑥	Area of erosion	1		0 = 0 1 = 1 2 = 2 3 = 3		EROSION_AREA
⑦	Severity of erosion	1		1 = 1 2 = 2		EROSION_SEVERITY
⑨	Area of tissue overgrowth	1		0 = 0 1 = 1 2 = 2 3 = 3		OVERGROWTH_AREA
⑩	Severity of tissue overgrowth	1		1 = 1 2 = 2		OVERGROWTH_SEVERITY
⑪	Total DET score	2				DETSORE_TOTAL

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score DK visit 2
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Please evaluate the skin on the photo using the DET score

Domain 1: Discolouration

Area of discolouration

0 3
1
2
3

Severity of discolouration

1 4
2

Domain 2: Erosion

Area of erosion

0 6
1
2
3

Severity of erosion

1 7
2

Domain 3: Tissue overgrowth

Area of tissue overgrowth

0 9
1
2
3

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score DK visit 2
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Severity of tissue overgrowth

1 10
2

Total DET score

11

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score DK visit 2
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Area of discolouration	1		0 = 0 1 = 1 2 = 2 3 = 3		DISCOLOUR_AREA
④ Severity of discolouration	1		1 = 1 2 = 2		DISCOLOUR_SEVERITY
⑥ Area of erosion	1		0 = 0 1 = 1 2 = 2 3 = 3		EROSION_AREA
⑦ Severity of erosion	1		1 = 1 2 = 2		EROSION_SEVERITY
⑨ Area of tissue overgrowth	1		0 = 0 1 = 1 2 = 2 3 = 3		OVERGROWTH_AREA
⑩ Severity of tissue overgrowth	1		1 = 1 2 = 2		OVERGROWTH_SEVERITY
⑪ Total DET score	2				DETSORE_TOTAL

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score DK visit 3
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Please evaluate the skin on the photo using the DET score

Domain 1: Discolouration

Area of discolouration

0	<input type="radio"/>	3
1	<input type="radio"/>	
2	<input type="radio"/>	
3	<input type="radio"/>	

Severity of discolouration

1	<input type="radio"/>	4
2	<input type="radio"/>	

Domain 2: Erosion

Area of erosion

0	<input type="radio"/>	6
1	<input type="radio"/>	
2	<input type="radio"/>	
3	<input type="radio"/>	

Severity of erosion

1	<input type="radio"/>	7
2	<input type="radio"/>	

Domain 3: Tissue overgrowth

Area of tissue overgrowth

0	<input type="radio"/>	9
1	<input type="radio"/>	
2	<input type="radio"/>	
3	<input type="radio"/>	

Production Germany 14. Jan. 2020: Primary matrix
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Severity of tissue overgrowth

1 10
2

Total DET score

11

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score DK visit 3
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Area of discolouration	1		0 = 0 1 = 1 2 = 2 3 = 3		DISCOLOUR_AREA
④ Severity of discolouration	1		1 = 1 2 = 2		DISCOLOUR_SEVERITY
⑥ Area of erosion	1		0 = 0 1 = 1 2 = 2 3 = 3		EROSION_AREA
⑦ Severity of erosion	1		1 = 1 2 = 2		EROSION_SEVERITY
⑨ Area of tissue overgrowth	1		0 = 0 1 = 1 2 = 2 3 = 3		OVERGROWTH_AREA
⑩ Severity of tissue overgrowth	1		1 = 1 2 = 2		OVERGROWTH_SEVERITY
⑪ Total DET score	2				DETSORE_TOTAL

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score final visit 1
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Please evaluate the skin on the photo using the DET score

Domain 1: Discolouration

Area of discolouration

0	<input type="radio"/>	3
1	<input type="radio"/>	
2	<input type="radio"/>	
3	<input type="radio"/>	

Severity of discolouration

1	<input type="radio"/>	4
2	<input type="radio"/>	

Domain 2: Erosion

Area of erosion

0	<input type="radio"/>	6
1	<input type="radio"/>	
2	<input type="radio"/>	
3	<input type="radio"/>	

Severity of erosion

1	<input type="radio"/>	7
2	<input type="radio"/>	

Domain 3: Tissue overgrowth

Area of tissue overgrowth

0	<input type="radio"/>	9
1	<input type="radio"/>	
2	<input type="radio"/>	
3	<input type="radio"/>	

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score final visit 1
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Severity of tissue overgrowth

1 **10**
2

Total DET score

11

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score final visit 1
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ Area of discolouration	1		0 = 0 1 = 1 2 = 2 3 = 3		DISCOLOUR_AREA
④ Severity of discolouration	1		1 = 1 2 = 2		DISCOLOUR_SEVERITY
⑥ Area of erosion	1		0 = 0 1 = 1 2 = 2 3 = 3		EROSION_AREA
⑦ Severity of erosion	1		1 = 1 2 = 2		EROSION_SEVERITY
⑨ Area of tissue overgrowth	1		0 = 0 1 = 1 2 = 2 3 = 3		OVERGROWTH_AREA
⑩ Severity of tissue overgrowth	1		1 = 1 2 = 2		OVERGROWTH_SEVERITY
⑪ Total DET score	2				DETSORE_TOTAL

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score final visit 2
Form: DET score by external nurse
Generated On: 30 Sep 2020 12:31:31

Please evaluate the skin on the photo using the DET score

Domain 1: Discolouration

Area of discolouration

0 3
1
2
3

Severity of discolouration

1 4
2

Domain 2: Erosion

Area of erosion

0 6
1
2
3

Severity of erosion

1 7
2

Domain 3: Tissue overgrowth

Area of tissue overgrowth

0 9
1
2
3

Production Germany 14. Jan. 2020: Primary matrix
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Severity of tissue overgrowth

1 10
2

Total DET score

11

Production Germany 14. Jan. 2020: Primary matrix

Folder: Measurements >> DET score final visit 2

Form: DET score by external nurse

Generated On: 30 Sep 2020 12:31:31

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
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④	Severity of discolouration	1		1 = 1 2 = 2		DISCOLOUR_SEVERITY
⑥	Area of erosion	1		0 = 0 1 = 1 2 = 2 3 = 3		EROSION_AREA
⑦	Severity of erosion	1		1 = 1 2 = 2		EROSION_SEVERITY
⑨	Area of tissue overgrowth	1		0 = 0 1 = 1 2 = 2 3 = 3		OVERGROWTH_AREA
⑩	Severity of tissue overgrowth	1		1 = 1 2 = 2		OVERGROWTH_SEVERITY
⑪	Total DET score	2				DETSORE_TOTAL

Production Germany 14. Jan. 2020: Primary matrix
Folder: Measurements >> DET score final visit 3
Form: DET score by external nurse
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Please evaluate the skin on the photo using the DET score

Domain 1: Discolouration

Area of discolouration

0 3
1
2
3

Severity of discolouration

1 4
2

Domain 2: Erosion

Area of erosion

0 6
1
2
3

Severity of erosion

1 7
2

Domain 3: Tissue overgrowth

Area of tissue overgrowth

0 9
1
2
3

Production Germany 14. Jan. 2020: Primary matrix
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Severity of tissue overgrowth

1 10
2

Total DET score

11

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⑦ Severity of erosion	1		1 = 1 2 = 2		EROSION_SEVERITY
⑨ Area of tissue overgrowth	1		0 = 0 1 = 1 2 = 2 3 = 3		OVERGROWTH_AREA
⑩ Severity of tissue overgrowth	1		1 = 1 2 = 2		OVERGROWTH_SEVERITY
⑪ Total DET score	2				DETSORE_TOTAL

Production Germany 14. Jan. 2020: Primary matrix
Folder: Administration
Form: DM Administration
Generated On: 30 Sep 2020 12:31:31

Analysis population PP No **1**
Yes

Analysis population ITT No **2**
Yes

Analysis population Safety No **3**
Yes

Analysis population Screen Failure No **4**
Yes

Production Germany 14. Jan. 2020: Primary matrix

Folder: Administration

Form: DM Administration

Generated On: 30 Sep 2020 12:31:31

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① Analysis population Per Protocol	1		0 = No 1 = Yes		POPULATION_PP
② Analysis population ITT	1		0 = No 1 = Yes		POPULATION_ITT
③ Analysis population Safety	1		0 = No 1 = Yes		POPULATION_SAFETY
④ Analysis population Screen Failure	1		0 = No 1 = Yes		POPULATION_SCREEN_FAILURE
