Participant ID No.		:	dd	mm	yy

CASE REPORT FORM

Study title: Monitoring wound status using multi-parameter optical fibre sensors

MHRA reference: CI/2021/0081/GB

Sponsor reference: 21040

Baseline visit date: ☐☐/☐☐/☐☐ (dd/mm/yy)

To Be Completed <u>During</u> Visit	Initials	Date
Part 1: Eligibility (page 2)		
Part 2: Demographic data (page 4)		
Part 3: Foot vascular and neurological tests (page 4)		
Part 4: Laboratory tests (page 5): Blood Results Checked and Printed		
Part 5: Foot characteristics: ulcer Description, Assessment of healing by podiatrist & ulcer area (page 6)		
Part 6: Current Medication (page 7)		
Part 7: Medical History (page 8)		
Part 8: Pain score (page 9)		
Part 9: Use of measurement devices (page 9)		
Part 10: Visit 2 (page 10)		
Part 11: Visit 3 (page 12)		
Part 12: Visit 4 (page 14)		
Part 13: signature sheet (page 16)		

Page completion verified

Researcher signature Date

Page completion verified

PI signature Date

Participant ID No.		:	dd	mm	yy

PART 1: ELIGIBILITY

Inclusion Criteria

(If <u>any</u> grey boxes are crossed, the patient is not eligible to participate)	Yes	NO
1. Patients with diabetes (according to WHO criteria: appendix 1).		
2. Aged 18 years or older.		
3. At least one full thickness ulcer below the malleolus of either foot, present for 4 weeks or more.		
4. Absence of wound necrosis, significant oedema or poor tissue viability that in the opinion of the investigator may at risk of deterioration with the use of OFSSWM optical probe.		
5. At least one palpable pulse on the foot of the index limb or an ABPI ≥0.9.		
6. Minimum ulcer diameter of 3 mm and a maximum diameter at any point of 25 mm.		
7. Able to attend clinic for 4 fortnightly visits.		
8. eGFR >20 and not receiving dialysis.		
9. Participant is willing and able to give informed consent for participation in the study.		

Participant ID No.		:	dd	mm	yy

Exclusion Criteria

(If <u>any</u> grey boxes are crossed, the patient is not eligible to participate)	Yes	NO
1. Planned revascularisation during the course of the study or within the 4 weeks preceding the start of the study.		
2. An ulcer of aetiology other than diabetes.		
3. Depth of ulcer to bone, suspected or confirmed osteomyelitis.		
4. Severe infection of the index ulcer in accordance with IDSA criteria.		
5. Active Charcot of the foot of the index ulcer.		
6. The need for negative pressure wound therapy.		
7. Unwilling or unable to give written informed consent.		
8. Any other significant disease or disorder which, in the opinion of the investigator, may either put the participants in the trial, may influence the result of the trail or the participants ability to participate.		
9. Wound located on the toes or between the toes.		
10. Wounds in a severe condition e.g. necrotic tissue and/or bleeding.		

Participant ID No.

	:	dd	mm	yy

PART 2: DEMOGRAPHIC DATA

Date of Birth: ☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy)

Sex: ☐ Male ☐ Female

Type of Diabetes: ☐ Type I ☐ Type II ☐ Other:

Year of Diagnosis ☐☐☐☐ (yyyy)

Age of Onset ☐☐

PART 3: FOOT VASCULAR AND NEUROLOGICAL TESTS

1. Peripheral pulse palpation
   (Please mark with a tick if present and a cross if absent in the appropriate box)

	Right	Left
Dorsalis pedis		
Posterior tibial		

2. Ankle brachial pressure index (ABPI) measurement.

Brachial: ☐☐☐/☐☐☐ mmHg
Systolic Diastolic

Ankle: ☐☐☐/☐☐☐ mmHg
Systolic Diastolic

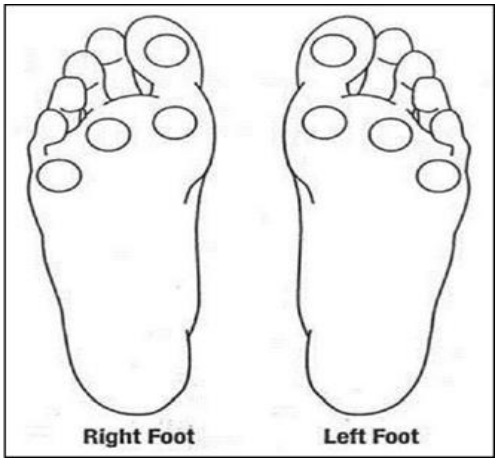
ABPI: ☐☐.☐

ABPI = highest ankle systolic pressure/highest brachial systolic pressure

Participant ID No.

	:	dd	mm	yy

3. 10g Monofilament



Site	Right	Left
Hallux		
1st metatarsal		
2nd metatarsal		
3rd metatarsal		

Please mark with a cross ☒ in the appropriate box if monofilament not detected and tick if detected

Part 4: LABORATORY TESTS

Only take HbA1c if no pathology blood results are available from within the last 12 months

Please attach anonymised blood results to this form and complete the results below.

HBA1C Result: ☐☐ mmols Date: ☐☐ / ☐☐ / ☐☐

EGFR: ☐☐☐ mL/min/1.73m2 Date: ☐☐ / ☐☐ / ☐☐

Participant ID No.		:	dd	mm	yy

PART 5: FOOT CHARACTERISTICS: ULCER DESCRIPTION & ULCER AREA

Study ulcer is defined as the largest eligible wound.

Site of ulcer (*tick box that applies)*:

	Left	Right
Fore foot		
Rear foot		
Dorsal		
Plantar		
Heel		

Assessment of Infection: IDSA Criteria

Infection	Yes	NO
Uninfected		
Mild Infection		
Moderate Infection		
Severe Infection		

Measurement with Silhouette wound imaging camera

Area: ☐☐.☐ cm^2

Depth: ☐☐mm

Estimated surface slough: ☐☐%

Is wound healed?

Yes ☐ No ☐

Participant ID No.		:	dd	mm	yy

PART 6: CURRENT MEDICATIONS

All medications and vitamin / herbal supplements

(*If over the counter include manufacturer details)*

Medication	Dosage details / route of administration	Type
		Prescribed ☐ Over the counter ☐
		Prescribed ☐ Over the counter ☐
		Prescribed ☐ Over the counter ☐
		Prescribed ☐ Over the counter ☐
		Prescribed ☐ Over the counter ☐
		Prescribed ☐ Over the counter ☐
		Prescribed ☐ Over the counter ☐

Participant ID No.

	:	dd	mm	yy

PART 7: MEDICAL HISTORY

Does the participant have a history of:	Yes	No	Unknown
Myocardial Infarction (MI)	☐	☐	☐
Heart Valve Disease	☐	☐	☐
Heart Failure	☐	☐	☐
Atrial Fibrillation	☐	☐	☐
Angina	☐	☐	☐
Stroke	☐	☐	☐
Angioplasty/CABG	☐	☐	☐
Leg Angioplasty/bypass	☐	☐	☐
Peripheral Vascular Disease	☐	☐	☐
High Blood Pressure	☐	☐	☐
High Cholesterol	☐	☐	☐
Gestational Diabetes	☐	☐	☐
Polycystic Ovary Syndrome	☐	☐	☐
Thyroid Disorder	☐	☐	☐

Other (or any other additional information):

Participant ID No.		:	dd	mm	yy

PART 8: PAIN SCORE

Visual analogue scale: /100

Patient completed scale on separate form (VAS OFSSWM version 1)

PART 9: USE OF MEASUREMENT DEVICES

*(Please mark with a cross **X** in the appropriate box)*

	Yes	NO
Removal of wound dressing from patient and storage in plastic bag		
pH measurement from swab taken from the wound exudate		
Measurement from wound area with OFSSWM whilst in supine position		
Conventional gas measurement from wound area whilst in supine position		
Conventional gas measurement from intact skin whilst in supine position		

Participant ID No.

	:	dd	mm	yy

Part 10: Visit 2

Visit 2 date: ☐☐/☐☐/☐☐ (dd/mm/yy)

Please mark with a cross **X** in the appropriate box

	Yes	NO
Verbal confirmation of consent		
Verbal confirmation of eligibility		

Assessment of Infection: IDSA Criteria

Infection	Yes	NO
Uninfected		
Mild Infection		
Moderate Infection		
Severe Infection		

Measurement with Silhouette wound imaging camera

Area: ☐☐.☐ cm^2

Depth: ☐☐mm

Estimated surface slough: ☐☐%

Is wound healed?

Yes ☐ No ☐

Participant ID No.

	:	dd	mm	yy

Changes to medication:	
Changes to medical history:	

PAIN SCORE

Visual analogue scale: /100

Patient completed scale on separate form (VAS OFSSWM version 1)

USE OF MEASUREMENT DEVICES

*(Please mark with a cross **X** in the appropriate box)*

	Yes	NO
Removal of wound dressing from patient and storage in plastic bag		
pH measurement from swab taken from the wound exudate		
Measurement from wound area with OFSSWM whilst in supine position		
Conventional gas measurement from wound area whilst in supine position		
Conventional gas measurement from intact skin whilst in supine position		

Participant ID No.

	:	dd	mm	yy

Part 11: Visit 3

Visit 3 date: ☐☐/☐☐/☐☐ (dd/mm/yy)

Please mark with a cross **X** in the appropriate box

	Yes	NO
Verbal confirmation of consent		
Verbal confirmation of eligibility		

Assessment of Infection: IDSA Criteria

Infection	Yes	NO
Uninfected		
Mild Infection		
Moderate Infection		
Severe Infection		

Measurement with Silhouette wound imaging camera

Area: ☐☐.☐ cm^2

Depth: ☐☐mm

Estimated surface slough: ☐☐%

Is wound healed?

Yes ☐ No ☐

Participant ID No.

	:	dd	mm	yy

Changes to medication:	
Changes to medical history:	

PAIN SCORE

Visual analogue scale: /100

Patient completed scale on separate form (VAS OFSSWM version 1)

USE OF MEASUREMENT DEVICES

*(Please mark with a cross **X** in the appropriate box)*

	Yes	NO
Removal of wound dressing from patient and storage in plastic bag		
pH measurement from swab taken from the wound exudate		
Measurement from wound area with OFSSWM whilst in supine position		
Conventional gas measurement from wound area whilst in supine position		
Conventional gas measurement from intact skin whilst in supine position		

Participant ID No.

	:	dd	mm	yy

Part 12: Visit 4

Visit 4 date: ☐☐/☐☐/☐☐ (dd/mm/yy)

Please mark with a cross **X** in the appropriate box

	Yes	NO
Verbal confirmation of consent		
Verbal confirmation of eligibility		

Assessment of Infection: IDSA Criteria

Infection	Yes	NO
Uninfected		
Mild Infection		
Moderate Infection		
Severe Infection		

Measurement with Silhouette wound imaging camera

Area: ☐☐.☐ cm^2

Depth: ☐☐mm

Estimated surface slough: ☐☐%

Is wound healed?

Yes ☐ No ☐

Participant ID No.

	:	dd	mm	yy

Changes to medication:	
Changes to medical history:	

PAIN SCORE

Visual analogue scale: /100

Patient completed scale on separate form (VAS OFSSWM version 1)

USE OF MEASUREMENT DEVICES

*(Please mark with a cross **X** in the appropriate box)*

	Yes	NO
Removal of wound dressing from patient and storage in plastic bag		
pH measurement from swab taken from the wound exudate		
Measurement from wound area with OFSSWM whilst in supine position		
Conventional gas measurement from wound area whilst in supine position		
Conventional gas measurement from intact skin whilst in supine position		

Participant ID No.		:	dd	mm	yy

PART 13: Signature sheet

Data entry completed by Investigator/Researcher

Printed name	Signature	Date (dd/mm/yyyy)
_____	_____	☐☐ / ☐☐ / ☐☐☐☐

Monitoring/CRF checked

Printed name	Signature	Date (dd/mm/yyyy)
_____	_____	☐☐ / ☐☐ / ☐☐☐☐

Principal Investigator confirmation that data is correct and complete

Printed name	Signature	Date (dd/mm/yyyy)
_____	_____	☐☐ / ☐☐ / ☐☐☐☐

Participant ID No.

	:	dd	mm	yy

Appendix 1: WHO Definition of diabetes mellitus

One of the following diagnostic tests:

- a random venous plasma glucose concentration ≥ 11.1 mmol/l or
- a fasting plasma glucose concentration ≥ 7.0 mmol/l (whole blood ≥ 6.1 mmol/l) or
- two hour plasma glucose concentration ≥ 11.1 mmol/l two hours after 75g anhydrous glucose in an oral glucose tolerance test (OGTT).
- HbA1c of 48mmol/mol (6.5%)

Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. 1.Diabetes mellitus – diagnosis. 2.Diabetes mellitus - classification. 3.Hyperglycemia. 4.Glucose tolerance test. I. World Health Organization. II. International Diabetes Federation. ISBN 92 4 159493 4

Appendix 2: Infectious Diseases Society of America and International Working Group on the Diabetic Foot Classifications of Diabetic Foot Infection

Clinical Manifestation of Infection	PEDIS Grade	IDSA Infection Severity
No symptoms or signs of infection	1	Uninfected
Infection present, as defined by the presence of at least 2 of the following items: • Local swelling or induration • Erythema • Local tenderness or pain • Local warmth • Purulent discharge (thick, opaque to white or sanguineous secretion)		
Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below). If erythema, must be >0.5 cm to ≤2 cm around the ulcer. Exclude other causes of an inflammatory response of the skin (eg, trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis).	2	Mild
Local infection (as described above) with erythema > 2 cm, or involving structures deeper than skin and subcutaneous tissues (eg, abscess, osteomyelitis, septic arthritis, fasciitis), **and** No systemic inflammatory response signs (as described below)	3	Moderate
Local infection (as described above) with the signs of SIRS, as manifested by ≥2 of the following: • Temperature >38°C or <36°C • Heart rate >90 beats/min • Respiratory rate >20 breaths/min or $PaCO_2$ <32 mm Hg • White blood cell count >12 000 or <4000 cells/μL or ≥10% immature (band) forms	4	Severe[a]

Abbreviations: IDSA, Infectious Diseases Society of America; $PaCO_2$, partial pressure of arterial carbon dioxide; PEDIS, perfusion, extent/size, depth/tissue loss, infection, and sensation; SIRS, systemic inflammatory response syndrome.

[a] Ischemia may increase the severity of any infection, and the presence of critical ischemia often makes the infection severe. Systemic infection may sometimes manifest with other clinical findings, such as hypotension, confusion, vomiting, or evidence of metabolic disturbances, such as acidosis, severe hyperglycemia, and new-onset azotemia [29, 43, 44].