HBO in diabetic foot lesion

Investigator : ____

Center : ____

Subject number : |___|___|___| |____________________|
site number

Subject initials : |___| |___| |___|

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Family Name : |_______________| First Name : |_________________|

Marital Name : |_______________| Sex : |___|

Date of Birth : |___| |___| |___| Age : |__|__| years

day month year

Weight : |___|___|___| kg Height : |___|___|___| cm

Subject number |___|___|___| |__________| Subject initials |___|___|___|

Pré-inclusion

Date of the pre Inclusion visit : |__|__| |__|__| |__|__|

day month year

Inclusion criteria :

Diabetes : Type I : |___| Type II : |___| |__|__|__|__|

Year of diagnosis

Foot Lesion : Wagner : |___|

Present for more than 12 weeks Yes : ☐ No : ☐

Exclusion criteria :

Secondary diabetes Yes : ☐ No : ☐

Planned revascularization procedure Yes : ☐ No : ☐

Vascular reconstruction less than 12 weeks ago Yes : ☐ No : ☐

Urgent amputation needed : Yes : ☐ No : ☐

Contra indication to HBO :

Acute respiratory disease : Yes : ☐ No : ☐

History of spontaneous pneumothorax : Yes : ☐ No : ☐

Acute ENT infection : Yes : ☐ No : ☐

Nonstabilized epilepsy : Yes : ☐ No : ☐

Nonstabilized HTA : Yes : ☐ No : ☐

Nonstabilized heart failure : Yes : ☐ No : ☐

Others : |____|

Renal failure (creatinine > 250 µmol/L [2.8 mg / dL]) or patient requiring dialysis Yes : ☐ No : ☐

Associated therapy by steroids or chemotherapy : Yes : ☐ No : ☐

Patient unable or not willing

to be followed for 1 year at the foot clinic : Yes : ☐ No : ☐

Ethic criteria : Yes : ☐ No : ☐

(pregnancy, children under 18, end of life, etc)

Patient participating in an other trial or having been

enrolled in an other trial within 6 months Yes : ☐ No : ☐

Informed consent not obtained Yes : ☐ No : ☐

Does the patient fit the screening criteria Yes : ☐ No : ☐

Subject Number : |__________| |________________________|

site number

Wagner grading system for diabetic foot lesion

Grade	Lesion
Grade 0	No open lesions ; may have deformity or cellulitis
Grade 1	Superficial ulcer
Grade 2	Deep ulcer to tendon, capsule, or bone
Grade 3	Deep ulcer with abscess, osteomyelitis, or joint sepsis
Grade 4	Localized gangrene - forefoot or heel
Grade 5	Gangrene of entire foot

Ref : Wagner. The diabetic foot. Orthopedics. 1987 ; 10 : 163-172.

The University of Texas Diabetic Wound Classification System

STAGE	GRADE: 0	I	II	III
A	Pre-or post-ulcerative lesion, completely epithelialized	Superficial wound, not involving tendon, capsule, or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
B	Pre-or post-ulcerative lesion, completely epithelialized **with infection**	Superficial wound, not involving tendon, capsule, or bone **with infection**	Wound penetrating to tendon or capsule **with infection**	Wound penetrating to bone or joint **with infection**
C	Pre-or post-ulcerative lesion, completely epithelialized **with ischemia**	Superficial wound, not involving tendon, capsule, or bone **with ischemia**	Wound penetrating to tendon or capsule **with ischemia**	Wound penetrating to bone or **joint with ischemia**
D	Pre-or post-ulcerative lesion, completely epithelialized **with infection and ischemia**	Superficial wound, not involving tendon, capsule, or bone **with infection and ischemia**	Wound penetrating to tendon or capsule **with infection and ischemia**	Wound penetrating to bone or joint **with infection and ischemia**

Ref : Lavery LA, Amstrong DG, Harkless LB.
Classification of diabetic foot ulcerations
J. Foot Ankle Surg. 1996 ; 35 : 528-31

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Pre Inclusion Evaluation

① Diabetes : *Type : |___|

* Duration : |___|___| years

* Usual treatment :

¤ diet : |___|

¤ sulfamide : |___|

¤ biguamide : |___|

¤ insuline : |___| Number of injections/day |___|

¤ Others : |_________________________________|

* Fasting blood sugar* : |___|___|___| mmol/L

* Glycosylated hemoglobin A_{1c}* : |___|___|___| %

② Other associated vascular risk factors

⇨ smoker Yes : ☐ No : ☐ |___|___| pack/year

⇨ hyperlipidemia Yes : ☐ No : ☐ Time from diagnosis |___|___| years

⇨ sedentary Yes : ☐ No : ☐

⇨ HTA Yes : ☐ No : ☐ Time from diagnosis |___|___| years

PA Systolic |___|___|___| mmHg

PA Diastolic |___|___|___| mmHg

* At the pre inclusion visit

③ Diabetes complications :

* Heart : ¤ Coronary artery disease : |___|

1. No
2. Without prior myocardial infarction
3. With prior myocardial infarction

¤ Heart failure : |___|
according to NYHA classification

* Eye : ¤ Visual acuity: RE |___|___| LE |___|___|
¤ DR Severity Scale : RE |___| LE |___|

* Kidney : ¤ Microalbuminuria* : Yes : ☐ |__|__|__|__| µg/L No : ☐
¤ Urea : |__|__|__| mmol/L
¤ Creatinine : |__|__|__| µmol/L
¤ Creatinine clearance |__|__|__| ml/min

* in the morning urine

Diabetic retinopathy severity scale for individuals eyes.

1. DR absent
2. Micro aneurysms only
3. Mild non proliferative DR
4. Moderately severe non proliferative DR
5. Severe non proliferative DR
6. Mild proliferative DR
7. Moderate proliferative DR
8. High risk proliferative DR
9. Cannot grade .

Ref : Derived from : Early Treatment Diabetic Retinopathy Study Research Group. Grading diabetic retinopathy from stereoscopic color fundus photographs-an extension of the modified Airlie House classification. ETDRS Report Number 10. Ophtalmology. 1991 ; 98 : 786-806.

ETDRS Final Retinopathy Severity Scale for individual Eyes		
Level	**Severity**	**Definition**
10	**DR absent**	Microaneurysms and other characteristics absent
12	Non-DR Abnormalities	
14	DR questionable	14A HE definite; microaneurysms absent
		14B SE definite; microaneurysms absent
		14C IRMA definite; microaneurysms absent
15[a]	DR questionable	Hemorrhage(s) definite; microaneurysms absent
20	**Microaneurysms only**	Microaneurysms definite; other characteristics absent
35[b]	**Mild NPDR**	35A Venous loops ≥ D/1
		35 B SE, IRMA, or VB = Q
		35C Retinal Hemorrhages present
		35D HE ≥ D/1
		35E HE ≥ M/1
		35F SE ≥ D/1
43	**Moderate NPDR**	43A H/Ma = M/4-5 or S/1
		43B IRMA) D/1-3
47	**Moderately severe NPDR**	47A Both Level 43 characteristics
		47B IRMA = D/4-5
		47C H/Ma = S/2-3
		47D VB = D/1
53	**Severe NPDR**	53A ≥ 2 of the 3 Level 47 characterictics
		53B H/Ma ≥ S/4-5
		53C IRMA ≥ M/1
		53D VB ≥ D/2-3
	53E Very Severe NPDR	53E ≥ 2 of 53B, 53C, and 53D
61	**Mild PDR**	61A FPD and/or FPE only (regressed PDR)
		61B NVE < ½ disc area in ≥ 1 field
65	**Moderate PDR**	65A NVE ≥ M/1 (≥ ½ disc area in ≥ 1 field=
		65B NVD = D and VH or PRH = A or Q
		65C VH or PRH = D and NVE < M/1 and NVD absent
71	**High-risk PDR**	71A VH or PRH ≥ M/1 (M = about 1 disc area)
		71B NVE ≥ M/1 and VH or PRH ≥ D/1
		71C NVD = D and VH or PRH ≥ D/1
		71D NVD ≥ M
75	High-risk PDR	75 NVD ≥ M and VH or PRH ≥ D/1
81	Advanced PDR: Fundus partially obscured, center of macula attached	NVD = cannot grade, or NVD < D and NVE = cannot grade in ≥ 1 field and absent in all others; and retinal detachment at center of macula < D
85	Advanced PDR: Posterior fundus obscured, or center of macula detached	85A VH = VS in Field 1 or 2 85 B Retinal detachment at center of macula = D
90	Cannot grade, even sufficiently for level 81 or 85	

[a] Levels 12, 14 and 15 are not considered separate steps in the scale, but are pooled with level 10 or 20 (or excluded).
[b] NPDR levels 35 and above all require presence of microaneurysms.

Abbreviations: DR = diabetic retinopathy; NPDR = non proliferative DR; PDR = proliferative DR; HE = hard exudates; SE = soft exudates; IRMA = intraretinal microvascular abnormalities; VB = venous beading; H/Ma = hemorrhages/microaneurysms ; NVE = new vessels elsewhere ; NVD = new vessels on or adjacent to optic disc ; VH = vitreous hemorrhage; PRH = preretinal hemorrhage

Severity categories are of the form (maximum severity/extent), where maximum severity can be absent (A), questionable (Q), definitely present (D), moderate (M), Severe (S), or very severe (VS) and extent is the number of photographic fields at that severity level. For example, M/2-3 means there are two or three fields from fields 3 to 7 with moderate severity and none with higher severity.

④ Foot evaluation :

(Only that one where the studied lesion is present)

* Neuropathy :

Neuropathy symptom score : |___|___|

Neuropathy disability score : |___|___|

Semmes Weinstein Monofilament : |___| / 6

* Vascular insufficiency

Toe pressure |___|___|___| mmHg

Toe brachial index : |___|,|___|___|

Ankle pressure |___|___|___| mmHg

Ankle brachial index |___|,|___|___|

¤ Transcutaneous PO2 :

Sub clavicular reference, ambient air |___|___|___| mmHg

Wound, ambient air |___|___|___| mmHg

Subclavicular reference, normobaric oxygen |___|___|___| mmHg

Wound, normobaric oxygen |___|___|___| mmHg

Optionnal :

Subclavicular reference, 2.5 Ata HBO_2 |___|___|___|___| mmHg

Wound, 2.5 Ata HBO_2 |___|___|___|___| mmHg

Neuropathy Symptom Score

Symptoms	**Absent**	**Present**	**Nocturnal exacerbation**
Muscular cramp	0	1	2
Numbness	0	1	2
Pin and needles	0	1	2
Abnormal cold or hot sensations	0	1	2
Lancinating pain	0	1	2
Deep aching pain	0	1	2
Burning pain	0	1	2
Irritation caused by bed clothes at night	0	1	2

Total : |____|____|

Ref : A.G.M. Boulton, A. Dedes, E. Vecioli, C. Manes, Comparison of risk factors for problems in diabetic patients, attending teaching hospital outpatient clinics in four European states. Diabetic Medicine, 1994 (11), 709-11

Neuropathy disability score

	Sensation Normal		Sensation impaired up to									
			Base of the toe		Midfoot		Ankle		Midleg		Knee	
	R	L	R	L	R	L	R	L	R	L	R	L
Pin	0	0	1	1	2	2	3	3	4	4	5	5
Cotton wood	0	0	1	1	2	2	3	3	4	4	5	5
Tuning fork	0	0	1	1	2	2	3	3	4	4	5	5
Icy tuning fork	0	0	1	1	2	2	3	3	4	4	5	5

Sensory score (total / 2) : |___|___|

	Normal		Elicited with reinforcement		Absent	
Reflex	R	L	R	L	R	L
Patellar	0	0	1	1	2	2
Achilles	0	0	1	1	2	2

Reflex score (Total) : |___|___|

Neuropathy Disability score : |___|___|

Ref : M.J Young, A.G.M. Boulton, A.F. Macleud, D.R.R Williams, F.H. Fonksen, Multicenter study of the prevalence of diabetic peripheral neuropathyin the U.K. Hospital clinic population. Diabetologia, 1993 (36), 150-54.

Guidelines for S-W monofilament examination

* a 10 g monofilament (5.07 Semmes-Weinstein) is used
* Examination must be done in a quiet and relaxed supine patient's position, closed eyes.
* First apply the monofilament on the patient's hands to teach him/her what to feel. The patient must not be able to see if the filament is applied
* The three sites are tested on both feet : the big toe pulp, Ist an Vth metatarsus head.
* Apply the filament perpendicular to test skin surface by sufficient force to cause the filament bending for about 45°, the whole procedure should take approximately 2 seconds.
* Ask the patient IF and WHERE they have felt the pressure applied.
* Repeat the measurement TWICE at the same site in a RANDOM order.
* Express the result separately for each foot in a ratio : ig 4/6 means the patient has felt 4 touches from 6, 6/6 means the patient has felt everything.
* During whole procedure, test twice by a blind application the patient's drive to comply with you. If the patient's answer positively while no filament is applied, cancel everything, explain this to patient more and repeat whole prodecure.

Ref : Adapted under the "Practical Guidelines on the Management and the prevention of the Diabetic foot" edited by International Working group on the Diabetic Foot, Amsterdam.

* Wound assessment

Size : |___|___|___|___|___|___| square millimeters

Location : Wound center |___|___|___|

Other area |___|___|___|
___	___	___
___	___	___
___	___	___

N.B. : Draw the wound on the pre-inclusion location form

Aspect : Necrotic : |__________| %
Purulent : |__________| %
Fibrinous : |__________| %
Granulation : |__________| %
Epithelialised : |__________| %

Depth : |__________| mm

Wagner grade |____|

University of Texas Diabetic Wound Classification :
grade |____| stage |____|

* Peri wound Hyperkeratosis : |___| Yes |___|___| mm |___| No

* Peri wound infection : |___| Yes |___|___| |___| No

1.1. Mild : Redness / Erythema (more than 1 cm around the wound)

1.2. Moderate : Redness between 1 and 5 cm around the wound / Swelling / Pain

1.3. Major : Wide spreading infection (Temperature over 38,5°C, redness more than 5 cm around the wound, cellulitis, ...)

* Bone or joint infection |___| Yes |___|___| |___| No

2.1. Exposed bone at the bottom of the ulcer

2.2. Abnormal X-Ray

2.3. Abnormal bone scan

2.4. Abnormal MRI

2.5. Positive culture of bone biopsy

2.9. Other : |____|

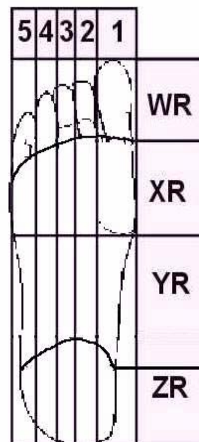
* Inflammatory components : - CRP |___|___|___| mg/l

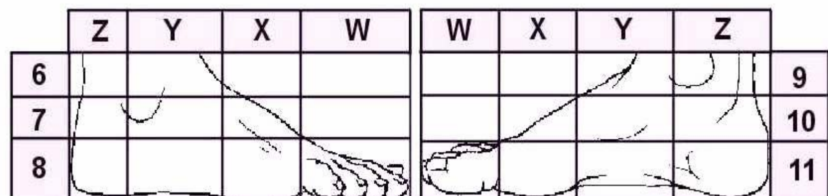
- Temperature |___|___| . |___| Celsius

- WBC |___|___|___|___|___| / mm^3

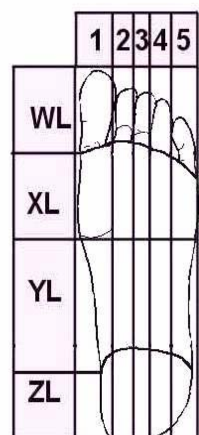
Pre Inclusion Visit

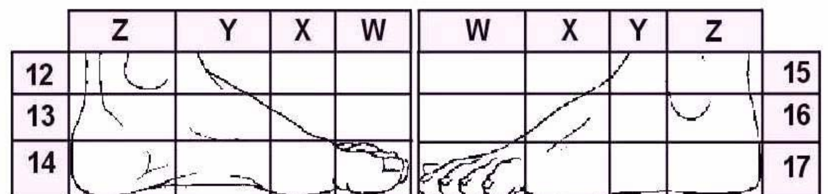
Location form





Right





Left

* Previous revascularization procedure :

Number of procedures	|___|
Endarterectomy	|___|
Bypass suprapopliteal	|___|
Bypass infrapopliteal	|___|
Bypass to pedal artery	|___|
Angioplasty (included stenting)	|___|

* Vascular evaluation has been done (< 1 year) :

No	|___|
Clinically	|___|
Colour Echo Doppler	|___|
Arteriography	|___|

* Arterial patency (according to the most sensitive method)

	over ankle	below ankle
Posterior tibialis Artery	|______|	|______|
Anterior tibialis / Pedialis Artery	|______|	|______|

* Revascularization possibility :

Yes	No
|___|	|___|

Current treatment :

*Diabetes equilibrium : Yes / No

* Weight bearing measures : Correct / Incorrect

* Dressing : Correct / Incorrect

* Antibiotic treatment (if infection) : Yes / No

(specific form to be filled) Adapted / Non adapted

Pre inclusion visit conclusion :

Does the patient fit the pre inclusion criteria :

	Yes	No
* Diabetes	|___|	|___|
* Foot lesion Wagner 2 - 4	|___|	|___|
* No revascularization possibility	|___|	|___|
* Correct treatment ordered	|___|	|___|

Inclusion visit

Date of the inclusion visit : |___|___| |___|___| |___|___|___|___|

day month year

Inclusion criteria :

	Yes	No
* Foot lesion persisting :	|___|	|___|
* No revascularization possibility :	|___|	|___|
* Correct treatment :	|___|	|___|
for 3 weeks		
¤ Diet followed	|___|	|___|
¤ Diabetes equilibrium	|___|	|___|
Fasting blood sugar	|______| g/L	
Glycosylated hemoglobine A_{1c}	|______| %	
¤ Weigh bearing measures	Applied / Unapplied	
¤ Surgical debridement	Correct / Incorrect	
¤ Dressing	Applied / Unapplied	
¤ Antibiotic treatment (if infection)	Applied / Unapplied	

The patient may be included : Yes |___| No |___|

Randomisation group : |_________|

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Inclusion Evaluation

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Location : Wound center |___|___|___|

Other area |___|___|___|
___	___	___
___	___	___
___	___	___

N.B. : Draw the wound on the inclusion location form

Aspect : Necrotic : |__________| %
Purulent : |__________| %
Fibrinous : |__________| %
Granulation : |__________| %
Epithelialised : |__________| %

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)
|___| nb of pictures

Neuropathy : Neuropathy symptom score : |___|___|

Neuropathy disability score : |___|___|

Semmes Weinstein Monofilament : |___| / 6

Transcutaneous PO2 :

Sub clavicular reference, ambient air |___|___|___| mmHg

Wound, ambient air |___|___|___| mmHg

Subclavicular reference, oxygen |___|___|___| mmHg

Wound, oxygen |___|___|___| mmHg

Optional :

Sub clavicular reference, 2.5 Ata HBO_2 |___|___|___|___| mmHg

wound, 2.5 Ata HBO_2 |___|___|___|___| mmHg

Patient hospitalized

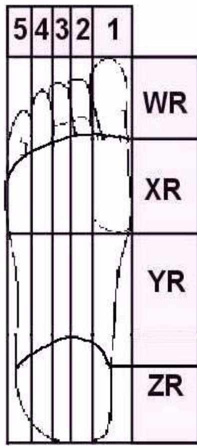
Yes |___| No |___|

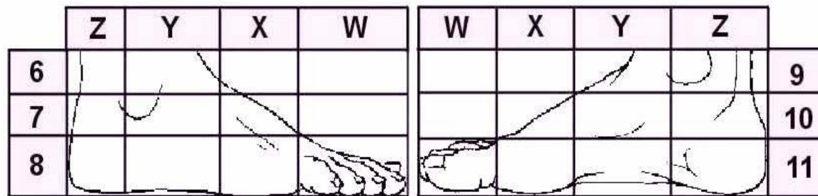
If yes, date of admission : |__|__| |__|__| |__|__|
day month year

Smoking habit : never |___| Stopped before study |___| Still smoking |___|

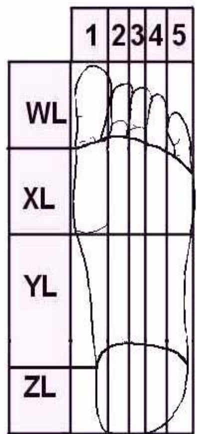
Inclusion Visit

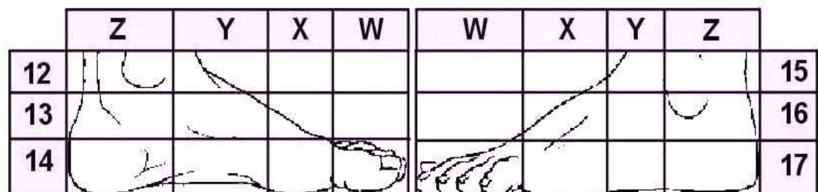
Location Form





Right





Left

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Week 1

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Aspect : Necrotic : |_________| %

Purulent : |_________| %

Fibrinous : |_________| %

Granulation : |_________| %

Epithelialised : |_________| %

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)

|___| nb of pictures

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Hospitalisation :

* If patient hospitalized on admission, is he still in hospital

Yes |___| No |___|

If no : Date of discharge |__|__| |__|__| |__|__|

day month year

* If patients non hospitalized on admission, has he been admitted in hospital

Yes |___| No |___|

If Yes : Date of admission |__|__| |__|__| |__|__|

day month year

Amputation :

* Has amputation been required : Yes |___| No |___|

* Type of amputation : |___|

1. Toe
2. Toe and metatarsal head
3. Mediotarsial
4. Below ankle
5. Below knee
6. Above knee

* Date of amputation : |__|__| |__|__| |__|__|__|__|

day month year

Week 2

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Aspect : Necrotic : |_________| %

Purulent : |_________| %

Fibrinous : |_________| %

Granulation : |_________| %

Epithelialised : |_________| %

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)

|___| nb of pictures

Transcutaneous PO2 (optional) :

Sub clavicular reference, ambient air |___|___|___| mmHg

Wound, ambient air |___|___|___| mmHg

Subclavicular reference, oxygen |___|___|___| mmHg

Wound, oxygen |___|___|___| mmHg

Optional :

Sub clavicular reference, 2.5 ata HBO_2 |___|___|___|___| mmHg

wound, 2.5 ata HBO_2 |___|___|___|___| mmHg

Subject number |___|___|___| |__________| Subject initials |___|___|___|

Hospitalisation :

* If patient hospitalized on admission, is he still in hospital

Yes |___| No |___|

If no : Date of discharge |__|__| |__|__| |__|__|

day month year

* If patients non hospitalized on admission, has he been admitted in hospital

Yes |___| No |___|

If Yes : Date of admission |__|__| |__|__| |__|__|

day month year

Amputation :

* Has amputation been required : Yes |___| No |___|

* Type of amputation : |___|

1. Toe
2. Toe and metatarsal head
3. Mediotarsial
4. Below ankle
5. Below knee
6. Above knee

* Date of amputation : |__|__| |__|__| |__|__|__|__|

day month year

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Week 3

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Aspect : Necrotic : |_________| %

Purulent : |_________| %

Fibrinous : |_________| %

Granulation : |_________| %

Epithelialised : |_________| %

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)

|___| nb of pictures

Subject number |___|___|___| |__________| Subject initials |___|___|___|

Hospitalisation :

* If patient hospitalized on admission, is he still in hospital

Yes |___| No |___|

If no : Date of discharge |__|__| |__|__| |__|__|

day month year

* If patients non hospitalized on admission, has he been admitted in hospital

Yes |___| No |___|

If Yes : Date of admission |__|__| |__|__| |__|__|

day month year

Amputation :

* Has amputation been required : Yes |___| No |___|

* Type of amputation : |___|

1. Toe
2. Toe and metatarsal head
3. Mediotarsial
4. Below ankle
5. Below knee
6. Above knee

* Date of amputation : |__|__| |__|__| |__|__|__|__|

day month year

Week 4

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Aspect : Necrotic : |_________|%

Purulent : |_________|%

Fibrinous : |_________|%

Granulation : |_________|%

Epithelialised : |_________|%

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)

|___| nb of pictures

Transcutaneous PO2 (optional) :

Sub clavicular reference, ambient air |___|___|___| mmHg

Wound, ambient air |___|___|___| mmHg

Subclavicular reference, oxygen |___|___|___| mmHg

Wound, oxygen |___|___|___| mmHg

Optional :

Sub clavicular reference, 2.5 ata HBO_2 |___|___|___|___| mmHg

wound, 2.5 ata HBO_2 |___|___|___|___| mmHg

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Hospitalisation :

* If patient hospitalized on admission, is he still in hospital

Yes |___| No |___|

If no : Date of discharge |__|__| |__|__| |__|__|

day month year

* If patients non hospitalized on admission, has he been admitted in hospital

Yes |___| No |___|

If Yes : Date of admission |__|__| |__|__| |__|__|

day month year

Amputation :

* Has amputation been required : Yes |___| No |___|

* Type of amputation : |___|

1. Toe
2. Toe and metatarsal head
3. Mediotarsial
4. Below ankle
5. Below knee
6. Above knee

* Date of amputation : |__|__| |__|__| |__|__|__|__|

day month year

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Week 5

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Aspect : Necrotic : |_________| %

Purulent : |_________| %

Fibrinous : |_________| %

Granulation : |_________| %

Epithelialised : |_________| %

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)

|___| nb of pictures

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Hospitalisation :

* If patient hospitalized on admission, is he still in hospital

Yes |___| No |___|

If no : Date of discharge |__|__| |__|__| |__|__|

day month year

* If patients non hospitalized on admission, has he been admitted in hospital

Yes |___| No |___|

If Yes : Date of admission |__|__| |__|__| |__|__|

day month year

Amputation :

* Has amputation been required : Yes |___| No |___|

* Type of amputation : |___|

1. Toe
2. Toe and metatarsal head
3. Mediotarsial
4. Below ankle
5. Below knee
6. Above knee

* Date of amputation : |__|__| |__|__| |__|__|__|__|

day month year

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Final Evaluation (End of week 6)

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Location : draw on the final evaluation location form

Aspect :
- Necrotic : |_________| %
- Purulent : |_________| %
- Fibrinous : |_________| %
- Granulation : |_________| %
- Epithelialised : |_________| %

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)
|___| nb of pictures

Neuropathy :

Neuropathy symptom score : |___|___|
Neuropathy disability score : |___|___|
Semmes Weinstein Monofilament : |___| / 6

Laboratory tests :

Fasting Blood Sugar |___|___|___| mmol/L
Glycosylated hemoglobin A_{1c} |___|___|___| %
C Reactive Protein |___|___|___| mg/L
White Blood Count |___|___|___|___| / mm^3

Transcutaneous PO2 :

Sub clavicular reference, ambient air |___|___|___| mmHg
Wound, ambient air |___|___|___| mmHg
Subclavicular reference, oxygen |___|___|___| mmHg
Wound, oxygen |___|___|___| mmHg

Optional :

Sub clavicular reference, 2.5 ata HBO_2 |___|___|___|___| mmHg
wound, 2.5 ata HBO_2 |___|___|___|___| mmHg

Hospitalisation :

* If patient hospitalized on admission, is he still in hospital

Yes |___| No |___|

If no : Date of discharge |__|__| |__|__| |__|__|

day month year

* If patients non hospitalized on admission, has he been admitted in hospital

Yes |___| No |___|

If Yes : Date of admission |__|__| |__|__| |__|__|

day month year

Smoking during study period : Yes |___| No |___|

Amputation :

* Has amputation been required : Yes |___| No |___|
* Type of amputation : |___|

1. Toe
2. Toe and metatarsal head
3. Mediotarsial
4. Below ankle
5. Below knee
6. Above knee

* Date of amputation : |__|__| |__|__| |__|__|__|__|

day month year

Patient hospitalized Yes |___| No |___|

* Diabetes complications :

* Heart : ¤ Coronary artery disease : |___|
  1. No
  2. Without prior myocardial infarction
  3. With prior myocardial infarction

  ¤ Heart failure : |___|
  according to NYHA classification

* Eye : ¤ Visual acuity: RE |___|___| LE |___|___|
  ¤ DR Severity Scale : RE |___| LE |___|

* Kidney : ¤ Microalbuminuria* : Yes : ☐ |__|__|__|__| µg/L No : ☐
  ¤ Urea : |__|,|__|__| mmol/L
  ¤ Creatinine : |__|__|__| µmol/L
  ¤ Creatinine clearance |__|__|__| ml/min

* Number of HBO sessions really done |___|___|

(If HBO treatment has been interrupted, fill the "HBO treatment" form)

End of study period evaluation : |____|

1. Healed
2. 50 % or more covered
3. Less of 50 % covered
4. No change
5. Aggravation

* in the morning urine

Treatment phase

Antimicrobial Medications

Medication (Generic names preferred)	Indication*	Daily Dose	Route**	First Day						Last Day					
				D		M		Y		D		M		Y	

* Indication : ¤ Peri wound infection :
- 1.1 Mild
- 1.2 Moderate
- 1.3 Major

¤ bone or joint infection
- 2.1. Exposed bone at the bottom of the ulcer
- 2.2. Abnormal X-Ray
- 2.3. Abnormal bone scan
- 2.4. Abnormal MRI
- 2.5. Positive culture of bone biopsy
- 2.9. Other : |____|

** Route : IV = Intravenous
PO = Oral
IM = Intramuscular
SC = Subcutaneous

Subject number |___|___|___| |_________| Subject initials |___|___|___|

HBO treatment form

* Has the HBO treatment to be interrupted ?	Yes ☐	No ☐
* Reason for interuption :		
* Unacceptable risk to continue HBO :	Yes ☐	No ☐
- HBO contra indication :		
¤ Acute respiratory disease	Yes ☐	No ☐
¤ Spontaneous pneumothorax	Yes ☐	No ☐
¤ Acute ENT infection	Yes ☐	No ☐
¤ Convulsion	Yes ☐	No ☐
¤ Others |____|		
- HBO adverse effect :		
¤ ENT barotrauma	Yes ☐	No ☐
¤ ENT pulmonary barotrauma	Yes ☐	No ☐
¤ Oxygen induced convulsion	Yes ☐	No ☐
¤ Others |____|		

* Others reasons :
    - Non compliance
    - Ulcer area increase by > 50 %
    - Need for amputation
    - Unwillingness of the patient
    - Others |____|

* If the HBO treatment has been interrupted, list the date of the session.

Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date Day month Year Number of sessions	Date Day month Year Number of sessions
Date	Date

Day month Year Number of sessions |___|___| |___|___| |___|___| |___|	Day month Year Number of sessions |___|___| |___|___| |___|___| |___|
Date Day month Year Number of sessions |___|___| |___|___| |___|___| |___|	Date Day month Year Number of sessions |___|___| |___|___| |___|___| |___|

* Number of HBO sessions really done |___|___|

* Cumulative duration of interuption |___|___| days

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Adverse effects

		Yes	No
¤ Adverse effects		☐	☐
* Barotrauma:	- Sinus	☐	☐
	- Middle Ear	☐	☐
	- Dental	☐	☐
	- Pulmonary	☐	☐
	- Other :	|________________________|	
* Seizure		☐	☐
* Cardiac intolerance			
	- Dysrythmia	☐	☐
	- Chest pain	☐	☐
	- Hypotension	☐	☐
* Psychologic intolerance		☐	☐

* Others (specify) |____|

¤ Ophtalmologic examination (at the end of treatment period)

- Visual acuity

RE |___|___| LE |___|___|

- DR severity scale

RE |___|___| LE |___|___|

¤ Does the adverse effects lead to stop HBO ☐ ☐

Nb of session done |___|___|

Follow up
Month 1

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Aspect : Necrotic : |_________| %

Purulent : |_________| %

Fibrinous : |_________| %

Granulation : |_________| %

Epithelialised : |_________| %

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)

|___| nb of pictures

Rehospitalisation for wound

Yes ☐ No ☐

Date |__|__| |__|__| |__|__|
day month year

If previously healed, wound recurence Yes |___| No |___|

Subject number |___|___|___| |__________| Subject initials |___|___|___|

Hospitalisation :

* If patient hospitalized on admission, is he still in hospital

Yes |___| No |___|

If no : Date of discharge |__|__| |__|__| |__|__|

day month year

* If patients non hospitalized on admission, has he been admitted in hospital

Yes |___| No |___|

If Yes : Date of admission |__|__| |__|__| |__|__|

day month year

Amputation :

* Has amputation been required : Yes |___| No |___|

* Type of amputation : |___|

1. Toe
2. Toe and metatarsal head
3. Mediotarsial
4. Below ankle
5. Below knee
6. Above knee

* Date of amputation : |__|__| |__|__| |__|__|__|__|

day month year

Other active treatment applied : Yes |___| No |___|

Specify : |____|

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Follow up
Month 3

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Aspect : Necrotic : |_________| %

Purulent : |_________| %

Fibrinous : |_________| %

Granulation : |_________| %

Epithelialised : |_________| %

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)

|___| nb of pictures

Neuropathy

: Neuropathy symptom score : |___|___|

Neuropathy disability score : |___|___|

Semmes Weinstein Monofilament : |___| / 6

Rehospitalisation for wound

Yes ☐ No ☐

Date |__|__| |__|__| |__|__|

day month year

Subject number |___|___|___| |__________| Subject initials |___|___|___|

Hospitalisation :

* If patient hospitalized on admission, is he still in hospital

Yes |___| No |___|

If no : Date of discharge |__|__| |__|__| |__|__|

day month year

* If patients non hospitalized on admission, has he been admitted in hospital

Yes |___| No |___|

If Yes : Date of admission |__|__| |__|__| |__|__|

day month year

Amputation :

* Has amputation been required : Yes |___| No |___|

* Type of amputation : |___|

1. Toe
2. Toe and metatarsal head
3. Mediotarsial
4. Below ankle
5. Below knee
6. Above knee

* Date of amputation : |__|__| |__|__| |__|__|__|__|

day month year

Other active treatment : Yes |___| No |___|

Specify : |____________________________________|

Follow up
Month 6

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Aspect : Necrotic : |_________| %

Purulent : |_________| %

Fibrinous : |_________| %

Granulation : |_________| %

Epithelialised : |_________| %

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)

|___| nb of pictures

Neuropathy : Neuropathy symptom score : |___|___|

Neuropathy disability score : |___|___|

Semmes Weinstein Monofilament : |___| / 6

	Yes	No
Rehospitalisation for wound	☐	☐

Date |__|__| |__|__| |__|__|__|__|

day month year

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Hospitalisation :

* If patient hospitalized on admission, is he still in hospital

Yes |___| No |___|

If no : Date of discharge |__|__| |__|__| |__|__|

day month year

* If patients non hospitalized on admission, has he been admitted in hospital

Yes |___| No |___|

If Yes : Date of admission |__|__| |__|__| |__|__|

day month year

Amputation :

* Has amputation been required : Yes |___| No |___|

* Type of amputation : |___|

1. Toe
2. Toe and metatarsal head
3. Mediotarsial
4. Below ankle
5. Below knee
6. Above knee

* Date of amputation : |__|__| |__|__| |__|__|__|__|

day month year

Other active treatment applied : Yes |___| No |___|

Specify : |______________________________________|

Follow up
Month 9

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Aspect : Necrotic : |_________| %

Purulent : |_________| %

Fibrinous : |_________| %

Granulation : |_________| %

Epithelialised : |_________| %

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)

|___| nb of pictures

Rehospitalisation for wound

Yes ☐ No ☐

Date |__|__| |__|__| |__|__|

day month year

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Hospitalisation :

* If patient hospitalized on admission, is he still in hospital

Yes |___| No |___|

If no : Date of discharge |__|__| |__|__| |__|__|

day month year

* If patients non hospitalized on admission, has he been admitted in hospital

Yes |___| No |___|

If Yes : Date of admission |__|__| |__|__| |__|__|

day month year

Amputation :

* Has amputation been required : Yes |___| No |___|

* Type of amputation : |___|

1. Toe
2. Toe and metatarsal head
3. Mediotarsial
4. Below ankle
5. Below knee
6. Above knee

* Date of amputation : |__|__| |__|__| |__|__|__|__|

day month year

Other active treatment applied : Yes |___| No |___|

Specify : |_____________________________________|

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Follow up
Final visit - Month 12

Date |__|__| |__|__| |__|__|

Wound evaluation :

Size : |___|___|___|___|___|___| square millimeter

Location : draw of the final visit location form.

Aspect : Necrotic : |_________| %
Purulent : |_________| %
Fibrinous : |_________| %
Granulation : |_________| %
Epithelialised : |_________| %

Depth : |___|___| mm

Infection |___|

Digital picture : Done / Not done (Mandatory)

|___| nb of pictures

Neuropathy : Neuropathy symptom score : |___|___|

Neuropathy disability score : |___|___|
Semmes Weinstein Monofilament : |___| / 6

Laboratory tests :

Fasting Blood Sugar |___|___|___| g/L
Glycosylated hemoglobin A_{1c} |___|___|___| %
C Reactive Protein |___|___|___| mg/L
White Blood Count |___|___|___|___| / mm^3

Yes No

Diabetes complications :

* Heart : ¤ Coronary artery disease : |___|

1. No
2. Without prior myocardial infarction
3. With prior myocardial infarction

¤ Heart failure : |___|

according to NYHA classification

* Eye : ¤ Visual acuity: RE |___|___| LE |___|___|

¤ DR Severity Scale : RE |___| LE |___|

* Kidney : ¤ Microalbuminuria* : Yes : ☐ |__|__|__|__| µg/L No : ☐

¤ Urea : |__|.|__|__| mmol/L

¤ Creatinine : |__|__|__| µmol/L

¤ Creatinine clearance |__|__|__| ml/min

· in the morning urine

Rehospitalisation for wound ☐ ☐

Date |__|__| |__|__| |__|__|

day month year

Subject number |___|___|___| |_________| Subject initials |___|___|___|

Hospitalisation :

* If patient hospitalized on admission, is he still in hospital

Yes |___| No |___|

If no : Date of discharge |__|__| |__|__| |__|__|

day month year

* If patients non hospitalized on admission, has he been admitted in hospital

Yes |___| No |___|

If Yes : Date of admission |__|__| |__|__| |__|__|

day month year

Amputation :

* Has amputation been required : Yes |___| No |___|

* Type of amputation : |___|

1. Toe
2. Toe and metatarsal head
3. Mediotarsial
4. Below ankle
5. Below knee
6. Above knee

* Date of amputation : |__|__| |__|__| |__|__|__|__|

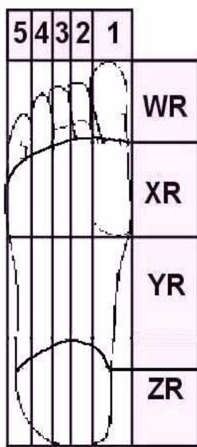
day month year

Other active treatment applied : Yes |___| No |___|

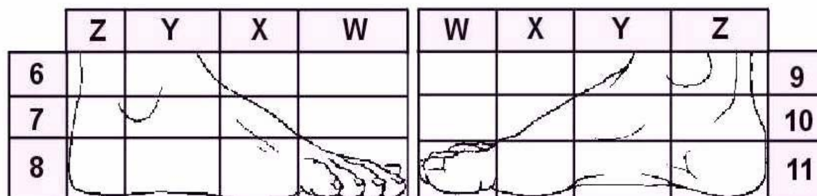
Specify : |_______________________________________|

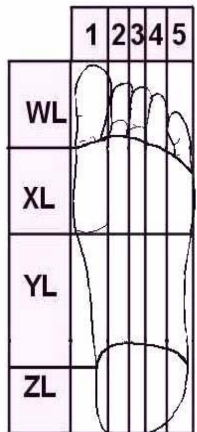
1 Year follow up Visit

Location form

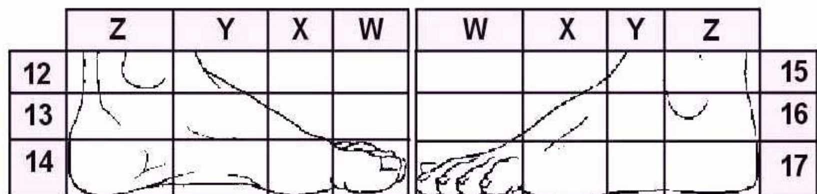


Right





Left



Conclusion

1) Major end point :

After 6 weeks, over 50 % healed 1 |___|

less than 50 % healed 2 |___|

2) Secondary end points : Yes No

* Infection at inclusion : ☐ ☐

Infection cured : during the study period : ☐ ☐

during the follow-up period : ☐ ☐

If yes , time for infection cure : |___|___|___| days

* Need for amputation : during the study period Yes ☐ No ☐

during the follow up period Yes ☐ No ☐

If Yes, amputation level : |____|

* Complete healing :

¤ During the study period : Yes ☐ No ☐

¤ During the follow-up period : Yes ☐ No ☐

Duration : |___|___|___| days

* Need for hospitalisation

¤ During the study phase : Yes ☐ No ☐

Duration : |___|___|___| days

¤ During the 1 year follow-up Yes ☐ No ☐

Duration (cumulated) : |___|___|___| days

* If wound previously healed, recurence : Yes ☐ No ☐

Investigator Conclusion and Comments :

date |___|___| |___|___| |___|___|___|___|

Day Month Year

Investigation name : ____

Investigation signature : ____