10.3 ANNEX 3 REPORT FORM FOR MANUFACTURER'S TO THE NATIONAL COMPETENT AUTHORITY

Report Form
Manufacturer's Incident Report

V.12/09

Medical Devices Vigilance System

(MEDDEV 2.12/1 rev 6)

1 Administrative information

Recipient

Name of National Competent Authority (NCA)

Address of National Competent Authority

MHRA,
Market Towers
1 Nine Elms Lane
Lonsdon SW8 5NQ

Stamp box for the Competent Authority (~ 60 x 40 mm)

Date of this report: 24/01/11

Reference number assigned by the manufacturer

Reference number assigned by NCA to whom sent (if known)

Type of report

- ☐ Initial report
- ☒ Follow-up report
- ☐ Combined Initial and final report
- ☐ Final report

Does the incident represent a serious public health threat?

- ☐ Yes
- ☒ No

Classification of incident

- ☐ death
- ☐ unanticipated serious deterioration in state of health, serious public health threat
- ☒ All other reportable incidents

Identify to what other NCAs this report was **also** sent

2 Information on submitter of the report

Status of submitter

- ☐ Manufacturer
- ☒ Authorised Representative within EEA and Switzerland

☐ Others: (identify the role)

3 Manufacturer information

Manufacturer name Teledyne Analytical Instruments	
Manufacturer's contact person Vasu Narasimham	
Address 16830 Chestnut Street	
Postal code 91748-1020	City City of Industry, California
Phone (626)961-9221	Fax 626)961-2538
E-mail VNarasimhan@teledyne.com	Country [2] USA

4 Authorised Representative information

Name of the Authorised Representative Viamed Ltd.	
The Authorised Representative's contact person Steve Nixon	
Address 15 Station Road, Crosshills	
Postal code BD207DT	City Keighley
Phone +44 1535634542	Fax +44 1535 635582
E-mail steve.nixon@viamed.co.uk	Country [2] UK

5 Submitter's information (if different from section 3 or 4)

Submitter's name N/A	
Name of the contact person N/A	
Address N/A	
Postal code N/A	City N/A
Phone N/A	Fax N/A
E-mail N/A	Country [2] N/A

6 Medical device information

Class

☐ AIMD Active implants

☐ MDD Class III
☐ MDD Class IIb
☒ MDD Class IIa
☐ MDD Class I
☐ IVD Annex II List A
☐ IVD Annex II List B
☐ IVD Devices for self-testing
☐ IVD General

Nomenclature system (preferable GMDN)

Nomenclature code

Nomenclature text

Commercial name/ brand name / make
Micro-Fuel Cell

Model number	Catalogue number
R-15	0110015
Serial number(s) (if applicable)	Lot/batch number(s) (if applicable)
see attached	see atached

Software version number (if applicable)
N/A

Device Manufacturing date,	Expiry date
see atached	
Implant date (for implants only)	Explant date (for implants only)
N/A	N/A

IDuration of implantation (to be filled is the exact implant or explant dates are unknown)
N/A

Accessories/ associated device (if applicable)
None

Notified Body (NB) ID-number
086

7 Incident information

User facility report reference number, if applicable
N/A

Manufacturers awareness date

Date the incident occurred
No incidents in Europe or countries supplied by Viamed

Incident description narrative
N/A

Number of patients involved (if known)	Number of medical devices involved (if known)
None	None

Medical device current location/disposition (if known)

Operator of the medical device at the time of incident (select one)

☐ health care professional ☐ patient

☐ other

Usage of the medical device (select from list below)

☒ initial use ☐ reuse of a single use medical device

☐ reuse of a reusable medical device ☐ re-serviced/refurbished

☐ other (please specify) ☐ problem noted prior use

8 Patient information

Patient outcome N/A

Remedial action taken by the healthcare facility relevant to the care of the patient

N/A

Age of the patient at the time of incident, if applicable

N/A

Gender, if applicable

☐ Female ☐Male

Weight in kilograms, if applicable

N/A

9 Healthcare facility information

Name of the health care facility

N/A

Contact person within the facility

N/A

Address N/A

Postcode

N/A

City N/A

Phone N/A

Fax N/A

E-mail N/A

Country [2)] N/A

10 Manufacturer's preliminary comments (Initial/Follow-up report)

Manufacturer's preliminary analysis

No reported incident in UK, Europe , or countries supplied

Initial corrective actions/preventive actions implemented by the manufacturer

Expected date of next report

11 Results of manufacturers final investigation (Final report)

The manufacturer's device analysis results

Remedial action/corrective action/preventive action / Field Safety Corrective Action

NOTE: In the case of a FSCA the submitter needs to fill in the form of Annex 4

Time schedule for the implementation of the identified actions

Final comments from the manufacturer

Further investigations

Is the manufacturer aware of similar incidents with this type of medical device with a similar root cause?

☐ Yes ☐ No

Number of similar incidents.

If yes, state in which countries and the report reference numbers of the incidents.

For Final Report only: The medical device has been distributed to the following countries:

- within the EEA and Switzerland:

☐ AT ☐ BE ☐ BU ☐ CH ☐ CY ☐ CZ ☐ DE ☐ DK ☐ EE ☐ ES ☐ FI ☐ FR ☐ GB ☐ GR ☐ HU ☐ IE
☐ IS ☐ IT ☐ LI ☐ LT ☐ LU ☐ LV ☐ MT ☐ NL ☐ NO ☐ PL ☐ PT ☐ RO ☐ SE ☐ SI ☐ SK

- Candidate Countries ☐ CR ☐ TR

☒ ALL EEA -, Candidate Countries and Switzerland

- others:

10 Comments

No incidents reported in UK,Europe, or any countries supllied

Submission of this report does not, in itself, represent a conclusion by the manufacturer and / or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

I affirm that the information given above is correct to the best of my knowledge.

.....

Name City date

10.4 ANNEX 4 EUROPEAN FIELD SAFETY CORRECTIVE ACTION REPORT FORM

V. 04/07

Report Form
Field Safety Corrective Action

Medical Devices Vigilance System

(MEDDEV 2.12/1 rev 5)

1 Administrative information

Destination Name of National Competent Authority Address of National Competent Authority MHRA, Market Towers 1 Nine Elms Lane Lonsdon SW8 5NQ	**Stamp box for the Competent Authority (~ 60 x 40 mm)**

Date of this report
24/1/11

Reference number assigned by the manufacturer

Incident reference number and name of the co-ordinating NCACompetent Authority (if applicable):

Identify to what other Competent Authorities this report was **also** sent

2 Information on submitter of the report

Status of submitter

☐ Manufacturer
☒ Authorised Representative within EEA
☐ Others: (identify the role):

3 Manufacturer information

Manufacturer name
Teledyne Analytical Instruments Micro Fuel cell

Manufacturer's contact person
Vasu Narasimham

Address
16830 Chestnut Street

Postal code 91748-1020	City City of Industry, California
Phone 626 961 9221	Fax 626 961 2538
E-mail VNarasimhan@teledyne.com	Country [2] USA

4 Authorised Representative information

Name of the Authorised Representative Viamed Ltd.	
The Authorised Representative's contact person Steve.Nixon	
Address 15. Station Road, Crosshills	
Postal code BD207DT	City Keighley
Phone +44 1535634542	Fax +44 1535635582
E-mail steve.nixon@viamed.co.uk	Country [2] UK

5 National contact point information

National contact point name Steve Nixon	
Name of the contact person Steve Nixon	
Address 15. Station Road, Crosshills	
Postal code BD207DT	City Keighley
Phone +44 1535634542	Fax +44 1535635582
E-mail steve.nixon@viamed.co.uk	Country [2] UK

6 Medical device information

Class

☐ AIMD Active implant

☐ MDD Class III	☐ IVD Annex II List A
☐ MDD Class IIb	☐ IVD Annex II List B
☒ MDD Class IIa	☐ IVD Devices for self-testing
☐ MDD Class I	☐ IVD General

Nomenclature system (preferable GMDN)

Nomenclature code

Nomenclature text

Commercial name/ brand name / make
Teledyne Analytical Instruments Micro Fuel cell

Model number R-15

Serial number(s) or lot/batch number(s)

Software version number (if applicable)

N/A

Manufacturing date/ Expiry date (if applicable)

Accessories/ associated device (if applicable)

N/A

Notified Body (NB) ID-number

086

7 Description of FSCA

Background information and reason for the FSCA,

Description and justification of the action (corrective/preventive)

Advice on actions to be taken by the distributor and the user.

Attached please find

☐ Field Safety Notice (FSN) in English ☐ FSN in national language

☐ Others (please specify) …

Time schedule for the implementation of the different actions

These countries within the EEA and Switzerland are affected by this FSCA:

- within the EEA and Switzerland:

☐ AT ☐ BE ☐ BU ☐ CH ☐ CY ☐ CZ ☐ DE ☐ DK ☐ EE ☐ ES ☐ FI ☐ FR ☐ GB ☐ GR ☐ HU ☐ IE
☐ IS ☐ IT ☐ LI ☐ LT ☐ LU ☐ LV ☐ MT ☐ NL ☐ NO ☐ PL ☐ PT ☐ RO ☐ SE ☐ SI ☐ SK

- Candidate Countries ☐ CR ☐ TR

☒ ALL EEA -, Candidate Countries and Switzerland

- others:

These countries outside the EEA and Switzerland are affected by this FSCA:

8 Comments

I affirm that the information given above is correct to the best of my knowledge.

.....

Name City date

Submission of this report does not, in itself, represent a conclusion by the manufacturer and / or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

R-15 Serial numbers for Recall

611531 611532 611533 611534 611535 611536 611537 611538 611539 611540
611541 611542 611543 611544 611545 611546 611547 611548 611549 611550
611551 611552 611553 611554 611555 611556 611557 611558 611559 611560
611561 611562 611563 611564 611565 611566 611567 611568 611569 611570
611571 611572 611573 611574 611575 611576 611577 611578 611579 611580
642470 642471 642472 642485 642486 642487 642488 642489 642490 642491
642492 642493 642494 642495 642496 642497 642498 642499 642500 642501
642502 642503 642504 642505 642506 642507 642508 642509 642510 642511
642512 642513 642514 642515 642516 642517 666158 666159 666160 666161
666162 666163 666164 666165 666166 666167 666168 666169 666170 666171
666172 666173 666174 666175 666176 666177 666178 666179 666180 666181
666182 666183 666184 666185 666186 666187 666188 666189 666190 666191
666192 666193 666194 666195 666196 666197 666198 666199 666200 666201
666202 666203 666204 666205 666206

R-15 Recall Locations:

11	Queen Elizabeth Hospital	UK UK sales
3	NHS Greater Glasgow & Clyde	UK UK sales
3	Sheffield Teaching Hospitals	UK UK sales
7	Yeovil DH NHS Foundation Trust	UK UK sales
4	Royal Cornwall Hospital	UK UK sales
1	Vandagraph Ltd	UK UK sales
2	Great Western Hospital NHS	UK UK sales
44	EX Export sales 4 Companies	EX Export sales
3	Calderdale & Huddersfield	UK UK sales
4	ECX EC Export Sale 2 Companies	ECX EC Export Sale
11	Surrey and Sussex Healthcare	UK UK sales
4	Cent Manchester & Childrens	UK UK sales
5	The Rotherham NHS Foundation	UK UK sales
1	Eden Medical (UK) Ltd	UK UK sales
2	Frimley Park Hosp NHS Trust	UK UK sales
1	Lothian Health Board	UK UK sales
2	Plymouth Hospitals NHS Trust	UK UK sales
2	Morecambe Bay Hospital Trust	UK UK sales
1	Bradford Hosps NHS Trust	UK UK sales
1	University Hospitals Bristol	UK UK sales
2	Taunton & Somerset NHS Trust	UK UK sales
1	University Hosps Bristol NHS	UK UK sales
1	Gateshead Health NHS	UK UK sales
3	James Cook University Hospital	UK UK sales