For issue and completion by purchaser: **PPQ Master Reference:**

<table>
<thead>
<tr>
<th>A unique reference (preferably ten characters maximum) must be given by the supplier:</th>
<th>Supplier’s Reference: 178G1005</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Generic Device Type:</strong> Nebuliser system</td>
<td><strong>Equipment Model:</strong> Eflow rapid (with eBase controller)</td>
</tr>
<tr>
<td><strong>Country of Origin:</strong> Germany</td>
<td><strong>Manufacturer:</strong> PARI GmbH</td>
</tr>
<tr>
<td><strong>Supplier:</strong> PARI Medical Ltd</td>
<td><strong>Telephone No:</strong> 01932 341122</td>
</tr>
<tr>
<td><strong>Fax No:</strong> 01932 341134</td>
<td>e-mail: <a href="mailto:infouk@pari.eu">infouk@pari.eu</a></td>
</tr>
</tbody>
</table>

**CE MARKING**

1. a) Does the product carry the CE marking? **YES**
   b) If YES, to which EC Directive(s):
      i) Active Implantable Medical Devices Directive (90/385/EEC) **YES**
      ii) Medical Devices Directive (93/42/EEC) **YES**
      If YES, state classification of device (93/42/EEC Annex IX) **IIA**
      iii) In Vitro Diagnostic Medical Devices Directive (98/79/EC) **YES**
      If YES, is the device: For self-testing? **YES** Covered by Annex II: List A? **YES** List B? **NO**
      For ii) and iii) above, Identification No. of Notified Body, if applicable **CE0123**
      iv) EMC Directive (89/336/EEC or superseding directive) **YES**
      v) Low Voltage Directive (73/23/EEC) **YES**
      vi) Other Directive(s) (please specify) **NO**

2. a) Is the product a ‘custom-made device’ (93/42/EEC)? **YES**
   b) Is the product intended for ‘clinical investigation’ (93/42/EEC) or ‘performance evaluation’ (98/79/EC)? **YES**
   If YES to a) or b) above, does the device comply with the UK Medical Devices Regulations? **YES**

**MANAGEMENT SYSTEM STANDARDS**

3. a) Is the manufacturer currently registered to any management system standards (eg ISO 9001, ISO 14001, ISO 13485)? **YES**
   If YES, please state the standard(s) and certification body: **EN 13485:2003**
   b) Is the supplier’s service and repair organisation currently registered to any management system standards? **YES**
   If YES, please state the standard(s) and certification body: **EN 13485:2003**

**SAFETY STANDARDS**

4. For products not CE marked to 1 b) i), ii) or iii) above, with which safety standard(s) does the product comply?

<table>
<thead>
<tr>
<th>Standard</th>
<th>Test House</th>
<th>Certificate Number</th>
<th>Date</th>
</tr>
</thead>
</table>

**SERVICE / SPARES / INSTALLATION**

5. Is service/repair information available? **YES**
   If NOT f.o.c. please state current price
   Indicate contents below:

   | (Please state YES, NO or N/A) | Full circuit diagrams | Fault finding procedure | Preventative maintenance | Repair information | Spare parts listing | List of special tools/test equipment/etc | Yes | No |
|---|---|---|---|---|---|---|---|
| YES | No | Yes | Yes | No | Yes | No | No | No |

If YES, please state whether also available on: Disk **NO** Website **YES** If Web, please state address: **www.pari.com**

6. a) In addition to the service/repair information/manual, will training be required before competent technical personnel can provide:

<table>
<thead>
<tr>
<th>(Please state YES, NO or N/A)</th>
<th>First-line maintenance</th>
<th>Calibration</th>
<th>Planned preventative maintenance</th>
<th>Repair</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>No</td>
<td>n/a</td>
<td>No</td>
<td>n/a</td>
</tr>
</tbody>
</table>

b) Is the supplier able to provide this training for the purchaser’s or a third party’s technical personnel? **YES**
   If YES, will this be free of charge? **NO** Or chargeable? **NO**
   If NO, please indicate if details of an organisation that is able to provide this training are available on request? **YES**
c) Is the provision of service/repair information conditional upon completion of training? YES  NO  x

d) In order to undertake maintenance/repair/calibration, is any special software/test equipment/tooling required? YES  NO  x
If YES, please indicate that details of special software/test equipment/tooling are provided on a separate sheet: 

7. a) Is the supplier able to provide an 'as required' repair/maintenance service in the UK? YES  NO  x
b) Is the supplier able to provide a contract repair/maintenance service? YES  NO  x
If YES, please confirm that details of repair/maintenance contracts are provided on a separate sheet. 

c) i) If repairs are normally performed by the supplier on the purchaser's site, please state typical response time: 2 days
   Company: PARI GmbH  Location: Germany  Typical turnaround time: 10 days
   ii) If repairs are performed off-site, where will these be carried out?
   iii) Is free of charge loan equipment normally available? YES  NO  x

8. Please state if repair parts will be available to the purchaser’s or a third party's suitably trained and equipped personnel: YES  NO  x
If YES, is the supply of repair parts conditional upon acquisition of repair information? YES  Or training? YES  NO

9. Please indicate when this model was first placed on the market: April 2012 (v.2)

10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed? 5 years
b) Is the product still in current production? YES  NO  x
If NO, indicate year of last manufacture:

11. Is installation necessary? YES  NO  x
If YES, please confirm that details of all services required are provided on a separate sheet:

12. Will software upgrades be notified? N/A  YES  NO  x

IONISING RADIATION

13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation? YES  NO  x

DECONTAMINATION / REPROCESSING  Handset only

14. a) i) Will the item be reprocessed (cleaned, disinfected, sterilised)? YES  x  NO  iii) If NO, go to Question 15.
   ii) If YES, is the item intended to be: Non-sterile for single use  Sterilised  Disinfected  Other
   iii) Is there a recommended maximum number of uses? YES  NO  x  If YES, please state:
   iv) Are decontamination/reprocessing instructions supplied? YES  x  NO  x  Temp: 93 °C
   v) Are instructions available for safe disposal?
   b) i) Is manual cleaning the only cleaning method specified before further reprocessing? YES  NO  x
   ii) What is the maximum temperature that can be used for thermal disinfection?
   iii) Are there any restrictions on detergent/disinfectant types? YES  x  NO  x  If YES, please state: Quaternary Ammonium Compounds recommended
   iv) Can the item withstand autoclaving at 137 °C for 3 mins? YES  NO  x
   v) Is the item compatible with other sterilization methods? YES  NO  x
   vi) Does reprocessing require the use of specified equipment? YES  NO  x
If YES, please state equipment type (eg containers, processors, etc) and, where appropriate, parameters of operation (eg temp, pressure, etc):

   c) i) Are tools required to aid dismantling/reassembly, or are lubricants required? YES  NO  x
   ii) If YES, are they supplied with the device or available optionally? Supplied  Optional  Neither
   d) Is decontamination/reprocessing training available? YES  x  NO  x  If YES will this be: Free of charge?  x  Chargeable?
   e) Are reprocessing instructions available on the Web? YES  x  NO  x  If YES, please state address: www.pari.com

WARRANTY

15. Please confirm that a copy of the warranty is provided on a separate sheet: YES  x

DECLARATION

When reference is made to this form and its attachments within the process of obtaining the item, we agree that the purchaser will be entitled to rely upon the contents and subsequent non-compliance with the statements contained herein will entitle the purchaser to seek redress.
Suppliers Reference: 178G1005

Repair/Maintenance for PARI eFlow®rapid

Replacement parts and accessories can be purchased. Technical training can be provided on request. The cost of any training requested will be negotiated according to what is required, but is normally free of charge.

The average operating life of the nebuliser components with regular use are:
- Nebuliser Handset (without aerosol head) - 12 months
- Aerosol Head - 3 to 6 months

WARRANTY

The control unit is guaranteed for 2 years. During the guarantee period, we will repair/replace any defects in the appliance resulting from faults in material or workmanship free of charge. The owner shall not be entitled to cancel the sale or demand a partial or full refund of the purchase price.

This warranty does not cover damage caused by improper use of the appliance. The guarantee shall become void if repairs are undertaken on the appliance by unauthorised persons.

No compensation will be paid for consequential or direct damage. In the event of a claim, please telephone PARI Medical Ltd. The guarantee period of shall commence on the date of purchase.