


Addendum Sheet for the 598 DFU

The following modifications / amendments should be incorporated into the DFU part number 144100, following the transfer of manufacture to the ALARIS® site in the United Kingdom.

Certificate of Conformity

The certificate of conformity found on page 2 should be replaced with the following:

	
EC Declaration of Conformity to Medical Devices Directive 93/42/EEC	
Manufacturer:	ALARIS Medical UK Ltd. The Crescent Jays Close Basingstoke Hampshire RG22 4BS United Kingdom. Telephone +44 1256 388200 Fax +44 1256 388388
Device	IVAC Volumetric Infusion Pumps
Description	IVAC 597/598
EC Product Class	II b
ALARIS Medical Systems at the address shown above hereby	
<i>declares that the products listed above and the attached Product Schedule conform to the relevant provisions of the EC Council Directive 93/42/EEC dated 14 June 1993 and are in accordance with Annex II Conformity Assessment Procedure and registered Quality System as verified by BSI (British Standards Institution), Notified Body No. 0086.</i>	
Signed: <i>C. Prisk</i>	Caroline Prisk
Date: <i>31/07/02</i>	Manager, Regulatory Affairs
<i>Signed as Agent for, and Designated Representative of, ALARIS Medical Systems</i>	
Declaration Reference: TF022	Declaration Date: 31 st July 2002

Disposal

The following statement is to be included in the manual:

The pump should be disposed of taking environmental factors into consideration. To ensure no risk or hazard remove the internal rechargeable battery and dispose of as outlined by the local country regulations. Do not send back to the manufacturer. All other components can be safely disposed of in the normal manner.

Service Contacts

The service contacts found on page 22 should be replaced with the following:

For service contact your local ALARIS Medical Systems® Affiliate Office or Distributor. ALARIS Medical Systems® Service Centre Addresses:

AE

ALARIS Medical Systems Middle East Office,
PO Box 5527,
Dubai, United Arab Emirates.
Tel: (971) 4 28 22 842
Fax: (971) 4 28 22 914

AU

ALARIS Medical Australia Pty Ltd,
3/167 Prospect Highway,
Seven Hills, NSW 2147,
Australia.
Tel: (61) 2 9838 0255
Fax: (61) 2 9674 4444

BE

ALARIS Medical Belgium B.V.,
Otto De Mentockplein 19,
1853 Strombeek - Bever,
Belgium.
Tel: (32) 2 263 09 75
Fax: (32) 2 267 99 21

CA

ALARIS Medical Canada, Ltd.
5975 Whittle Road,
Suite #120,
Mississauga, Ontario L4Z 3N1,
Canada.
Tel: (1) 905-507-1131
Fax: (1) 905-507-6664

CN

ALARIS Medical Systems Office,
Suite 401 No. 88 Chang Su Road,
Shanghai PC 200040,
China.
Tel: (56) 8621-62488591
Fax: (56) 8621-62482567

DE

ALARIS Medical Deutschland,
GmbH,
Pascalstr. 2,
52499 Baesweiler,
Deutschland.
Tel: (49) 2401 604 0
Fax: (49) 2401 604 121

ES

ALARIS Medical España, S.L.,
Avenida Valdelaparra 27,
Edificio Alcor,
28108 - Alcobendas, Madrid,
España
Tel: (34) 91 657 20 31
Fax: (34) 91 657 20 42

FR

ALARIS Medical France, S.A.,
95, rue Péreire,
78105 St Germain en Laye
Cedex.
France.
Tél: (33) 1 39 10 50 09 / 10
Fax: (33) 1 30 61 22 23

GB - Manufacturer's Address:

ALARIS Medical UK Ltd.,
The Crescent, Jays Close,
Basingstoke, Hampshire,
RG22 4BS, United Kingdom.
Tel: (44) 0800 389 6972
Fax: (44) 1256 388 411

HU

ALARIS Medical Systems Office
Döbrentei tér 1,
H - 1013 Budapest.
Magyarország.
Tel: (36) 12 14 2229
Fax: (36) 12 01 5987

IT

ALARIS Medical Italia S.P.A.
Via Ticino 4,
50019 Sesto Fiorentino,
Firenze, Italia.
Tél: (39) 055 34 00 22
Fax: (39) 055 34 00 25

NL

ALARIS Medical Holland, B.V.,
Kantorenpannd "Hoefse Wing",
Printerweg 5,
3821 AP Amersfoort.
Nederland
Tel: (31) 33 455 51 00
Fax: (31) 33 455 51 01

NO

ALARIS Medical Norway A/S
Hamang Terrasse 55,
PO Box 248,
N-1301 Sandvika, Norge.
Tel: (47) 67 57 58 50
Fax: (47) 67 57 58 60

NZ

ALARIS Medical NZ Ltd.,
Unit 14, 13 Highbrook Drive,
East Tamaki, Auckland,
New Zealand.
Tel: (64) 9 273 3901
Fax: (64) 9 273 3098

SE

ALARIS Medical Nordic, AB
Box 452,
191 24 Sollentuna
Sverige.
Tel: (46) 8 544 43 200
Fax: (46) 8 544 43 225

SG

ALARIS Medical Systems Office,
65 Chulia Street,
#40-04 OCBC Centre,
Singapore 049513.
Tel: (65) 5345351
Fax: (65) 5345516

US

ALARIS Medical Systems, Inc.
10221 Wateridge Circle
San Diego, CA 92121, USA.
Tel: (1) 800 854 7128
Fax: (1) 858 458 6179

ZA

ALARIS Medical S.A. (Pty) Ltd.,
Unit 2 Oude Molen Business Park,
Oude Molen Road, Ndabeni,
Cape Town 7405, South Africa.
Tel: (27) 0860 597 572
Fax: (27) 21 5107567

