

April 27, 2004

Medical Device Correction

Dear VariSource User:

The VariSource High Dose Rate Afterloader is subject to a labeling correction to clarify the proper use of the Emergency Retract Hand Wheel. This labeling correction applies to VariSource model 200, 200t, and ID series.

Excessive turning of the Emergency Retract Hand Wheel when the active wire is parked can cause the active wire to become dislodged from the shielding. The Emergency Retract Hand Wheel is to be used to retract the active wire only and does not control the dummy wire. Please see the attached Customer Technical Bulletin clarifying the Instructions For Use.

Please advise the appropriate personal working in your radiotherapy department of the content of this letter and attached instructions.

We sincerely apologize for any inconvenience and thank you in advance for your co-operation. If you require further clarification, please feel free to contact your local Varian Customer Support Representative.

Sincerely,



Mark H. Kattmann
Manager, Regulatory Affairs & Quality Systems

En: CTB-VS-366A

Title	Clarification on the use of the Emergency Retract Hand wheel to prevent accidental exposure.		
Date		Initial Release: 4/12/2004	

Est. labor hours	N/A	CTB	CTB-VS-366A
		DWG. No.	N/A

Purpose	To warn users of the VariSource 200 series and ID model afterloaders that excessive turning of the handwheel when the active wire is parked can cause the active wire to become dislodged from the shielding.
Effectivity	VariSource 200, 200t, ID
Prerequisites	

REV	DATE	STB	INT	DESCRIPTION OF CHANGE	FILE NAME
A	4/12/04	N/A	YI	Initial Release	CTB-VS-366A

Tools & Equip	N/A
Reference Documents	Series 200 High Dose Rate Remote Afterloader System User Manual. P/N: TM59781000 Series ID High Dose Rate Remote Afterloader System User Manual. P/N: TM59651000

Modification Overview	
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Kit Part Number	Description
N/A	

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Created By	DATE	MARKETING	DATE	REGULATORY	DATE	R&D	DATE	Operations	DATE	Tech Support	DATE	SHEET	
John Morrison												1 OF 5	
Checked By	DATE	Tim Clark / Ted Jackson / Dave Hall		Mark Katmann / Paul Vardon / Juergen Handke		Ted Jackson / Chris Heath / Gottfried Navratil		Mark Katmann / Ken Mills / Wolfgang Zindler		John Morrison		CTB-VS-366A	REV A

1. TITLE

Clarification on the use of the Emergency Retract Hand wheel to prevent accidental exposure.

2. **DO NOT TURN THE EMERGENCY RETRACT HANDWHEEL WHEN THE ACTIVE WIRE IS PARKED**

Please refer to chapter 6 of the Series 200 High Dose Rate Remote Afterloader System User Manual. P/N: TM59781000 or chapter 2 of the Series ID High Dose Rate Remote Afterloader System User Manual. P/N: TM59651000 as applicable, for a discussion of the use of the emergency retract handwheel. In addition, please be aware of the following warning:



Excessive turning of the emergency retract handwheel, after the active wire is parked, can cause it to move outside of the internal shielding. If use of the handwheel is necessary, stop turning it as soon the independent radiation monitor has stopped detecting radiation. It is predicted that the number of revolutions of the handwheel necessary to cause the wire to move from the shielded position is in excess of 20.

3. **THE DUMMY WIRE IS NOT CONNECTED TO THE EMERGENCY RETRACT HANDWHEEL**

The handwheel is not used for retracting the dummy wire. If the dummy wire becomes stuck outside the afterloader, you must manually clear the obstruction to return the dummy wire to its to parked position by creating a system reset (remove and reapply power to the Afterloader.)

Please advise the appropriate personal working in your radiotherapy department of the content of this letter.

The User Manuals, emergency procedures and the handwheel labeling will be updated to reflect this clarification at your next service visit.

We sincerely apologize for any inconvenience and thank you in advance for your co-operation. If you require further clarification, please feel free to contact your local Varian Customer Support Representative.

Page 2 OF 5	CTB-VS-366A	N/A DWG NO.	A REV	ATTENTION: This information is provided for use by Varian Medical Systems Customers and Service Representatives. Customers are assumed to have received the training recommended for the use of the indicated product Copyright © 2004, Varian Medical Systems, Inc. All rights reserved.
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Varian BrachyTherapy
700 Harris Street
Suite 109
Charlottesville, VA 22903

RECIEPT VERIFICATION CARD

Customer receipt verification:

Fill out the Receipt Verification Card and FAX or e-mail immediately To Varian
BrachyTherapy:
866-385-1322, or (949) 221-7631

CTB Number: CTB-VS-366A, Clarification on the use of the Emergency Retract
Handle wheel to prevent accidental exposure.

Product Code:

Serial Number:

Name of Institution:

Date of Receipt:

Customer Name:

Comments:

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Varian BrachyTherapy Technical Support Contacts

Toll Free Telephone Support

Country	Access number	Country	Access number	Country	Access number
Australia	1 800 144 130	Hungary	06 80013 318	Norway	800 16 327
Belgium	0800 74 248	Indonesia	001 803 0441 1109	Portugal	800 880 183
Canada	1 888 226 8633	Ireland	1 800 551 716	Singapore	800 44 11 100
Denmark	80 88 07 45	Israel	1 800 944 11 80	South Africa	0800 992 872
Finland	0800 11 68 92	Italy	800 790 535	Sweden	0200 21 45 08
France	0800 905 397	Japan	00531 78 22 21	Switzerland	0800 83 75 77
Germany	0800 182 6937	Luxembourg	0800 25 67	Taiwan	0080 04 40 99
Holland	0800 022 5072	Malaysia	1 800 808 605	UK	0800 068 06 88
Hong Kong	0800 96 21 42	New Zealand	0800 445 938	USA	1 800 360 7909 1 888 295 3199

In addition, toll free access using the AT&T International direct dialing network is available in over 150 countries. To access this number, dial first the AT&T access number in your area (for the access code in your area, see internet address: [http://www.att.com/business traveler/guides and access/international dialing.html](http://www.att.com/business%20traveler/guides%20and%20access/international%20dialing.html)). Then after hearing the AT&T signature noise, and, "Please enter the number you are calling", dial: **800-360-7909**

For countries not listed above or not in the AT&T International dialing network, Telephone Support may be obtained via the following numbers:

UK: +44 1293-601-327

USA: +1-434-979-1540

Our Applications Specialists can immediately return any calls received on these numbers.

Fax Support

Please fax your questions to BrachyTherapy Technical Support on:

UK: +44 1293-542-626

USA: +1-866-385-1322

+1-949-221-7631

e-Mail

To submit a support request or general inquiry, please compose an email with a blank subject line, to: brachyhelp@varian.com. Please indicate the name of your institution, your name and phone number, the product you are commenting on, and your system number (if known), as well as the description of the problem or question.

www

Note that Customer Technical Bulletins for Varian Medical Systems may be found on the internet at: <http://www.varian.com/onc/index.html>, under 'Support'. They are organized by year of issue and title.

Page 4 OF 5	CTB-VS-366A	N/A DWG NO.	A REV	<p>ATTENTION: This information is provided for use by Varian Medical Systems Customers and Service Representatives. Customers are assumed to have received the training recommended for the use of the indicated product</p> <p>Copyright © 2004, Varian Medical Systems, Inc. All rights reserved.</p>
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Varian Medical Systems - BrachyTherapy Offices**USA**

109-700 Harris Street
Charlottesville, VA 22903
Tel: 434-977-8495

United Kingdom

Gatwick Road
Crawley, Sussex, RH10-9RG
Tel: 44-1293-601219

Germany

Bergische Strasse 16
42781, Haan
Tel: 49-2129551-0

Varian Medical Systems - Oncology Systems Field Service Offices**United States Centers****Headquarters**

596 Alder Drive
Milpitas, CA 95035
Tel: 408-321-9400

Northeast

100 Walnut Avenue
Suite 201
Clark, NJ 07066
Tel: 732-381-5300

Southeast

2250 Newmarket Parkway
Suite 120
Marietta, GA 30067
Tel: 770-955-1775

Midwest

200 East Howard Street
Suite 202
Des Plaines, IL 60018
Tel: 847-296-0660

Southwest

403 International Pkwy
Suite 503
Richardson, TX 75081
Tel: 972-238-7017

West

650 East Parkridge Avenue
Suite 109
Corona, CA 92879-1092
Tel: 1-909-280-4406

International Centers**Australia**

Unit 6, 81 Frenchs Forest Road (East)
Frenchs Forest
New South Wales 2086
Tel: 61-2/9975-8830

Brazil

Rua Viradouro, 63-Conj. 131
Itaim Bibi 04538-110
Sao Paulo
Tel: 55-11/829-6705

Denmark

Lyskaer 9
DK-2730 Herlev
Tel: 45-44/500-100

France

C.A.A. Tolbiac-Maséna
5, rue Watt
75644 - Paris Cedex 13
Tel: 33-1-53.60.82.11

Germany

Alsfelder Strasse 6
D-64289 Darmstadt
Tel: 49-6151/7313-0

India

Ground Floor, Municipal MKT
behind Dinanath Mangeshkar Hall
Tejpal Road, Vile Parle (E)

Italy

Via Brescia 28D1
20063 Cernusco S/N (MI)
Italy
Tel: 39-02-921-351

Hong Kong

Room 1018-20, Tower A
Mandarin Plaza
14 Science Museum Road
Tsimshatsui East, Kowloon
Tel: 852/2724-2836

Netherlands

Nederland B.V
Kokermolen 2
3994 DH Houten
Netherlands

P.R China

76 Zhichun Road
Haidian District
Beijing PRC 100086
Tel: 86-10/6512-3667

Spain

Via dos Castillas, 33
Compl. Atica, Edif. 7 Bajo
28224 Pozuelo de Alarcon
Madrid, Spain
34 91 799-4530

Switzerland

Chollerstrasse 38
Postfach 3363
CH-6303 Zug
Tel: 41-41/749-8844

United Kingdom

Gatwick Road
Crawley, Sussex
RH10 2RG-U.K.
Tel: 44-1293/53 12 44

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CTB-VS-366A

Page

5 OF 5