

11.

ML092580179 Letter dated 8/26/2009 Varian Medical Systems, Inc.
Event 44774 with enclosures



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August 26, 2009

Document Control Desk
US Nuclear Regulatory Commission
11555 Rockville Pike
Rockville MD 20852

Re: Varian Medical Systems, Inc., Event 44774

Varian Medical Systems, Inc. is submitting this additional information related to Event 44774. All attached correspondence is company confidential.

Very truly yours,

A handwritten signature in black ink that reads "Richard G. Piccolo." The signature is written in a cursive style.

Richard G. Piccolo, CHP
Varian Brachytherapy RSO

- Encl:
- a. Amended root cause statement
 - b. Spreadsheet
 - c. VariSource HDR unit maintenance checklist – see 5.3
 - d. VariSource HDR unit excerpt from service manual – see marked pages
 - e. VariSource HDR unit service schedule – see marked pages
 - f. Tech Tip 01247C (current revision)

cc: Regional Administrator
USNRC Region I
475 Allentown Road
King of Prussia, PA 19406

**Report No. 4 to the NRC related to VariSource HDR source wire events
occurring in December 2008**

NRC Event 44774

This report is provided to state the root cause of the above events. It also discusses current events, actions going forward, a summary of the tracking and trending seen in the implementation of maintenance guidance provided in Tech Tip TT-VS-1247 (as revised) and the amendment of Varian's service license, No. 45-30957-01 to include the maintenance described in the Tech Tip.

1. Root cause

Varian Medical Systems, Inc. has concluded that the root cause for these events is that we did not properly evaluate the necessity to routinely clean specific components in the source wire path and include this action in the maintenance schedule.

Basis for root cause

In correspondence dated May 11, 2009, Varian provided the probable cause to these events in accordance with 10 CFR 30.50 (c)(2)(i) as the accumulation of debris in the small bore of the wedge block above the V-drive.

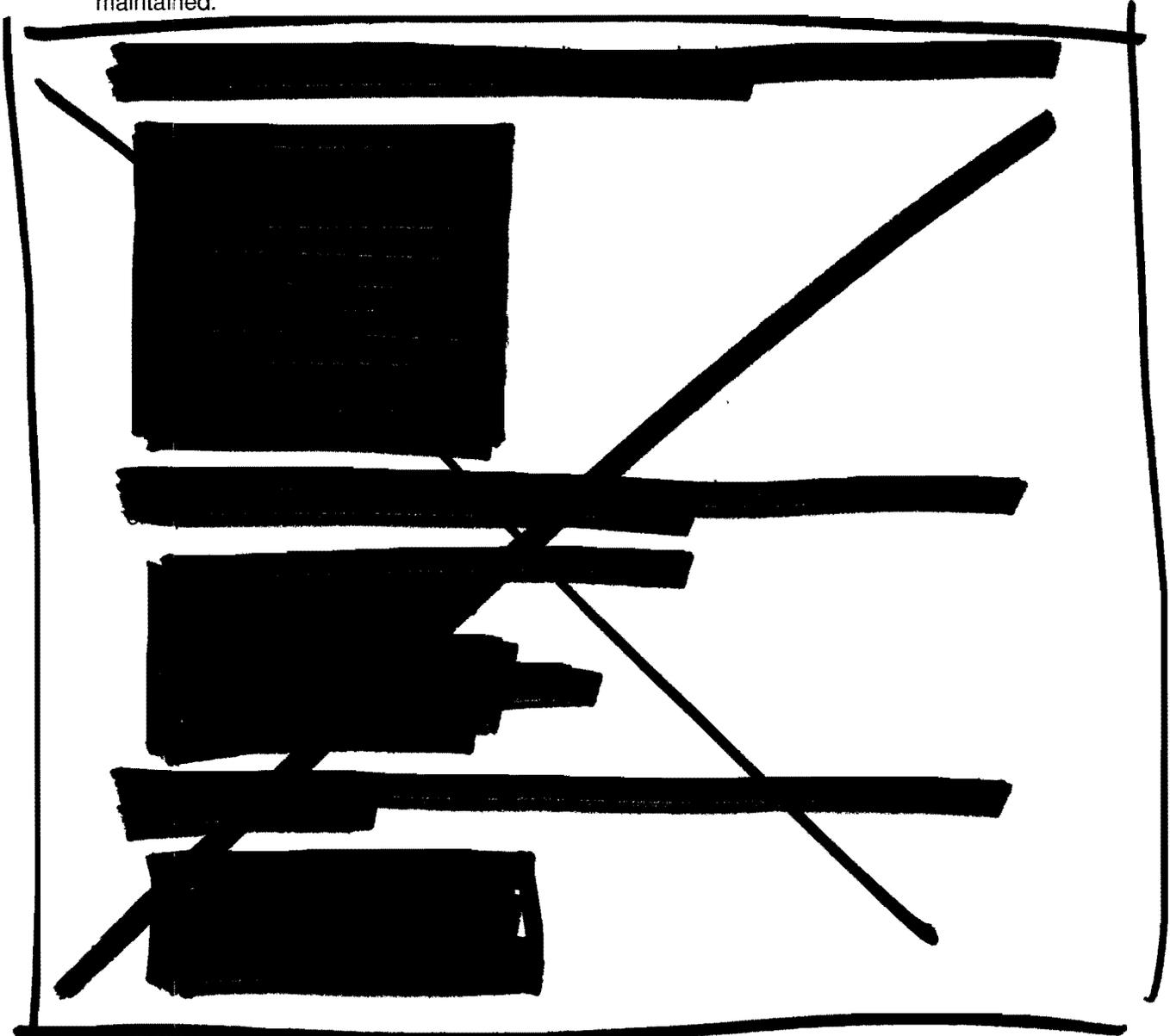
During the past 8 months Varian has conducted extensive analyses of the materials and components involved in the events where the source wire experienced restricted movement as it was retracting to the parked position in the tungsten shield. These are found in the submittals dated February 13, 2009 and May 11, 2009. There is no singular common element that ties the three events together. There may be a contributing probability from any of the following, but there is no evidence that any one is the root of the problem.

- a. [REDACTED]
- b. [REDACTED]
- c. The wedge block lot that is installed in the units affected
- d. Anodization process for the wedge block
- e. Applicator selection and use by the hospital
- f. Sterilization techniques used on applicators by the hospital
- g. Other activities and actions at the hospital site that may contribute
- h. Source wire manufacturing processes
- i. Source wire handling
- j. Use of thread locking compounds
- k. Material incompatibility
- l. Use of lubricants
- m. Contamination during packaging or transportation
- n. Relationship of error codes to the source wire events

The analysis of all data points to the need to include scheduled cleaning of specific components to mitigate the risk of a recurrence of this type of event.

Examples of current maintenance

There are many existing routine maintenance procedures that are conducted on varying schedules. The inclusion of additional maintenance activity as detailed in Tech Tip TT-VS-1247 (as revised) "Removing Dirt Build Up" addresses this important issue. Examples of current maintenance are given below and reflect the attention that Varian Medical Systems, Inc. has given to making sure that the HDR units are properly maintained.



2. Current conditions and actions going forward

Varian Medical Systems, Inc. notified the NRC as soon as we realized there was a problem. Our response to each event was immediate and radiation safety was the

highest priority. Source wires were recovered with low radiation doses to all participants and similarly, the cumulative dose was low.

Importantly, no patients were involved in any of the events, and each site was back up and running in short order.

Customer Technical Bulletin CTB-VS-640A, "Potential for a source wire path constriction inside the VariSource HDR afterloader" was issued on February 3, 2009 and sent to all VariSource users. The CTB is included in the HDR unit documentation that all new customers receive.

Varian promptly developed and implemented Tech Tip TT-VS-1247(as revised) and it has been in use for 8 months at the 28 sites of interest, and has been expanded to include the entire installed base of VariSource units as preventive maintenance that is conducted every fourth source exchange. Note that source exchanges are typically performed every 13 weeks, though a few sites have source exchanges every 17 weeks.

Each time the Tech Tip is executed at one of the 28 sites of interest, a spreadsheet report is completed that captures important information about what the service representative observed (discussed in Section 3 below). We are using this data in our continuing evaluation of these events to ensure the effectiveness of the Tech Tip. There has not been a recurrence and we believe the maintenance prescribed in the Tech Tip is appropriate.

The events have been thoroughly reviewed with all Field Service Representatives and they understand the importance and significance of the event. The most recent training was provided to all service representatives in May 2009.

Varian is continually developing new products and we confirm that the applicable Lessons Learned stated in the May 11, 2009 correspondence are of utmost importance in any new product line. These include:

- a. Ensure that all bores and constrictions the source wire passes through are appropriately sized.
- b. Evaluate areas where debris can collect and determine if the collection point is critical.
- c. Ensure that the emergency retract handle can retract the source to the unit's tungsten shield in all reasonable scenarios.
- d. Ensure that physical layout and access to important components is clear and unobstructed in keeping with ALARA.
- e. Ensure that the scheduled maintenance addresses the need to clean debris that may collect in specific components.

Following the three events and one precursor event we conducted exhaustive analyses of components and materials that were used in the manufacture and ongoing use of the HDR unit. We relied on in-house expertise as well as contracted outside engineering and analytical firms to provide expert independent analyses and opinions. Hospitals were

also contacted by Technical Support to investigate everything from cleaning fluids that were used by janitorial services to applicator sterilization techniques looking for any contributing factor.

3. Tracking and Trending - summary of experience in applying the Tech Tip maintenance procedure

The maintenance described in the Tech Tip is being performed at each source exchange at 28 sites of interest. The 28 sites were chosen based on the cluster of three events that had a source wire experience restricted movement on retraction, and one other event that may have been a pre-cursor event.

The data in the spreadsheet captures the following information:

- a. Site name and unit serial number
- b. Name of the service representative
- c. The number of times a position verification test was run
- d. Did the service representative notice unusual wire movement?
- e. The number of active wire cycles since the last source exchange
- f. Number of [REDACTED] (s) in the past 3 months
- g. The number and type of trouble and emergency service calls in the past 3 months
- h. Difficulty of cleaning the wedge block bore
- i. Amount of debris that has collected in the wedge block
- j. Location of the most abundant amount of debris
- k. Confirmation that the Tech Tip was properly executed
- l. Comments on the condition of the old source wire
- m. Comments on difficulty in loading the dummy wire
- n. Statement of whether or not the customer has noticed any unusual wire movement

The information in the spreadsheet provides a good description of what is being seen in areas of the source wire pathway. As of July 23, 2009 the data indicates:

- a. There have been no slippage errors at any of the sites
- b. Only one trouble call occurred and that was not related to these events.
- c. Active wire cycles range from a low of 55 to a high of 943 with no problems at any site
- d. Debris tends to collect most at the home switch and V-drive funnel. Both locations are subject to cleaning in accordance with the Tech Tip.
- e. All old source wires were visually normal after 3 months of use.
- f. The customers did not notice any unusual source wire or dummy wire movements.

4. License amendment to include Tech Tip

At the request of the NRC, we are amending our license to include the maintenance described in Tech Tip TT-VS-1247 (as revised) as part of routine unit maintenance. The maintenance will be performed at all VariSource sites in the U.S. during every 4th source exchange. The amendment request is being sent to USNRC Region I under separate cover.

Encl. B

Spreadsheet

VariSource 200/iX Series Maintenance Checklist

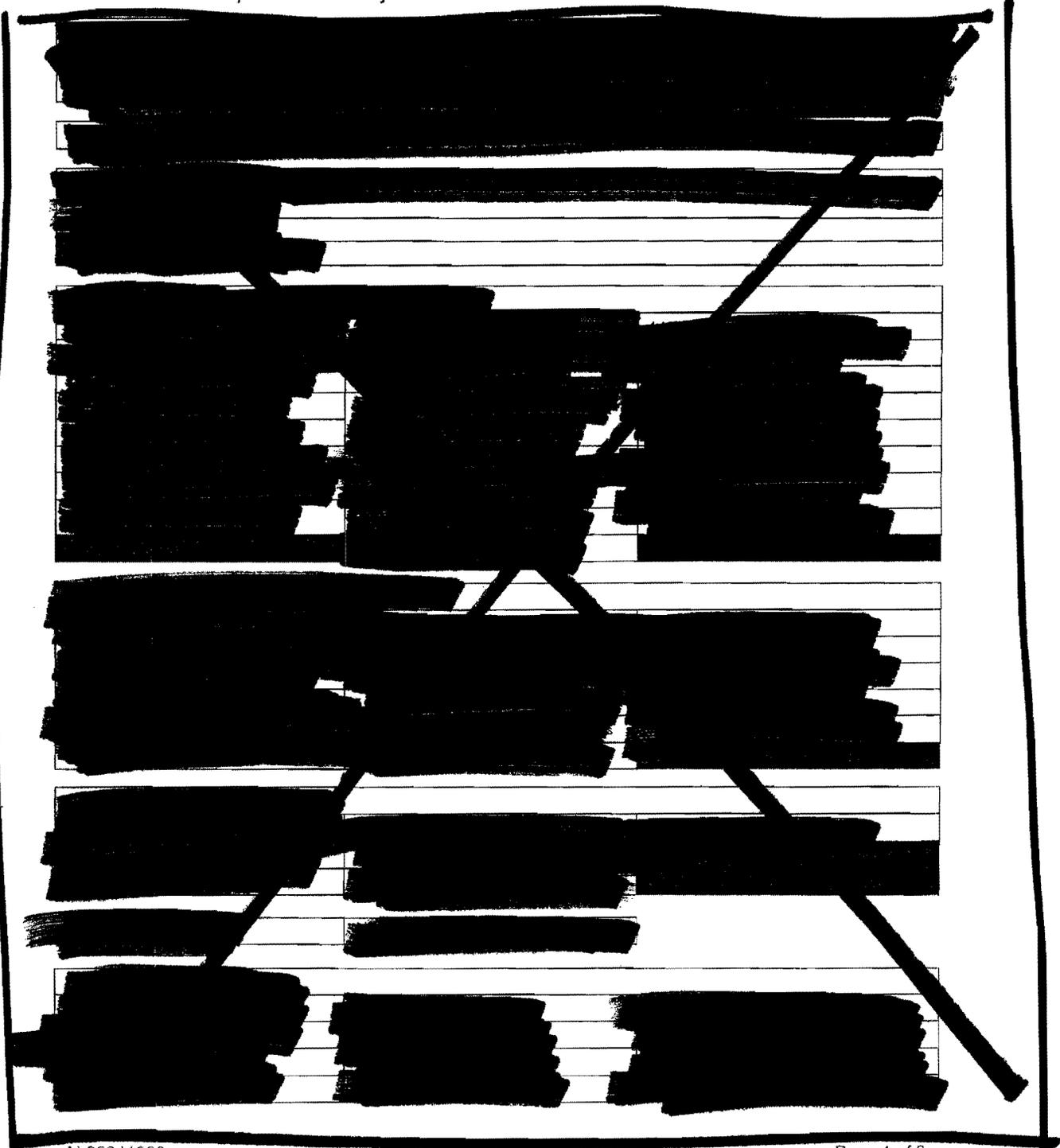
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ENGLISH

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Serial Number	Institution	Service Rep	Date	FSR No.

To be completed in conjunction with 200/iX Series Service Schedule



VariSource 200/iX Series Maintenance Checklist

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GERMAN

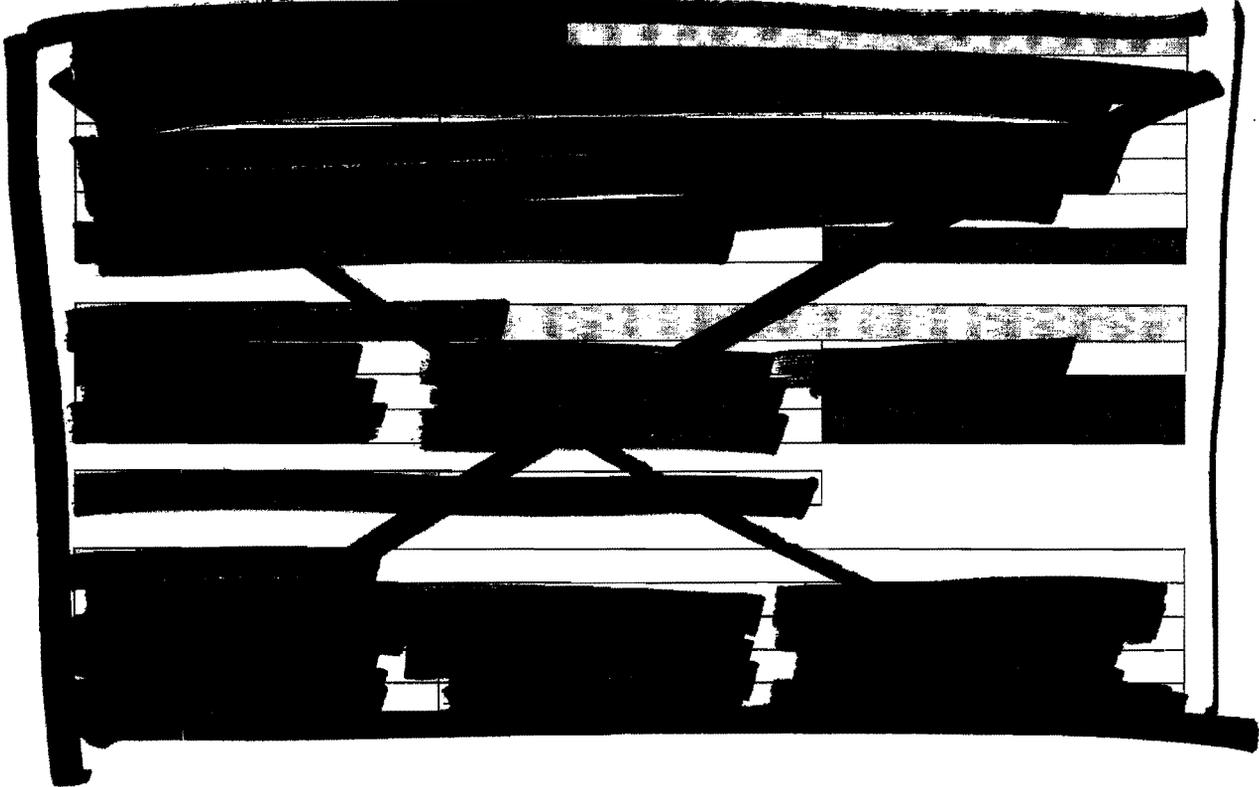
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Serial Number	Institution	Service Rep	Date	FSR No.

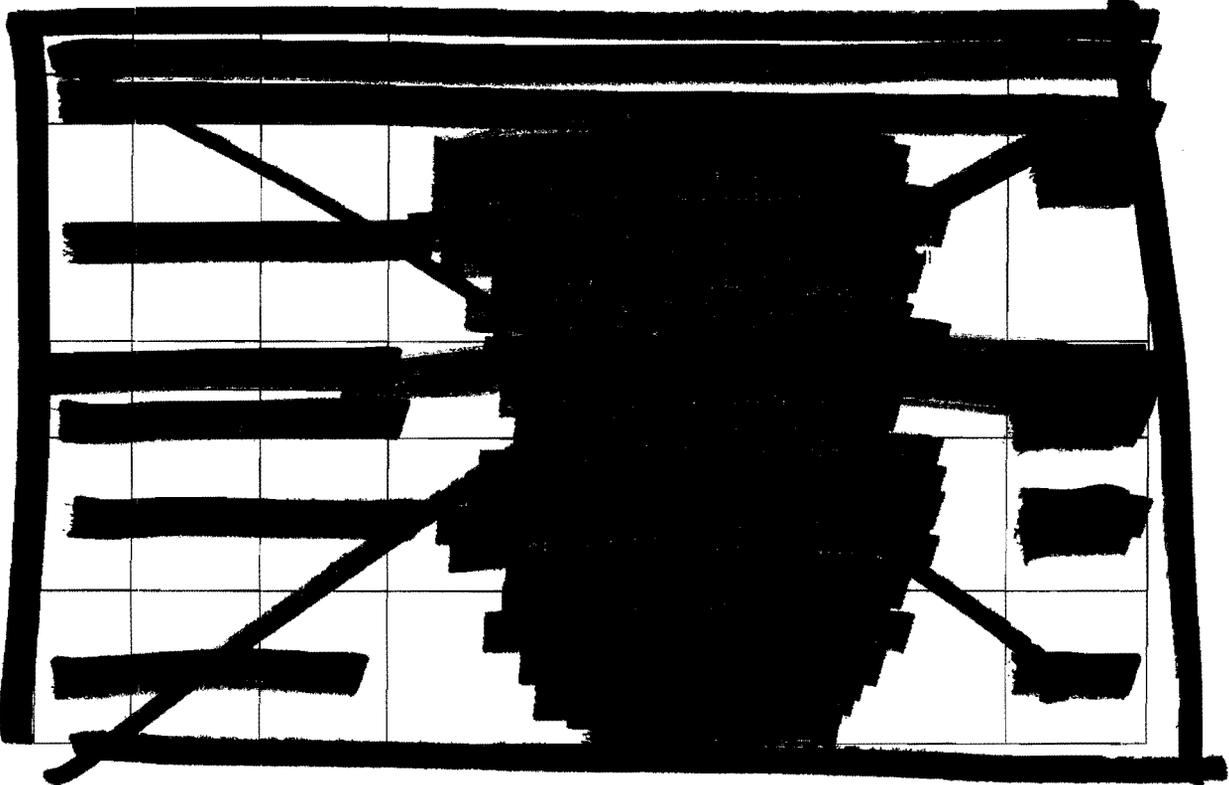
Checkliste Wartung gemäß 200/iX Series Service-Plan ausfüllen

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VariSource 200/iX Series Maintenance Checklist

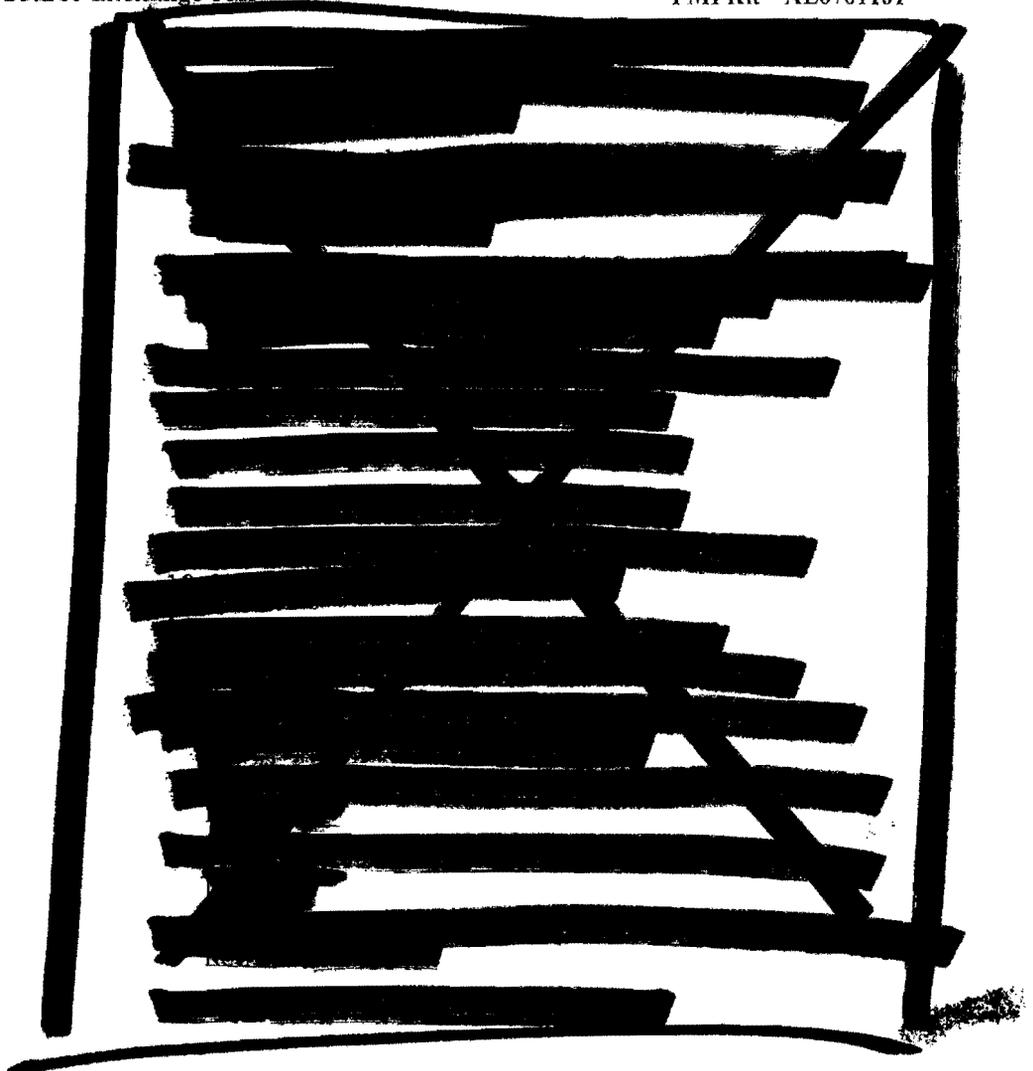


Amendment Record



7.3.2 4th Source Exchange PMI

PMI Kit - AL0701101



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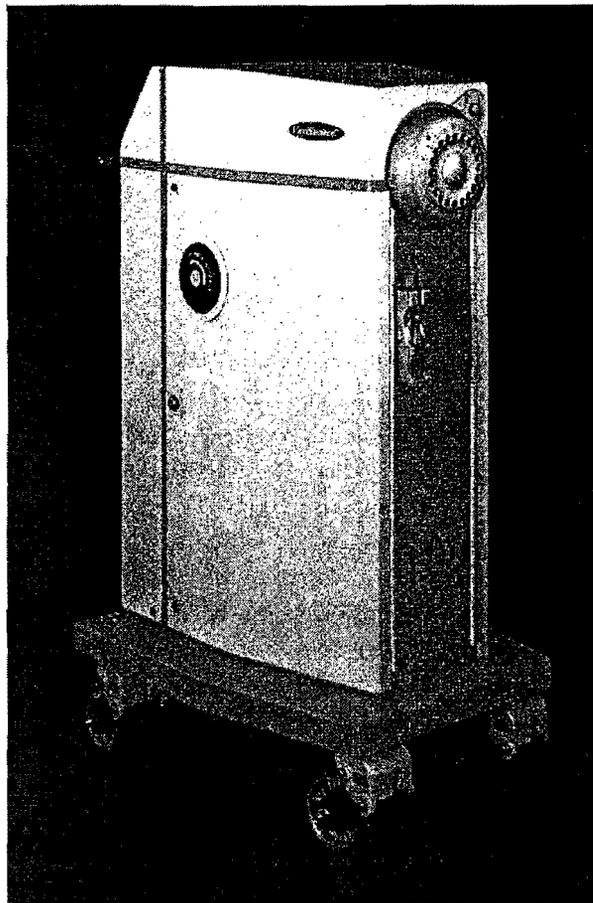
VariSource

Series 200/iX High Dose Rate Remote Afterloader

Service Manual

(Incorporating Transportable VariSource System 200t/iX(t))

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VARIAN
medical systems

P/N: AL25512000

Issue 2

May 2009

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Abstract

The *VariSource Service Manual* provides instructions for the 200/iX Series Remote Afterloader to be serviced in both its standard and Transportable configurations.



If you cannot find information in this manual, you can contact us as follows:



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BS ISO 13485:2003

Varian Medical Systems products are designed and manufactured in accordance with the requirements specified BS ISO 13485:2003 quality standard.



If the CE mark is affixed to the product, it indicates compliance with Council Directive 93/42/EEC of 14 June 1993, concerning Medical Devices.

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AMENDMENT RECORD

Issue	Incorp. by	Date	Manuals/Chapters affected	ECO No.
1	DS	09/2006	New Part Number Updated for iX system Updated error classes Chapter 7 - Inclusion of TT-VS-00869a, TT-VS-00827a	EC12719
2	DS	05/2009	Remove type on loading	12927

For Previous Amendment History please refer to the following documents:

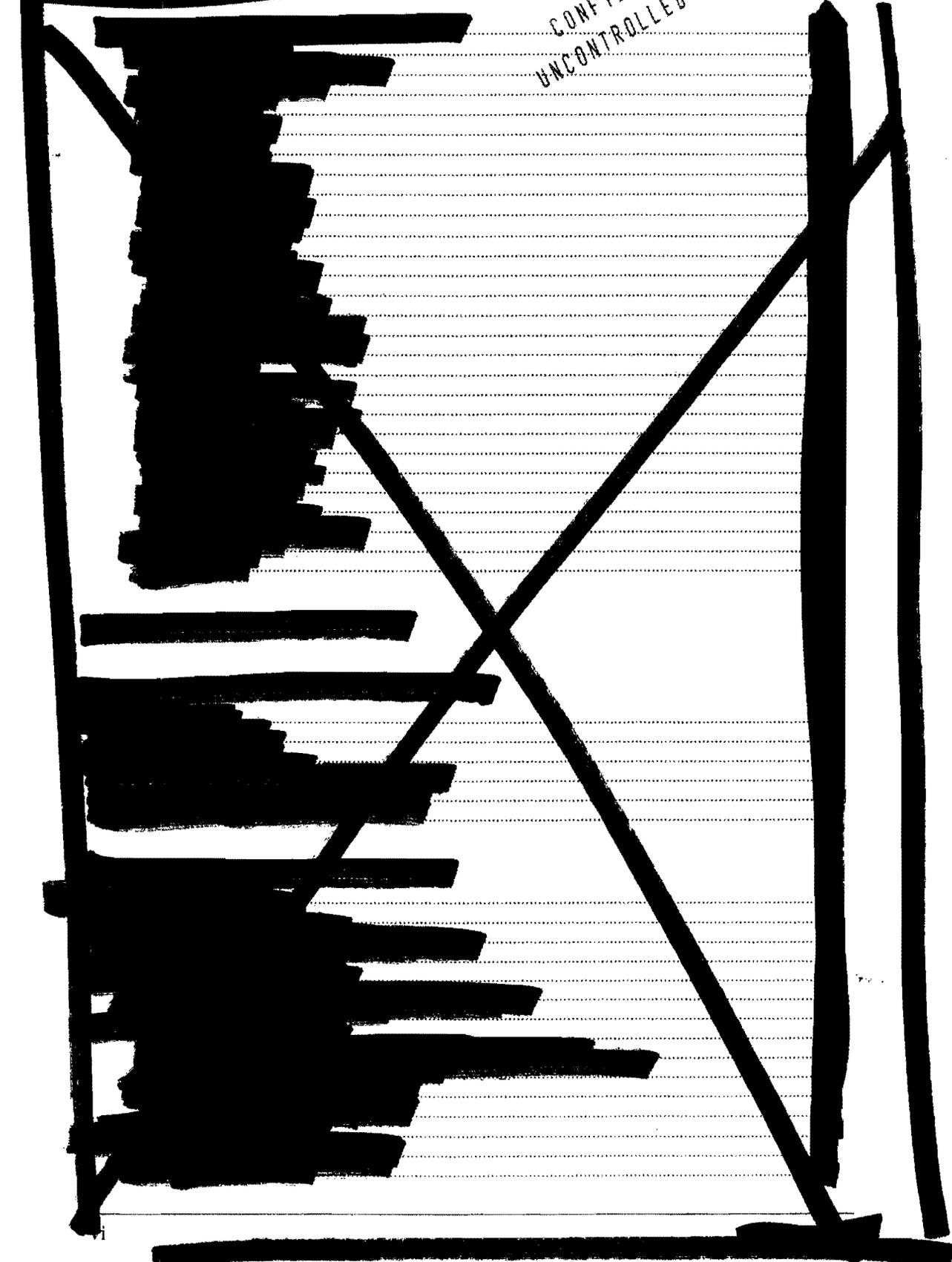
TM59782000 – 200 Series Service Manual Chapter 00
 TM59783000 – 200 Series Service Manual Chapter 01
 TM59784000 – 200 Series Service Manual Chapter 02
 TM59785000 – 200 Series Service Manual Chapter 03
 TM59786000 – 200 Series Service Manual Chapter 04
 TM59787000 – 200 Series Service Manual Chapter 05
 TM59788000 – 200 Series Service Manual Chapter 06
 TM59783000 – 200 Series Service Manual Chapter 07
 TM59790000 – 200 Series Service Manual Chapter 08
 TM59791000 – 200 Series Service Manual Chapter 09
 TM59792000 – 200 Series Service Manual Chapter 10
 TM59793000 – 200 Series Service Manual Chapter 11
 TM59794000 – 200 Series Service Manual Chapter 12
 TM59795000 – 200 Series Service Manual Chapter 13
 TM59796000 – 200 Series Service Manual Chapter 14

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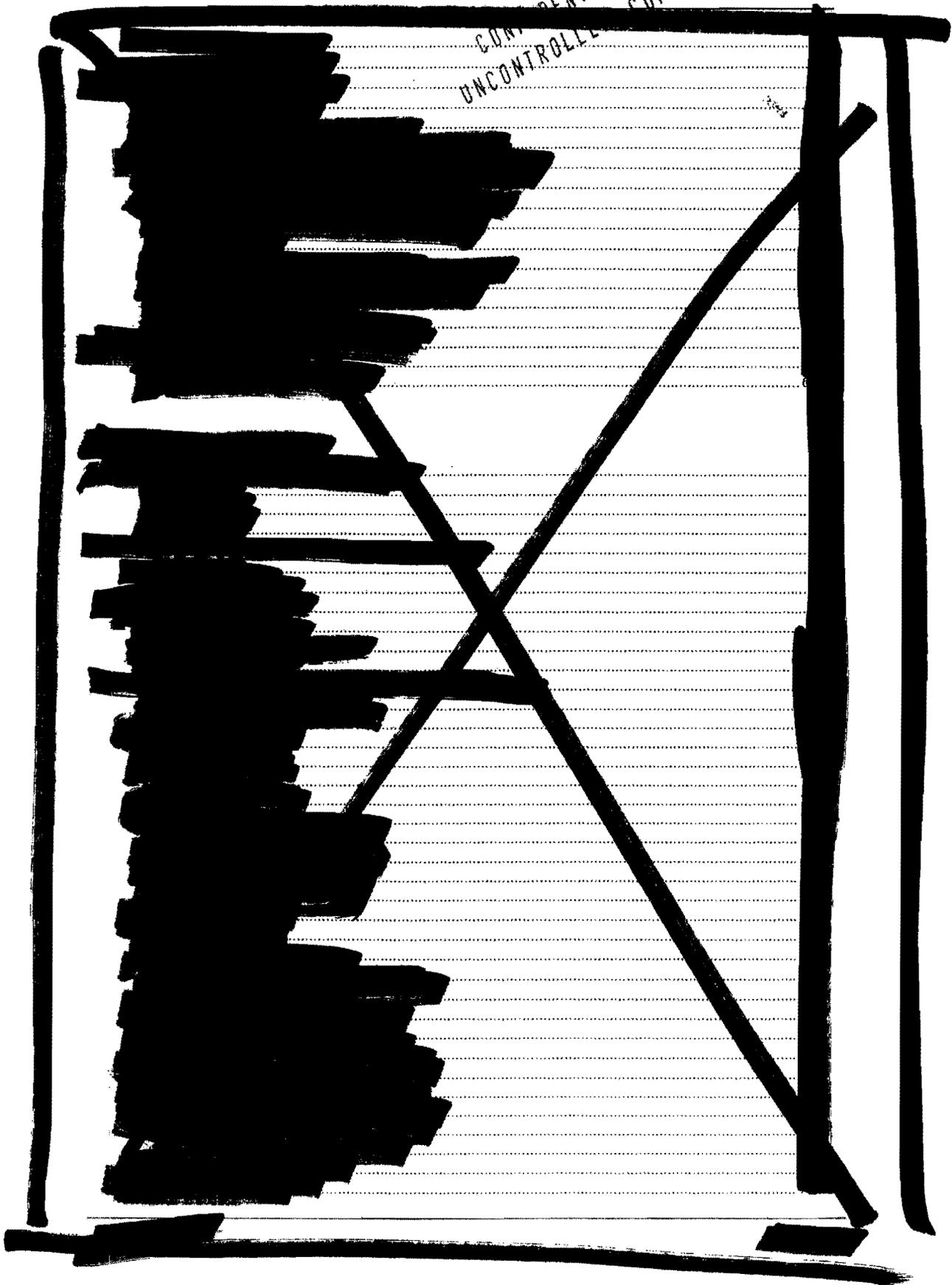
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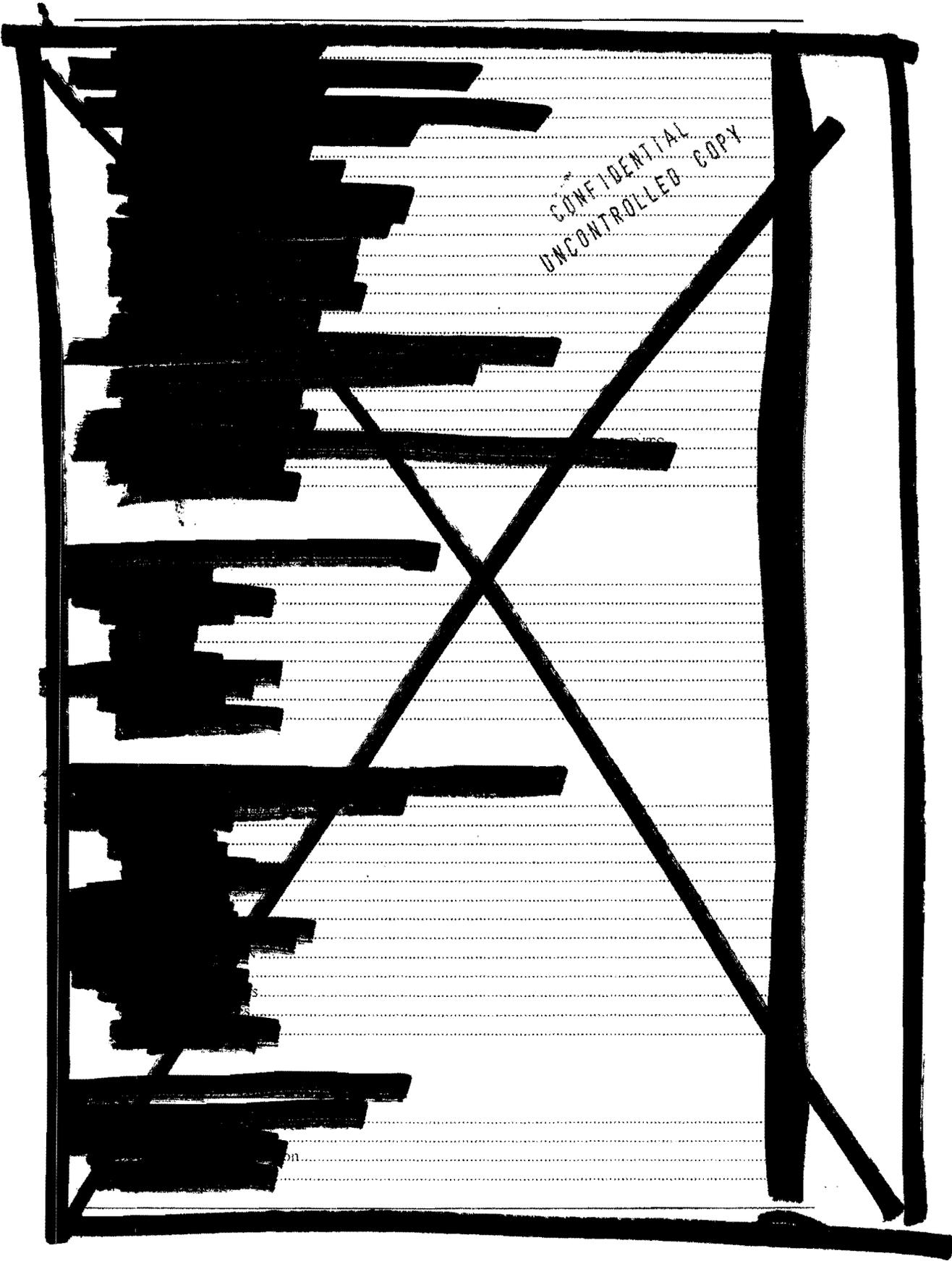
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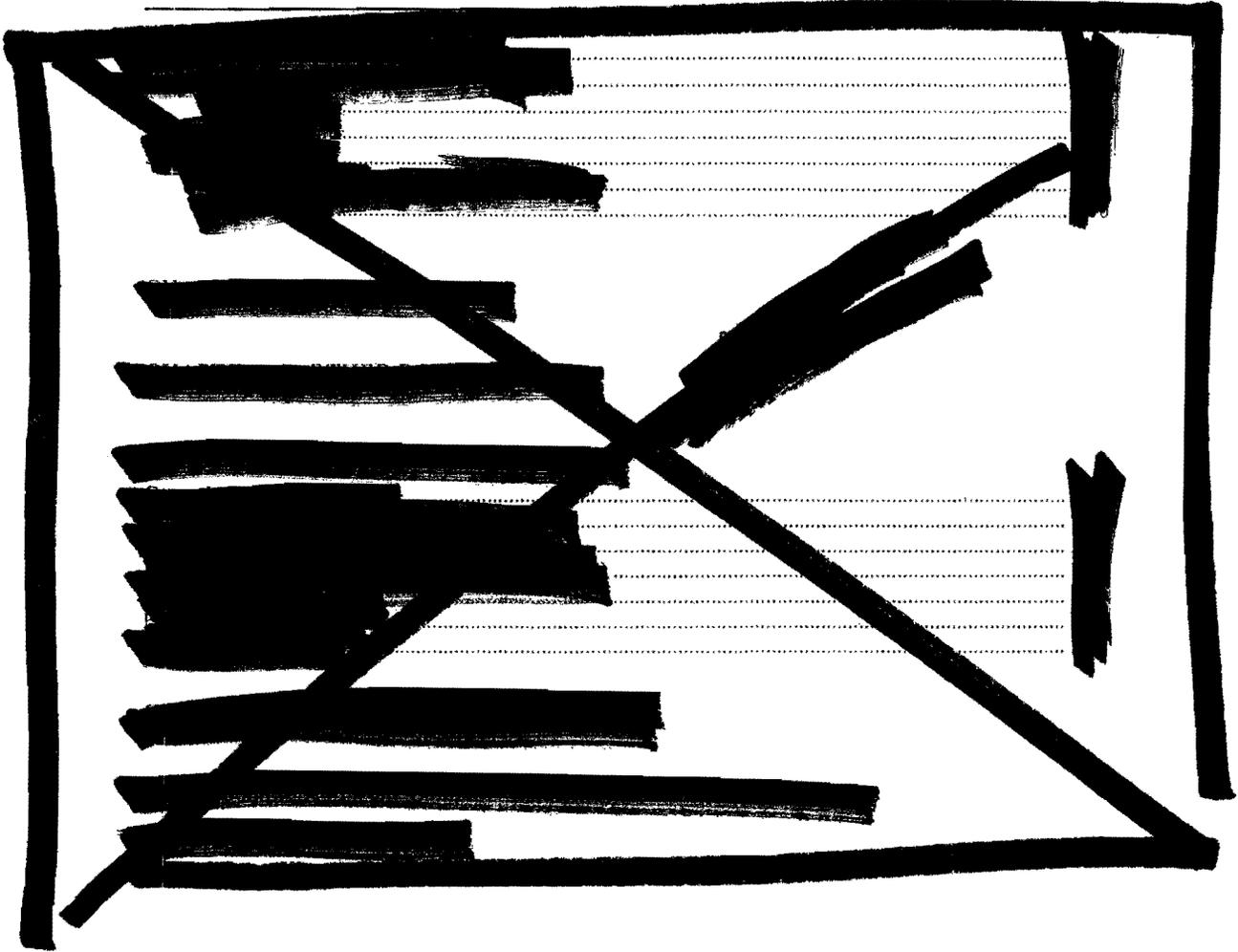


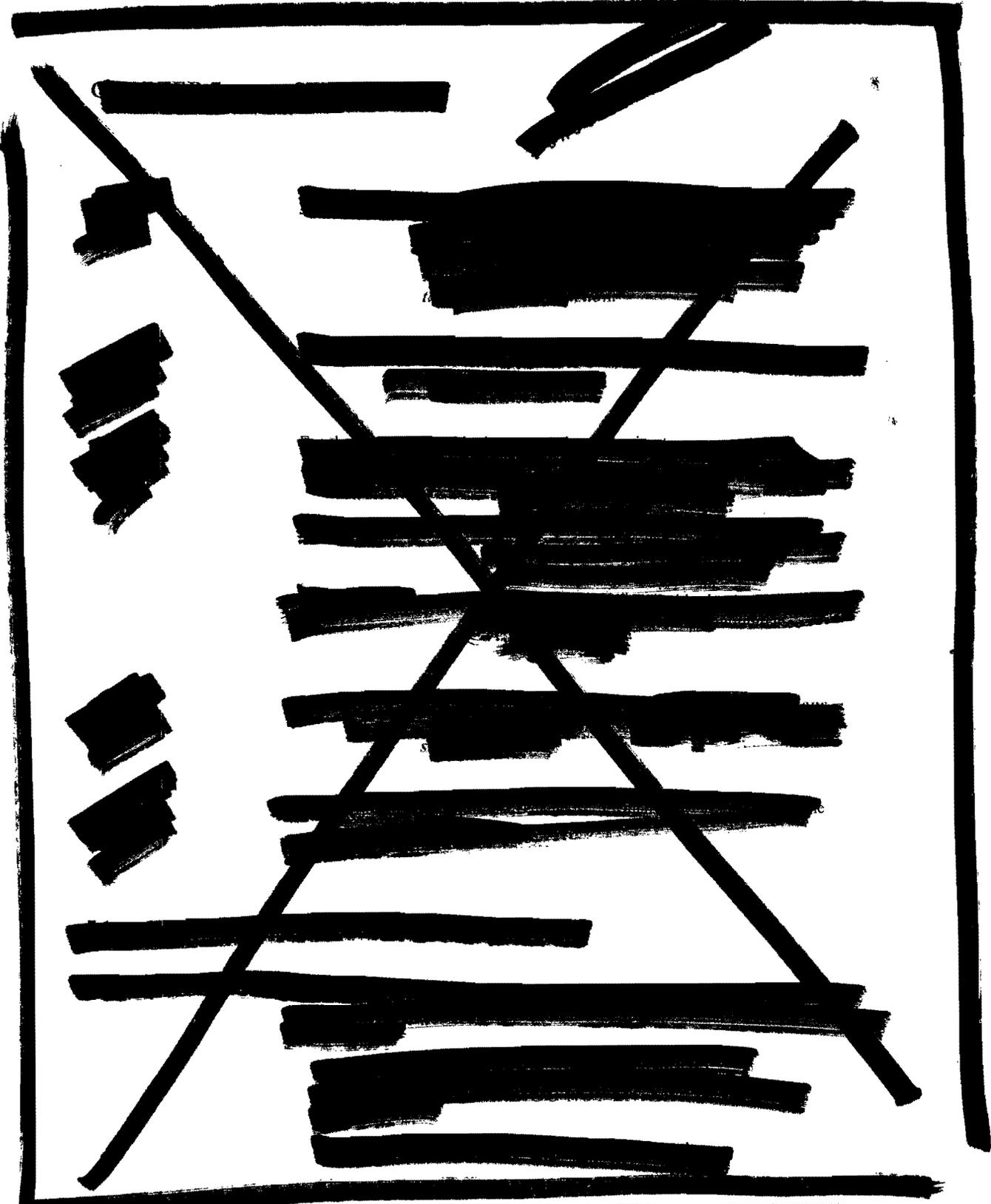
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Tech Tip Information

		Approved Release Date:	
Title/Subject:	Removing Dirt Build Up	TT Number:	TT-VS-01247
PC/EFF:	Product Code: H60, Product Name: VariSource H600430 to H600505 or as required		
Tools As Required:	[REDACTED]		
Reference Documents:	AL25512000 – VariSource Service Manual		

Document Information

REV	CREATION DATE	INT	DESCRIPTION OF CHANGE	File Name
A	Jan. 07, 2009	DS	Initial Release	TT-VS-01247a
B	Jan 14, 2009	DS	Extend Effectivity from 435 – 462 to 430 - 505	TT-VS-01247b
C	August 2009	DS	Changed wording to 'may' from 'can and will' added 'as required' statement to PC/EFF Added some dummy side funnels to be cleaned also	TT-VS-01247c

Part Number Information

Part Number	Description
N/A	

These notes are to provide guidance specifically with cleaning the wedge block on the input to the retract assembly and other areas where dirt can build up. Analysis of the material obtained from field systems has shown it to predominately consist of a mixture of PTFE and nitinol.

If you find a large amount of dirt or have problems during this process please contact PSE [REDACTED] immediately. Do NOT load a new source wire in these circumstances.

1. Areas to Clean

The following are areas within the system where dirt is known to collect.

- Turret
- Home Switch
- Wipe Block
- Funnels on the entry and exit of the V-drive (Active and Dummy)

[REDACTED] – note, recent experiences have shown this is a component where excessive build up of may cause the source wire to experience restricted movement. This in turn may result in the need to use the emergency handcrank to return the source to the parked and shielded position.

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AUTHOR	DATE	CHECKED BY ENGINEERING	DATE	PSE MANAGER	DATE	SHEET
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	1 OF 3
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	REVISION

2. Cleaning

2.1. Turret

Ensure the turret area particularly the brass ring and the flag of the Quick Connects are clear. Use an alcohol wipe

2.2. Home Switch

Dismantle the switch and clean out any of the dirt which has built up on any of the surfaces

2.3. Wipe Block

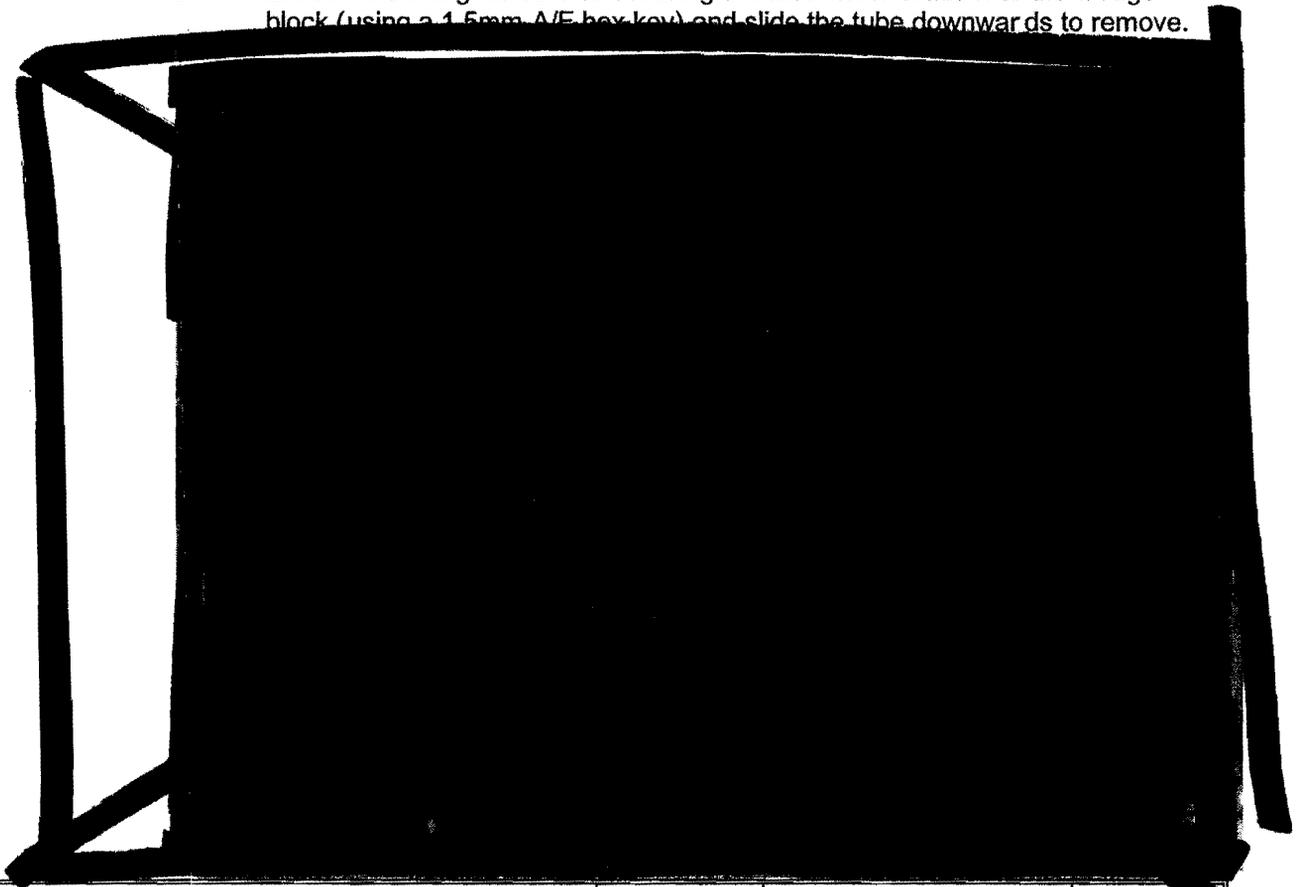
Simply open and clean

2.4. V-Drive Funnels (Active and Dummy)

Remove the V-drive and clean out the funnels on the entry and exit.

2.5. Active Wedge Block

1. Remove the V-drive
2. Loosen the two grub screws securing the tube which leads into the wedge block (using a 1.5mm A/E hex key) and slide the tube downwards to remove.



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C
Revision

TT-VS-012471247

SHEET
2 of 3

3. Note the required drill sizes at the end of this procedure, and where to get them (US only). DO NOT use any other drill sizes as this will cause damage to the components.
4. Remove the block in between the V-drive and wedge block to gain access to the underside of the hole. The one displayed in this picture shows the screw on the active side of the track plate. Some machines may have the screw through an identical block on the dummy side of the plate.
5. [REDACTED] st. Insert it into a pin chuck so that 27mm is visible from the end. This is so that the wheel and pinch rollers are not damaged by the drill going too far through the wedge block.
6. Gently use the drill to clean out any black material from beneath.
7. Swap to the large [REDACTED] eat.

This hole varies in size between [REDACTED] may not fit.



CAUTION: This process should NOT remove any metal, it is meant solely to remove any build up of debris.

2.6. Reassembly

When reassembling the tube into the wedge block, note that the distance extending underneath the mounting block (ie, the distance extending into the V-Drive funnel when fitted, shown on the diagram) should be 10.5mm.

All other components should be fitted in accordance with the service manual instructions.

3. Drill Details

As these drills may be difficult to source in the US we have found the following supplier:

[http://www.wttool.com/product-exec/product_id/22555/nm/Number Size Jobber Drills WT Import](http://www.wttool.com/product-exec/product_id/22555/nm/Number%20Size%20Jobber%20Drills%20WT%20Import)

Part No 0142-0346-[REDACTED]

Part No 0142-0341-[REDACTED]

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Service Schedule

VARISOURCE 200/iX Series Afterloader



VariSource 200/iX Service Schedule

The table content is almost entirely obscured by redaction. A diagonal line is drawn across the table from the top-left to the bottom-right. A rectangular box highlights a section of the table in the upper-left quadrant, which is also redacted.

VariSource 200/iX Service Schedule

The table content is almost entirely obscured by heavy black redaction marks. The grid structure is visible as a series of lines forming approximately 10 columns and 10 rows. A large rectangular area in the middle-left portion of the table is completely blacked out. The only legible text is the title 'VariSource 200/iX Service Schedule' at the top center.

VariSource 200/iX Service Schedule

The table content is almost entirely obscured by redaction. Two rectangular boxes are visible, one near the top and one in the middle, which likely represent redacted headers or specific data points. A large 'X' is drawn across the entire table area.

VariSource 200/iX Service Schedule

The table content is almost entirely obscured by heavy black redaction bars. Only the header and footer information are visible.

VariSource 200/iX Service Schedule

The table content is completely obscured by redaction bars. The structure of the table is not discernible from the image.

VariSource 200/iX Service Schedule

