

# Patient Safety Alert

**Veterans Health Administration Warning System  
Published by VA Central Office**

AL10-04

December 14, 2009

**Item:** **Possible blood contamination in hemodialysis machines**

**Specific Incident:** At one VAMC using B. Braun Dialog Plus Dialysis System machines blood contamination was detected inside multiple machines during scheduled maintenance. It was found that at this one dialysis site, staff purchased and used disposable disk filters (see Photographs 1c & 3) instead of the external transducer protector (see Photographs 1b & 4) for the arterial, venous and blood pump exit pressure monitoring lines. The disk filter, unlike the transducer protector, permits two-way flow and allowed passage of blood into the interior of the machine and contaminated a short portion of the internal tubing and the internal transducer protectors before being blocked by the internal transducer protector (see Photograph 5). Since normal practice is that only the external blood set tubing, including the external transducer protectors, are changed between patients, the possibility of cross-contamination between patients exists as blood from subsequent patients could contact the contaminated components of the machine's internal pressure tubing.

**NOTE: THIS PATIENT SAFETY ALERT APPLIES TO ALL HEMODIALYSIS SYSTEMS AND ACCESSORIES, REGARDLESS OF MANUFACTURER OR MODEL.**

**General Information:** The issue of blood contamination in dialysis machines was reported by the FDA in a Safety Alert in May 1999 (see Attachment 1) and subsequently in a Baxter Safety Alert in June 2004 involving Baxter Arena hemodialysis machines (see Attachment 2). Contamination issues are not limited to any one brand or model of dialysis equipment, but can occur with any dialysis machine. In addition, the FDA Safety Alert mentioned that the possibility of cross contamination exists even if the blood tubing set and external transducer protectors are changed appropriately. For example, if the external transducer protector is not securely attached to the machine, an air leak could allow blood to travel all the way up the external pressure monitoring tubing lines. While it is routine for some blood to travel part way up the external pressure monitoring lines during treatment, depending on the clinical situation with the patient's access line and patient activities such as coughing that change the pressure and thus the fluid levels in the lines (see Photograph 2). Conditions for dialysis operators to be aware of include fluctuation of fluid levels in the arterial drip chamber (see Photograph 2), pressure alarms, rapid and frequent changes in blood line pressures and/or wetted external transducer protectors. Contamination of the machine's interior

pressure lines and internal transducer protectors is possible even when the correct external transducer protectors are used if they have been compromised or breached. The external transducer protector could be wetted by saline inadvertently introduced into the pressure monitoring line during the priming process. Research in the literature about transmission of hepatitis C virus in dialysis units has identified wetting of the external transducer protectors and contamination of the pressure monitoring systems as potential sources (see References).

**Actions:**

1. By close of business (COB) December 15, 2009, the **Facility Director (or designee)** will ensure that all Dialysis staff and Biomedical Engineering staff are made aware of this Patient Safety Alert.
2. By COB December 16, 2009, **Dialysis Unit Managers (or designee)** will assure that their staff are:
  - a) using only the manufacturer's recommended external transducer protectors
  - b) monitoring the level of blood in the pressure monitoring lines to avoid contamination and breakthrough (sometimes referred to as strikethrough) of the external transducer protectors and examining the external transducer protectors at the end of the treatment.
  - c) immediately replacing any external transducer protector that comes into contact with blood during the treatment and inspect it .
  - d) If during, or at the conclusion of the treatment on that patient, blood is visible on the side of an external transducer protector that faces the machine:
    - i), remove the machine from service and
    - ii) report the contamination of external transducer protectors to Patient Safety and Biomedical Engineering or a qualified service vendor so that any internal contaminated items are replaced and disinfection of the pressure monitoring pathways is performed before the machine is used for another patient.
3. By COB December 18, 2009, the **Biomedical Engineering staff** shall have qualified personnel inspect all machines including the internal pressure tubing, feed through connectors and internal transducer protectors for signs of blood contamination (see Photograph 5).
4. **If internal contamination has occurred,**
  - a) By COB December 23, 2009, **Biomedical Engineering** shall have qualified personnel replace all affected parts and disinfect the surfaces and pressure monitoring pathways before the machine is returned to clinical use and
  - b) By COB December 23, 2009 **Facility Leadership** must prepare an Issue Brief describing the situation to be forwarded through their VISN Director to Central Office.

5) By COB December 28, 2009, the **Patient Safety Manager** shall document the status of this Patient Safety Alert on the VHA Hazardous Recalls/Alerts website.

**Attachments:**

1. FDA Safety Alert, May 1999
2. Baxter Safety Alert, June 2004
3. Photographs
  - 1) Dialysis machine with empty blood set [1a], depicting the correct external transducer protector [1b] & incorrect disk filter [1c]
  - 2) Dialysis machine in operation with blood in the blood set
  - 3) Incorrect 5 micron Disk Filter
  - 4) External transducer protector with protective cap
  - 5) Internal transducer protectors

**References:**

- a) Fabrizi F, Messa P, Martin P; Transmission of hepatitis C virus infection in hemodialysis: Current concepts. Intl J. Artificial Organs 2008 31(12): 1004-1016.
- b) Sartor C, Brunet P, Simon S, Tamalet C, Berland, Y, Drancourt M; Transmission of Hepatitis C Virus Between Hemodialysis patients Sharing the Same machine: Infection Control & Hosp Epidemiology 2004 25(7): 609-611.
- c) Delarocque-Astagneau E, Baffoy, N, Thiers V, Simon N, de Valk H, Laperche S, Courouce A, Astagneau P, Buisson C, Desenclos J; Outbreak of Hepatitis C Virus Infection in a Hemodialysis Unit: Potential Transmission by the Hemodialysis Machine? Infection Control & Hosp Epidemiology 2002 23(6): 328-334.

**Source:**

A VA Medical Center

**Contacts:**

Thomas Bauld PhD or Judith Anderson, MD, National Center for Patient Safety (NCPS) at (734) 930-5890

**Attachment 1: FDA Safety Alert May, 1999**

**FDA Safety Alert: Potential Cross-Contamination Linked to Hemodialysis Treatment**

**(You are encouraged to copy and distribute this Alert)**

May 1999

To: Hemodialysis Treatment Centers                      Hospital Renal Dialysis Director  
Hospital Risk Manager                                      VA Hospitals

Recent incidents of blood contamination of internal components of hemodialysis equipment at a number of treatment centers have raised concerns about patient safety. The cause of the contamination is still being determined and may include many factors, including faulty blood lines and transducer protectors. We will update you as to the cause of this problem as soon as we have the proper information

In the meantime, our principal concern is the possibility that the equipment cross-contamination with blood could permit the transfer of blood-borne pathogens from patient to patient. It is thus critically important that hemodialysis facilities be on the alert for signs of equipment contaminated by blood, and that they take corrective steps as necessary.

***BACKGROUND***

Although FDA has not received any MDR reports, we have learned that since December 1998, several incidents of blood contamination of equipment during hemodialysis treatments have occurred. During an ECRI investigation of these incidents, it was reported that staff members noticed fluctuation of fluid levels in the arterial drip chamber, rapid and frequent change in blood line pressures, and/or wetted transducer protectors. Some of these incidents resulted in breach of transducer protectors and subsequent contamination of the hemodialysis machine.

It is important to note that under normal conditions of daily use, such internal contamination with blood of the hemodialysis machine would not be readily evident to staff members. Under certain conditions, cross-contamination is possible despite the use of new blood tubing sets and external transducer protectors. Please also note that routine maintenance is not adequate to detect internal machine contamination.

***RECOMMENDATIONS***

FDA is continuing to work with industry, ECRI and the healthcare community to better characterize the problem and identify a solution. In the meantime, we recommend the following steps be taken to minimize risk:

- Immediately have qualified personnel inspect all machines, including the internal pressure tubing set and pressure sensing port, for possible blood contamination. If contamination has occurred, the machine must be disinfected before it is used again.

**Attachment 1: FDA Safety Alert May, 1999 (continued)**

- Always use an external transducer protector and utilize pressure alarm capabilities as indicated in the manufacturer's instructions.
- If the external transducer protector becomes wetted, replace it immediately and inspect it. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine and check for contamination (as identified in the first bullet) after the treatment is completed.
- If contamination has occurred, the machine must be taken out of service and disinfected before further use.
- Frequent blood line pressure alarms or frequent adjusting of blood drip chamber levels may be an indicator that this problem is occurring.

***REPORTING ADVERSE EVENTS TO FDA***

While these incidents, taken separately, might be characterized as isolated malfunctions, we believe that the number of incidents, and their public health significance, makes it imperative that all future incidents of equipment contamination be reported without delay. We therefore urge hemodialysis facilities to voluntarily report these and similar problems, so that we can quickly identify trends and expedite a solution strategy.

Submit voluntary reports directly to the FDA's voluntary reporting program, MedWatch; by telephone at (800) FDA-1088, by FAX at (800) FDA-0178, or by mail to: MedWatch, Food and Drug Administration (HFA-2), 5600 Fishers Lane, Rockville, MD 20857-9787.

***GETTING MORE INFORMATION***

Send questions about this Safety Alert to the Issues Management Staff, Office of Surveillance and Biometrics, HFZ-510, 1350 Piccard Drive, Rockville, Maryland, 20850, FAX 240-276-3356, or e-mail [phann@cdrh.fda.gov](mailto:phann@cdrh.fda.gov). You may photocopy or print this notice from the CDRH homepage at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm>.

Additionally, a voice mail message may be left at 240-276-3357 and your call will be returned as soon as possible. Future FDA Safety Alerts, Public Health Advisories, and other FDA postmarket safety notifications can be obtained by list server subscription via e-mail. To subscribe, visit:

[https://service.govdelivery.com/service/multi\\_subscribe.html](https://service.govdelivery.com/service/multi_subscribe.html)

Sincerely yours,

Elizabeth D. Jacobson, Ph.D.  
Acting Director, Center for Devices and  
Radiological Health

- Page Last Updated: 06/23/2009

Attachment 2: Baxter Safety Alert June, 2004

Baxter Healthcare Corporation  
Route 120 & Wilson Road  
Round Lake, Illinois 60073-0490

**Baxter**

**Safety Alert**

June 10, 2004

Dear Hemodialysis Unit Manager,

This communication is being forwarded to advise you that Baxter has received reports of blood contamination of the pressure monitoring line(s) of hemodialysis equipment at several Canadian treatment centers. While the root cause of the contamination is still being investigated, in the interest of patient safety, Baxter is recommending that all customers ensure that contamination assessment and disinfection procedures for the pressure monitoring line(s) found in your Service and Operator's Manual for your hemodialysis and hemofiltration hardware be followed.

In May 1999, the Food and Drug Administration (FDA) Center for Devices and Radiological Health issued a Safety Alert regarding similar incidents of blood contamination of internal components in hemodialysis equipment and the potential for transfer of blood-borne pathogens from patient to patient. In response to the FDA's communication, Baxter communicated this potential issue to all United States customers on June 25, 1999. We have attached, for your review, FDA's Safety Alert, "Potential Cross-Contamination Linked to Hemodialysis Treatment" dated May 1999 to this communication. Please ensure that this communication is shared with all operators and any satellite units and/or home patients you may have provided hemodialysis and hemofiltration products.

Baxter is fully committed to investigating the root cause of these reports and supporting our customers during this investigation.

Please complete the attached response form and return it via fax to Baxter using the fax number indicated on the form. The completed response form will verify your receipt of this letter, confirm training of all operators relative to this issue and give Baxter the information needed to provide you with appropriate follow-up information. **Please note that you are not being asked to return or remove your equipment from use.**

If you have any questions, please contact Baxter Instrument Services at 1-800-553-6898, select prompt 3, option 2, Monday through Friday, 8:30 AM to 5:00 PM EST.

Sincerely,

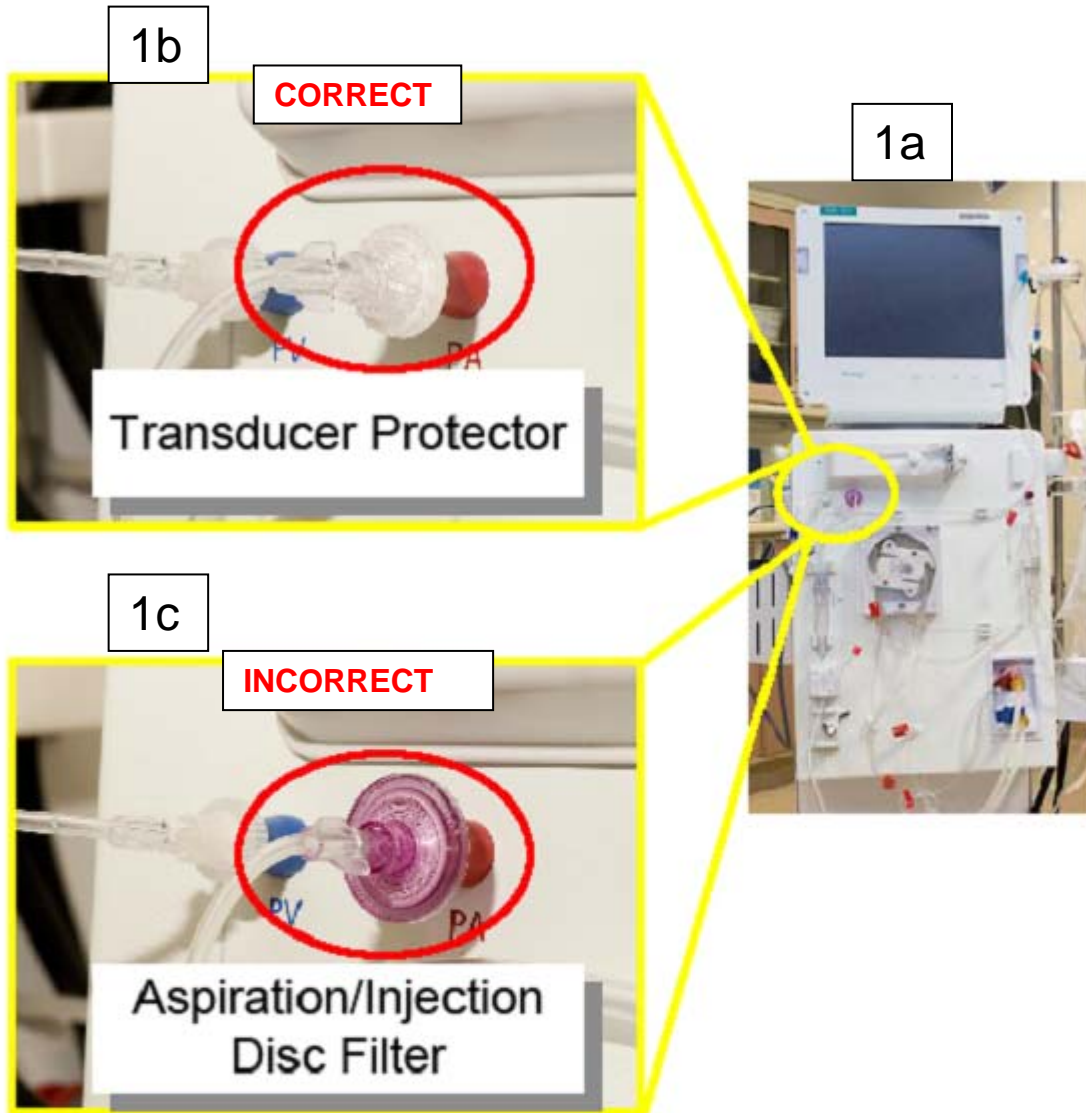


Rick Wilson, M.D.  
Vice President  
Global Regulatory Affairs and Medical Vigilance

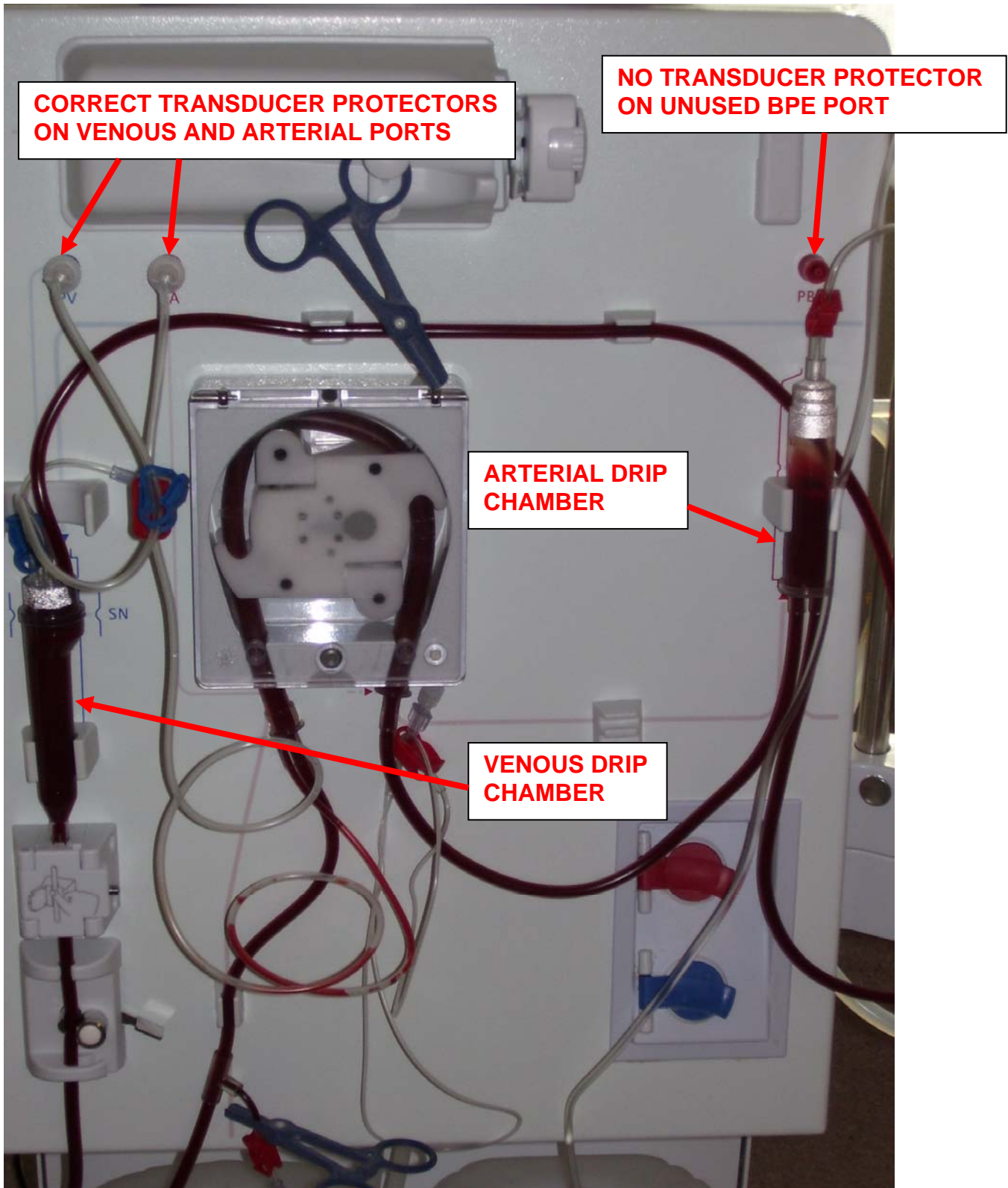
Attachment

Note: The cited Baxter Attachment is the FDA Safety Alert May 1999, our Attachment 1

**Photograph 1** Dialysis machine with empty blood set [1a], depicting the correct external transducer protector [1b] & incorrect disk filter [1c]



**Photograph 2** Dialysis machine in operation with blood in the blood set





Photograph 3 Incorrect 5 Micron Disk Filter



**Photograph 4** External transducer protector with protective cap



Photograph 5 – Internal transducer protectors

