Home Hemodialysis: Technical Assessments

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Disclosure Information

- No Financial relationship to disclose

Objectives

- Define Home Hemodialysis
- Learn about the most common equipment options available today
- Key Aspects of a Home Technical Assessment
- Understand the Regulations for Home Hemodialysis that effect the biomedical technician
- Review the most common challenges and investigate some options available to remedy some of these challenges

DTX19

What is Home Hemodialysis?

Three methods of Home Hemodialysis (HD) routinely available to home patients:

1. Conventional Home HD (treatments generally 3 to 4 hours, 3 days a week).
2. Short Daily Home HD (2-3 hours, 5-6 days/week).
3. Nocturnal Home HD (6-8 hours, 3 to 6 nights/week).

Transitional Care (Treatments done in centers/Home Programs) *New Trend*

Equipment Options

Standard Equipment options include:

1. Conventional water treatment components and single-pass (conventional) dialysis machine.
2. Integrated systems which used manufacturer packaged, bagged dialysate or which incorporated water treatment and dialysate preparation and delivery into one system.
3. Sorbent-based systems which utilized columns (cartridges) of chemicals to regenerate the used dialysate for recirculation through the dialyzer.

What Standards are we dealing with?

- CMS Regulations
- AAMI Standards
  - RD52 Annex C
- Manufacturer Instructions for Use
- Others??

CMS Regulations for Home Dialysis

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V-580

Condition-level noncompliance should be considered in, but not limited to, the following circumstances:

- Serious or pervasive problems with the oversight of care or provision of services for home dialysis patients which has or could impact the health and safety of those patients;
- Patients and/or helpers inadequately trained yet verified as competent in performing home dialysis procedures, resulting in poor clinical outcomes or adverse events;
- A pattern of failure to review clinical or technical lab reports and records; and
- Insufficient monitoring of the water treatment system for home hemodialysis.

Technical Regulation Highlights:

- V403 : *(b) Standard: Equipment maintenance.* The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

V581

- For all home dialysis patients of the certified ESRD facility whose treatments incorporate the use of a dialysis machine, CMS reimbursement rules require that there be one machine used exclusively for each individual patient's home dialysis treatments. The same dialysis machine must not be used for treatment of multiple home patients.

V585

- The "full range" of home dialysis techniques would include: Specific (step-by step) instructions on how to use the patient's prescribed dialysis equipment (e.g. hemodialysis machine and water treatment components, peritoneal dialysis cycler);
- Technical problems to be recognized, managed and reported would include power outages, failure of the PD cycler or HD machine, failure of water treatment components (e.g., chlorine/chloramine breakthrough), clotting of the hemodialysis circuit, dialyzer blood leaks, line disconnection, water supply problems or leaks, and problems with supply delivery.

V585

- According to AAMI, as part of their training for home hemodialysis, the patient/helper should be instructed in any water/dialysate sample collection or any water/dialysate quality tests that they will be expected to perform in their homes. AAMI also states that the patient/helper shall be trained how to perform the chlorine analysis and shall be trained regarding what action to take if chlorine is detected above the specified limit. Depending upon the chlorine test used, the patient/helper should be capable of distinguishing between different shades of pink or a digital meter should be used to indicate the chlorine concentration.

V588

- Whether the home dialysis training facility provides the patients' home dialysis equipment and supplies or the patient contracts with a DME supplier to obtain the equipment and supplies, the dialysis facility must provide all required support services, as listed in the following tags, either directly or by arrangement, to all home dialysis patients. A DME cannot provide home dialysis training or support services; these services must be provided by an ESRD facility certified for home training and support.

V593

- (v) Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation

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V594

- Testing of the water and dialysate system in accordance with—

(A) The recommendations specified in the manufacturers' instructions; and

(B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate.

V595

- The facility must meet testing and other requirements of ANSI/AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.

V596

- (C) The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if—
- (1) Analysis of the water and dialysate quality indicates contamination; or
- (2) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination.

V597

- (vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.

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V599

- (2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in § 414.330(a)(2) of this chapter.

Key Components of a Technical Home Assessment

- Utilities
  - Water Supply
  - Drain
  - Power
- Environment
- Equipment Selection

ANSI/AAMI RD52:2004, ***Dialysate for hemodialyzers ; Amendment 1—Annex C: Special considerations for home hemodialysis***

Water Supply/Quality

Water Pressure

Instructions for Use

	2018 AAMI Standard Limits	Units	11/7/2018 Results	Diff.
Aluminum	0 - 0.01	mg/L	**0.338**	NA
Antimony	0 - 0.006	mg/L	<0.005	NA
Arsenic	0 - 0.005	mg/L	<0.002	NA
Barium	0 - 0.1	mg/L	0.031	NA
Beryllium	0 - 0.0004	mg/L	<0.0004	NA
Cadmium	0 - 0.001	mg/L	<0.0010	NA
Calcium	0 - 2	mg/L	**19.01**	NA
Chromium	0 - 0.014	mg/L	<0.005	NA
Copper	0 - 0.1	mg/L	<0.005	NA
Fluoride	0 - 0.2	mg/L	**0.8**	NA
Lead	0 - 0.005	mg/L	<0.002	NA
Magnesium	0 - 4	mg/L	1.624	NA
Mercury	0 - 0.0002	mg/L	<0.0002	NA
Nitrate	0 - 2	mg/L	<0.20	NA
Potassium	0 - 8	mg/L	3.847	NA
Selenium	0 - 0.09	mg/L	<0.005	NA
Silver	0 - 0.005	mg/L	<0.003	NA
Sodium	0 - 70	mg/L	25.999	NA
Sulfate	0 - 100	mg/L	14.3	NA
Thallium	0 - 0.002	mg/L	<0.002	NA
Zinc	0 - 0.1	mg/L	<0.005	NA

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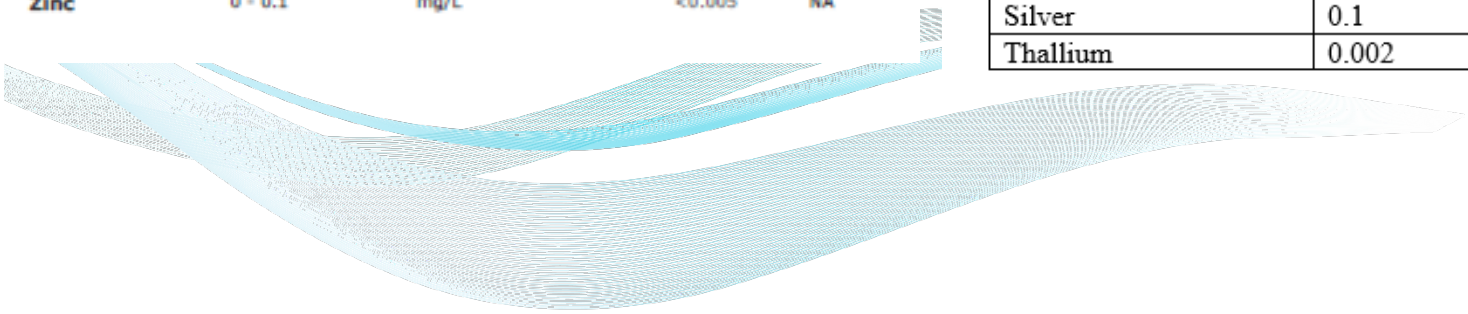
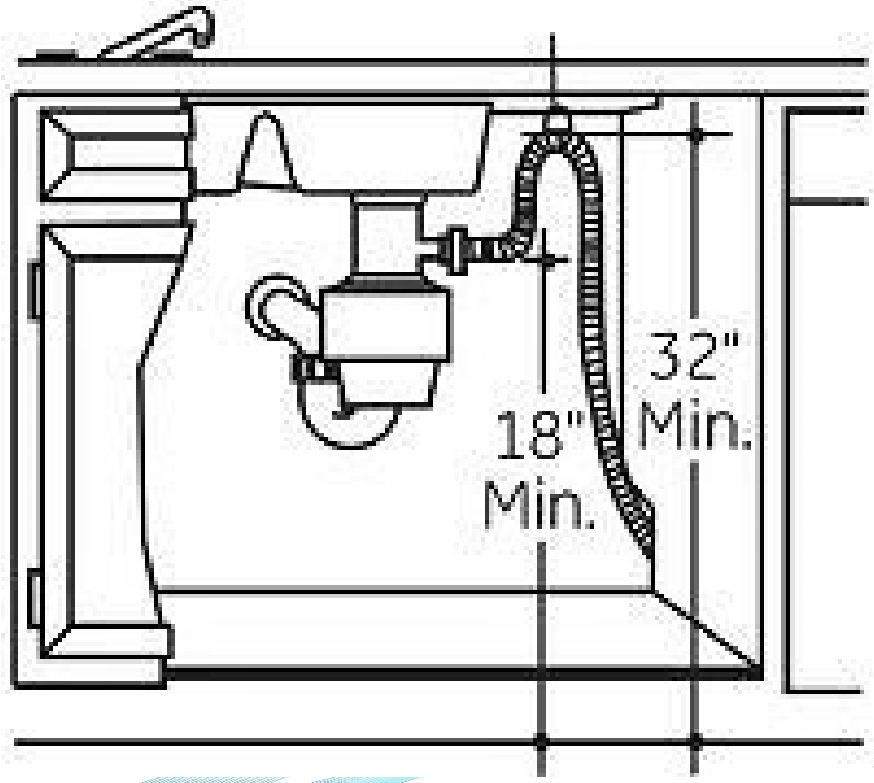
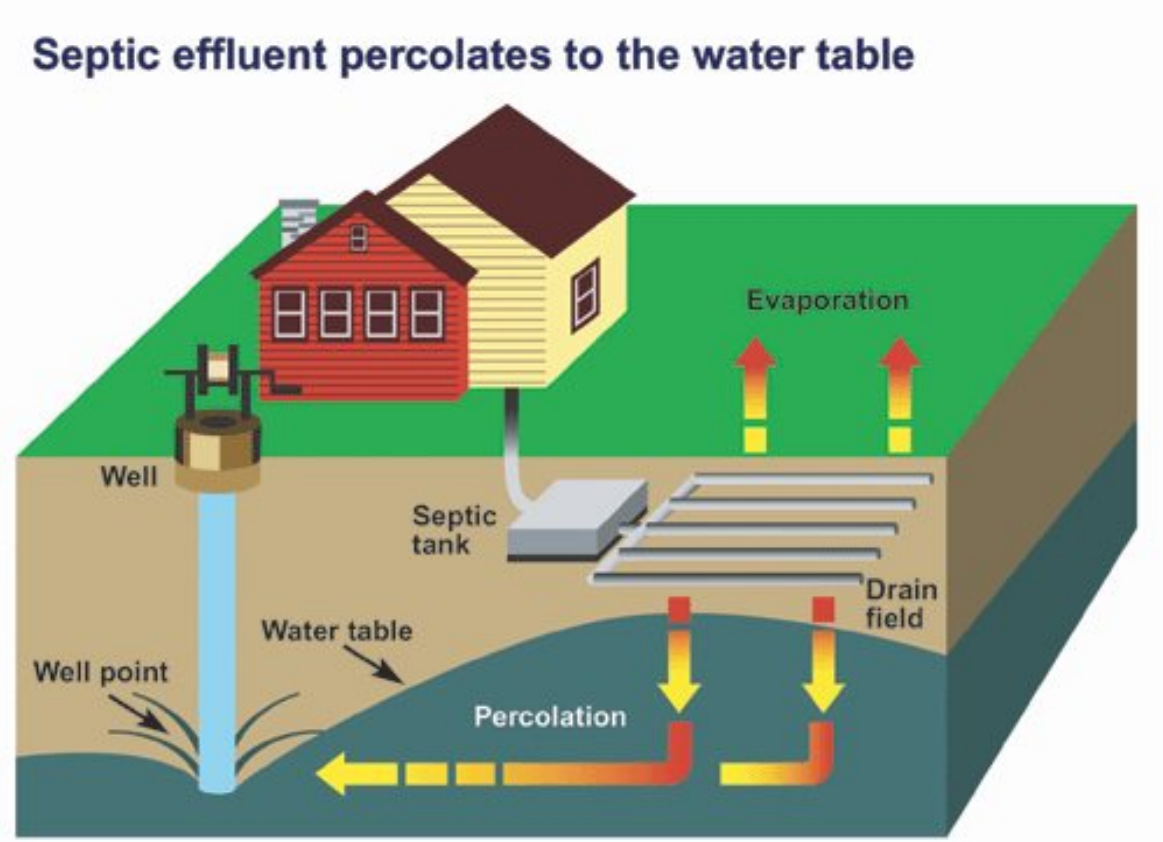
Contaminant	Source Water (mg/L)
Aluminum	0.2
Chloramines	4.0
Free Chlorine	4.0
Total Chlorine	4.0
Copper	1.3
Fluoride	4.0
Lead	0.015
Nitrates (as N)	10
Sulfate	250
Zinc	5
Calcium	No Limit
Magnesium	No Limit
Potassium	No Limit
Sodium	No Limit
Antimony	0.006
Arsenic	0.01
Barium	2
Beryllium	0.004
Cadmium	0.005
Chromium	0.1
Mercury	0.002
Selenium	0.05
Silver	0.1
Thallium	0.002



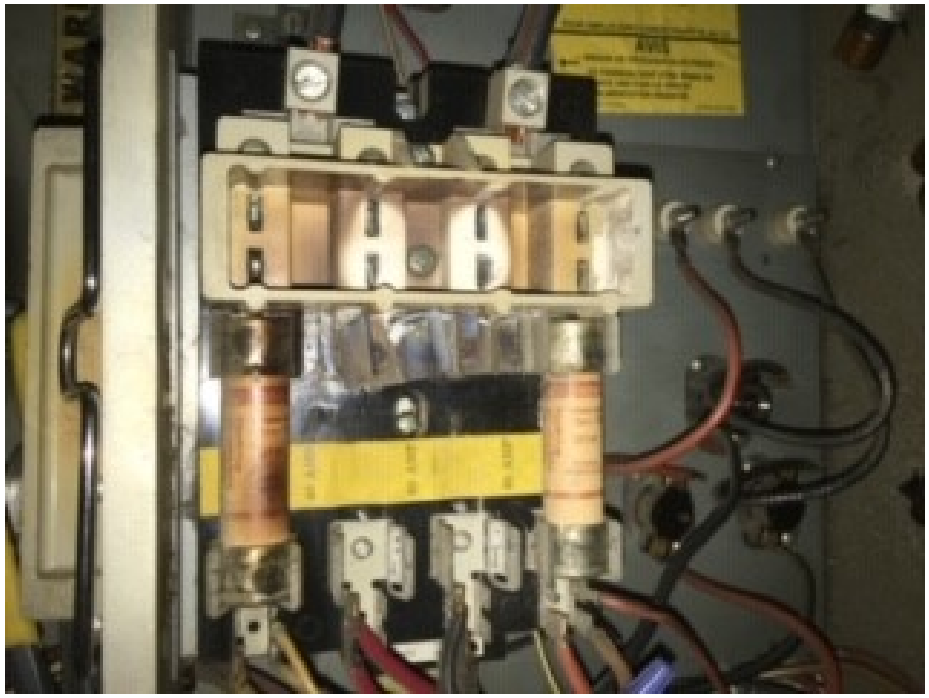
Drains



Septic


Septic effluent percolates to the water table
Evaporation
Well
Septic tank
Drain field
Water table
Well point
Percolation

Electrical



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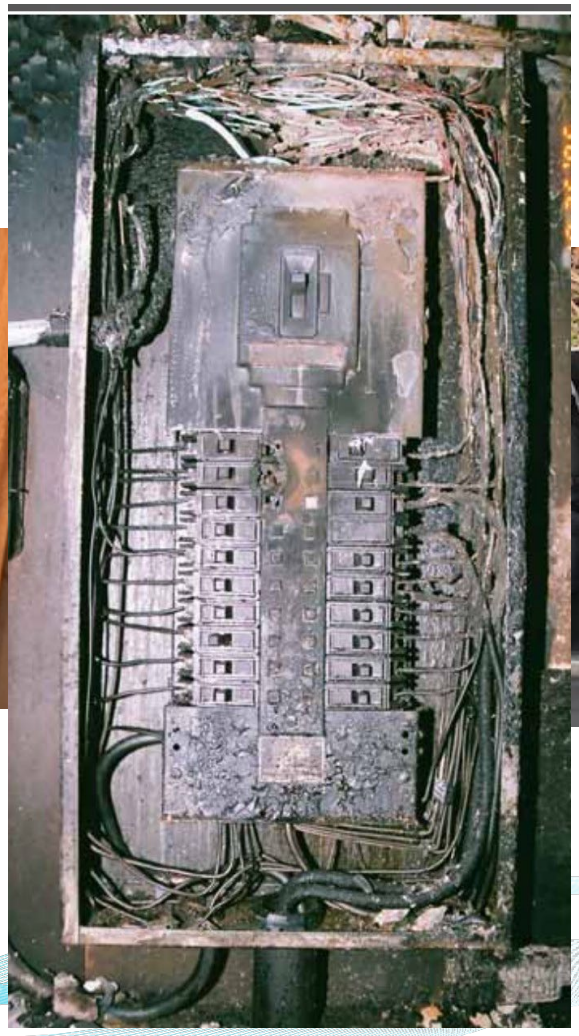
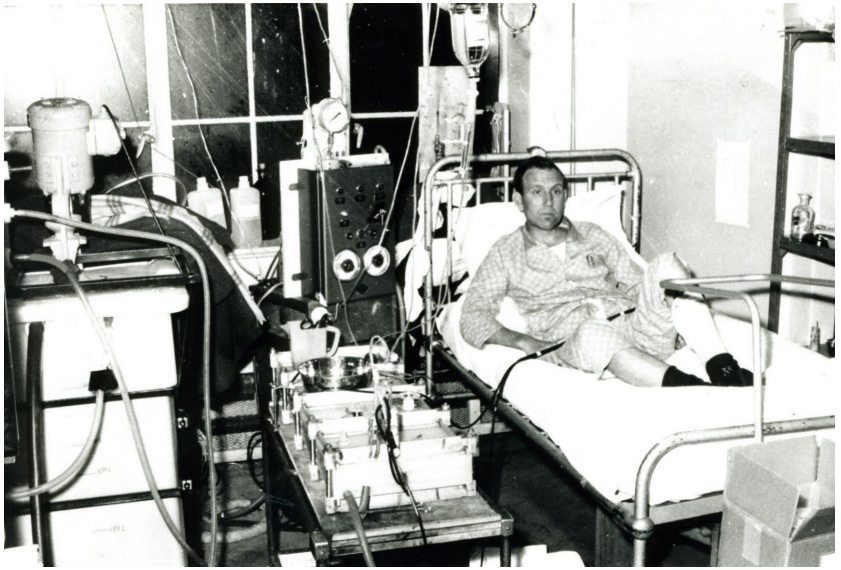


Environment

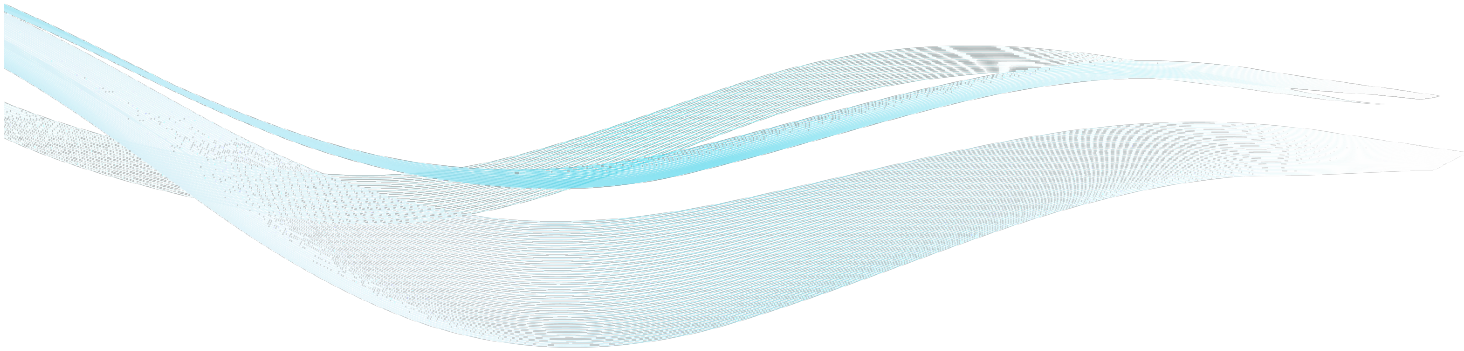
Treatment Area



Equipment Selection

Important to Remember

- Assess the home before you select the equipment
- Report findings to the Team
- Form a plan to execute needed modifications
- Use the expert for the task at hand
- Don't be afraid to STOP if needed



Common

Challenge #1

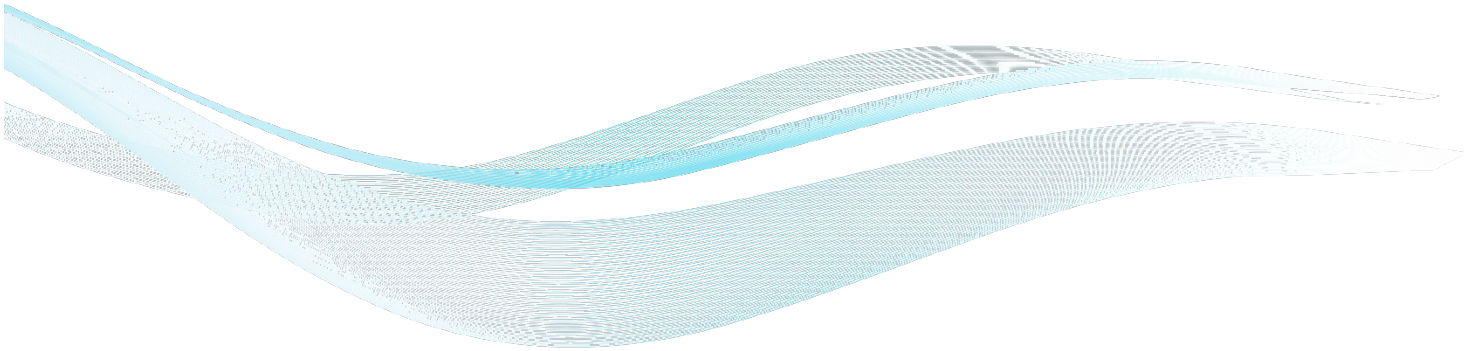
- A technical home assessment was performed at Mr. Smiths home. During the assessment, you noted the following concerns:
  - The patient has a Well and Septic system
  - The Patient's electrical panel is full and does not have room for more outlets

Challenge #2

- The Home Nurse calls the biomedical Technician and states that Mr. Jones has been training in the center and plans to go home next week. They need the home to be ready for Mr. Jones and his water system and dialysis machine by the end of this week.

Challenge #3

- A water analysis from the source (feed) water for the patient came back and the patient shows high levels of Nitrates above safe drinking water standards.



Challenge #4

- The patient has been trained to draw their own environmental samples. The results came back above action level last month for Chemical Analysis. There was no notification made until QAI.

Questions?

Supplementary Resources

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ANSI/AAMI RD52:2004, *Dialysate for hemodialyzers Amendment 1—Annex C: Special considerations for home hemodialysis*