

# Sodium Bicarbonate Mixing Considerations

Robert Berube

The proper mixing of bicarbonate concentrate is a top safety issue for every patient, at every facility, every day. Yet in spite of the universal importance of proper bicarbonate mixing, there are still questions and uncertainties about this critical task. In a straightforward and succinct way, this article covers not only the actual mixing of the bicarbonate, but also the labeling and testing required to make sure that the bicarbonate concentrate and the concentrate delivery system it passes through are safe for use with patients.

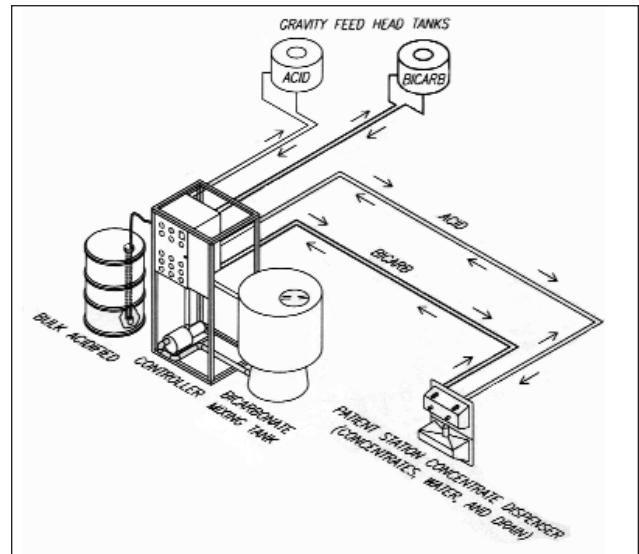
## Bicarbonate Concentrate Mixing and Distribution Systems

Mixing systems for sodium bicarbonate generally fall into three types. In small-scale or acute settings, concentrate is mixed in reusable jugs. Water is measured into the jug and the correct dosage of sodium bicarbonate is added to the water. The jug is closed and shaken until the bicarbonate has been dissolved. Larger-scale systems employ tanks equipped with mechanical mixing devices. The tank is filled with purified water (see side bar) to a pre-determined volume and sodium bicarbonate is added from packages of known weight, and then mixed until dissolved. Bicarbonate concentrate generators represent a third method of delivering concentrate to the dialysis machine. A cartridge with a pre-measured amount of sodium bicarbonate, sufficient for one treatment, is attached directly to the machine and a water line is attached to the cartridge. With this system, the bicarbonate concentrate is mixed at the point of use.

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The information in this article contains recommended policies and procedures compiled by Church & Dwight Co., Inc., based on a review of published literature relative to the mixing of bicarbonate concentrate for hemodialysis. The policies and procedures of your facility as well as manufacturers' directions for use may be different.



**Figure 1.** Gravity feed concentrate distribution system.

Mixing equipment in bulk systems is sized to ensure turnover of the solution, but with adequate control so that agitation and incorporation of air is not excessive. Surfaces of the mixing tank should be smooth and have sloping bottoms to ensure complete draining. Tanks should also be equipped with alarms and switches that help prevent damage from tank overflow or running pumps dry and disrupting dialysis procedures by running low on concentrate. Lids should be tight-fitting. Tanks must be fitted with sub-micron filter vents to prevent contamination as the liquid levels change and the tank “breathes.”

Distribution systems range from physically carrying a jug of concentrate to a dialysis machine to gravity-fed or pumped distribution loops feeding a series of machines. Individual jugs can make it easier to customize concentrate for dialysate preparation, but concentrate delivery systems can provide significant labor savings and faster turn-around. A diagram of a gravity feed distribution system is shown in Figure 1. With this type of system, a pump transfers the bicarbonate concentrate from the bicarbonate mixing tank to a separate overhead tank. The overhead tank then delivers the bicarbonate solution via gravity into the bicarbonate concentrate loop that supplies the dialysis

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stations. The loop design creates flow within the piping that aids in the reduction of bacteria colonization and prevents precipitation. The use of gravity to drive concentrate flow through the distribution loop depends on adequate change in elevation, a feature that may not be available in all settings. Air lock within the loop can be a source of problems, but generally can be minimized through proper design and procedures.

Pressure-driven systems use a pump rather than gravity to circulate the concentrate through the loops. Because a pump pulls the concentrate directly from the bicarbonate mixing tank and pressurizes the solution through the loops, there is no need for overhead tanks. The caveat with pressure-driven systems is that dialysis machines are designed to suction concentrate rather than have it delivered under pressure. To compensate, the inlet regulator for the dialysis machines must be set at a higher tolerance. Care must be taken in pumping system design to avoid excessive agitation and heat transfer.

All materials that come in contact with the water, concentrate, or dialysate in the clinic's mixing and dialysate delivery system must be:

- non-leaching—do not degrade the water by contributing metals or other contaminants
- corrosion-resistant—non-rusting or otherwise electrochemically degraded
- inert—stable and do not easily combine with other materials that could harm patients

Some materials that have these qualities are high-purity polyethylene plastics, polypropylene plastics, and high grades of stainless steel (e.g., 316L). Not only is it necessary to construct the mixing and delivery system out of these materials, it is extremely important to repair the system using only non-leaching, corrosion-resistant, inert tools, materials, and equipment, as well. Materials that can dissolve in acid (like aluminum) or rust (like iron) can contaminate concentrate and seriously injure or kill patients.

### Maintain the Proper Proportions of Bicarbonate and Water

Having the right proportions of bicarbonate and water is necessary for successful bicarbonate concentrate mixing. If there is too much bicarbonate—either because there is not enough water or too much bicarbonate was added—precipitation may occur. If there is too little bicarbonate—either because there is too much water or not enough bicarbonate was added—the dialysis treatment may be less effective. However, dynamic proportioning systems will cope with a slightly dilute concentrate, and the bicarbonate concentration of the final dialysate and the treatment efficacy will not be compromised.

To avoid problems caused by adding too much or too little bicarbonate, bicarbonate powder should be added to the mixing tank only after the water fill cycle is complete. Adding bicarbonate before or during water fill displaces mixing-tank water. The effect is a solution with a bicarbonate concentration higher than prescribed. To prevent this, the outside of the bicarbonate tank should be clearly marked with:

- final water level
- type of bicarbonate powder to use and its corresponding symbol
- level attained when bicarbonate powder is completely dissolved in the water

Incoming water temperature of 76 to 98.6 °F (24 to 37 °C) aids in the quick and thorough dissolution of the bicarbonate powder. Keep in mind that the addition of sodium bicarbonate to water results in cooling (exotherm) of the solution; if the starting water temperature is cool, the mixing time required will be extended. In certain climates it

### Water Quality is Critically Important

A particular area of concern associated with the use of bicarbonate concentrate is the potential for the proliferation of bacteria in liquid bicarbonate concentrate. It is important to understand that dry sodium bicarbonate for use in hemodialysis is not a significant source of microbiological contamination. Rather, it is the water that is mixed with the bicarbonate that is more likely to introduce bacteria.

Dialysis industry guidelines for preparing dialysate and concentrate require purified water that meets the standards set by the Association for Advancement of Medical Instrumentation (AAMI). The article “High quality dialysate: Its importance to the dialysis patient” by Hoenich, et al. in this publication provides more information about this important topic.

High water purity is extremely important, because a week's worth of treatment exposes dialysis patients to more than 25 times the amount of water most people drink in a week. In other words, three years on dialysis equals a lifetime of water for the average person. Moreover, the risk of harm from inadequately purified water is much greater to dialysis patients.

Because one bacterium can grow to thousands overnight, dialysis concentrate tanks should not be pre-filled with water which is left to stand overnight for use the next morning.

may be desirable to have the ability to temper the water to ensure operational consistency throughout the year.

## Avoid Over-Mixing

Over-mixing of bicarbonate can occur with concentrate delivery systems. Over-mixing must be avoided because it can cause the release of carbon dioxide (CO<sub>2</sub>), degradation of carbonic acid, and the formation of carbonate that causes an increase in pH and may result in calcium or magnesium precipitation within the dialysate flow path. Therefore, bicarbonate concentrate should not be mixed longer than the pre-set time unless a significant amount of undissolved bicarbonate powder remains on the tank bottom. Bicarbonate concentrate should never be mixed the night before and left to recirculate.

## Use Bicarbonate Concentrate Promptly

Because sodium bicarbonate solution can provide an excellent media to support bacterial growth, in general it is preferable to use it as soon after it has been prepared as is practically possible. Some systems allow for preparation of

## Label for Safety

Concentrate mixing and storage tanks and portable containers must be labeled with:

- Date and time of mixing (and for jug, time dispensed)
- Proportioning ratio with corresponding color and symbol (circle, square, triangle, diamond)
- Additives used, with amount and signature
- Comments about content
- Initials of person who prepared concentrate

- Do not mix concentrate from different batches
- Make sure the concentrate and the delivery system have the same proportioning ratio, with corresponding symbols
- Discard unused concentrate at the end of the day.

sodium bicarbonate concentrate several hours before use. Such practices emphasize the need for excellent cleaning and disinfection procedures, and vigilant monitoring of microbiological and endotoxin limits that can indicate the development of biofilms.



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## Sodium Bicarbonate Mixing Considerations

Before each patient shift, it is important to check for degradation of the bicarbonate solution by performing all manufacturer-suggested and facility validated quality tests on both the concentrate and dialysate. Generally conductivity, specific gravity, and pH are used to assure product consistency.

### Test Accurately and Consistently

There is a wide range of tests that must be performed on a regular basis to assure concentrate and dialysate quality as well as patient well-being. Some tests must be performed before each patient treatment, others daily, and some on a weekly or monthly basis. Manufacturer testing guidelines for each piece of equipment should be followed accurately and consistently. In addition, to prevent serious patient consequences, AAMI standards for a wide variety of contaminants must be adhered to (see Table 1). Among the most common tests are for conductivity, pH, bacteria, endotoxin, chemical elements, and disinfectant residue.

<b>Contaminant</b>	<b>Maximum Concentration (mg/L)</b>
Calcium	2 (0.1 mEq/L)
Magnesium	4 (0.3 mEq/L)
Potassium	8 (0.2 mEq/L)
Sodium	70 (3.0 mEq/L)
Antimony	0.006
Arsenic	0.005
Barium	0.10
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Lead	0.005
Mercury	0.0002
Selenium	0.09
Silver	0.005
Aluminum	0.01
Chloramines	0.10
Free Chlorine	0.50
Copper	0.10
Fluoride	0.20
Nitrate (as N)	2.0
Sulfate	100
Thallium	0.002
Zinc	0.10

**Table 1.** Maximum allowable chemical contaminant levels in water used to prepare dialysate and concentrates from powder at a dialysis facility and to reprocess dialyzers for multiple uses. (Reproduced from ANSI/AAMI RD62:2001)

NOTE: American National Standards are revised every three to five years. Users should consult the most recent

1). Among the most common tests are for conductivity, pH, bacteria, endotoxin, chemical elements, and disinfectant residue.

### Conductivity, Specific Gravity, and pH

Tests must be performed for acceptable conductivity levels each time a new batch of concentrate is used as a means of confirming the correct bicarbonate concentration. Because the specific gravity of a sodium bicarbonate solution increases in a manner that is directly proportional to its concentration, it can also be used as a test of solution strength. The pH of the dialysate must also be tested before every

treatment; this will help prevent the wrong concentrate from being used.

### Bacteria and Endotoxin

Bacteria and endotoxin testing of the bicarbonate is a requirement for manufacturers who provide liquid bicarbonate concentrate. When clinics make large volumes of liquid bicarbonate, they must adhere to the same standards. Testing should be done at least once a month for established systems and once a week for new systems until a pattern is established. Testing should also be conducted if the system is worked on or opened for any reason. Frequent testing allows for more proactive control. Typically samples of dialysate solution are drawn for this purpose. A sampling system is employed to ensure that all machines are sampled over some period of time—monthly, quarterly, annually—depending on the size and configuration of the distribution loop.

AAMI standards state that total microbial counts have a maximum allowable limit of 200 CFU/mL of water used to prepare dialysate (action level is >50 CFU/mL), and also no more than 200 CFU/mL in proportioned dialysate (action level is >50 CFU/mL) as it leaves the dialyzer. The standards also indicate that both water and dialysate must have an endotoxin level that is < 2 EU (endotoxin unit) per mL (action level is >1 EU/mL).

### AAMI Standards

AAMI standards also set limits and testing standards for approximately two dozen chemical elements (see Table 1). Many of these contaminant limits go beyond those set by the EPA for normal drinking water. They also serve as a resource for recommended limits where manufacturers are not required to provide specific information. A chemical analysis of the water should be done at least annually to check for these contaminants.

### Disinfect the System

Generally speaking, the entire concentrate distribution system must first be virtually free of any remaining bicarbonate before it is disinfected. Any remaining bicarbonate concentrate must be discarded. The process for both removing the bicarbonate and disinfecting the system should start from the mixing tank and head tanks, then continue through the loop and the patient station concentrate dispensers. Each bicarbonate port must be manually opened to flush the concentrate out and move the disinfectant through what would otherwise be an isolated por-

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## A leading force in modern bicarbonate hemodialysis

Church & Dwight's contribution to modern dialysis dates back to the early 1980s, when medical literature about the benefits of bicarbonate-buffered dialysate over acetate began to appear. Anecdotal reports, and then clinical studies, showed an improved response when patients were dialyzed with bicarbonate instead of acetate.

Beginning in 1982, Church & Dwight applied their technological expertise to the task of establishing exacting standards for hemodialysis grade sodium bicarbonate. Within two years, they were meeting those standards in full-scale production. When USP specifications for sodium bicarbonate used in hemodialysis were published in 1987 and formally issued in 1988, Church & Dwight hemodialysis grade sodium bicarbonate not only met the specifications, it exceeded them.

The company's continuous focus on quality is demonstrated by the experimental model in their Princeton (NJ) R&D laboratory. With this model, Church & Dwight scientists can evaluate how their bicarbonate performs under actual dialysis conditions as well as optimize performance for different equipment and procedures.

## Unique program benefits patients and staff

Church & Dwight's overall commitment to quality in the dialysis field is represented by their Partners in Quality Care™ program. This is a unique alliance between Church & Dwight and the nation's leaders in the supply of dialysate chemicals and equipment. Through this alliance, Church & Dwight provides their partners with resources for dialysis professionals and their patients. These resources add value to the company's pure ARM & HAMMER brand sodium bicarbonate for hemodialysis as well as enhance the roles dialysis professionals play in their facilities.

### Educational materials currently available through the Partners in Quality Care program include:

*Hemodialysis Step by Step* – for use with new hemodialysis patients

*Proper Testing for Better Patients Outcomes* – an ANNA-accredited CE program for nurses

*Teaming Up for Quality* – a 15-minute motivational video for dialysis facility staff

*Directions in Quality Care* – a manual to help facility personnel reduce errors and improve the safety of dialysis operations

*Managing Fluid Intake* and *Taking Control of Your Life on Dialysis* – patient education pamphlets, available in both English and Spanish

→ To order any of these materials, send a fax on facility letterhead to 267-893-5681.



Partners in Quality Care focuses on four key areas to help assure the highest possible standard of care for patients. First is Church & Dwight's strong emphasis on product quality, reliable supply, and scientific product support. Second is the quality of the dialysate manufacturers who use the ARM & HAMMER product. Third is the ability of Church & Dwight to make a direct contribution to improving patient compliance. And fourth is professional support, including ANNA-accredited continuing education programs for nurses.

## Eye on the future

For dialysis professionals and industry leaders alike, this is an exciting time in the field of dialysis, filled with opportunities and challenges. Church & Dwight is committed to sharing a bright future with the dialysis community as an active contributing partner and a valuable scientific resource.

# Practical Matters

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tion (or “dead leg”) of the system. This process must also be completed with a rinse cycle that uses AAMI-quality water. With the aid of built-in spray mechanisms, complete disinfection of internal surfaces can be done with a minimal volume of disinfectant. Rinsing is also enhanced with these spray mechanisms.

The bicarbonate concentrate container should be cleaned after every use, disinfected every night, and inverted to dry. All tubing and piping in the bicarbonate concentrate distribution system must be cleaned and disinfected at the end of each day. In addition, the concentrate pathways should be cleaned every 6 to 12 months to remove precipitate that has built up in the system. A 1:34 ratio of vinegar to water is usually sufficient, with the vinegar cleaning carried out in the same way as a disinfection and rinse procedure. Other compatible acids such as citric acid may also be used.

The bicarbonate mixing tank should be emptied of any bicarbonate concentrate that’s left at the end of the day and the concentrate must be discarded. Then disinfection should be carried out according to the clinic’s procedures, and should include all internal surfaces of the tank. The spray from the built-in spray mechanism should reach all internal surfaces of the tank, including those normally above the fluid level, to help prevent bacteria from colonizing on the inner surfaces of the tank.

The disinfection dilution and dwell time (i.e., the amount of time the disinfectant should remain in the system) depend on the type of chemical used. Commonly used disinfectants include sodium hypochlorite and peracetic acid. Some equipment can be disinfected with hot water. Dilutions and dwell times specified on product or equipment labeling must be strictly adhered to. The minimum standard for residual disinfectant must be met or the cleaning process must be repeated until a minimum level test result is achieved.

### Inadequate Disinfection or Rinse Endangers Patients

There are four major consequences of inadequate cleaning, disinfection, and rinse of the concentrate delivery system: bacteria build-up, biofilm formation, precipitation build-up, and the presence of disinfectant residues.

### Bacteria Build-Up

Bacteria can multiply very rapidly in bicarbonate concentrate. Therefore, if disinfection is inadequate, one organism can grow into hundreds of thousands—literally

overnight. This has led to incidents involving patient endotoxin reactions that resulted directly from contaminated dialysate. Bacteria can adhere to surfaces and lead to biofilm formation.

### Biofilm Formation

Mixing large quantities of bicarbonate concentrate and then distributing the solution through a loop creates a large amount of surface area for the bicarbonate to come in contact with. This process encourages the formation of biofilm, and in turn, endotoxins, if the system is not adequately and routinely disinfected.

### Precipitation Build-Up

Carbonate deposits throughout the delivery system are an inevitable byproduct of the concentrate. The amount of precipitate is directly proportional to the volume of concentrate passing through the system. Avoiding prolonged storage of sodium bicarbonate powder will help to minimize solution precipitation problems associated with increased carbonate levels. Proper flushing of the bicarbonate solution and sufficiently frequent acid rinse keeps the build-up to acceptable levels that will not impede flow or cause more bacterial growth in the system (smooth surfaces are less likely to “anchor” biofilm).

### Disinfectant Residues

Testing for the presence of disinfectant solution during circulation and its absence after the rinsing cycle must be performed on each bicarbonate port at each of the patient stations. If one of these steps is missed, the ports may either grow bacteria, or be filled with disinfectant that potentially could be released to a patient.

### Summary

Proper preparation of bicarbonate concentrate is critical to the safe and effective delivery of dialysis treatment. The development and consistent use of procedures based on these recommendations will help to reduce the potential for mixing errors, product loss, and chemical and bacterial contamination, and positively influence staff efficiency and patient well-being. ■

#### For more information:

- ANSI/AAMI RD5:2003, *Hemodialysis systems*
- ANSI/AAMI RD52:2004, *Dialysate for hemodialysis*
- ANSI/AAMI RD61:2000, *Concentrates for hemodialysis*
- ANSI/AAMI RD62:2001, *Water treatment equipment for hemodialysis applications*

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