



VistaClear

Dental Waterline Treatment Systems

and

Backflow Prevention

For All Single and Multiple Operatory Models:

1000 1000-23-C 1000-34-C 1000-46-C 1000-47-C

VistaClear Dental Waterline Treatment System

Description of System:

VistaClear Dental Waterline Treatment System is a closed system that is used and maintained by a dental office or clinic for the express purpose of providing filtered water to a dental delivery unit. Every system model provides built-in mechanical and biochemical backflow protection including the use of multiple VistaCheck Dual Check Valve Backflow Preventers that are provided with each system.

Water provided by a VistaClear system is used solely for the operation of air/water syringes, handpieces and scalers for treating dental patients.

The system consists of specialized water treatment components that are intended to improve the microbiological and chemical quality of water to meet certain water quality goals and standards set by the Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Centers for Disease Control & Prevention (CDC) and the American Dental Association (ADA) for use during dental procedures.

For the multiple operatory version of the VistaClear, a distribution system consisting of approved 1/4" O.D. copper tubing is also specified to distribute the water to the dental delivery units since copper exhibits certain antimicrobial properties and also meets plumbing codes for use in walls, floors and ceilings as required by building design. The retrofit model 1000 VistaClear includes a distribution system consisting of 1/4" O.D. flexible tubing for use in one operatory only where distribution lines are not enclosed in walls, floors or ceilings.

Other water treatment components may necessary ahead of a VistaClear system if the potable source water contains unusually high levels of contamination (excessive hardness, iron, sulfur, manganese, etc.). VistaClear is typically installed with potable municipal water.

Certifications:

Each patented VistaClear system has been cleared by the FDA as a Class I Medical Device (510(k) 001053), is listed as a Pest Control Device with the EPA (Est. No. 73593-OH-001) and materials of construction meet ANSI/NSF 42, 51, 53, 58 and 61.

Each patent pending VistaCheck backflow preventer is transparent for visual inspection, is testable without invasive methods and the internal check cartridges are UL / IAPMO / CSA listed (Neoperl P/N 30.4010 DW10), and meet ASME A112.18.3, ASME A112.18.1, NSF 61/9 and CSA B125.

Specifications:

Where a VistaClear Dental Waterline System is installed, the potable water system can be protected, if required, by a reduced pressure backflow preventer located between the potable water system and the input to the VistaClear system. The VistaClear and distribution piping are maintained as a unit and do not require separation by back flow prevention within the VistaClear and distribution system or between the outlets of the purified water distribution system and individual dental delivery units.

All VistaClear Dental Waterline Treatment Systems are constructed from materials that do not interact chemically or physically so as to adversely affect the purity of the water used for dental treatments. The materials used are also compatible with the types of cleaners and antimicrobial agents used to cleanse the purified water distribution system.

Tubing in the purified water distribution systems should preferably be free of joints and connections if possible to eliminate areas where contaminants might tend to collect. If joints are necessary in the distribution system, materials of construction should be compatible for use with potable water systems and should be constructed to minimize dead flow areas. Mechanical, threaded and glued slip fit joints are acceptable if necessary but the tubing size in the distribution system should be 1/4" O.D. only to allow for certain velocity characteristics during cleansing procedures and to minimize the volume of water being stored in the distribution system.

Background:

Dental treatments are medical procedures provided to millions of people in the United States each day. As described below, a supply of purified water is necessary for dental treatments. The Food and Drug Administration regulates as medical devices the systems used to prepare purified water for dental delivery units and patient care.

Currently, the Uniform Plumbing Code (UPC) does not specifically address the installation and use of water purification systems for dental treatments. Over the years there have been several interpretations of the UPC that have the potential to cause harm to a patient during dental treatments according to these interpretations.

Recently, the UPC has been amended to address the absence of clear guidance on water purification systems for hemodialysis. The purpose was to ensure that the quality of water used for dialysis is maintained to protect patients from harm during their treatments, while at the same time protecting the potable water supply. Like hemodialysis, water used for dental treatments must also protect both patients and the potable water supply. Equipment for purifying water for hemodialysis and dental treatments is regulated by the FDA and the EPA, is installed in a similar fashion and must protect both patients and the municipal water.

Rationale:

The following rationale was presented to support the proposed changes to the UPC for hemodialysis equipment and would also be applicable for dental water treatment.

Water used for patient care must meet certain chemical and microbiological quality standards if the potential for patient injury is to be avoided. For example, in the case of hemodialysis, the purified water used must be free of disinfectants, such as chlorine and chloramines, since these substances are well known to destroy red blood cells. The absence of these disinfectants creates a situation where bacteria can proliferate in the purified water unless extreme care is taken.

Approximately 180 liters of purified water are required for a four-hour dialysis treatment and a typical dialysis facility might perform 60 treatments per day, six days per week. Even less water is used in dental offices. Only 1-2 liters of water are used each day in each dental operatory.

After purification through the water filtration devices, a distribution system then delivers the purified water to its points of use. The distribution system must not re-contaminate the

purified water during distribution. The water purification devices and the equipment that uses the purified water are regulated as medical devices and require FDA 510(k) registration (or exemption).

Contamination may get into the distribution system via dead legs, connections of devices at tubing terminations, quick disconnects, etc. and may create chemical deposits and/or allow microorganisms to grow and form biofilms. This contamination and any resulting biofilm must be routinely removed from the filtration device and connecting distribution system. This is accomplished by periodic cleansing using cleaners and antimicrobial agents. Thus, the water system must be designed to prevent bacterial growth and allow for easy disinfection or cleansing of the system.

Backflow prevention devices:

In several states, the UPC has been interpreted to mandate the use of a backflow prevention device preceding each dialysis machine and in each individual dental operator. The wording could be interpreted to require a backflow prevention device be placed between the water purification system and each dialysis machine or dental delivery system. The basis for this interpretation is protection of the potable water supply.

Installation of a backflow prevention device between the potable water supply and the dialysis or dental water purification system to isolate the water purification system from the potable water supply may be desirable, additionally protecting the potable water system from possible contamination. However, placing a further backflow prevention device in the water supply line after each individual dialysis machine or VistaClear system adds no additional protection. To the contrary, placing a backflow prevention device in the water supply line to an individual dialysis machine or dental delivery unit could be hazardous to the patient for any one the following:

- 1) Bacterial contamination of the water used for patient treatment presents a potential source of patient injury. Backflow prevention devices have internal flow paths that are not easily disinfected. Such devices have atmospheric vents and test valves that can introduce bacteria into the distribution lines. Bacteria can colonize the backflow prevention device and re-contaminate the purified water, leading to patient injury.
- 2) Chemical germicides may be trapped in the internal flow paths of backflow prevention devices during routine disinfection. The trapped germicide may then be released into the treated water during a dialysis treatment, exposing the patient to the risk of toxicity from the germicide.
- 3) Most backflow prevention devices are constructed of materials not suitable for use with medical devices. Certain metals can contaminate the water and present a hazard for patients and may interfere with procedures.
- 4) The pressure drop across backflow prevention devices lowers the pressure available to operate the purification equipment. This reduction in pressure may necessitate the installation of additional pumps and storage tanks, increasing the complexity of the system and making it more difficult to maintain. Although Section 610.2 of the UPC states that "... No water filter, water softener, backflow prevention device, or similar device regulated by this code shall be installed in any potable water supply piping when the installation of such device produces an excessive pressure drop in any such water supply piping ...," several states have required the insertion of backflow prevention devices which has caused pressure drop concerns.

For the above patient safety reasons, the use of backflow prevention devices should be limited to the protection of the potable water supply and prohibited from use in the purified water distribution system used for hemodialysis and dental water delivery systems. This is the position taken in the UPC 2006 ROC for hemodialysis systems. This position also appears to be consistent with that of the FDA, since 510(k) registrations for water systems issued to date have not allowed or required the use of backflow prevention devices in the purified water distribution system. Further, RPZ devices are not required at each outlet but may be installed on the service supply to the office according to AWWA M-14 and IPC 608.16.9. VistaClear and modern dialysis machines have built in backflow prevention systems that serve to protect the purified water and potable water supply.

NOTE 1: The preceding was a description of the VistaClear system including product specifications and certain language directly from UPC 2006 - August 2005 ROC including new sections 603.4.23, 604.14 and 606.1.4, that proposed changes to the UPC as they relate to hemodialysis equipment. Dental delivery equipment is also regulated by the FDA and is similar in that it provides purified irrigant water to dental patients while hemodialysis provides purified water to renal patients. Both systems must be protected from re-contamination of the treated water caused by backflow devices that could endanger patients.

NOTE 2: Also found in UPC 2006 - August 2005 ROC under 603.4.23 is a discussion about integral backflow prevention devices for fixture fittings and proposed language changes to reference ASME A112.18.1 and ASME A112.18.3 in the code. These are two of the standards met by the VistaCheck Dual Check Valve Backflow Preventers that are included with each VistaClear Dental Waterline Treatment System. According to the discussion in the ROC, these integral devices have been used satisfactorily for many years and historically have provided adequate protection against the risk of backflow and this standard reference in section 603 of the code would provide an awareness of the current technology being used specifically for integral devices for plumbing fixture fittings. Such integral devices are found in each VistaCheck and enhance the backflow protection of the entire designed system.

NOTE 3: In some states and municipalities, the VistaClear system is considered one of the following: 1) medical device, 2) designed system, or 3) engineered system. In many cases due to these classifications, VistaClear has been exempted from any requirement to use backflow prevention devices before or after the system due to its design and built-in mechanical and biochemical backflow features. For example, the state of Wisconsin uses isolation protection but has approved VistaClear as an “acceptable form of backflow protection of the water supply serving dental units.” (See <http://www.vistaresearchgroup.com/docs/wi.pdf>) The City of Los Angeles has also approved all VistaClear models under Los Angeles Plumbing Code and/or Los Angeles Mechanical Code. (See <http://www.vistaresearchgroup.com/docs/la.pdf>)

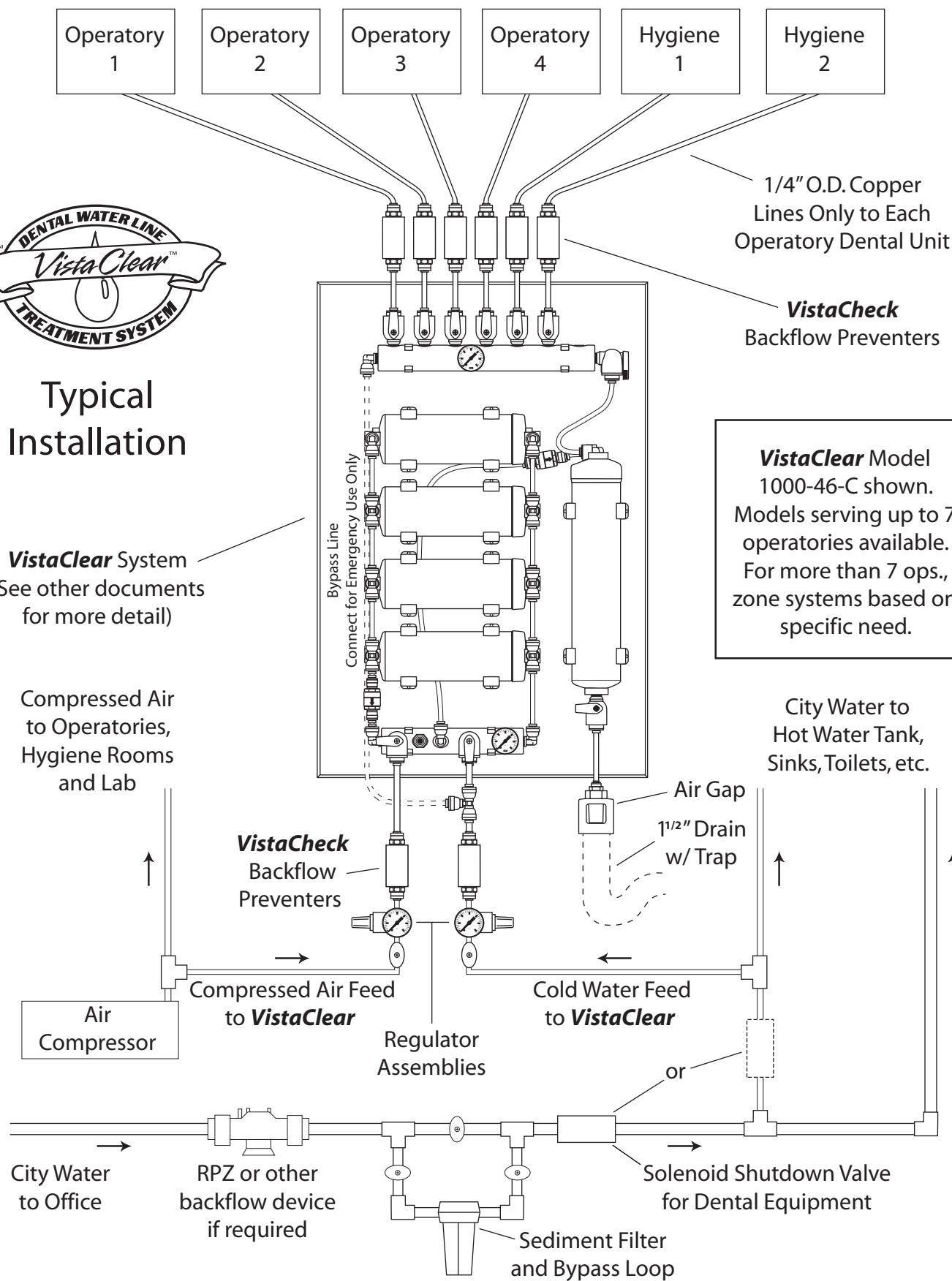
For more information on VistaClear, VistaCheck and all Vista Research Group products, go to <http://www.vistaresearchgroup.com/> or contact Jim Chandler, President, at 419.281.3927.



Typical Installation

VistaClear System
(See other documents for more detail)

Compressed Air to Operatories, Hygiene Rooms and Lab



VistaClear Model 1000-46-C shown.
Models serving up to 7 operatories available.
For more than 7 ops., zone systems based on specific need.

City Water to Hot Water Tank, Sinks, Toilets, etc.

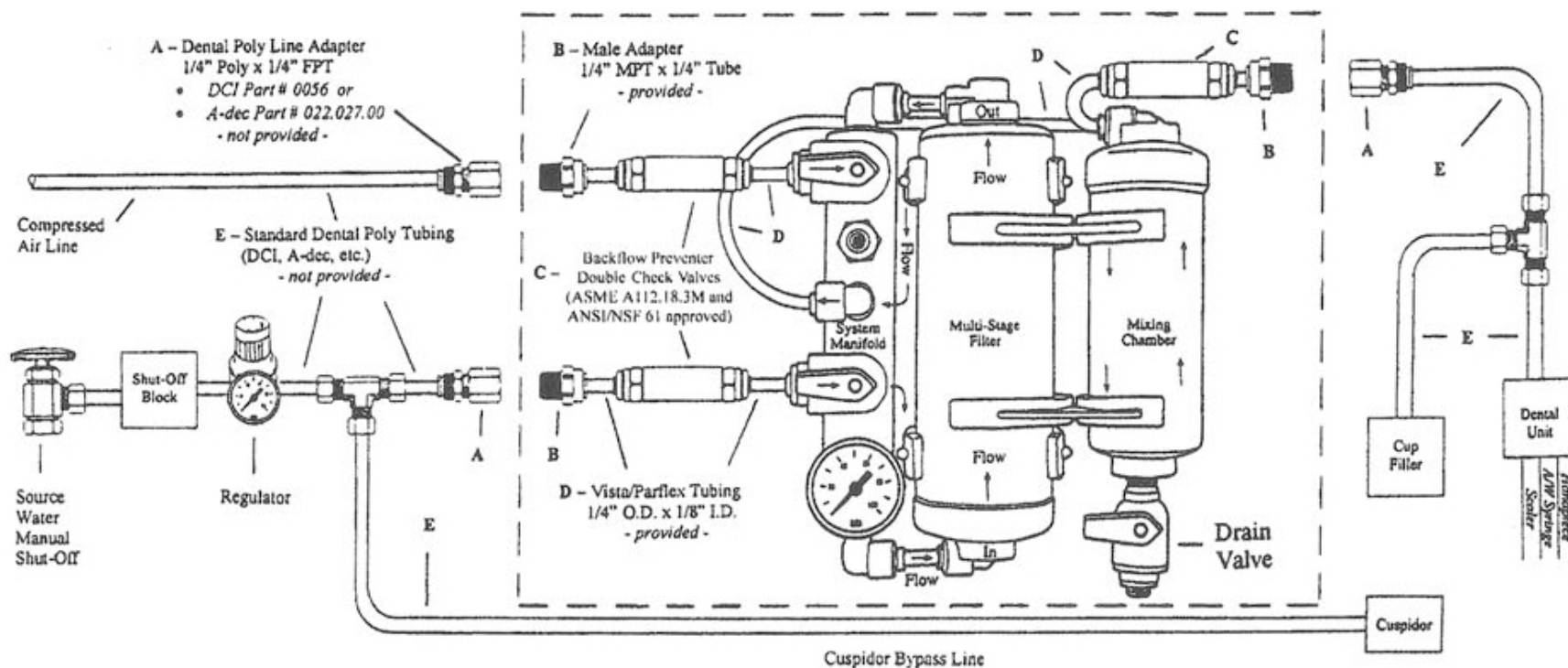
"VistaClear – Typical – Multiple"

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Installation Schematic for *VistaClear*™ MODEL 1000

Pat. No. 6,423,219 and other patents pending



IMPORTANT

- All items within the dashed lines are included with the *VistaClear* system (except mounting screws)
- *Vista (Parflex)* tubing **MUST** be used on the system and all fittings within the dashed lines (1/4" O.D. x 1/8" I.D. tubing is included)
- Do **NOT** use tubing inserts with *Vista (Parflex)* tubing
- The *VistaClear* system **MUST** be connected to the water system **AFTER** the dental waterline shut-off block and pressure regulator
- If a cuspidor is present, **ALWAYS** feed the basin directly from the unfiltered water supply - **NEVER** from the *VistaClear* system
- In-line check valves ("C" above) must **ALWAYS** be used - be sure to install them in the proper flow direction as shown
- The maximum operating pressure for air and water into the *VistaClear* system is 100 psi - preferably 40 psi for both water and air

"IS-1000-A"
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"VistaClear - Typical - Single"

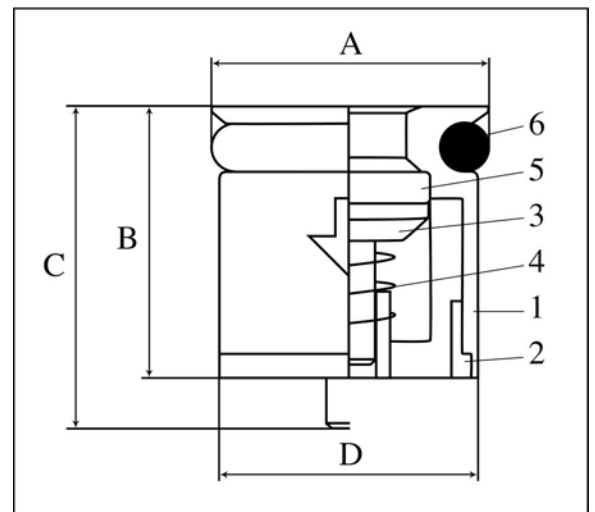
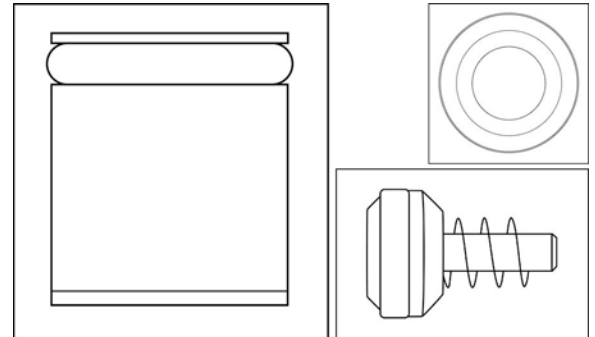
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DIMENSIONS

Ref	mm	Tolerance	In	Tolerance
A	10.30	+ 0.25 / - 0.00	.406	+ .010 / - .000
B	10.50	+ 0.15 / - 0.00	.413	+ .006 / - .000
C	12.30	+ 0.60 / - 0.60	.484	+ .024 / - .024
D	10.00	+ 0.00 / - 0.15	.394	+ .000 / - .006
E	19.05	+ 0.56 / - 0.00	.750	+ .022 / - .000
F	52.40	+ 0.38 / - 0.38	2.063	+ .015 / - .015

MATERIALS

Ref	Item	Material
<i>Check Valve Assembly Cartridge</i>		
1	Housing	Acetyl
2	Guide	Acetyl
3	Plunger	Acetyl
4	Spring	Stainless Steel - AISI 302
5	O-Ring Seal	Silicone Rubber
6	O-Ring Seal	Silicone Rubber
<i>Main Check Valve Body</i>		
7	Housing	Clear PVC
8	Standard " Fittings	White Polypropylene



CERTIFICATION

System:

ASSE 1026 – Interim
Dual Check Backflow Preventers
for Medical / Dental Applications

Check Valve Cartridges:

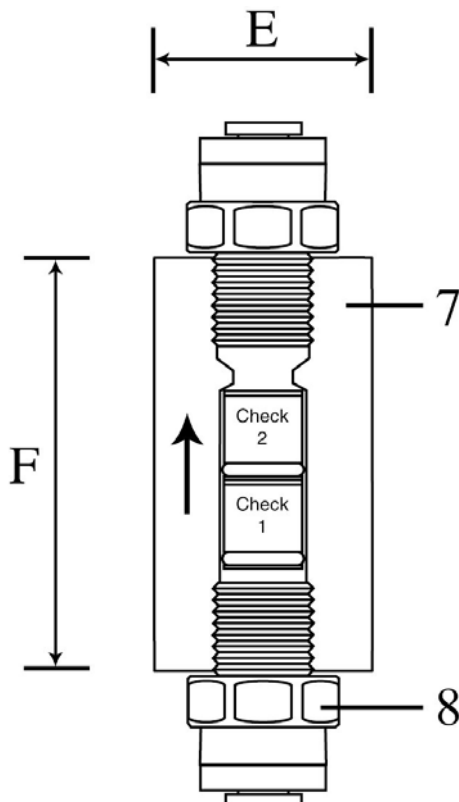
ASME A112.18.3 & A112.18.1
NSF 61/9 & CSA B125
UL / IAPMO / CSA Listed
Neoperl P/N 30.4010 (DW10)

System Body:

NSF 61 & FDA Title 21

Fittings:

NSF 51, 58 & 61



Background on Dental Units and Backflow Preventers in Dental Operatories

The modern dental office faces several problems relative to water supply. First is a concern for development of biofilms in dental unit waterlines. Biofilms occur everywhere in nature but are of particular concern in the dental office due to the slow flow, low daily volume and quiescent conditions within the water system. For a number of years, the American Dental Association, the CDC, OSAP and other organizations have been strongly recommending treatment or other methods for controlling biofilm development due to concern for patient and staff health.

Although they have not recommended any one particular remedy, one that was thought to be a potential answer was to disconnect the dental system from the municipal water system and install bottle reservoirs. The bottles are to be filled daily with distilled, deionized or “clean” water deemed appropriate by the dental practitioner. Since the organisms that end up colonizing the waterlines were determined to have come mostly from the heterotrophic, mesophilic organisms that co-exist with the chlorine residual in public water supplies, the thought was that by eliminating this “source,” biofilm development could be eliminated, reduced or at least controlled in some manner. The problem is that many of the other sources for water that are used to fill the bottles are microbiologically no better than the tap water and in many cases far worse.

Another concern for the bottle systems is that even though microbiologically “good” quality water may be used to fill the bottles, environmental contamination can compromise the batch. For example, when the bottle is removed for filling, it is instantly exposed to bacterial aerosols that exist in the room. Also, a clinical worker may have not properly washed their hands, not been properly gloved or in some other way, like touching or breathing over the bottle, contaminate it with even pathogenic organisms – far worse than the organisms that normally reside within the municipal water system. Having to remove a bottle from the dental unit daily is virtually the same as a daily “water main break” for a municipal water system relative to contamination potential.

Although bottle systems can be flushed with certain chemicals to help keep biofilms in check within the dental waterline system, the frequency and efficacy with which this maintenance is done is dubious. From our research in speaking with dental service technicians, bottle systems have actually made biofilm growth and plugging of systems worse in many cases. This, of course, is of great concern for patients and staff. In addition, the idea of having to fill bottles every day in every operatory and perform maintenance weekly, if not daily, takes dentistry back years technologically and is costly for the dental practice for water and chemical expenditures as well as staff time.

Our belief is that municipally-provided water is best for a dental office for a number of reasons. From an efficacy standpoint, the water is properly treated by professionals and is delivered to the customer in a sealed water piping network with the proper chlorine (or other) residual. Microbiologically, this means that the pathogenic organisms are not generally of concern since they’ve been killed by the treatment process. Chemically, other contaminants and factors like iron, manganese, TDS, pH, turbidity, etc. have been dealt with and properly adjusted or brought into compliance under public water standards. In addition, municipalities and community water systems must monitor water quality with great frequency and can take appropriate measures should a parameter fall out of compliance. Yet another reason is that the dental staff saves time and money by not having to buy water, fill bottles, buy chemicals, perform frequent maintenance flushes, etc.

Now comes the second problem. By connecting the dental system directly to the municipal water system, some water authorities have a concern for potential cross contamination. Some municipalities practice containment and require backflow preventers on the main building connection. Some also require backflow preventions in each operatory in addition to primary containment devices. This can be extremely costly from both capital and annual maintenance cost standpoints. Some states practice isolation and require vented backflow prevention at each outlet. Any required devices add to the cost burden of running the dental practice.

Additionally, a potential microbiological concern exists with vented backflow preventers. Test valves and atmospheric vents can badly contaminate a system. For example, an inspector can inadvertently drive organisms into the water system during the testing process. And, when vents “vent,” they spurt water when the pressure drops during maintenance procedures. Environmental organisms can colonized the moist interior surfaces of the test valves and vent ports that potentially transfer bacteria to the waterlines each time the port vents or the test valve is used. This could present serious health concerns for the patient and clinical staff in the operatories as the lines are the colonized with even more potentially pathogenic organisms.

The AWWA, CDC, ADA, EPA and others believe that regulation should be commensurate with risk and that the likelihood of salivary fluids and blood entering the public water system from dental units is theoretically possible but virtually nil.

Some of the reasons cited include the fact that the transmission of bloodborne diseases has not been reported through the use of any type of water source. Further, for bloodborne infection to be transmitted, all four conditions of the chain of infection must be present (see CDC Fact Sheet):

- A susceptible host or person who is not immune
- An opening through which the microorganism may enter the host
- A microorganism that causes disease
- Sufficient numbers of the organism to cause infection

The CDC indicates that the “risk of infection” would be effectively stopped if any one or more of these parameters is broken or not met. Therefore, it is strongly suggested by the CDC that the risk of transmission of a bloodborne disease through water supplies is very low.

Again, the CDC indicates based upon available scientific information that the risk of infection from cross-connections in dental units is virtually nil. They indicate that dental units present a very low degree of hazard. Due to the presence of anti-retraction valves and other procedural measures they actually present less of a risk than a standard residential faucet spray hose. For example, if a dentist or hygienist detected an interruption in flow during a procedure, they would immediately stop work to investigate the problem. Even if a slight amount of fluid was aspirated into the dental unit, the volume of fluid is minuscule and would be overwhelmingly diluted.

In summary, the dental office has two basic choices relative to water connections:

1. If dentists disconnect from the municipal water system they must use independent bottle systems that must be filled with water manually each day from another water source. New contamination potentials then exist due to the quality of water used, environmental and human contact. They must also purchase biocides and perform flushing of the systems on a regular basis that is costly, time consuming and often ineffective. Further, information

reveals that the “maintenance” on bottle systems is not done as frequently as required which potentially puts patients and healthcare workers at greater risk of infection.

2. In some states, if they stay connected to the municipal water system, they must install backflow preventers in each operatory in addition to any others required on the main connection to the building. If RPZ and DCVIAV devices are required, there is substantial expense due to the initial cost and even more costly if annual maintenance and inspection fees are also required. Further, with this option, they will still have the development of biofilms due to backflow device vents and/or test valves. Some states, however, do allow non-vented double check valve backflow preventers on individual branch lines which offers suitable backflow protection without the risk of infection of waterlines potentially caused by RPZ and DCVIAV devices. Further, the use of RPZ and other vented devices may violate FDA codes.

Based on the CDC “chain of infection” scenario, the risk of backflow contamination from dental unit cross connections of public waters is near zero while the potential infection risk to patients is relatively high. For example, infection of a susceptible patient/host (like a person with a cold, cancer or other immune deficiency) is much more likely than the near zero risk of backflow into the water system.

SOLUTION

We believe that the best overall solution for solving the dental unit / dental waterline / backflow protection situation calls for:

- Dental units to be connected to properly maintained public water supplies instead of bottle systems in order to have the dental unit provided with water that meets SDWA standards and avoids the contamination potential inherent with the opening and closing of bottle systems on a daily basis.
- Dual check valve backflow prevention valves to be used on each branch line feeding dental units. DVCAs without vents and test valves should be used so that contamination from such vents and valves can be eliminated to protect vulnerable patients and healthcare workers.
- Any standard RPZ vented backflow protection device, if required, should be placed ahead of (not after) any medical water treatment device so that biological and chemical contaminants may not enter the water delivery stream dedicated for patient care as described in AWWA M-14, IPC 608.16.9 and the proposed new language under UPC Section 603.

NOTES:

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administrations (FDA) have been voicing concern for backflow prevention devices placed in the water distribution loop between medical devices. The use of such devices raises a number of potential serious public health concerns. The following information was obtained from FDA and other documents regarding backflow prevention devices (BFPs) required in hemodialysis facilities but would also apply to dental clinics since both use FDA 510(k) regulated medical devices.

The incorporation of backflow prevention devices may lead to the growth of bacteria in purified water lines as a result of stagnation, or they may serve as reservoirs for chemical contaminants that could be toxic or of concern for patients. “The distribution system must be installed and maintained in a manner that does not contaminate purified water during distribution.” – *Timothy Ulatowski, FDA, 08/2004.*

According to the FDA, hemodialysis machines, water treatment systems and the distribution loop used in medical facilities are medical devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act. “The problem that we had with plumbing codes has to do with interpretation of the 2000 Uniform Plumbing Code published by IAPMO, especially with regards to Chapter 6, section 603 (Cross Connection Control and Backflow Prevention).” – *Matthew Arduino, CDC, 11/2004.*

For example, in the dialysis setting, some plumbing code authorities are requiring hemodialysis facilities to place unapproved BFPs in the treated water circuit prior to each hemodialysis machine. Further, there are no manufacturer's with FDA 510K approved, stand alone, backflow prevention devices. Some code authorities do not realize that hemodialysis and dental systems are regulated as medical devices and by requiring facilities to install BFP devices in the distribution system after such devices are then adulterating a medical device and are in violation of the Food, Drug and Cosmetic Act.

In addition to being in violation of FDC regulations, in many cases these BFP devices are made of incompatible components and should not be used with filtered and ultrapure water, have air vents that may introduce environmental organisms and provide locations for biofilm accumulation thus potentially making the water microbiologically unsuitable for use with patients.