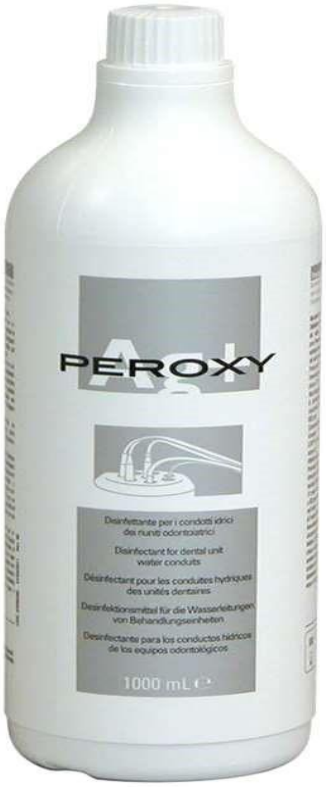
Peroxy Ag+ Dental Operating Manual

Cleaning, Disinfection and Biofilm Removal of DUWL's and Ancillary Equipment.



Contents and Purpose

This manual describes the detailed procedure for the application of Hydrogen Peroxide products in the following areas within a dental practice.

- Dental Unit Water Line (DUWL) disinfection, cleaning & biofilm removal.
- DUWL water analysis.
- Ancillary equipment cleaning and disinfection

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Product Information

General

Peroxy AG+ H202 is one of the most advanced, highly developed and accredited silver stabilised hydrogen peroxide products on the global market. It is a solution of hydrogen peroxide, which is stabilised using a specially formulated ionic silver-based chemistry which is Biocidal Product Regulations (BPR) compliant. The stabilisation process makes Peroxy AG a powerful water disinfectant that provides a wide spectrum of biocidal activity.

Peroxy AG is a highly effective, stable, broad spectrum, ecological disinfectant that is safe to the environment as well as being colourless, odourless and tasteless in ready to use concentrations. When dosed into a water system, its efficacy is independent of pH and has a proven half- life of 5 weeks. Independent testing has shown Peroxy AG to be a highly effective Bactericide, Virucide, Sporicide, Fungicide, Algaecide and Amoebicide.

Peroxy AG offers many advantages over traditional disinfection chemistries including chlorine and chlorine dioxide. It is more effective than chlorine dioxide for removing biofilm in water systems. It is non-corrosive at the concentrations used and is much more stable.

Peroxy AG is a well proven, trusted product used across all disinfection market sectors for water treatment and legionella control. It is certified for use by DEFRA & NSF, and the use of silver stabilised hydrogen peroxide (SHP) is contained within HSG 274 - Legionnaires Disease Technical Guidance.

It is safe to handle at the shock dose concentrations which destroys sessile biofilm and is ingestible at the lower constant dosage concentrations, which kills planktonic bacteria and prevents reforming. Peroxy AG is also fully bio-degradable.

PEROXY AG for Dental Use

PEROXY AG DILUTED is a solution of stabilised hydrogen peroxide with a strength of 600ppm as H2O2. This solution is ready to use for standard shock dose & diluted for routine use. At 600ppm the product is safe for ingestion, and completely non-hazardous for handling & disposal.

PEROXY AG is a solution of stabilised hydrogen peroxide with a strength of 3% as H2O2 and is a highly effective surface disinfectant.

Roles & Responsibilities

The Government issued Health Technical Manuals (HTM) 04-01 & 01-05 contain specific instruction on responsibilities within the dental practice. Further information on water disinfection can also be found within the HSE Guidance document HSG 274, which is a technical manual ensuring compliance with the Approved Code of Practice L8 - The control of legionella bacteria in water systems.
Dental practice staff shall be suitably informed by this procedure to competently undertake the specified activities provided all steps are performed as instructed.

Further general information and advice on this procedure and the products contained within can be obtained from the supplier, Dental Decontamination Ltd.

For detailed technical advice on the products efficacy, enquiries can be directed to Dental Decontamination Ltd.

Procedure

Safety & Hygiene

P E R O X Y A G are regulatorily classified as non-hazardous. However, when using PEROXY AG, it is advised wear safety glasses, particularly when spraying above chest height, as there have been rare cases of mild eye irritation occurring if large amounts are inadvertently in contact with the eyes.

For hygiene purposes it is advised to wear gloves (laboratory style nitrile or similar) when handling equipment during disinfection & cleaning activities.

Daily Surgery Use (Routine DUWL Disinfection)

The dental chair water bottle should be filled for routine use with a solution of minimum 600 ppm hydrogen peroxide. At this strength the water (potable, RO, or distilled) will be disinfected continuously against pathogens and restrict biofilm growth.

Place the empty 1 litre chairside water bottle under the pump nozzle and slowly but firmly press the pump ONCE to dispense 20 MLS of the solution. Or alternatively dispense from a measuring instrument. Once the product has been dispensed, fill the bottle with water and shake to mix. For 2 litre bottles use 40 mls.

Attach the bottle to the chair unit and then flush through each attached water line for 30 seconds. On the final line, during the flush, use the test strips to confirm the approximate value of hydrogen peroxide strength.

To use the test strip, place under the flowing water stream for a couple of seconds, then remove and wait for the final colour change for 30 seconds. Compare the colour of the test strip with the comparator chart on the side of the tube containing the test strips. If the value is less than 600 ppm, remove the bottle and dispense 10 mls more press of the pump into the bottle before repeating the flush and strength check.

PEROXY AG mixed to 600 ppm is intended as a continuous use disinfectant, the bottle does not require removal, draining and inversion when not in use overnight and at weekends. The guidelines stated in HTM 01-05 are to follow the manufacturer's instructions, therefore the bottle should only be removed when refilling when using PEROXY AG mix.

To ensure effective disinfection.

- At the start of a working week (following the weekend or holiday periods), each water line should be flushed for 30 seconds, and the strength checked as per the above procedure with test strips. If the tested value is less than 600 ppm, empty the bottle into the sink and refill as per normal procedure.
- At the start of each working day, or if the chair has not been in use for more than a couple of hours, the lines should be flushed through for 30 seconds.
- In between patients, each line should be flushed for 15 seconds to ensure no oral contamination between patients.

Quarterly Shock Dose (DUWLs, Quarterly)

Once per Quarter the chair lines should be given a routine shock dose over the weekend to prevent biofilm accumulation. To undertake this routine shock dose.

- Remove and empty the units water bottle.
- **Fill the water bottle with diluted Peroxy Ag+ solution.2% equal to 600 ppm.**
- Replace the water bottle on to the unit and flush through each line for 30 seconds.
- Use the test strips to prove the flushed water is in excess of 600ppm.
- Leave in place over the weekend.

On the Monday morning, following a routine shock dose.

- Remove and empty the units water bottle.
- Fill the water bottle with distilled water.
- Remove any inline filters and implements from each water line.
- Flush each line for 60 seconds and confirm the strength of the flushed water is less than 600ppm peroxide with test strips. If the strength is greater than 600 ppm, continue flushing.
- Once the lines are flushed, replace the removed filter and implements.
- Flush each line again for 30 seconds.

The unit can now be used as per routine daily procedures i.e 2% Peroxy Ag..

NOTE: If for any reason, following a routine shock dose, the unit is not flushed of concentrated product, the concentrated solution is safe to ingest and will cause no harm to patients.

Routine Testing (DUWLs, Quarterly)

Water from the unit should be tested for microbiological activity once per quarter after the quarterly shock dosing using the dipslide sampler.

To complete this routine analysis.

- Ensure gloves are being worn to prevent cross-contamination during sampling.
- Remove the dipslide via the red paddle and fill the sample pot to the 18ml mark on the side with water from the unit.
- Replace the dipslide into the pot and hold the sampler horizontally for 30 seconds with the red side upwards.
- After 30 seconds, remove the dipslide from the sampler and empty the pot.

- Place the dipslide back into the empty pot, attach a label with details on the sample date and location.
- The sample should be incubated for 7 days in a room/area with an ambient temperature of ~20'C.

After 7 days the dipslide plate should be compared with the chart provided by the manufacturer for microbiological activity.

- <100 cfu/ml - no further action is required, continue with ongoing disinfection routines.
- >100 cfu/ml - undertake intensive system shock dose.

If an intensive shock dose is required, analysis should be performed immediately after this task and results monitored.

Results should be recorded on to the dental practices DUWL Disinfection Log, including actions taken and the results of any re-sampling.

Intensive Shock Dose (DUWLs, non-routine)

An Intensive Shock Dose with PEROXY AG should be undertaken if a high microbiological count is seen following routine sampling, when a chair is being brought back into service after a significant period of redundancy, or when a chair with no proof of historical disinfection is being brought back into service.

To undertake an intensive shock dose;

- Remove and empty the units water bottle.
- Fill the bottle with PEROXY AG +.
- Spray the external threads on the bottles neck with Peroxy Ag+.
- Remove any inline filters (if possible) and the units implements.
- Replace the water bottle on to the unit and flush through each line for 30 seconds.
- Use the test strips to prove the flushed water is in excess of 5,000 ppm.
- Spray the removed in-line filter and implements with Peroxy Ag+.
- Leave in place for 10 minutes.

After the 10 minutes shock dose period;

- Remove and empty the units water bottle.
- Fill the water bottle with diluted PEROXY AG +as per daily use instructions.
- Flush each line for 60 seconds and confirm the strength of the flushed water is not less than 600 ppm with test strips. If the strength is greater than 600 ppm, continue flushing.
- Once the lines are flushed, replace the removed filter and implements.
- Flush each line again for 30 seconds.

Once the unit has been flushed undertake routine microbiological analysis to confirm effectiveness of the shock dose.

Chair Dormancy

If a unit is intended to be not used/dormant for any period greater than 7 days then the unit should be dosed with diluted PEROXY AG +as per the routine shock dose procedure and left with the concentrated solution in place. It is advised that the unit is flushed through once per week for 30 seconds.

Once the unit is to be brought back in to service it should be flushed with diluted PEROXY AG as per the routine shock dose procedure and microbiological testing performed if the unit has been out of service for more than a month.

Routine Hygiene Practices (Ancillary Equipment)

Alongside the routine DUWL disinfection and cleaning procedures the following hygiene practices should be undertaken with Peroxy Ag+ from the trigger spray. On all occasions the product can simply be left in place after spraying, and if required wiped down with a clean cloth prior to use.

- At the end of each working day, spray the spit bowl and tap Peroxy Ag+.
- Spray the unit's tray & dental implements regularly.

Peroxy Ag+ can also be used to effectively disinfect all surfaces within the practice including the chair. For full efficacy it should be left in place after spraying for at least 60 minutes before wiping away.

References:

- HSG 274 Part 2. 2014. Paragraph 2.116. Refers to Silver stabilised Hydrogen Peroxide as an approved chemical disinfectant.
- HTM 04-1. Part A. Section 3.18. Copper pipes and other materials. The concentrations of H2O2 used are non-corrosive to all materials of construction.
- HTM 04-1. Part A. Section 4.9. PEROXY Ag has been submitted for approval under the Biocidal Product Regulations (BPR).
- HTM 04-01. Part A. Section 4.13 and 4.21. Concentration checks and monitoring. This is defined in the operating protocol.
- HTM 04-10 Part B. Section 4.9. Use of biocides requires meticulous monitoring - described in this operating protocol. Also refers to biocidal treatment which may affect taste and odour - H2O2 is tasteless and odourless at the concentrations used.
- HTM 04-01 Part B. Section 6.70. Monitoring and sampling is covered by this operation protocol.
- HTM 04-01 Part B. Section 7.53 Table 1. Frequency of monitoring Biocide Treatment systems covered by this operating protocol.
- HTM 04-01 Part B. Section 9.1. TVC monitoring where there are taste and odour problems. H202 is tasteless and odourless. If there is a residual concentration, micro-organisms should not exist.
- HTM 04-01 Part B. Section 10.4. Legionella sampling. Covered by this operation protocol.
- HTM 01-05. Section 6.37. Surface Disinfection. H2O2 3 trigger sprays are recommended for surface disinfection. Covered by this operation protocol.
- HTM 01-05. Section 6.82-6.84. Daily, Weekly flushing of Dental Unit Water lines. This is covered in this operating protocol.
- HTM 01-05. Section 19.65. Summary check list for temperatures. Replace this summary check list with concentration test strip results which is covered in this operating protocol.
- HTM 01-05 Appendix 2 Daily Test sheet. A schedule and results record sheet is included in this manual.
- C.E Notable body.
- BPR 95 Registered Parts 1-6
- DEFRA Registered
- NSF Registered
- Please refer to: https://www.cqc.org.uk/guidance-providers/dentists/dental-mythbuster-5- legionella-dental-waterline-management

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PEROXY Ag+

PRODUCT INFO SHEET

Disinfectant for Dental Unit water conduits

THE PRODUCT

The microbial contamination of water circuits on dental units, which can occur either by way of entry, colonisation and multiplication of microorganisms from the water supply, with the formation of dangerous bacterial *biofilms*, or by way of retrograde penetration of microorganisms from the patient's oral cavity, is a well known problem. Such viruses and bacteria can, in addition to contaminating the liquid, find in biofilm a habitat suitable for colonisation and/or multiplication.
To ensure dental treatment of outstanding clinical quality and to prevent the risk of cross-infection, the assurance and maintenance of suitable hygiene levels in both the water delivered by the instruments and the water circuit inside the dental unit is of primary importance.
Peroxy Ag+ has been specifically designed for this purpose and can be applied in two different ways: applied pure (100%) in intensive circuit disinfection systems, when the unit is not in use on patients; applied diluted (2% in water – equal to 600 ppm H_2O_2) in the instrument spray feed using automatic dosing systems that add the disinfectant to the water supplied to the dental unit or via manual addition of the product to the independent feed tank liquid.
Peroxy Ag+ is a Medical Device Accessory, carrying the CE mark (EC Directive 93/42).

COMPONENTS

Hydrogen Peroxide 3%, Silver (as Ag+ ions) 0.001%, stabilizers and water.

ACTIVITY

PURE PRODUCT (100%) FOR DISINFECTION CYCLES

The disinfectant action of 3% Hydrogen Peroxide is widely documented and has been known for decades, as has its application in the disinfection of dental unit water circuits. The presence of Silver ions increases the biocide capacity of the peroxide and gives the solution a residual disinfectant action. It has been demonstrated that the product exerts an effective anti-microbial action with 10 minutes of contact:

- **Mycobactericide activity** [2] on *Mycobacterium marinum* ATCC 25177 reduction 99.999% (6 Log);
- **Fungicide activity** [3] on *Candida* spp (pool of 5 oral clinical isolates) reduction 99.9999% (6 Log);
- **Bactericide activity** [3] against a bacterial pool 10^7 CFU/ml, consisting of *Pseudomonas aeruginosa* (ATCC 27853), *Escherichia coli*, (ATCC 7075), *Klebsiella pneumoniae* (LIC2), *Salmonella enterica (sierotipo typhi)* (LIC3), *Bacillus atrophaeus*, *Enterococcus faecalis* (GO2) and *Staphylococcus aureus* (ATCC 6538), with each strain in concentrations greater than 10^8 CFU/ml: reduction 99.9999% (> 6 Log);
- **Biocide activity on biofilm** [4]:
  after 10 minutes of treatment on already-formed biofilm, reduction of at least 99% of living microorganisms in the biofilm (*Pseudomonas aeruginosa Staphylococcus aureus* and *Streptococcus faecalis);*
- **Moderate Sporicidal activity** [1, 2] on *Bacillus subtilis*: reduction > 99.9% (> 3 Log);
- **High level process** [6]
  The use of PeroxyAg+ in the intensive disinfection system for dental unit water circuits with cycles of 10 minutes of contact has showed high bactericidal activity, also against Legionella, yeasticidal activity, mycobactericidal activity and a notable sporicidal activity, that ensure the high reliability of the process.

DILUTED PRODUCT (600 ppm) FOR CONTINUOUS FEED

The effect of continuously adding the product, diluted at 600 ppm as H2O2 (0.06%), to the water supply was assessed according to its capacity to inhibit the microbial growth (bacteriostatic action), to reduce the microbial load (bactericidal activity) of numerous microorganisms, as well as to prevent Legionella contamination.

- **Protection from *Legionella*** [7]
  Continuously added at 600 ppm (as H2O2) to the water supply, PeroxyAg+ reduces the load of *Legionella pneumophila* by more than 6 times, bringing back within legal limits even a water having a bacterial load up to six times beyond limits.
  After a period of one hour in the circuit and without any other intervention: reduction of *Legionella* > 99.99 %.
- **Bacteriostatic action (600 ppm H2O2)** [5]
  against *Prevotella intermedia*, *Porphyromonas gingivalis*, *Veillonella parvula* (parodontal pathogenic bacteria), and against pathogenic bacteria or opportunistic pathogens such as *Escherichia coli*,

PEROXY Ag+

PRODUCT INFO SHEET

Disinfectant for Dental Unit water conduits

Pseudomonas aeruginosa, *Pseudomonas stetzieri*, *Streprococcus faecalis*; *Staphylococcus aureus*, *Mycobacterium marinum*, *Candida Krusei*, *Candida tropicalis*, *Candida albicans*, Peroxy Ag+ diluted at 600 ppm shows effective inhibition of bacterial growth;

- **Synergic Bactericide action (600 ppm H2O2)** [3]
  tested on *Staphylococcus aureus*, *Pseudomonas aeruginosa* Peroxy Ag+ diluted at 600 ppm gives a reduction of 99.999% (5 Log) in 30 minutes;
- **Biofilm prevention (3)**
  on *Pseudomonas aeruginosa* as a clinical isolate and on E. faecalis, prolonged contact with Peroxy Ag+ at 600 ppm (as H2O2) reduces biofilm formation by over 60%.

(1) *Savino A et Al: Decontaminazione batterica dei riuniti odontoiatrici. Il Dentista Moderno, Sept. 2003*
(2) *Università di Ferrara – Analysis certifications*
(3) *Del Nero S et Al: Attività antibatterica di formulati a base di perossido di idrogeno e Sali di Argento. Dental Cadmos, 2012; 80(2): 96-107*
(4) *Omrì G et Al: Evaluation of Antimicrobial-Antibiofilm Activity of a Hydrogen Peroxide Decontaminating System Used in Dental Unit Water Lines. The Open Dentistry Journal, 2010, 4, 140-146*
(5) *Omrì G et Al: Valutazione dell'attività antimicrobica di un sistema decontaminante a base di perossido d'idrogeno. Risultati in vitro e su riunito odontoiatrico. Il Dentista Moderno, December 2006*
(6) *Università Sapienza Roma – Dip di Sanità Pubblica e Malattie infettive. Certification 16/12/2014*
(7) *Università di Torino . Dip Scienze della Sanità Pubblica e Pediatriche. Certification 11/12/20*

USE

THIS PRODUCT IS FOR PROFESSIONAL USE – Use it according to the label indications

- Intensive disinfection of circuits:
  Following the instructions in the dental unit's manual, where applicable: introduce pure product into the disinfectant tank for circuit disinfection cycles and activate disinfection cycles as described in the Manual.
- Continuous addition to water supply:
  Automatic: following the instructions in the dental unit's user manual, introduce the pure product into the special tank disinfectant tank for continuous addition.
  Manual: introduce 20 ml of product into the independent feed tank for every litre of water.

WARNINGS AND PRECAUTIONS FOR USE

The product is not classified as dangerous.
P262 - Do not get in eyes, on skin, or on clothing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
As part of proper health and safety practices: wear suitable work clothes, gloves and eye goggles. Do not eat, drink or smoke when using the product.

STORAGE

Keep out of children's reach. . Store the product in its original container, ensure it is closed securely and store at a temperature between 5 and 40 °C, away from flames, ignition and heat sources. In the event of a leaking or damaged container gather up the product with absorbent material and rinse with water.

DISPOSAL

Dispose of the liquid as dangerous waste. Do not dispose of waste in sewage drains. Do not contaminate soil, surface waters or underground waters with the product. The container is made of polyethylene: after rinsing to remove any residue it can be sent for differentiated waste plastic collection, recycling, incineration or disposal at an approved facility

NOTES

For further information please refer to the SAFETY INFORMATION SHEET.
The information on this sheet is provided in good faith and according to the best of our knowledge, and does not exempt the user from storing, handling and using it as indicated above and according to proper working practices and hygiene standards.
The product provider cannot be held liable for any consequences deriving from its improper use.

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