

## Instructions and Directions For Use for Optizyme Ultra D Dental Multi-enzyme Detergent Sanitiser Concentrate

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### 1. PURPOSE

This Instruction For Use (IFU) procedure outlines the process to effectively use Optizyme Ultra D in dental clinic environments for the cleaning and sanitizing of dental instruments. This IFU provides the following outcomes:

- Proper preparation of Optizyme Ultra D.
- Correct application & dilution for use in;
  - Manual (sink / bucket) baths
  - Ultrasonic baths
  - Auto washers
- Optimal effectiveness of Optizyme Ultra D enzyme detergent sanitizer.
- Correct PPE adherence.

The purpose of acting in accordance with this IFU is to have an uninterrupted, smooth and effective cleaning process that ensures the correct process and use of the product is followed.

### 2. PROCEDURE DESCRIPTION AND PROCESS FLOW

The Instructions and Directions for Use procedure is to be conducted in accordance with the Directions For Use as stipulated on the original Optizyme Ultra D container label only. Users must also refer to instructions for use in relation to instrument, ultrasound bath and auto washer manufacturer's instructions.

The steps in these instructions for use of Optizyme Ultra D are as follows:

1. Preparation
  - a) Product Handling & Packaging
  - b) Review SDS
  - c) PPE and OH&S Requirements
2. Applications and In-use Instructions
  - a) Manual (sink / bucket) Baths
  - b) Ultrasonic baths
  - c) Auto washers
3. After use
  - a) Rinse
  - b) Disinfection and sterilization

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### 3. INSTRUCTIONS AND DIRECTIONS FOR USE

#### 1. Instructions

##### a. Product Handling & Packaging

- Always consult the product Safety Data Sheet (SDS) prior to use and handling.
- Do not mix with other chemicals.
- Store at below 25°C (77 °F) away from sunlight.
- Keep in original container.
- Do not use product past its labelled expiry date.

##### b. PPE and OH&S Requirements

- Wear protective gloves and eye protection when using.
- Wash hands thoroughly after handling.
- Do not spray or create mist.
- Causes serious eye damage. Causes skin irritation. Harmful if swallowed.
- If in eyes, rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do so. Continue rinsing. Immediately call poison center / doctor.
- If on skin, wash thoroughly with water. If any irritation persists, seek medical advice
- If spilled on clothing remove contaminated clothing and wash affected items in hot water before wearing it again.
- When diluted correctly, the solution is classified as non-hazardous in-use.

#### 2. Direction For Use

##### a. **Manual bath (sink / tub):**

1. Remove any visible gross contamination from instruments to be cleaned by rinsing with water or wiping with moistened paper towel.
2. Discard contaminated water and place all contaminated paper towel in appropriate contaminated waste receptacle.
3. Ensure sink or tub is clean and fill with fresh **warm water (@ 40°C)** to required level to ensure all instruments to be clean will be completely immersed. Water level should not be within 10-15cm of rim to minimize any splash or overflow.
4. **Dose 6ml of Optizyme Ultra D per liter of warm water (@ 40°C)** into bath and mix thoroughly. One full Optizyme Ultra D pump depression dispenses 30ml, sufficient for up to 5L of water.
5. Submerge instruments in bath solution for **15 minutes** and allow to soak. Brush if required.
6. Safely remove cleaned instruments and discard water into appropriate sink or drain.
7. After cleaning, all instruments are safe to handle.
8. Rinse instruments thoroughly in clean water, preferably RO or distilled water if available.
9. Cleaned instruments are ready for disinfection and final sterilization as per requirements.

##### b. **Ultrasound bath:**

1. Remove any visible gross contamination from instruments to be cleaned by rinsing with water or wiping with moistened paper towel.
2. Discard used / contaminated ultrasound bath water and place all contaminated paper towel in appropriate contaminated waste receptacle.
3. For ultrasound units without built-in heating element, fill ultrasound bath to manufacturer's instructions with **fresh warm water (40°C - 60°C)**.

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4. For ultrasound units with built-in heating, fill ultrasound bath with fresh water as per manufacturer's instructions. Turn on and pre-heat water to 40°C (**max 60°C**) as per manufacturer's instructions.
5. When required as per ultrasound manufacturers instructions, test ultrasound is working effectively as per manufacturer requirements.
6. **Dose 6ml of Optizyme Ultra D per liter of 40°C warm water** into the ultrasound bath water and mix thoroughly. One full Optizyme Ultra D pump depression dispenses 30ml, sufficient for up to 5L of water.
7. Where available place instruments to be cleaned into appropriate tray or cassette and ensure instruments are not touching other instruments as per manufacturer's instructions.
8. Submerge instruments into ultrasound bath, ensuring all instruments are completely immersed and replace ultrasound lid.
9. Run cleaning cycle as per manufacturer's instructions or for **5 minutes**.
10. After cleaning, remove instruments. All instruments are safe to handle.
11. Rinse instruments thoroughly in clean water, preferably RO or distilled water if available.
12. Cleaned instruments are ready for disinfection and final sterilization as per regulatory / manufacturer requirements.
13. To check sanitation efficacy of ultrasound bath water solution dip (1cm) of a **HYDRION QUAT** test check 100 strip into the ultrasound bath water solution for 5 seconds and then remove.
14. Observe if there is any colour change of the test strip and measure against the colour indicator on the pack. A colour change that indicates a quat level of above 20ppm indicates that the sanitation efficacy of the water solution is still effective and the water solution can be used again.
15. If there is no colour change or the change indicates a level of less than 20ppm the water solution is no longer sanitary and the water should be discarded and fresh water be used following above steps 3 onwards.
16. It is recommended that all ultrasound bath water solutions be changed twice daily or more frequently where heavy re-use / multiple cycles are carried out within a day.
17. All ultrasound bath water solutions should be emptied at the end of each day and the inside of the ultrasound bath cleaned as per manufacturer's instructions.

### c. Auto washer (auto dosing systems):

1. Remove **Optizyme Ultra D** container cap and replace with matching auto dosing cap and dip tube and ensure cap is tightly closed and dip tube is correctly in place.
2. Follow auto washer manufacturer's instructions for correct use and loading of instruments.
3. Where possible, set auto dosing to **2-4mL of Optizyme Ultra D per liter of wash cycle water**
4. Where auto dosing is pre-set by manufacturer, refer to manufacturer's instructions.
5. Set wash cycle temperature to **(45°C - 60°C)**.
6. Run required wash cycle as per manufacturer's instructions.
7. After cleaning, all instruments are safe to handle.
8. Cleaned instruments are ready for disinfection and final sterilization as per regulatory and manufacturer's instructions.

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