

TITLE: OPERATION OF WISECLAVE® DIGITAL AUTOCLAVE DOC. NO. CWD-OPN-013 REVISION NO. 00 | EFFECTIVE DATE: December 28, 2016 Page 1 of 6 NAME SIGNATURE **AUTHOR** Ethel O. Paderes willow REVIEWED BY: Engr. Joselito A. Gillera APPROVED BY: Engr. Restituto B. Sumanga Sr. DOCUMENT HISTORY RECORD Form No. DATE REVISED REV NO. AUTHOR REASON FOR REVISION DCN 2016-12-033 Ethel O. Paderes N/A Initial Issue Important Note.

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#### PURPOSE

- 1.1 The objective of this documented information is to provide standard instruction for the operation Wiseclave® Digital Autoclave
- 1.2 To determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

1.3 To ensure that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;

are maintained to ensure continuing fitness for their purpose.

1.4 Retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

#### 2.0 SCOPE

2.1 The scope applies to the safe operation of the autoclave by the authorized laboratory personnel

2.2 Measurement traceability. When measurement traceability is a requirement, or is considered by CWD to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

b) identified in order to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

2.3 To determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary

#### RESPONSIBILITY 3.0

- 3.1 The Headof the Laboratory shall manage the administrative and technical operations of the laboratory.
- 3.2 The Laboratory Analyst must control and maintain the equipment.

#### 4.0 DEFINITIONS

- 4.1 Sterilization destruction or removal of all viable organisms from an object or from a particular environment
- 4.2 Autoclave is a pressure cooker that sterilizes, or kills all microorganisms and their spores

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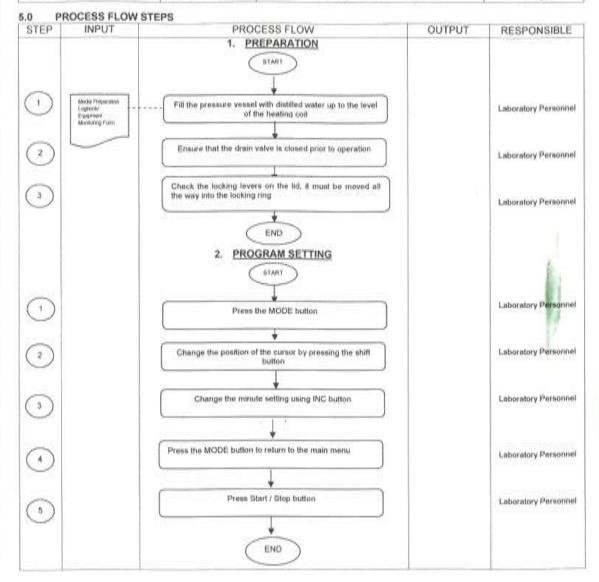
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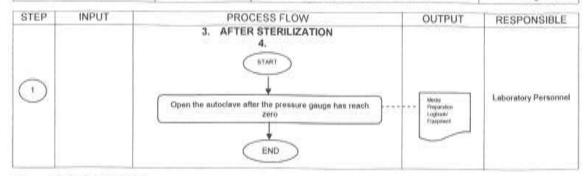




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# PROCESS DETAILS: 6.1 Preparation

Fill the pressure vessel with distilled water up to the level of the heating coil	60
Ensure that the drain valve is closed prior to operation	
Check the locking levers on the lid, it must be moved all the way into the locking ring	

6.2 Program Setting

Press the MODE button



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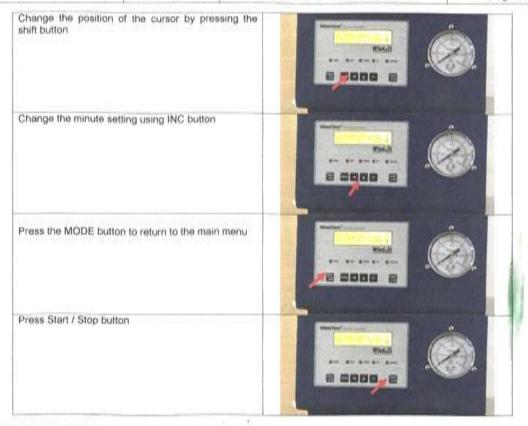
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## 6.3 After sterilization

Open the autoclave after the pressure gauge has reach zero



# 6.4 HEALTH AND SAFETY

- 6.4.1 Personal Protective Equipment (Apron, Goggles and Heat resistant gloves) must worn when removing the sterilized items
- 6.4.2 The handle should only be gripped at the experiment end and step back when opening the sterilizer
- 6.4.3 Autoclavable bags should be partially opened to prevent it from bursting.

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6.4.4 Do not sterilize pressure - sealed vessels

#### 7.0 RECORDS RETENTION

- 7.1 Active Retention indefinite retention period for current or active documents for both electronic and hardcopy/Controlled Copy.
- 7.2 Inactive/Archival Retention shall be kept for active three (3) years or may request for an extension as deemed necessary (hardcopy), for electronic/soft file; it shall be kept in a separate folder named "Obsolete Copy"

### 8.0 REFERENCE DOCUMENTS

- 8.1 ISO 9001:2015 QMS Standard
- 8.2 QMS Manual
- 8.3 Statutory and Regulatory Requirements 8.4 WiseClave® Digital Autoclave Operation Manual 8.5 WHO Biosafety Manual 2004

### 9.0 ATTACHMENTS

- 9.1 Media Preparation Logbook 9.2 Equipment Monitoring Form

### 10.0 DISTRIBUTION LIST

# Note 1: Select Relevant Recipient to Appear in below List.

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8	Laboratory (Quality Control Division)		

Note 2: Master Copy is in the custody of the Document Control Center.



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