

STANTON TERRITORIAL HEALTH AUTHORITY

Yellowknife, Northwest Territories

TITLE: M11 Ultraclave Sterilizer	Revision Date: 07-April-2017	Issue Date: 07-April-2015
Document Number: MIC81200	Status: Approved	
Distribution: Mycobacteria Manual	Page: 1 of 9	
Approved by: Gloria Badari, Director, Corporate Services and Chief Financial Officer	Signed by: (Original Signed Copy in Microbiology)	


PURPOSE:

To standardize the general use, quality control and maintenance of the MII UltraClave (autoclave/sterilizer) in the Mycobacteria Room.

SPECIAL SAFETY PRECAUTIONS:

- Handle all patient samples and testing reagent using “Routine Practices”
- Please refer to the Northwest Territories Infection Prevention and Control Manual, march 2012
- Prior to testing all patient are to be identified as per I-0500 Use of Two Patient Identifiers.

MII ULTRACLAVE

Equipment	Information
MII UltraClave Automatic Sterilizer	
	<p>Manufacturer:</p> <ul style="list-style-type: none"> • Ritter® by Midmark • M11 UltraClave <p>Serial #: V1264477</p> <p>Model # currently unattainable (on back of equipment)</p>

NOTE: This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against electronic version prior to use.

FILENAME: MIC81200MIUIltraClaveSterilizerPRO.doc | PRINT DATE: 9 March 2015

TITLE: M11 Ultraclave Sterilizer	Revision Date: 07-April-2017	Issue Date: 07-April-2015
Document Number: MIC81200	Status: Approved	
Distribution: Mycobacteria Manual	Page: 2 of 9	

INFORMATION ABOUT ULTRACLAVE USE:

- **Wrapping items** - loosely wrap equipment items to be sterilized (such as the pipettors for Vitek saline), in pouches or a clean towel. Seal with autoclave tape. Wrapping helps to retain sterility and autoclave tape aids as a visual check that the load has been autoclaved (tape display black stripes when proper autoclave temperature is reached).
- **Water reservoir** - use only distilled water to fill the reservoir tube. Tap water is unsuitable as it may contain chlorine, which is corrosive to stainless steel chamber.
- **Precautions** – Improper packaging, improper loading, and sterilizer malfunctions can cause autoclave failures and the load must be re-sterilized as the items cannot be considered properly sterilized.
- **Build-in monitoring of physical controls** – the sterilizer is equipped with temperature and pressure measuring devices that help detect sterilizer malfunctions. If the sterilizer controls senses physical conditions outside of established limits the system aborts the cycle.
- **Sterility monitors** - Monitoring of Biological and Chemical indicators – The use of Attest, autoclave tape and Chemical Strip help in process monitoring and indicate if conditions in the sterilizing chamber were adequate to achieve sterilization (although this is never a guarantee).
- **Print-out** - The sterilizer is equipped with a printer that records a record of each load's cycle time, temperature and pressure. Keep print-outs for record keeping.

Autoclave settings:

- Use “**P1**” button (a manually programmed setting) for large loads such as MGIT tubes in large orange autoclave bags, or Wet discard container of processing pour-offs.

NOTE: This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against electronic version prior to use.	
FILENAME: MIC81200MIIUltraClaveSterilizerPRO.doc	PRINT DATE: 9 March 2015

TITLE: M11 Ultraclave Sterilizer	Revision Date: 07-April-2017	Issue Date: 07-April-2015
Document Number: MIC81200	Status: Approved	
Distribution: Mycobacteria Manual	Page: 3 of 9	

- Use the “**Packs**” button to sterilize packages of material (pre-programmed for 30 mins with a 30 min dry time). Example of a “pack” = Vitek 2 pipettor.
- Use the “**Pouches**” button to sterilize small packages of material (pre-programmed for 5 mins with a 30 min drying time). Example of a “pouch” = metal forceps.
- For a full description of Controls, refer to M9/M9D/M11/M11D Self-Contained Steam Sterilizer Installation & Operation Guide Controls & Indicators, page 9-10 and “Standard Cycle Parameters” page 16.

CONTROL POUCH:

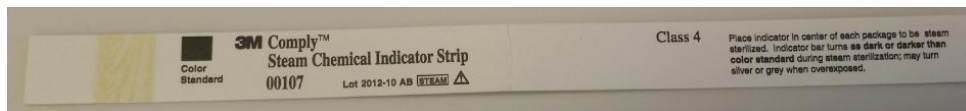
For every autoclave load, add a “control” pouch containing:

1. An Attest™ Biological Indicator vial labelled using a Sharpie as “test” and date.

Do not crack the Test vial before sterilization.



2. A (folded in half) 3M Comply™ Steam Chemical Indicator Strip.



3. Fold ends and seal loosely with autoclave tape so steam can enter pouch (see picture below). Place control pouch on top of load.



NOTE: This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against electronic version prior to use.

FILENAME: MIC81200MIIUltraClaveSterilizerPRO.doc | PRINT DATE: 9 March 2015

TITLE: M11 Ultraclave Sterilizer	Revision Date: 07-April-2017	Issue Date: 07-April-2015
Document Number: MIC81200	Status: Approved	
Distribution: Mycobacteria Manual	Page: 4 of 9	

ATTEST INDICATORS:

- Biological Indicator → vials contain spores of *Geobacillus stearothermophilus*
- Built-in chemical indicator → label on vial changes from pink to brown upon steam exposure. Not a measure of sterility; this gauges effective placement in load.
- Run an unsterilized vial (label with “control” and date) with the autoclaved vial (“test”).
- Do not handle the Test vial (sterilized vial) until it has completely cooled (vial may burst).
- Handle vials by the cap when crushing and incubating.
- Crack vials in the Attest incubator along the inside of the wells at a 45° angle and then insert in any available slot.
- Leave vials overnight for 24 hours incubation at 56°C in the Attest steam incubator.
- Record Lot #, date, growth or no-growth (using the colour of vial as the indicator).

In-Control results:	
Test Colour: Purple Growth: No growth	Control Colour: Yellow Growth: Growth of <i>Geobacillus sp.</i>
Interpretation: Load successfully sterilized & Attest vial working as expected Action: Discard load into Biohazard bag in Bacteriology room.	
Sterilization failure:	
Test Colour: Yellow	Control Colour: Yellow
Interpretation: Attest vial working as expected however load not sterilized. Action: Check load parameters and placement. Repeat sterilization.	

TITLE: M11 Ultraclave Sterilizer	Revision Date: 07-April-2017	Issue Date: 07-April-2015
Document Number: MIC81200	Status: Approved	
Distribution: Mycobacteria Manual	Page: 5 of 9	

Attest vial failure:	
Test Colour: Purple	Control Colour: Purple
<p>Interpretation: Attest vial failed to grow <i>Geobacillus sp</i> within the 24 hour time period, cannot guarantee load sterility.</p> <p>Action: Check lot and expiry date. Repeat if within date. If still same results, use a different lot. Discard old lot. Attest vial positive control must display yellow growth within 24 hours max, and Test vial must be completely purple at this timeframe, to consider a successful sterilization cycle.</p>	
Mix-up of vials:	
Test Colour: Yellow	Control Colour: Purple
Action: Cannot guarantee load sterility. Label vials as indicated above.	

GUIDELINES FOR LOADING:

Follow M9/M9D/M11/M11D Self-Contained Steam Sterilizer Installation & Operation “Guidelines for Loading” page 13-15 for a complete description of item placement and load capacities.

- Pouches may overlap, but should not be stacked on top of one another
- Containers should be placed on their side to allow steam to enter and condensate to exit
- Items should be kept “open” (ie. Jars)
- If items cannot be wrapped in towel or a pouch, place item on a towel or absorbent paper (rather than directly on the metal tray)
- Never sterilize items that contain volatile substances
- Never force the door open. Door should automatically unlock and open when exhausting air. If door does not move freely, wait 40 minutes for the load to cool down and depressurize before opening the door.

NOTE: This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against electronic version prior to use.	
FILENAME: MIC81200MIIIUltraClaveSterilizerPRO.doc	PRINT DATE: 9 March 2015

TITLE: M11 Ultraclave Sterilizer	Revision Date: 07-April-2017	Issue Date: 07-April-2015
Document Number: MIC81200	Status: Approved	
Distribution: Mycobacteria Manual	Page: 6 of 9	

CYCLE OPERATION

- Fill reservoir with distilled water until past the marked fill line.
- Load items.
- Display shows “SELECT CYCLE” → Close and latch door
- Press button for cycle parameter (ie. Packs, P1, etc)
- Press start button
- Sterilizer beeps and the printer begins to record the start of cycle.
- Display will show the sterilizer cycling through its activities ie filling chamber, sterilizing (with temp & PSI), Drying, etc.
- Autoclave beeps when the door is about to open as a warning. Door opens to facilitate drying.
- Wait until items completely cool before removing from chamber.

ULTRACLAVE MAINTENANCE:

- Autoclave displays “Perform Weekly Maintenance” to inform user that maintenance is due. Instrument does this automatically after 7, 14 and 21 days after it’s plugged in.
- Never use abrasive (ie. Steel wool, scouring pads) or bleaching agents (ie. Accel TB) in chamber because of possible damage to metal surfaces and other components

Daily:

- Clean external surfaces using quaternary disinfectants only and allow to air dry (phenol and iodine may damage the unit).
- Examine and clean gasket seal with a damp cloth

TITLE: M11 Ultraclave Sterilizer	Revision Date: 07-April-2017	Issue Date: 07-April-2015
Document Number: MIC81200	Status: Approved	
Distribution: Mycobacteria Manual	Page: 7 of 9	

Weekly:

- Drain water from reservoir, and refill with fresh distilled water
- Wash the interior chamber and trays with mild soap or Speed-Clean (dilute with distilled water), followed with a distilled water rinse.

Monthly:

- Time monthly maintenance so that no loads are to be processed during cleaning
- Drain water from reservoir, and refill with fresh distilled water
- Clean the Chamber and Plumbing. (Keep trays inside chamber while cleaning).
 1. Add an ounce of Speed Clean Sterilizer Cleaner to the bottom of chamber. Close door.
 2. Select “**Pouch**” cycle and start the program.
 3. Stop the cycle when the Drying portion of cycle begins.
 4. Re-drain reservoir and re-fill with fresh distilled water.
 5. Start the “**Unwrapped**” cycle to rinse chamber and plumbing free of cleaner.
 6. Re-drain the reservoir and again, re-fill with fresh distilled water.
- Pressure Relief Valve check (leave Mycobacteria Room door open to help vent steam, and as an extra precautionary safety measure).
 - Pressure Relief **Lever** is a square-shaped lever located on the top center of the sterilizer, connecting to the **Valve**.
 - Pressure Relief **Valve** is opened by the lever and functions to vent steam below the sterilizer towards the back.
 1. Place a cloth towel underneath/around the bottom of the sterilizer to prevent scalding from escaping steam from the sides.
 2. Start the “**Unwrapped**” cycle again.

TITLE: M11 Ultraclave Sterilizer	Revision Date: 07-April-2017	Issue Date: 07-April-2015
Document Number: MIC81200	Status: Approved	
Distribution: Mycobacteria Manual	Page: 8 of 9	

3. Wait until pressure reaches 20 PSI (138 kPa) → Display should read “*Heating – Unwrapped XXX°F 20.0 PSI*”) → Pull UPWARDS on the pressure relief lever for 3 seconds.
 - Steam will vent quickly from below while the lever is pulled up. This is normal and it should occur so don’t be alarmed.
4. Watch that the pressure relief lever closes easily when released. If it does not, repeat pulling upwards again, this time release it quickly so the valve snaps back into place. Repeat until the valve sits properly.
 - When lever is seated properly, the valve should close and steam should stop escaping from underneath unit.
5. If all it well, pressure relief check is complete. Press the STOP button to abort the cycle. Stopping prevent unit from overheating.

Note: If the Pressure Relief Lever does not seat properly after multiple tries, or if excessive force is required on the lever to open the pressure relief valve, a call for Servicing should be made.

- Trays- wipe down with a damp cloth/towel. Allow chamber to completely cool before removing metal trays for a wipe-down.
- Filters – remove and clean
- Wipe down chamber with a damp cloth/towel. Take care not to damage the heating element (bottom of chamber), steam temperature probe or level sensor probe (at back of chamber).
- Replace filters and tray rack

RECORD KEEPING:

- Keep sterilizer print-outs and file in top drawer inside Mycobacteria room cabinet (below centrifuge). Record the date & approx time load was done, if Attest QC passed, and initial.
- Record Maintenance on sterilizer sheet; record Attest results on QC sheet.

NOTE: This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against electronic version prior to use.	
FILENAME: MIC81200MIUIltraClaveSterilizerPRO.doc	PRINT DATE: 9 March 2015

TITLE: M11 Ultraclave Sterilizer	Revision Date: 07-April-2017	Issue Date: 07-April-2015
Document Number: MIC81200	Status: Approved	
Distribution: Mycobacteria Manual	Page: 9 of 9	

MAINTENANCE AND QC SHEETS:

- Found in Mycobacteria Manual Manual → “MIC81210 M11 Sterilizer Maintenance Sheets”.

RELATED DOCUMENTS & REFERENCES:

- Midmark. (2011). *M9/M9D M11/M11D Self-Contained Steam Sterilizer Installation & Operation Guide* (Vols. 003-1249-00 Rev.Z). Versailles, Ohio: Midmark Corp.

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	11-Feb-15	Initial Release	L. Driedger