SUBJECT: V-113 ATTEST IN THE OPERATING ROOM	POLICY #: 1236	
	VERSION: 2	
APPROVED BY:		
ASC Approvers, Aram. Messerlian (CHIEF PHYSICIAN I ANESTHESIOLOGY), Beryl Brooks (ADMR,COMP AMB HEALTH CARE CENTER), Leila Adriano (NURSE MANAGER)		
DATE APPROVED: 09/06/2018		

- **PURPOSE:** To allow rapid reliable biological monitoring of the 270 degree Fahrenheit/132 degree Celsius gravity displacement steam sterilization process.
- **POLICY:** The monitoring process will be done every schedule work morning, when sterilizing implants, or whenever deemed necessary

PROCEDURE:

AUTO READER BIOLOGICAL INDICATOR DAILY CONTROL

The biological Attest incubator will be left ON at all times. If the incubator loses power, the auto reader incubator needs to warm up for at least one hour prior to use.

- 1. For your positive control, use a non-processed Attest Rapid Readout Biological Indicator with the same manufacturing date and lot number as the test biological indicator.
- 2. Use a new control indicator each day you test the sterilizer with a biological indicator.
- Place asked information in logbook including relative humidity (RH). Immediately report to Facilities Department and Nursing Supervisor, Nurse Manager or Charge Nurse any RH result of > 60%. Steam sterilization will not be used until RH is within normal range.
- 4. Seal indicator.
- 5. Crush unprocessed indicator in crusher well.
- 6. Tap indicator vial until media wets strip at bottom of vial. Write a "C" and a date on the label of the positive control indicator.
- 7. Place indicator in incubation well.
- After one hour of incubation press and hold the positive control in the readout well. The processed indicator results are no valid until the (+) control reads fluorescent positive (red light, +). After the one-hour of fluorescent readout, continue to incubate the positive control for a visual color change and discard. If

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the positive control remains purple, check the incubator temperature and storage conditions. Retest the auto-reader and incubator with a new positive control. (See trouble shooting guideline poster, posted near the Attest incubator).

9. Discard all positive result indicators in the sharps container.

The positive control must provide a fluorescent positive result (red light). If the positive control reads fluorescent negative (green), check the incubator temperature and the auto reader UV light. The incubator temperature can be checked with a mercury thermometer, with the range as follows: 60 degrees Celsius plus or minus 2 degrees (140 degrees Fahrenheit plus or minus 3 degrees). The UV light must be changed every 6 months, check the side of the incubator for the calendar for the given month.

If control result is negative, retest with a different lot number. Notify the Ambulatory Surgical Center (ASC) Nursing Director or designee and the Attest Company of the negative control results.

PROCESSING BIOLOGICAL INDICATORS

- 1. Process the indicator as usual in every 270F/132C gravity displacement steam sterilizer. Always use the perforated instrument tray.
- 2. After the completion of the cycle, one should fully open the sterilizer door for a minimum of 5 minutes prior to removing the Attest Biological indicator.
- 3. Remove the Biological indicator from the sterilizer and if possible allow to cool for an additional 10 minutes prior to crushing. Next carefully press cap down. Check chemical indicator on the label for a color change from rose to brown. This change confirms that the biological indicator has been exposed to the steam process. This color change does not indicate that the process was sufficient to achieve sterility. If chemical indicator is unchanged, check the sterilization process.
- 4. Identify the Attest Readout Biological Indicator by noting the sterile number, load number and processing date on the indicator label. Place the needed information in the logbook.

READOUT DETERMINATIONS

1. After processing, seal the indicator and crush the indicator in crusher well. Tap the vial until the biological indicator media wets strip at bottom of vial. Place the

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biological indicator in the incubator for one hour. Read both the positive control and processed indictors for early detection of positive (+) results at convenient time intervals such as 15, 30, and 45 minutes. The final negative florescent reading is made in 1 hour. The indicators must be incubated between readings.

- Press indicator down into reader will and read red (+) or green (-) negative results. Note: wait five seconds before reading the next Attest Rapid Readout Biological indicators.
- 3. A positive (+) red light in the auto-reader indicates an inadequate sterilization process. A negative (-) green light indicates an adequate sterilization pressure.

Act on any positive (+) biological test results immediately. Retest the sterilizer by placing several Attest Rapid Biological Indicators in sterilizer trays (perforated instrument tray). Do not sue the sterilizer until all the biological indicator results are negative (-). If the biological result continues to be positive (+) notify Building Crafts, ASC Nursing Director or designee and quarantine the sterilizer.

AUTO-READER DAILY CALIBRATION

Use only the first processed Attest Rapid Readout Biological indicator of the day shift to calibrate the reader.

- 1. Seal the indicator
- 2. Crush processed indicator in crusher well
- 3. Leave indicator in well for one minute
- 4. Press and hold vial down
- 5. Wait until the red (+) or green (-) light illuminates
- 6. Press and release calibration button on the back right side of Auto-Reader. Yellow light will stop flashing when calibration is completed.
- 7. Place the indicator in the well for one hour and continue to incubate as per policy
- 8. Proceed to crush, incubate the knead all processed biological indicators

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STORAGE AND SHELF LIFE

- 1. Store Attest Rapid Readout biological indicators under normal room conditions. (59-86 degrees Fahrenheit/15-30 degrees Celsius)
- 2. Do not store biological indicators near sterilants or other chemicals.
- 3. Attest Rapid Readout biological indicators have a 2-year shelf life. The manufacturing date is printed on the label of the Attest Rapid Readout biological indicator. The expiration date is printed on each box of biological indicators and shipping carton.

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