| University of Washington Medical Center 1959 NE Pacific Street. Seattle, WA, 98195 | Original Effective Date: 03-11-16 | Number: EQ-0008.02 |
|--|-----------------------------------|-----------------------|
| Transfusion Services Laboratory Policies and Procedures Manual | Revision Effective Date: | |
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TITLE: Tube Sealer Operation and Maintenance

PURPOSE:

Provide instructions to seal PVC tubing using the Genesis Rapid Seal II Tube Sealer SE540

PRINCIPLE & CLINICAL SIGNIFICANCE:

A tube sealer is used to seal PVC tubing, connecting blood containers, to allow separation of the containers while retaining the sterility of the blood component. Sealers are also used to make tubing segments used for sterile sampling of the blood component.

If the seal leaks creating an open system after cutting, the component must be transfused within 24 hours if stored at 1-6°C or within 4 hours if stored at 20-24°C.

POLICIES:

Maintenance:

Cleaning of the front panel and handheld unit is performed weekly and as needed

SPECIMEN REQUIREMENTS:

NA

REAGENTS/SUPPLIES/EQUIPMENT:

| Reagents: | Supplies: | Equipment: |
|-----------|-----------|-----------------------|
| NA | NA | Genesis Rapid Seal II |
| | | Tube Sealer SE540 |

QUALITY CONTROL:

NA

INSTRUCTIONS:

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Sealing Tubing
Front Panel Cleaning
Handheld Unit Cleaning

| Sealing | g Tubing | | |
|----------------|--|---|--|
| STEP | ACTION | | |
| | | | |
| | If using | Then | |
| | Main unit | | |
| | | Figure 1: Splash Guard | |
| 1 | | | |
| | | Push both sides to take Push in till the protector locks. | |
| | | off the protector. Figure 2: sealing protector | |
| | Ensure splash guard is installed and sealing protector is securely | | |
| | | attached. | |
| | Hand unit | | |
| | | Figure 3: head protector | |
| | | Ensure head protector is securely attached. | |
| | Turn power switch on | | |
| 1 | If Indicator Lamp is | Then | |
| _ | Green | Proceed to next step | |
| 2 | Yellow | Sealing Protector Head is removed or not properly mounted on the sealing head Replace if removed or reposition to secure it Proceed to next step when the indicator lamp turns green | |
| | 2 1 100000 to Hoxt Stop When the indicator famp tame grown | | |
| | Use To | Seal Then | |
| 3 | | ubing Place tubing in the sealing head and depress the trigger level, the indicator lamp on the main unit will turn RED | |
| | | Remove the tubing after the trigger level releases the tubing and the indicator lamp turns GREEN | |

| STEP | ACTION | | | |
|------|---|------------------------|---|--|
| | Hand unit | 1/8" or 1/4" tubing | Place tubing in sealing head of hand unit and pull the trigger lever. The sealing indicator lamp on the handheld turns GREEN Release the trigger level when the sealing indicator lamp turns off NOTE: Must use hand unit to seal 1/4" tubing on cell processing sets. Tubing must be pulled all the way to | |
| 4 | Make 2 more seals close the first one and cut the tubing at the middle seal, taking care not to open the seal NOTE: If you do not have enough tubing for three seals close to each other, one seal is acceptable | | | |
| 5 | Clean if nee | eded | | |

Front Panel Cleaning

| STEP | ACTION |
|------|--|
| 1 | Turn power switch off |
| 2 | Remove seal head protector by pinching both sides then pulling. (See Figure 2 above) |
| 3 | Clean head using either dry cloth, cloth dampened with water, a mild detergent, or 70% alcohol for decontamination |
| 4 | Dry the sealing head area thoroughly |
| 5 | Reassemble the seal head protector by pushing it back into the front panel until it clicks |
| 6 | Allow to dry thoroughly for several minutes if any liquids were used for cleaning |
| 7 | Turn power switch on and test the unit by making a seal. |

Handheld Unit Cleaning

| STEP | ACTION |
|------|---|
| 1 | Turn power switch off |
| 2 | Remove the RF cable from the hand unit |
| 3 | Loosen the screw on the bottom of the protector head then push head off |

| STEP | ACTION | |
|------|---|--|
| 4 | Remove clamp by: • Push clamp inward • Pull lever down • Release the clamp How to disassemble and reassemble the clamp Figure 4 | |
| 5 | Clean clamp, protector head and sealing area thoroughly using either dry cloth, cloth dampened with water, a mild detergent, or 70% alcohol for decontamination | |
| 6 | Allow to dry thoroughly for several minutes if any liquids were used for cleaning | |
| 7 | Reassemble clamp by (see figure 4 above): • Pull lever down • Push clamp in • Push lever up • Release clamp | |
| 8 | Reassemble protector head: • Push protector head on • Fasten screw on the bottom | |
| 9 | Connect RF cable | |
| 10 | Turn power switch on and test unit by making a seal | |
| 11 | Document the following on the Bench Equipment Maintenance form to indicate weekly cleaning was performed • Date of cleaning • Tech ID | |

CALCULATIONS/INTERPRETATIONS/RESULTS REPORTING/NORMAL VALUES/CRITICAL VALUES:

NA

CALIBRATION:

NΑ

NOTES AND LIMITATIONS:

• Hand unit operates without the head protector installed but it is not recommended.

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- Scalding may occur if you touch any metal part on the hand unit while pulling the trigger lever.
- Pulling the end of the trigger lever provides optimal pressure to ensure reliable seals.
- Making 3 seals close together prevents contamination of the blood component if a leak occurred when the tubing is cut. When there is not enough tubing to make 3 seals, one seal is acceptable. If only one seal is made and it leaks upon cutting, the component is considered air contaminated and should be processed as such.

REFERENCES:

- User's Manual, Genesis Rapid Seal II Tube Sealer Model #SE540; No. CAT # 53418Ae
- Technical Manual. Bethesda, MD: AABB, current edition
- Standards for Blood Banks and Transfusion Services. Bethesda, MD; AABB, current edition

RELATED DOCUMENTS:

FORM Bench Equipment Maintenance

ADDENDUM:

NA

TITLE: Tube Sealer Operation and Maintenance

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| UWMC SOP Approval: | | | |
|--------------------------------|----------------------|------|--|
| UWMC CLIA Medical Director | | | |
| | Mark H. Wener, MD | Date | |
| Transfusion Service Manager | | Date | |
| | Nina Sen | | |
| Compliance Analyst | | Date | |
| Transfusion | Christine Clark | | |
| Service | | | |
| Medical Director | | Date | |
| | Monica R. Pagano, MD | | |
| UWMC Biennial Re | eview: | | |
| | | | |
| | | Date | |
| | | Date | |
| | | | |

07/14/2021: Added policy to specify weekly cleaning and instructions for documenting cleaning on the *Bench Equipment Cleaning* form.