

April 18, 2022

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Dear Ms. Morrison and Dr. Maples,

The following report contains a detailed manufacturing summary for the Clinical Retractable Infant Barrier. Within this report, the C.R.I.B. team has presented the processes that will be used to manufacture this device, as well as the processes taken to create the prototype device and further explained the components' functions. Firstly, a manufacturing overview has been written to summarize the general procedures to be used in the manufacturing process for this clinical solution. Next, part drawings have been generated for the computer-aided design models created for the main body and folding arm components. Such drawings are part of the essential specifications package that is to be provided to suppliers prior to full-scale production. Additionally, the materials needed and necessary procedures for production of the prototype model have been provided. Finally, documentation of the preliminary working prototype has been included to demonstrate the effectiveness of our manufacturing plan.

Best,

The C.R.I.B. Team

Kalani Carter, Josh Duzan, Jack Oberman, and Hunter Thomas

Manufacturing Report for the Clinical Retractable Infant Barrier, presented to Dr. Jill Maples, Assistant Professor at UTMCK, and Ms. Rebecca Morrison, Executive Director at the Center for Women and Infants.

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Manufacturing Overview

A fully functioning Clinical Retractable Infant Barrier device will consist of two main parts: the main supporting body and the folding arm, which houses the retractable netting mechanism. The two main parts will be joined using a pivot hinge and screws. The main body will include a 6061-T651 aluminum plate, that will be cut to an “I” shape, as seen in Figure 1 below. This cut will be made to reduce the total weight of the prototype unit, and hollow, square aluminum tubing will be used to create this structure and reduce costs in production units.

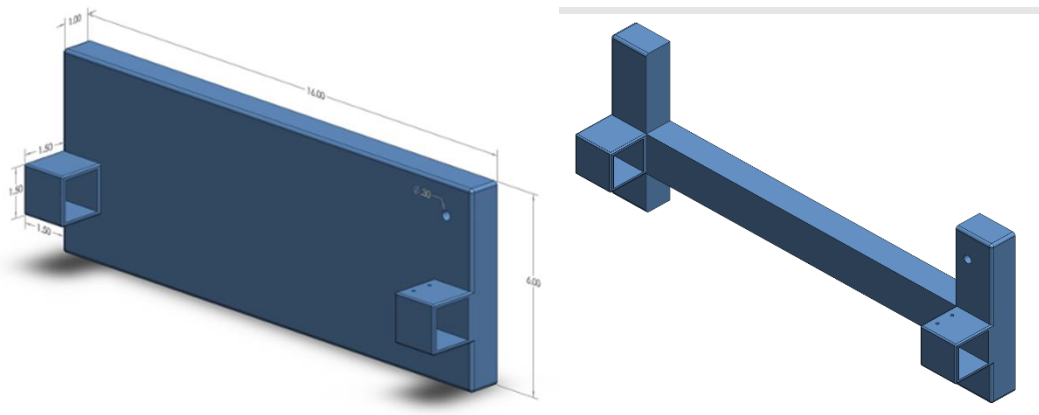


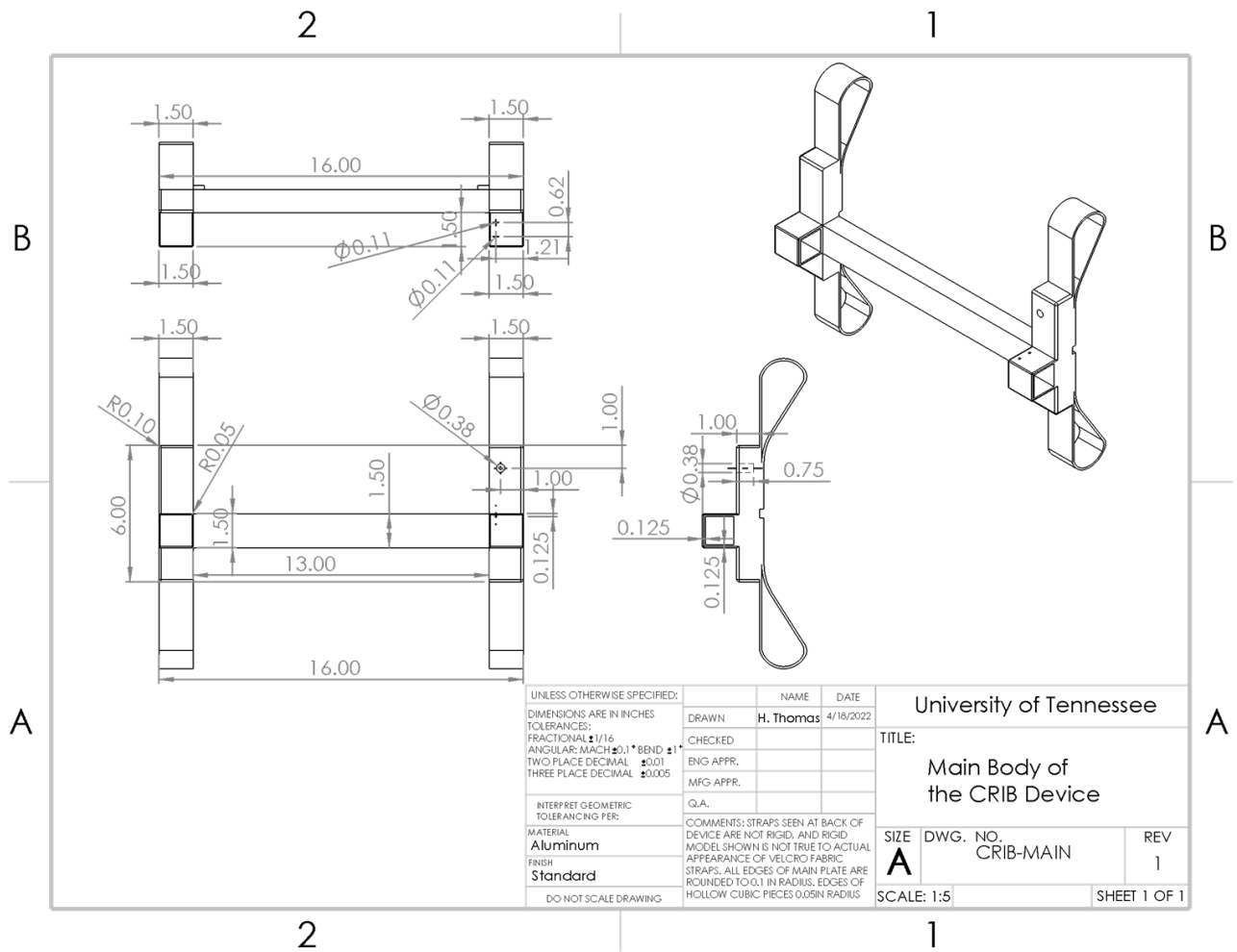
Figure 1: Cutout of the Main Body of the CRIB Device

The main body will have a 0.375” hole drilled into one side, and two 1.5” by 1.5” square hollow aluminum tubes will be screwed onto either side of the solid plate (below the drilled hole) to support the folding arm. Four hook and loop Velcro-style straps will be fastened to the main body and will serve as connection points to the lower railing of the hospital bed. Next, the folding arm will be constructed from 16” by 1.5” by 1.5” square hollow aluminum tubing with a 13” long, ¼” wide slit cut in the middle. A 0.375” diameter hole will also be drilled 1.87” from the bottom of this hollow aluminum tube. The retractable netting mechanism will be enclosed inside the folding arm. This mechanism will consist of a 14” long ¾” diameter stainless steel dowel rod. A polycotton sheet will wrap around the dowel rod to serve as the netting and

protective barrier. The netting will be secured on the rod with two small hooks to hold it in place. The top of the dowel rod will have a knob that allows the netting to easily retract when turned. Additionally, two hook and loop Velcro-style straps will be sewn to the free end of the polyester-cotton blend netting to allow attachment to the upper railing. Finally, a 3” stainless steel pin with a 7-½” chain will be placed in the 0.375” diameter hole on the metal plate and folding arm when the device is in use. The chain of the pin will be attached to the main body to allow the pin to freely hang from the device when not in use. A full flowchart of the manufacturing process can be observed in Appendix A.

Part Drawings

See the following figures for all dimensional specifications of the components that make up the CRIB Device. The included figures depict the main body and folding arm of the device, which have been modeled in SolidWorks. All additional components, including Velcro straps, screws, and dowel rod have no technical drawings. The main device assembly has also been shown in a technical drawing below.



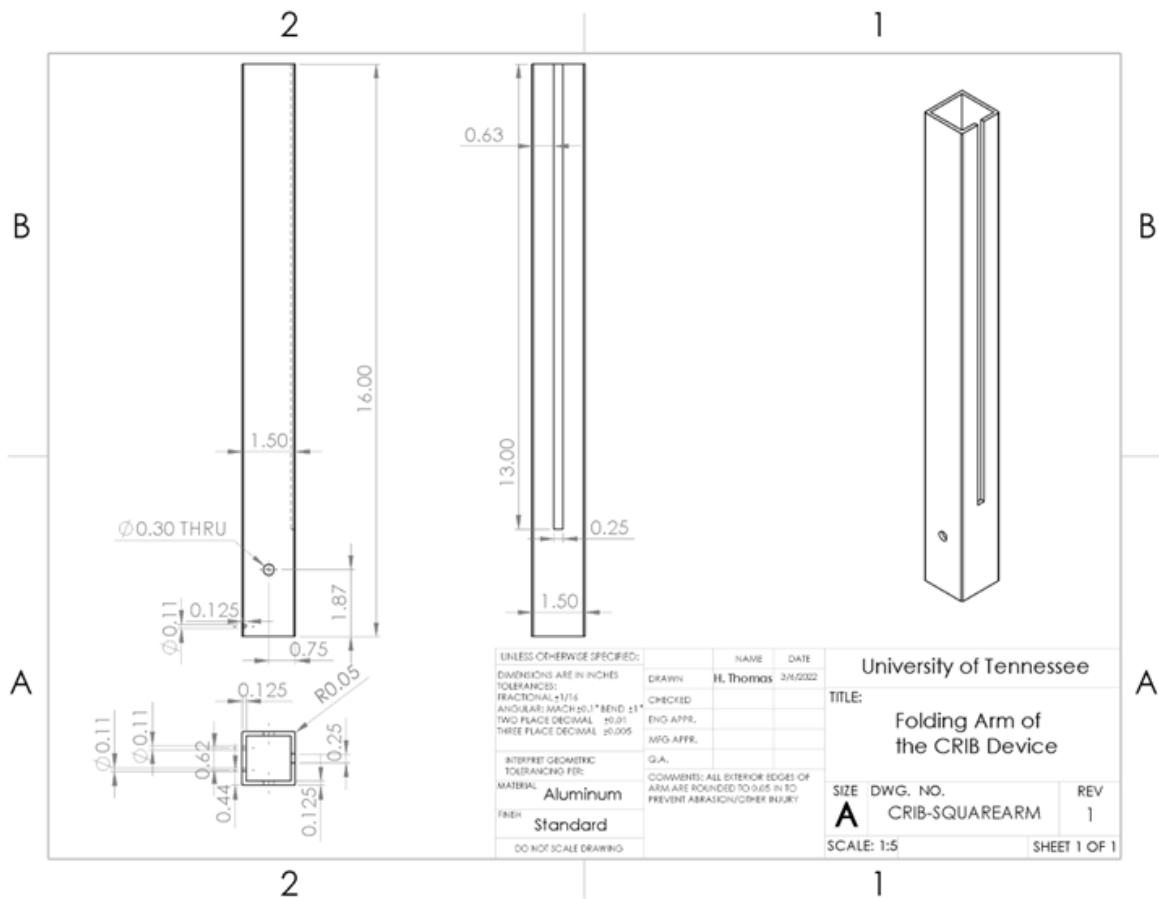


Figure 3: Technical Drawing of the Folding Arm of the CRIB Device

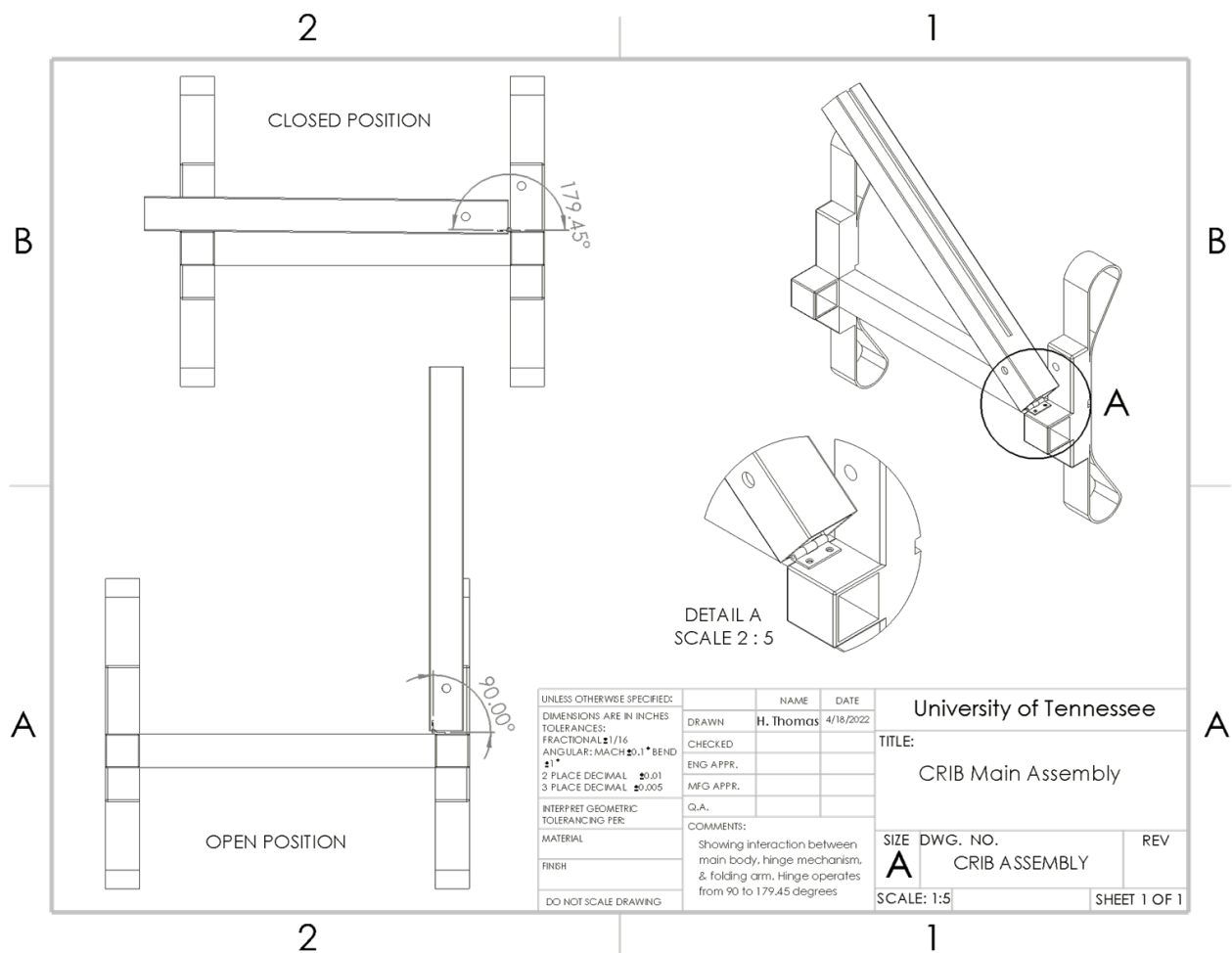


Figure 4: Technical Drawing of the CRIB Device Main Assembly



Figure 5: Rendering of the CRIB Device Assembly in the Hospital

Materials and Cost

The following materials will be used to assemble one C.R.I.B. device.

- A. Main Body: One (1) Solid Aluminum Plate (6" by 16" by 1"): **\$172.92**
- B. Rotating Arm: One (1) Square Hollow Aluminum Tube (1.5" by 1.5" by 19", 1/8" thickness): **\$22.22**
- C. Locking Pin: One (1) Stainless Steel Sliding Door Lock Pin (3 3/8") with 7 1/2" chain: **\$3.54**
- D. Hook and Loop Straps: Four (4) 2" by 10" Stretchable Loop (0.1" Thick.): **\$98.40**
- E. Arm Hinge: One (1) Fiberglass Pivot Hinge (270-degree range of motion, 1 3/16" by 1 3/16"): **\$17.26**
- F. Velcro/ Arm Rest Screws: Eight (8) 1-1/4" Zinc Plated Steel Phillips Head Self-Drilling Screws: **\$9.98**
- G. Hinge Screws: Four (4) 1/2" Zinc Plated Steel Phillips Head Self-Drilling Screws: **\$9.98**
- H. Velcro Washers: Four (4) Galvanized Bonded Sealing Washer: **\$2.54**
- I. Netting Rod: One (1) 304 Stainless Steel Round Bar (14" length, 3/4" diameter): **\$69.72**
- J. Turning Knob: One (1) ABS/steel 3-prong turning knob (1" diameter knob): **\$5.41**

K. Polycotton Netting: One (1) 12" by 36" sheet of polyester-cotton blend fabric: **\$4.40**
L. Pin Lock for Door: Two (2) 3" long, 3/8" diameter Pin Lock: **\$10.58**
M. Rubber Screw Bumpers: 7/8" Rubber Screw Bumpers: **\$5.90**

- Total Cost of Materials: **\$388.41**
- Shipping Costs: **\$48.16**
- Budget Leftover: **\$563.43**

Manufacturing Procedure

Main Body Preparation

To construct the main body, first, cut out two large rectangles from the upper and lower portions of the main aluminum plate, part A, to leave an "I" shape that is 1.5" thick in all directions using an OMAX Waterjet cutter. This will be done for the prototype unit, while production units will require square, hollow aluminum tubing to be attached in the "I" shape for reduced weight and material cost. Next, use a measurement device (ruler, calipers) to cut two (2) 1.5" pieces in length from the hollow aluminum tubing with a band saw. These pieces will serve as the rest for the rotating arm (Alpha and Beta). Next, use a measurement device to measure 1.5" from the bottom of the main body (part A) on one side of the device. Draw a line across the long dimension of the device so that the bottom of the support blocks are on the bottom of the line and the hollow ends of the arm rests are oriented to the left and right of the device. Using clamps, secure the arm rests to the main body. On the opposite side of the device, use a 1/9" drill bit to drill into the main body of the device (B) and arm rests. Drill two 1/9" holes on one of the arm rests (Alpha) so that the hinge (part E) folds from a flat position (facing the other arm rest, Beta) to an upright vertical position. The holes should be 5/8" from the main body of the device and the edge of the arm rest, respectively. Finally, drill a 0.375" hole 1" from the top edge of the

device on the same side as the arm rest Alpha. The hole should be 0.75" from the side edge of the main body and should be above the arm rest Alpha with the holes for the hinge.

Rotating Arm Preparation

Using the leftover material from part B, measure out 5/8" from the edge on one side of the arm. Using a table saw and a 1/4" blade, cut a 13" slit down the long side of the arm so that only one side of the device has a slit for the netting material. Drill a 0.375" hole in the center of the side of the arm to the left of the slit, 1 7/8" above the bottom of the device. This will be used to hold the pin that maintains the arm in an upright position. On the side of the arm to the left of the pin hole and opposite the slit, drill two 1/9" holes 2/7" from the bottom of the device and 5/8" from the edge of the face. These holes will be tapped to produce threading that allows the arm and hinge to become joined.

Rotating Arm Attachment

Using two of the screws from part H, secure the hinge (part E) to the arm through the holes previously drilled. Rest the arm so that it lays flat horizontally and the hinge rotates 180 degrees. Use the other two screws from part H to secure the other end of the hinge to the arm rest containing the holes (Alpha). Ensure the hinge can rotate to 90 degrees with the arm in an upright position.

Locking Chain Attachment

Holding the arm in its vertical position, insert the locking pin through the arm and main body to prevent the device from rotating. Attach the anchor to the chain and the chain to the pin

on the device. Screw the chain anchor to the side of the main body so that the pin can be pulled and hangs to the side of the rotating arm.

Retractable Netting Preparation

The metal rod will have a 3-prong knob inserted into its top, and a small tab will descend from one of the prongs on this knob to catch the polycotton fabric and initiate the rolling process when the rod is later turned. To attach the polycotton barrier, lay the fabric (part I) flat on the work bench. Place the metal rod along the width of the sheet (12”) and roll the sheet over the rod so that it touches itself. Sew the sheet to itself with the rod inside the loop and roll the sheet so that it coils around the rod, leaving room (approximately 6”) to sew the hook and loop onto the netting itself.

Hook and Loop Attachment

On the main body of the device, drill four holes on the side opposite the arm attachments. The holes should be 1” from the inner edge of the arm rests, with the first two being 1” from the top edge of the device and the second two located 1.5” below the first set. Using the four washers from part G and the rest of the screws from part H, attach two hook and loop straps (part D) to the back of the main body. On the netting of the device, arrange the hook and loop straps so that they extend away from the direction of the dowel rod. Sew the strips to the netting so that pulling on the straps will unfurl and deploy the netting when the dowel rod is secured.

Device Assembly/ Operation

There should only be two separate components at this point; the main body with attached arm rests, locking pin, hook and loop straps, and rotating arm attachment, as well as the

retractable netting/ dowel rod component. To complete the device, slide the dowel rod into the rotating arm while it is in its upright position so that the netting hook and loop straps extend out of the slit on the arm. When these straps are pulled, the netting should extend out of the device and uncoil the rod so that the straps attach to the upper hospital bed railing.

Working Prototype

The first iteration of the C.R.I.B. device was tested on hospital beds located in the Mother Baby Unit at the University of Tennessee Medical Center in Knoxville. Figures 6 and 7 show the deployed device on one of these beds.



Figure 6: C.R.I.B. Device seen from inside the bed



Figure 7: C.R.I.B. device seen from outside the bed

As seen in Figures 6 and 7, the device was successfully attached to the lower railing, and the folding arm which contained the polycotton netting was able to be attached to the upper railing of the bed while providing adequate protection from gap between the rails. Another key feature of the C.R.I.B. device is the ability to extract the netting out of the folding arm. At the time of testing, the knob that is to be attached to the upper portion of the steel dowel rod sitting inside the hollow folding arm had not arrived. However, the netting was still able to easily extend out of the slit cut into the folding arm. Unfortunately, since the knob did not come in, the process of putting the netting back into the hollow folding arm was more cumbersome. Overall, the device successfully met the stakeholder needs minus a few features which will be improved upon in future iterations.

The C.R.I.B. Team followed the aforementioned processes to manufacture the prototype device. Once all the main materials had been ordered and delivered, the modifications to each part and assembly could begin. The team started the modifications by generating two .dxf files

using OMAX software. These files set specified cut paths that will allow the OMAX waterjet cutter to remove material from the major metal components. The first file was a cut path to be used on the large aluminum plate, which gave the main body of the device its desired I-shape. The second file was a much simpler cut path that cut the hollow aluminum tubing to the appropriate size for the folding arm and support blocks. Once these files had been created and imported to the OMAX waterjet cutter, the main metal components could be cut to size.

Next, the main body and folding arm were taken to a shop so that the team could begin drilling holes for all necessary attachment points within the aluminum components. The drilling began on the main body, which required four pilot holes to be drilled into the back of the aluminum plate. Five holes had to be drilled into the front of the plate: two small pilot holes for each supporting block and one larger hole for the locking pin, which was cut last to ensure proper alignment with the larger hole in the side of the folding arm. Each supporting block received two holes that aligned with the holes in the front face of the main body. The block that would hold the hinge and serve as the bending point for the folding arm received two additional holes. Three holes were drilled into the aluminum arm: two at its base and one larger hole in the side of the arm that would hold the locking pin. All holes in the aluminum components were made with a drill press and the respective drill bits for each of the holes.

Once the team was finished operating the drill press, the newly created pilot holes were tapped with a metric size five (M5) bit to produce threads for the attachment of machined screws. The team chose to switch to these machined screws rather than self-tapping screws as the thickness and rigidity of the selected aluminum plate caused the self-tapping screws to fail upon insertion. For future units, the aluminum plate will be made from softer aluminum material or

assembled from hollow, square aluminum tubing such as the material used for the folding arm and support blocks.

At first, an impact driver was used to tap threads into the pilot holes, resulting in a broken, over-torqued tapping bit. The bit was replaced, and the process of tapping the pilot holes could continue, although the team had to produce the threading of each hole by hand. Once this tedious process had been completed, the supporting blocks were attached to the front face of the main body. A change to the supporting blocks was made here to aid in the manufacturing process. Rather than having support blocks with cubic profiles, a chop saw was used to make angular cuts off the sides of the blocks, generating a trapezoidal profile when looking at the support blocks from the top or bottom of the device. This was done to ease the process of accessing the screws needed to attach the blocks to the main body. The hinge was then attached to the proper supporting block and the bottom of the folding arm. With these components modified and the assembly underway, the aluminum pieces had begun to take the shape of a true C.R.I.B. device.

After assembling the main body and folding arm, the netting that serves as the primary protective barrier was fabricated. Two 13" by 3.5' sheets of polyester-cotton blend fabric were cut from a larger sheet of fabric. The edges of each fabric piece were then hemmed by two inches using a Brother XL2600i sewing machine with a number 2 straight stitch and white cotton thread. Next, the sleeve for the 16" long, 3/8" diameter dowel rod was created by folding over one side of the fabric by 1.5 inches. This fold was then sewn to the rest of the fabric with a 5/8" seam allowance, and the dowel rod was placed inside the new opening. Finally, two sets of 6" by 2" hook and loop Velcro style straps were sewn onto the other side of the netting opposite the dowel rod sleeve using the same number 2 straight stitch on the sewing machine. With the netting

wrapped around the rod, it could then be placed inside the folding arm. The C.R.I.B device was now fully functional.

As mentioned previously, the first iteration of the device met most of the functions and requirements of the stakeholders. The first need that was identified was for the device to prevent infants from falling off the hospital bed (Function F1). The region where the falls had occurred most often was in the gap found between the upper and lower railing of the hospital bed. As shown by Figures 6 and 7, this gap has been completely covered by the polycotton fabric sheet. The tension on the sheet was also sufficient enough to stop the infant from collapsing the netting and falling to the ground. However, one weak spot was identified after testing the first iteration of the device. The lower part of the sheet did not maintain as high of a tension when compared to the upper part of the sheet, particularly in between the upper and lower railing. Future iterations of the device will seek to address this lack of tension by experimenting with new attachment points for the upper Velcro straps as well as considering a third attachment that goes on the underside of the bed. Along with the need to cover the gap between the upper and lower railing, the polycotton cotton sheet was required to hold up to twenty pounds in order to simulate the weight of a falling baby (Requirement R1). Preliminary testing showed that the current iteration of the device was strong enough to hold this desired weight.

The second need that was addressed was the need for the device to not inhibit patient care (Function F2) and to be operated quickly (Requirement R3). For the first iteration of this device, there is some concern about meeting this need. The Velcro straps that were initially used were notably too long, making it cumbersome and difficult to attach properly. Additionally, the retractable mechanism was not fully functional as the knob meant to roll the fabric back onto itself had not arrived at the time of testing. Thus, it took significantly longer than expected to

return the netting back into the hollow folding arm. Future iterations of the device will employ the turning knob to reduce the time it takes to return the fabric back into the folding arm, and the Velcro straps length will be reduced. The folding arm and hinge mechanism worked as intended, so once the retractable mechanism is addressed, there should be no issue completely meeting this need.

The third need identified was to ensure that the device poses no threat to the infant or mother when attached to the bed (Function F3). Additionally, the device must maintain attached to the railing when the mother and baby are in bed (Requirement R2). To address the concern of mother and infant safety, the sharp edges of aluminum that had been cut with the waterjet cutter were sanded to reduce sharpness. Future iterations may attempt to completely round the edges of the device in order to improve safety as well as provide an aesthetic that more closely aligns with other devices in the hospital room. Additionally, rubber screw bumpers were placed on all exposed screws to eliminate the risk of injury. Finally, the switch in material design of the netting from an open netting to a solid sheet of fabric eliminates the possibility of injury to the infant should one of its limbs get caught in the netting. However, the transition to a single sheet of fabric does increase the chance of suffocation. Future iterations will attempt to minimize this risk. The device itself stayed secured on the hospital bed through most of the testing. It was noted that the folding arm bowed out away from the lower railing, but this will likely be eliminated as the length of the Velcro straps are reduced. Additionally, a different style of Velcro straps with a buckle or clamps may be implemented. As testing progressed, however, one of the screws tore through the Velcro strap. To address this, future iterations will cauterize the Velcro at the site of the screw attachment in order to prevent this from happening again.

The final need that was addressed was the need for the device to be made from fire-safe and non-toxic materials (Requirement R4) and also be made from approved materials that are reusable between patients (Function F4). This need has been completely met as polycotton fabric is a material that is already implemented in hospital settings and is easily washed to sterilize the sheet. Additionally, the materials that were used to make the main body as well as the rest of the device are non-toxic and non-flammable. Thus, this need has been sufficiently addressed.

APPENDICES

Appendix A: Manufacturing Overview Flowchart

