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DESIGN, CONSTRUCTION AND TESTING OF A MALIGNANT HYPERTHERMIA MA--ETC(U)
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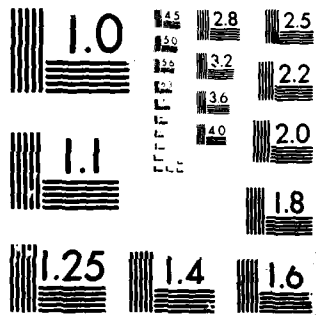
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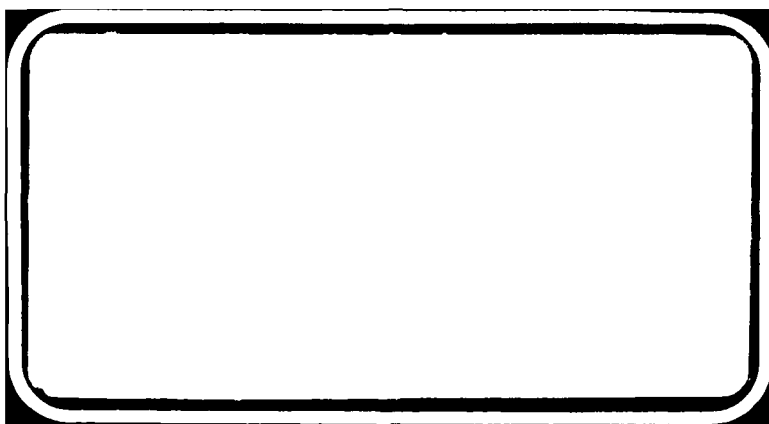
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6 DESIGN, CONSTRUCTION AND TESTING OF
A MALIGNANT HYPERTHERMIA MATTRESS
PROTOTYPE II, FOR EVALUATION BY CANADIAN
FORCES MEDICAL SERVICE

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ABSTRACT

At the request of the Surgeon General Canadian Forces Medical Service, through National Defence Medical Centre, Ottawa, DCIEM constructed a prototype Malignant Hyperthermia Mattress, the design of which was based on an NDMC Anesthesia Department concept.

Tests of the first prototype in simulated operating room conditions revealed several shortcomings. In collaboration with NDMC, DCIEM redesigned and constructed a second prototype. Simulated operating room tests and preliminary evaluation at NDMC have indicated that the Malignant Hyperthermia Mattress, prototype II could contribute significantly in the clinical management of Malignant Hyperthermia patients.

INTRODUCTION

Malignant hyperthermia is a life-threatening clinical condition stemming from a complication during the administration of an anesthetic under operating conditions. A reaction between the anesthetic agent and the patient's body tissues causes a rapid rise in body temperatures, which if not reduced promptly, could cause death. An important part of the treatment procedure for this anesthetic complication is to promote rapid body cooling by covering the patient with crushed/cube ice. The NDMC rationale for construction of a prototype malignant hyperthermia mattress envisaged its use to simplify this technically difficult and time consuming procedure. It was believed that its use would:

- a. facilitate and improve the efficiency of the ice envelopment procedure.
- b. reduce the time necessary to conduct this procedure.
- c. maintain a proper operative field during the ice treatment procedure, with minimal interruption to the Surgeon, his I.V. lines, the anesthetist and his anesthetic hose and life support equipment.
- d. allow the treatment team easy access to the patient requiring this treatment procedure.
- e. help reduce the mortality associated with malignant hyperthermia.

NDMC had foreseen use of this method in connection with:

- a. Prevention (patient suspected of having malignant hyperthermia)
- b. Emergency (patient develops malignant hyperthermia during routine surgery)
- c. Exercise (practise of operating room protocol for the treatment of malignant hyperthermia.

A prototype malignant hyperthermia mattress (Figure 1) was constructed by DCIEM and tested by the Department of Anesthesia NDMC. This prototype conformed to specific dimensions prescribed by NDMC and consisted basically of an inflatable skeleton (oriented to operating table dimensions), an inflation/deflation system, and a drainage system. The inflation system was comprised of a manually operated 0.50 lb

CO₂ cylinder located at the caudal end of the mattress and an oral inflation system located at the top lower, left boundary. If the CO₂ inflation system was inoperative, the mattress could be inflated orally. The oral inflation valve/tubing could be utilized for deflation purposes. The drainage system consisted of orifices on the floor of the mattress connected to drainage tubes. The NDMC specification insisted on materials sturdy enough to withstand the weight of ice on the side walls, immediate inflation capability, bilateral recesses at the head end to allow access to the patient's arms (monitoring, infusion, placement of arterial lines, etc.) and a floor thin and strong enough to prevent compression against the underlying table in the event of the requirement for external cardiac massage.

The prototype mattress was therefore constructed of Neoprene coated nylon, a very durable reasonably lightweight fabric used in the manufacture of liferafts. At that time, in the absence of the now acquired RF sealing machine, all seams, and joints had to be glued by hand - a difficult and time consuming method. NDMC operating room tests and exercises with the prototype I malignant hyperthermia mattress seemed to justify the original philosophy for its use in the clinical management of malignant hyperthermia patients. The tests, however, revealed some shortcomings in the original design:

- location of the CO₂ cylinder and oral inflation valve.
- relocation of the drainage ports to clear the edges of the underlying operating table.
- modification to drainage ports to prevent blocking by a single ice cube.
- the requirement for an increased cooling capacity (walls of the inflatable section to be extended vertically to provide double the inflated depth).
- no central recess at the head end to provide passage for anesthetic hoses.
- redesign of the bilateral arm recesses to prevent damageable pressure points on the posterior aspects of the patient's arms.
- poor design of the foot end of the mattress with the consequences that the corners developed leaks.

After consultation with the NDMC office of prime interest (OPI) DCIEM effected modifications which resulted in production of the malignant hyperthermia mattress prototype II described in this report.

METHOD

Description

The malignant hyperthermia mattress prototype II (Figure 2) differs greatly from the original prototype I concept (Figure 1). It is manufactured from polyurethane coated six ounce plain weave nylon and all seam sealing was accomplished using a 3 KW RF Sealing machine. (Figure 3). The CO₂ valves, oral inflation valve, and the drainage plugs in the floor of the mattress were hand glued using Bostik 1125A adhesive (Figure 4,5,7).

The prototype II mattress consists of an inflatable skeleton, again oriented to operating room table dimensions, having higher walls (tapered towards the foot) to provide increased cooling capacity; a floor incorporating four drainage plugs and hoses and safety straps which secure the mattress to the operating table (Figure 4); an inflation/deflation system; improved bilateral recesses for the patient's arms with protective sleeves to prevent ice water leakage (Figure 6); a head recess to permit passage of anesthetic hoses (Figure 5) and two manually operated CO₂ cylinders to provide an inflation capability compatible with the deeper walls of the mattress (Figure 7). The cylinders each containing a 0.50 lb CO₂ charge are attached to the outside of the head end.

Dimensions

Inside length, 6' 2"
Inside width at head end, 24"
Inside width at foot end, 20"
Walls 16" high with 45° bilateral
arm recesses 10" long x 15" high,
constructed 12" down from inside head end,
Wall thickness, 5½"
Head end recess, 6" long x 8" high

A carrying case and spare parts case (Figure 10) were manufactured using polyurethane coated nylon, RF sealed, to ensure in transit protection, facilitate shelf storage and provide items necessary for servicing the prototype II mattress after use.

Carrying Case

Height 4"
Width 12"
Length 32" - bottom and sides are lined with ½" felt
4 flaps with velcro hook/pile closure

Spare Parts Case

Height 3"
 Width 6"
 Length 14"
 Zipper closure
 Accommodates spares;-
 ea 2 CO₂ cylinders
 ea 12 teflon washers for CO₂ cylinders
 ea 2 felt protective covers for CO₂ cylinders
 ea 1 special deflation tool

Materials and Assembly

To visualize the parts required in the assembly of the prototype II malignant hyperthermia mattress, it is necessary to refer to the drawings (Figure 11, 12):

- a) One piece base of inflated wall (coated side up).
- b) Four pieces, partitions for the head end (incorporating holes for air passage). Two pieces are cut short, coated side down. The two longer pieces are joined to form a U, coated side up.
- c) Four pieces, partitions for the foot end (incorporating holes for air passage). Two pieces are joined to form a U, coated side down. Two other pieces are joined coated side up.

Note 1. The top and bottom corners on the 45° end of each piece of part B and C are cut off $\frac{1}{4}$ " from each side.

- d) One piece, top of head end, coated side down. An oral inflation valve is installed hereon approximately 6" from top left side of the head end recess (drawing D, part Q-1 Figure 11).
- e) One piece, top of foot end, coated side down.
- f) Two pieces, one left and one right, coated side down.
- g) Two pieces which form the inside and outside walls of the foot end, coated sides inwards. These have the bilateral arm recesses, are tapered towards the centre and are of different overall length.

- h) Two pieces which form the inside and outside walls of the head end, coated side inwards. These contain the head end recess. The outside piece incorporates two CO₂ cylinder valves and a patch with pockets for the cylinders, attached on centre line.

Note 2. The CO₂ valves and the cylinder mounting patch are installed after the partitions (part B) have been installed.

- j) One piece with two holes for the CO₂ cylinder valves and two pockets for the CO₂ cylinders.
- k) Two pieces to form the pockets for the CO₂ cylinders (sewn to part J).
- l) Two pieces, one left and one right which form a water dam at the bilateral arm recesses.
- m) Two pieces, one left and one right, which form a funnel shape which is integral with part L.
- n) One piece, coated side down, forming the floor portion and incorporating four drain tubes and four securing patches for the safety straps.
- o) Four pieces, two right side and two left sides parallel to the side walls under the bilateral arm recesses (to permit air passage to the foot end and to prevent ballooning of the fabric on inflation).
- p) Flaps, each side, to help contain the ice which envelopes the malignant hyperthermia patient.
- q.1) One oral inflation valve (mounted at part D Figure 11).
- 2) Four pieces of oral inflation valve tubing (attached to part N Figure 12).
- r) Five pieces 3" diameter with $\frac{1}{4}$ " centre hole to form reinforcing patches for the oral inflation valve and drains.
- s) Each two CO₂ inlet valves. (Mounted in part H Figure 12).

- t) Two pieces $3\frac{1}{2}$ " diameter with $1\frac{1}{2}$ " centre hole to form reinforcing patches for the CO₂ inlet valves.
- u) Four securing strap patches of polyurethane coated nylon each $1\frac{1}{2}$ " x 4", reinforced with 1" x $2\frac{1}{2}$ " cotton webbing to secure single 1" D rings for the safety strap attachment.
- v) Two safety securing straps 1" wide x 44" long with 8" straps of velcro pile on each end and velcro hook adjacent to permit easy strap adjustment.
- w) Each two 0.50 ($\frac{1}{2}$) lb charged CO₂ cylinders NSN 4220-21-852-2221.
- x) Four drain filters 2" long x $\frac{1}{4}$ i.d 1/16" wall tygon tubing, perforated top to bottom to prevent drain blockage (Figure 8).

Assembly

(Foot End)

- a) Attach two pieces of C together at foot end with a $\frac{1}{4}$ " seam. Seal these two joined pieces using the seam at centre to the centre line on G, either top or bottom partition line and work each way up to arm recess, inside and outside walls.
- b) Repeat the above procedure using the remaining two pieces of C and attach to G at either top or bottom partition line not previously used, inside and outside walls.

Note 3. The seams should be one to the top and one to the bottom.

- c) Seal E to G inside and outside walls starting at the centre line of the foot end, leaving last 2" of E free.

Note 4. When attaching inside walls G and H to base A leave $\frac{1}{4}$ " of the lower edge of G and H free for attaching floor N later.

- d) Seal A to G inside and outside walls, starting at the centre line of the foot end, up to within 3" of the short side of arm recess.
- e) Attach two pieces of O centred on the centre line of F at a 45° angle to form three equal chambers under arm on both sides with the coated sides facing into the centre.
- f) To seal arm recess top F to E, begin at the centre line of F and centre line of arm recess, G work towards the foot end by sealing F to G inside and outside.
- g) On coming to partitions C secure them to F and G. Arriving at the top leave the last $\frac{1}{4}$ " for a seam, then finish sealing E to G and E to F.

(Head End)

- h) Seal the two full size pieces of B together at the square end with a $\frac{1}{4}$ " seam.
- i) Seal B coated side up using seam as centre line, to lower partition line centre line on H, inside and outside leaving the last 2" of H loose.
- j) Seal right and left short pieces of B coated sides down starting at the top partition line on H at arm recess leaving seam allowance for attaching D. Seal to inside and outside leaving the last 2" of H free at this time.
- k) Next take D with the oral inflation valve installed, line up the centre line of D with centre line of H inside and outside and seal. On coming to partition B secure it to D, continue sealing leaving the last 2" of H free.
- l) Install CO₂ valves and the patch containing the CO₂ cylinder pockets on the outside of H in the centre of the lower inflation chamber. Allow glue to set. The head end is now ready for attachment to the base and the foot end.

Note 5. When attaching inside walls G and H to base A leave $\frac{1}{4}$ " of lower edge of G and H free for attaching floor N.

- m) Start at the centre line of inside H, line up the centre line inside of the head end of A and seal both ways leaving the last inch of H free.
- n) Seal outside H to A starting at centre lines and working both ways leaving the last inch of H free.
- o) Seal outside G to H vertically, ensuring that they match the base A. Do not seal A to G or H in this area at this time.
- p) Seal upper and lower partitions of B to G and H.
- q) Seal arm recess top F to D. Begin at the centre line of F and centre line of arm recess G and work towards the head end by sealing F to G inside and outside. On coming to partitions B secure them to F. Arriving at the top leave the last $\frac{1}{2}$ " for a seam, then finish sealing D to H and G and D to F.
- r) Seal O to base A under the arm recess on both sides.
- s) Seal base A to inside and outside walls G and H under the arm recess area.

(Arm Recess Sleeves)

- t) Seal the long curve of M to the inner circle of L leaving the top open.
- u) Seal assembled parts L and M to the bottom inside wall G arm recess starting from the centre line with the sleeve facing outwards.
- v) Seal P to inside wall G above L one side only. Next take floor N with the four drains Q-2, reinforcing patches R and securing strap patches U already in position.
- w) To install the floor N, line up the centre line of inside wall H with centre line on floor N (Head end). Seal, working both sides towards the foot end.

Testing at DCIEM

On completion of the malignant hyperthermia mattress, prototype II, the integrity of all sealing was carefully checked. The mattress

was inflated to a pressure of 5 p.s.i. with compressed air (induced through the oral inflation valve) and allowed to stand for several hours to check for leaks. The mattress was then deflated to permit inspection of seams and repetition of tests (five inflations were conducted to 5 p.s.i. pressures). Manual inflation was accomplished by operating the two CO₂ cylinders (approximate 2 p.s.i. pressure). Four successful inflations were made. Leak tests on all external seams, the CO₂ inlet valves, and the oral inflation valve were effected using an approved industrial leak testing liquid.

Clinical Evaluation

The malignant hyperthermia mattress, prototype II was forwarded to NDMC in December 1978, for a clinical evaluation by the Department of Anesthesia. Their report will be published on completion.

RESULTS

The DCIEM tests proved the modified design concept, the integrity of all seam sealing and valve installations, and the immediate inflation capability achieved by two 0.50 (½) lb CO₂ cylinders.

DISCUSSION

The two-CO₂ cylinder inflation concept in the prototype II mattress was examined during the construction of the inflatable walls. To provide a sufficiently hard inflation to maintain wall rigidity, it was necessary to taper the walls towards the foot end thereby reducing the internal volume and ensuring that the inflation required could be achieved.

The concept of inflating walls of the mattress using a single (1.0 lb charged) CO₂ cylinder was explored. Non availability of this item necessitated the use of the two 0.50 lb CO₂ cylinders for inflation purposes. This system proved ideal in that over inflation of the head end was prevented. One CO₂ cylinder is discharged prior to operating the other, thus allowing gas from the first cylinder to disperse towards the foot end via a relatively small passageway under the arm recesses.

The assembly of all material pieces was oriented to the capabilities of the 3 KW dielectric sealing equipment (Figure 3). All sealing had to be done using the portable electromagnetic pliers. Brass dies, compatible with the sealing pliers, were manufactured in the Life Support Equipment workshop to facilitate sealing, as the dies designed for the 3 KW machine were too long.

CONCLUSION

It is concluded that:

- a) The malignant hyperthermia mattress prototype II is a considerable improvement of the original design (prototype I).
- b) The mattress, prototype II will withstand repeated use, inflated to the normal pressures produced by the two CO₂ cylinders.
- c) The modifications embodied to overcome original shortcomings are fully justified in the final product.

RECOMMENDATION

It is recommended that:

- a) A report (or interim report) on the clinical evaluation of the malignant hyperthermia mattress prototype II be provided by NDMC.
- b) DCIEM be tasked with further development of this mattress if the NDMC clinical evaluation produces the requirement.

REFERENCES

1. NDMC letter 16530-Op Rm 11 Mar 77
2. DCIEM letter 3614F-04 (MLSD) 9 Dec 77
3. NDMC letter 16530 (ANAES) 10 Jan 78
4. NDMC letter 16500-2 (ANAES) 15 Feb 78
5. NDMC letter 6755-1 (ANAES) 24 May 78
6. NDMC letter 6755-1 (ANAES) 19 Feb 79



Figure 1: Prototype I malignant hyperthermia mattress (rubberized nylon, all seams glued)

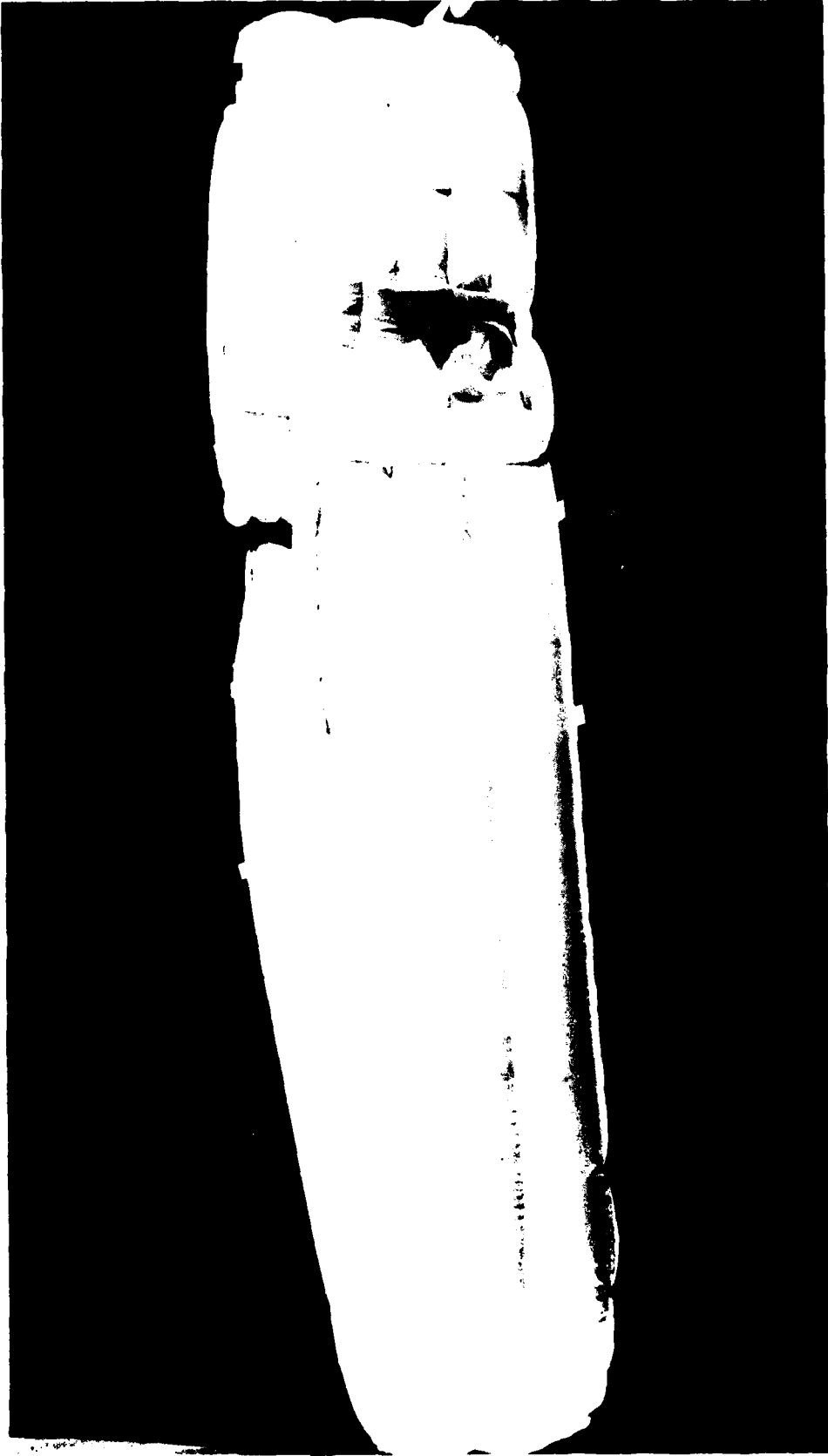


Figure 2: Prototype II malignant hyperthermia mattress (polyurethane coated nylon R.F. sealed)



Figure 3: Callinan dielectric sealing equipment model 30 with electromagnetic pliers, and dies power output 3 Kilawatts. Frequency 35 Megacycles.

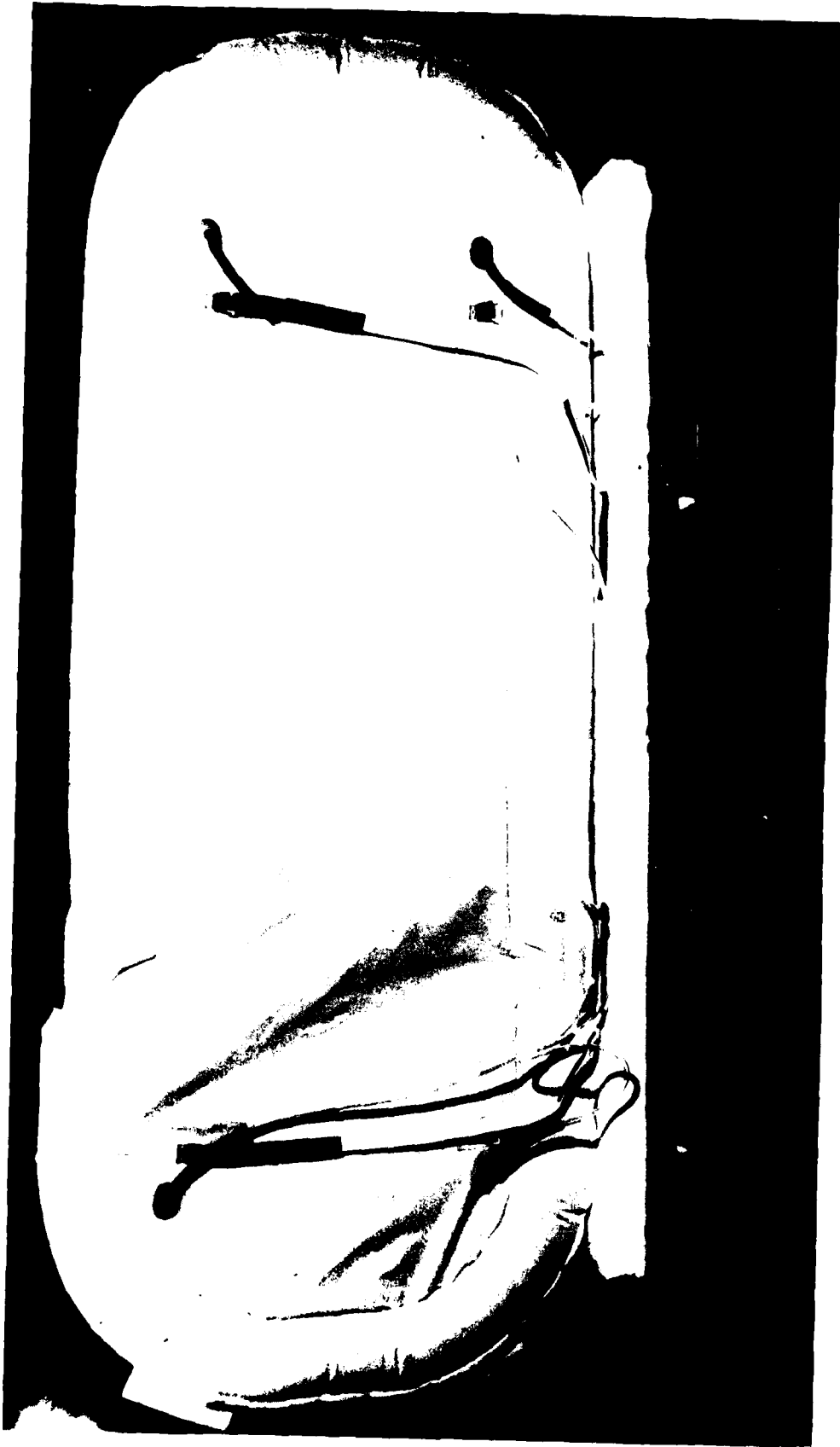


Figure 4: Bottom view of prototype II showing drains and nylon securing straps.



Figure 5: Prototype II showing oral inflation valve and cut outs for operating theatre services and for patient's arms.



Figure 6: Prototype II showing sleeved portion to provide access to patient's arms and prevent water egress.

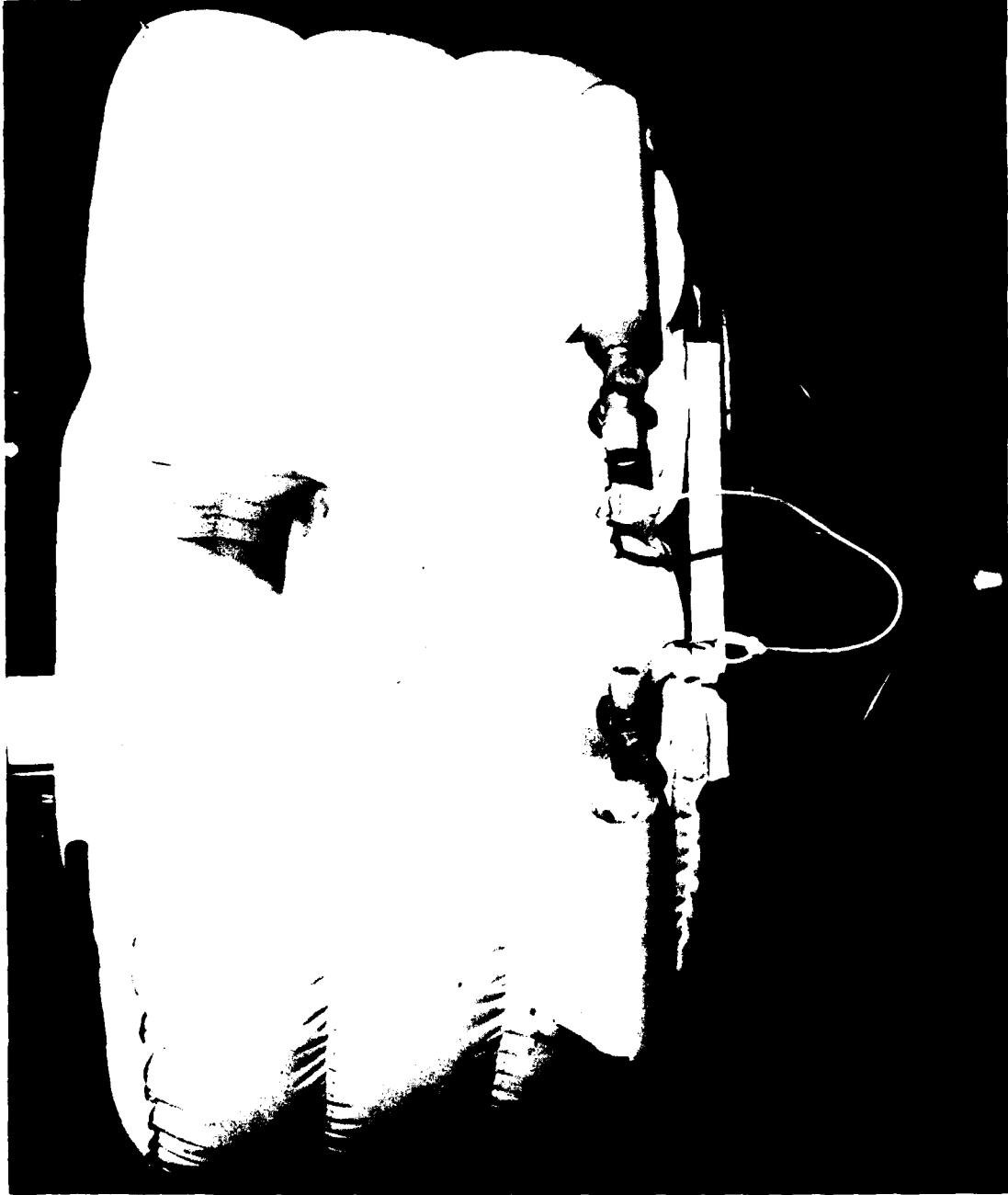


Figure 7: Prototype II showing CO₂ manual inflation mode.

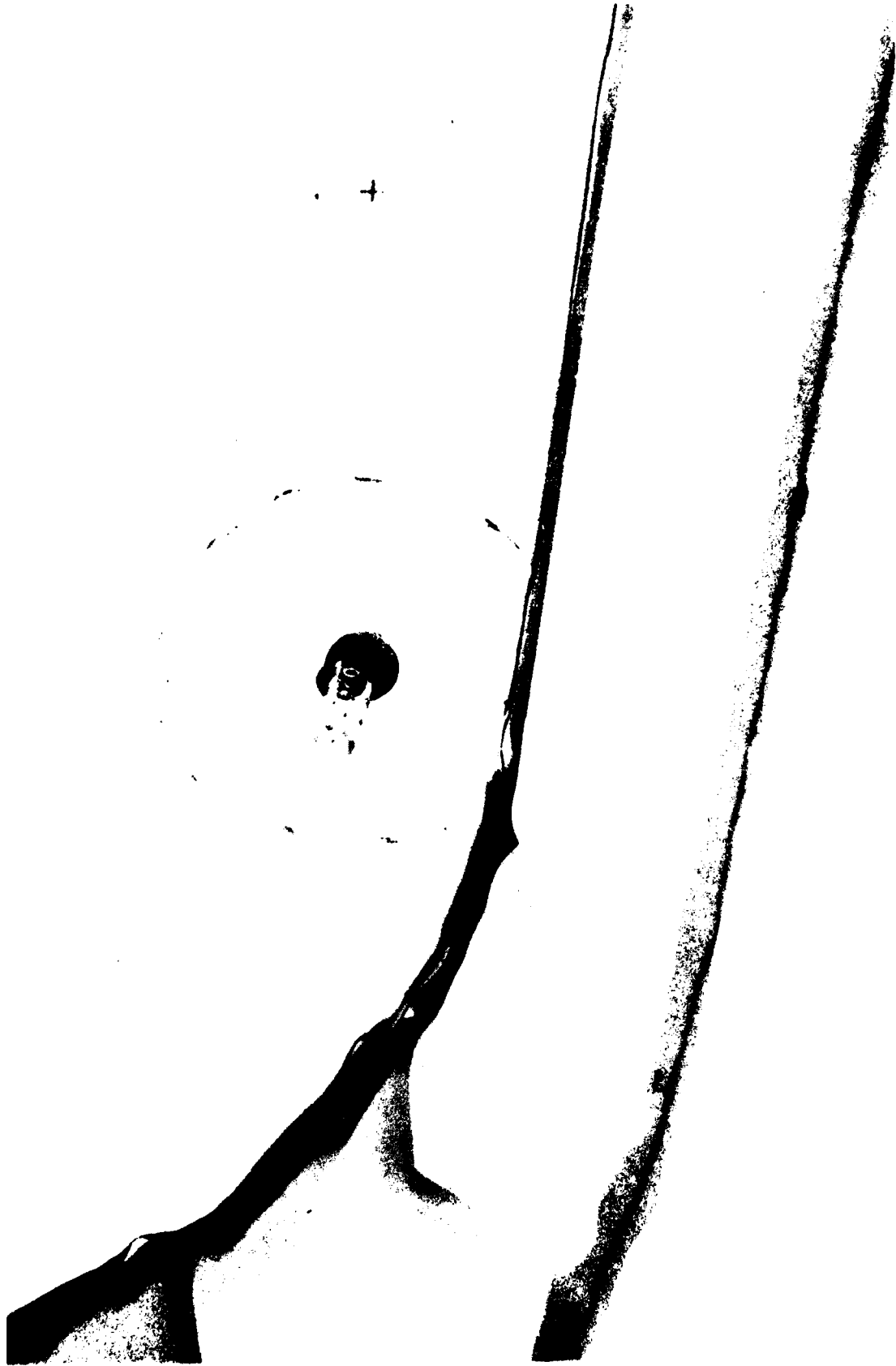


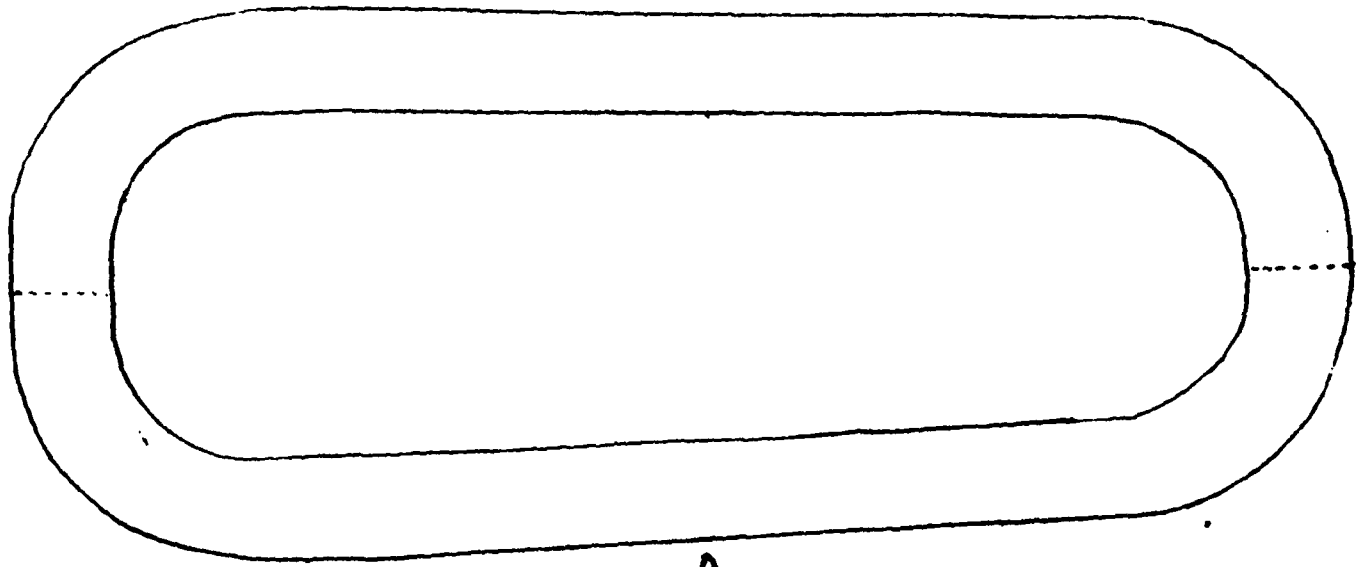
Figure 8: Prototype II showing tygon tube insert and drain valve.



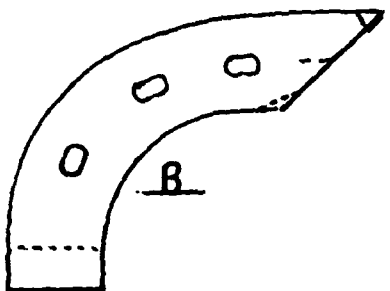
Figure 9: Prototype II showing accommodation for patient.



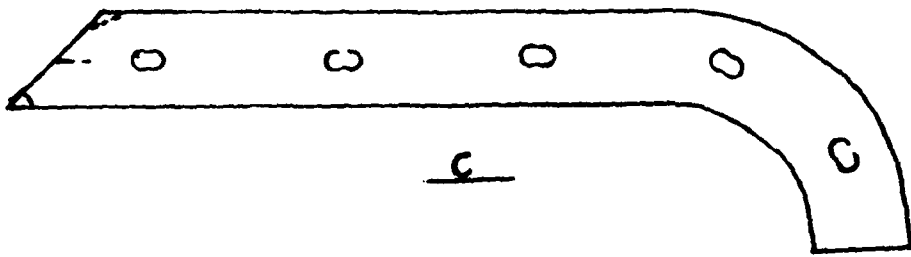
Figure 10: Prototype II packaged for transportation/shelf storage with spare parts kit in foreground.



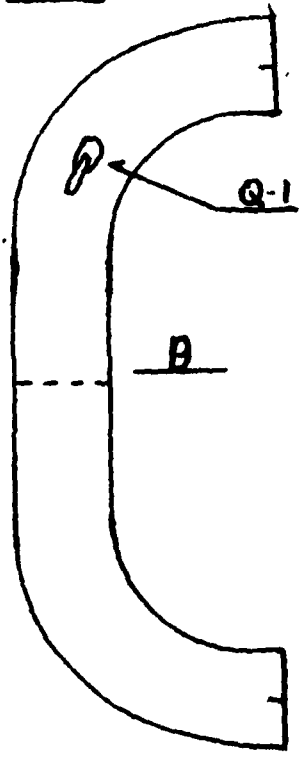
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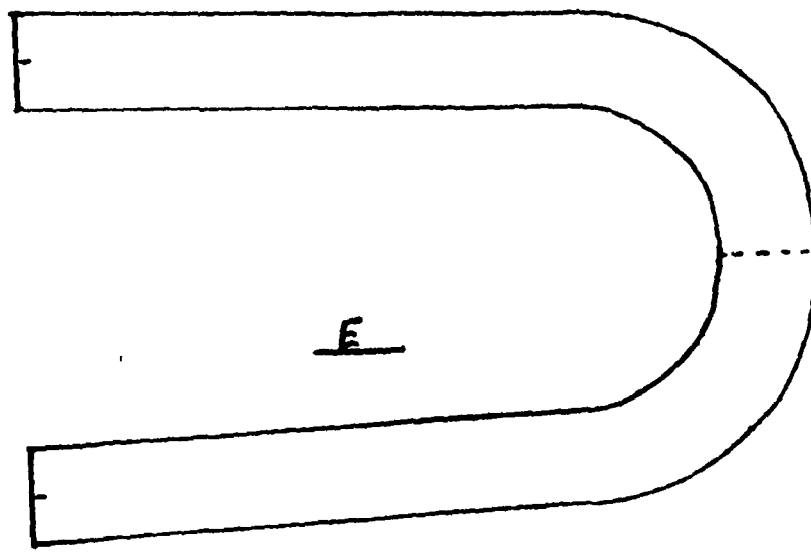
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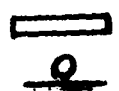
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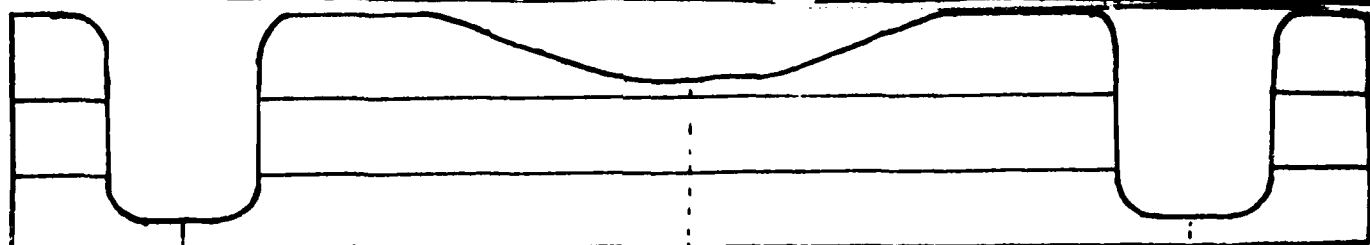


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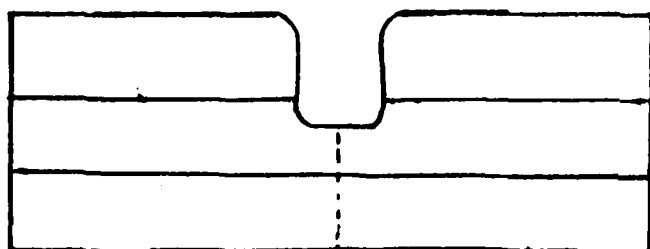


O

Figure 11: Identification of material pieces A to F plus O



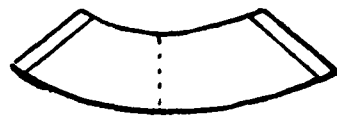
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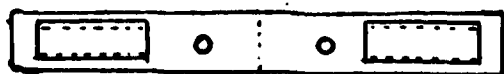
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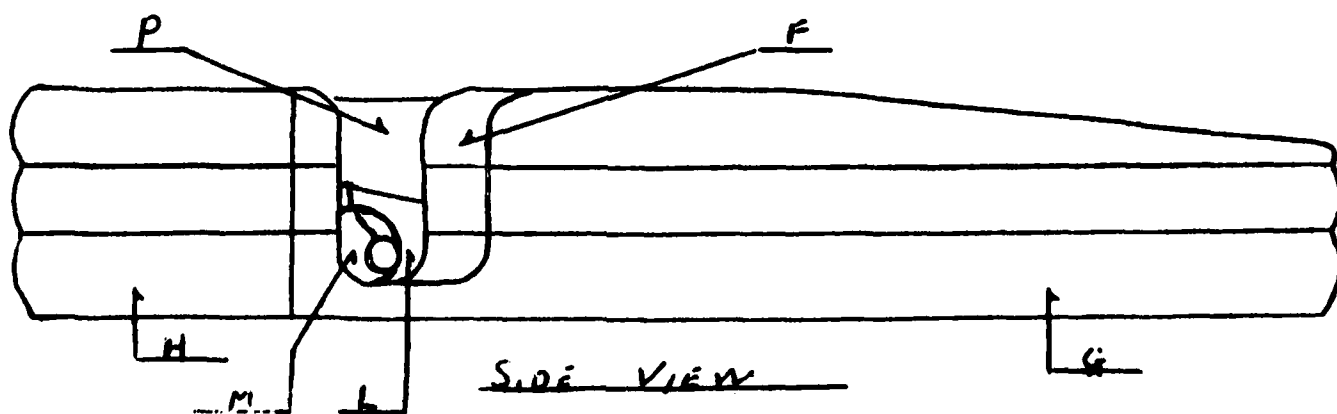
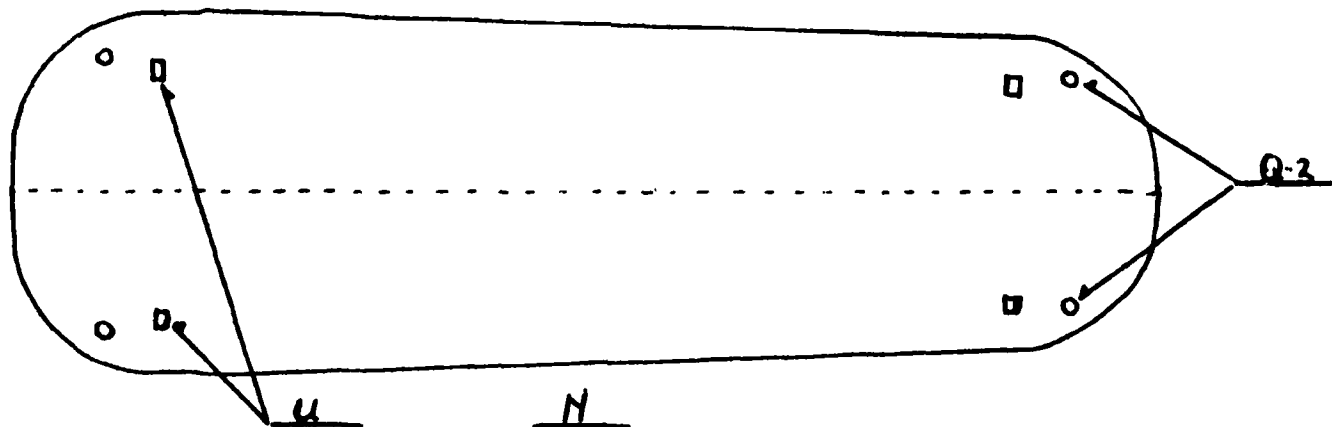


Figure 12: Identification of material pieces G to P.