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Hurtig et al.

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[54] CLINICAL SAMPLE CONTAINER

[72] Inventors: **Carl R. Hurtig,** Scituate; **Andres Ferrari; Amin J. Khoury,** both of Dover, all of Mass.

[73] Assignee: **Damon Corporation,** Needham Heights, Mass.

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[52] **U.S. Cl.** **128/2,** 73/425.6, 128/276

[51] **Int. Cl.** **A61m 1/00**

[58] **Field of Search**.....128/2, 216, 231, 232, 233, 128/276, 278, DIG. 5; 73/425.6

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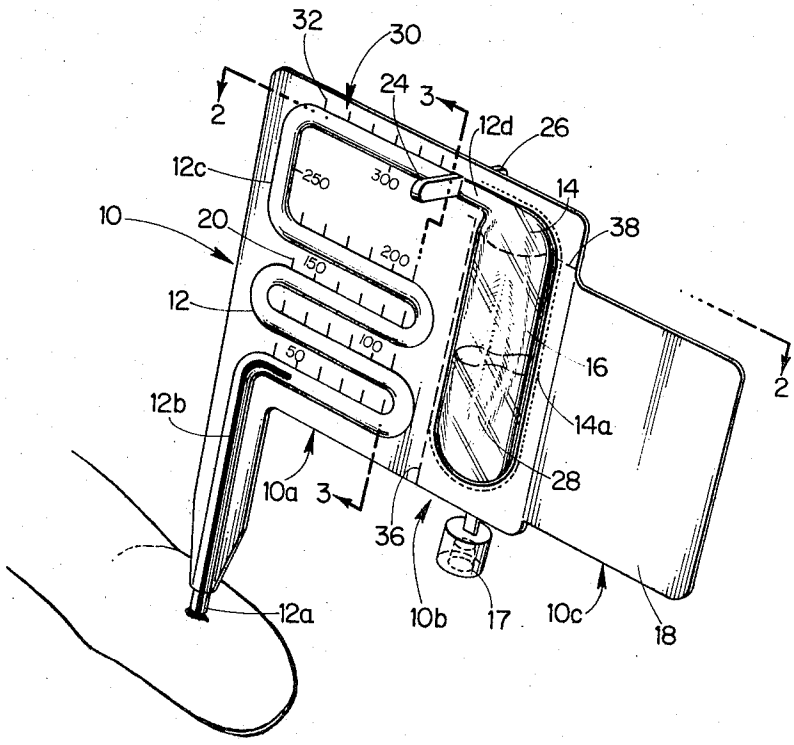
Primary Examiner—Aldrich F. Medbery
Attorney—Kenway, Jenney & Hildreth

[57] **ABSTRACT**

A container for the collection, storage and processing of a sample of body fluid has a graduated receiving tube for collecting the sample and which feeds a chamber that is resiliently collapsible to aspirate the sample into the tube and thence into the chamber. Initially, a frangible seal closes the tube-chamber junction to maintain a sample-treating reagent within the chamber. The tube and chamber are in a unitary, self-supporting structure which also has a panel or the like for carrying indicia identifying the sample.

11 Claims, 4 Drawing Figures



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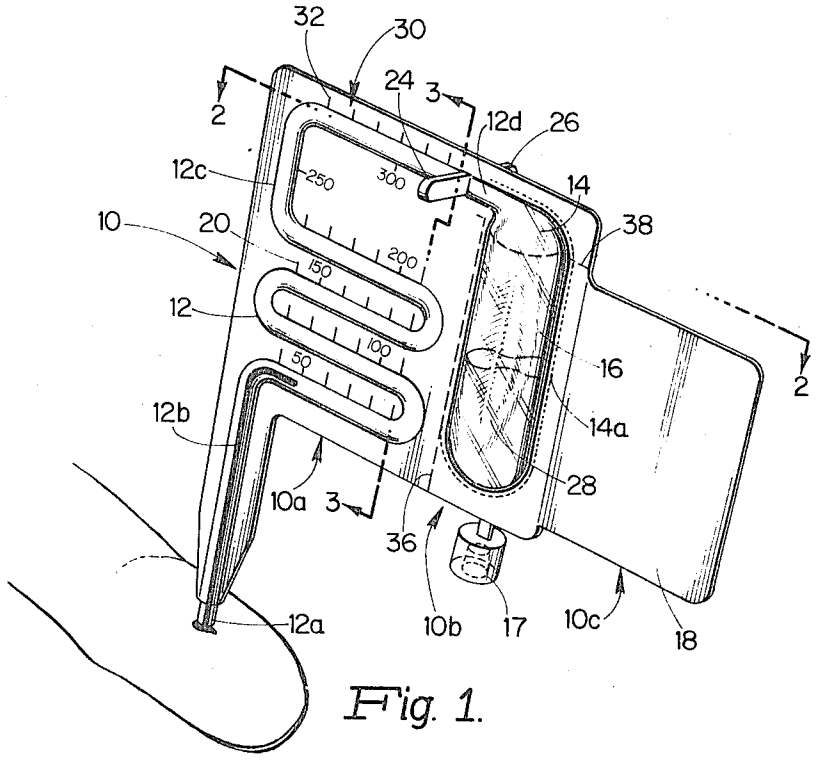
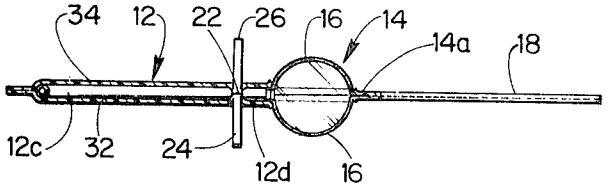


Fig. 1.

Fig. 2.



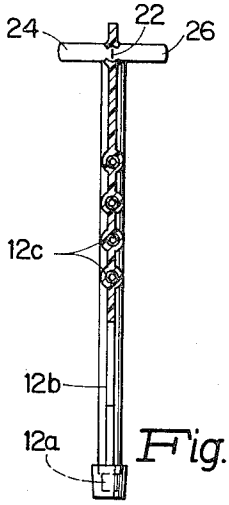


Fig. 3.

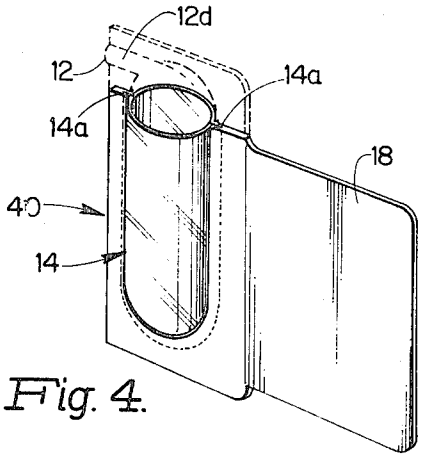


Fig. 4.

INVENTORS
CARL R. HURTIG
ANDRES FERRARI
AMIN KHOURY

BY
Kenway, Jenney & Hildreth
ATTORNEYS

CLINICAL SAMPLE CONTAINER

BACKGROUND

This invention relates to clinical sample container equipment and in particular provides such equipment for collecting a measured volume of the sample and for storing it under aseptic conditions. The equipment, hereinafter for ease in reference designated as a container system or simply container, can further be used to feed the sample directly to diagnostic analysis equipment. The container includes a panel for carrying indicia identifying the sample and, where desired, designating the analysis to be performed on it.

A myriad of sample-handling liquid-containing structures are known in the medical arts, and particularly in the field of clinical diagnosis equipment. In general, capillary or syringe structures are used in the prior art to collect a sample, for example from a dermal puncture. The collected sample is then transferred to a storage vessel, and the collecting device discarded. The storage vessel or still another container is then used to carry the sample through whatever diagnostic analysis operations are desired.

These prior practices require a number of fluid containers, and the transfer from one to the other subjects the sample to spillage as well as contamination. Also, the label identifying the sample is subject to loss and mixup each time the sample is transferred.

In addition, much prior art sample container equipment is too costly to be disposable, and hence requires preparation for each use. The prior container apparatus is also deficient in regard to providing ease in storage, handling and operation.

Accordingly, it is an object of the present invention to provide a single container for the initial collection of a sample of body fluid, the subsequent storage thereof with or without reagents, and for the ultimate containment or delivery of the sample for analysis.

A further object of the invention is to provide such a container carrying with secure attachment the record identifying the sample, the analysis to be preformed on it, and whatever other information is desired.

It is also an object of the invention to provide a container of the above character that maintains a reagent sealed therein without spillage but which is readily placed in use without the likelihood of introducing contamination.

A further object of the invention is to provide a container of the foregoing character in which a sample can be transported without further packaging.

Another object of the invention is to provide a container of the above character that can be manufactured at such a low cost that it can, with practical economy, be discarded after a single use.

Other objects of the invention will in part be obvious and will in part appear hereinafter.

The invention accordingly comprises the features of construction, combinations of elements, and arrangement of parts exemplified in the constructions hereinafter set forth, and the scope of the invention is indicated in the claims.

SUMMARY OF INVENTION

In brief, the invention provides a unitary and self-supporting container system having a liquid-collecting collection tube, the volume of which is graduated therealong from the point of liquid entry. The tube feeds into a liquid-storing chamber, and a panel for carrying whatever indicia are pertinent to the sample is secured to the container system. The chamber is collapsible, and resiliently resumes its normal shape, to enable the operator to aspirate the sample into the collecting tube and then into the chamber from the tube.

In addition to sealing the complete container in a sterile wrap or otherwise sealing the receiving end of the collecting tube to ensure that it is free of contaminants, the entry of the tube into the chamber is sealed so that whatever liquid or gas is provided in the chamber during manufacture does not spill or otherwise escape, or conversely become contaminated.

This seal is opened immediately prior to using the container, and in such a way that the container system, throughout the collecting tube length and the chamber, remains closed from the environment.

A still further feature of the container is that the collecting tube portion can be removed from it, and the chamber opened for access to the contained sample, to facilitate delivering the sample for diagnostic analysis.

The invention thus provides a clinical container system for collecting a liquid sample in measured volume directly from a patient, for containing the sample during storage and transport, and for direct delivery of the sample to analysis equipment. The sample thus contained is never exposed to the spillage, contamination, or label loss inherent with prior clinical equipment that requires the sample to be transferred from one container to another. Further, the present container is of low cost so as to be economically practical to discard after a single use.

BRIEF DESCRIPTION OF FIGURES

For a fuller understanding of the nature and objects of the invention, reference should be had to the following detailed description taken in connection with the accompanying drawings, in which:

FIG. **1** is a pictorial view of a container embodying the invention disposed for collecting a blood sample from a dermal puncture in a patient's finger;

FIGS. **2** and **3** are cross-sectional views of the container of FIG. **1**, but prior to opening of the frangible seal therein, taken along lines **2—2** and **3—3** respectively, of FIG. **1**; and

FIG. **4** is a perspective view of the container of FIG. **1**, with portions thereof cut off, for disposition in sample analyzing equipment.

DESCRIPTION OF ILLUSTRATED EMBODIMENT

FIG. **1** shows a container **10** embodying the invention being used to collect a blood sample from a dermal puncture in a patient's finger. The drawing shows that approximately 50 microliters of blood have already been collected in a collection tube **12** that feeds into a chamber **14**. The chamber walls **16** are shown slightly collapsed, as the medical technician or other operator normally would do during the sample collection process simply by squeezing the chamber prior to placing the tube entry end **12***a* into the fluid being collected. Upon being released by the operator, the resiliency of the chamber walls restores the chamber to an uncollapsed condition, thereby drawing the sample into the collection tube under positive pressure conditions. The operator controls the expansion of the chamber walls until he has collected the desired volume of sample, at which point he simply removes the container from the fluid source and fully releases the chamber walls, allowing them to aspirate the collected sample into the chamber **14**.

After the desired volume of sample is collected, the entry end of the collection tube **12** can be sealed shut either by the use of a cap **17** carried on the casing **30** but readily removable therefrom, by means of a metallic clamp, or a heat seal, all of which are conventional.

A record panel **18** for bearing the identification of the sample being collected, the identification of the patient, his physician, and the designation of the diagnostic tests to be performed on the sample, extends from the container along the side of the chamber **14** and serves, together with the coiled collection tube and chamber, as a handle for the secure holding of the container during the sample collecting process.

Considering FIGS. **1**, **2** and **3** in greater detail, the illustrated container **10** has a generally cardlike rectangular outline, from which the collection tube **12** protrudes to its entry end **12***a*. The tube **12** has a nozzle section **12***b* extending from the entry end **12***a*, a feed end **12***d* that feeds into the chamber **14**, and a coiled section **12***c* between the nozzle section and the feed end. The illustrated section **12***c* of the tube is ar-

ranged in a serpentinelike, single layer coil and compactly accommodates the length of tubing necessary to contain the maximum volume of sample that is to be collected and processed with the particular container.

A scale **20** has graduations disposed along the length of the tube **12** calibrated, for example in microliters, to indicate the volume of the tube along the length thereof beginning from the entry end **12***a*. The scale **20** thus enables the operator to measure the volume of sample being collected directly, as it is being collected.

Adjacent the juncture of the tube with the chamber **14**, i.e., at the tube feed end **12***d*, the tube is initially closed with a frangible seal **22** shown in FIGS. **2** and **3**. The seal, which is fluidtight, illustratively is formed by compressing the tube closed and sealing the opposed walls together, roughly along a tube diameter. As shown in FIG. **3**, the seal is in the plane of the cardlike container shape. At the site of the seal, pull tabs **24** and **26** are secured to the walls of the tube on either side of the seal. With this arrangement, the operator places the container in condition for use simply by pulling the tabs apart, which pulls the opposed tube walls apart and hence opens the seal.

With further reference to FIGS. **1**, **2** and **3**, the chamber **14** is a tubular pouch with resiliently collapsible opposed sidewalls **16—16**. The chamber is oriented in the container alongside the collection tube coiled section **12***c*, with the chamber bottom adjacent the tube end near the nozzle **12***b*. The chamber top is adjacent the entry of the feed end of the tube into the chamber. The chamber is fluidtight except for this connection with the tube.

The chamber volume is tailored to the maximum volume of sample which is to be collected in the tube of the container. The illustrated chamber contains this volume of sample, and a corresponding amount of a reagent **28**, in roughly one-half to two-thirds of the chamber volume.

As noted, the opposed chamber walls **16—16** can be depressed inward, to reduce the chamber volume by at least twice the volume of the tube **12**. Upon being released, the walls restore automatically to their normal concave shape, shown in FIG. **2**, with sufficient resilient force to aspirate the sample liquid into the tube **12** and thence into the chamber.

The reagent **28** is selected according to the sample being collected and the analysis to be performed on it. It can for example be an anticoagulant, or a preservative. A known volume of the reagent preferably is placed in the chamber **14** prior to effecting the seal **22** at the time the container **10** is initially manufactured. Then the physician, technician or other user of the container is free from concern as to the identity, volume or quality of the reagent. Also, the container with the desired reagent already in it is ready for use simply upon removing it from its sterile wrap (not shown).

The collection tube **12** is made of a nonwetting material inert to the sample with which the container is to be used and to the reagent **28**, and which can be processed to provide the frangible seal **22**. The material for the chamber **14** has the same inert qualities and has the desired resiliency for the chamber walls **16—16**. Polyethylene and polyvinyl chloride are considered preferable materials for both the tube and the chamber, with a density that has considerable flexibility.

The illustrated container **10** has the complete collection tube **12** and chambers **14** structure, with the tube seal **22** and the tabs **24** and **26** thereon, mounted in a casing **30**. The casing thus forms a manually holdable frame for mounting the tube and chamber. The casing is formed of two opposed and mating panels **32** and **34**. Each panel is recessed with a channel to receive the collection tube, and has a cutout through which the opposed chamber sidewalls **16—16** protrude and are accessible for the pumping operation that aspirates the sample. The seal-opening tabs **24** and **26** also pass through the panels **32** and **34**, respectively.

With this construction, the tube and chamber structure is placed between the casing panels and the two panels are then bonded or otherwise sealed together with the collection tube sandwiched between them and with the tabs **24** and **26** and chamber sidewalls **16—16** protruding through the panels at the appropriate apertures. A relatively inert and stiff, protective and self-supporting synthetic resin is preferred for the casing panels. The illustrated chamber **14** has a peripheral flange **14***a* that is sandwiched between the panels along the periphery of the chamber cutouts therethrough to secure the chamber in the casing **30**. Also, the scale **20** can be carried on one or both panels of the casing **30**.

The illustrated record panel **18** of the container **10** is formed by the casing panels **32** and **34** along the side of the chamber **14** opposite from the coiled tube section **12***c*. The panel **18** is illustrated as having a mat surface on which indicia can be written. However, other forms of record panel can be used. One alternative arrangement is to form a record pocket (not shown) between the opposed casing panels **32** and **34** for carrying a document bearing the desired indicia. Another alternative is simply to attach a document onto the outer surface of the record panel **18**, using any one of many conventional fastening means including adhesives, mechanical clips, buttons and the like.

Whatever construction is used for the record panel **18**, the indicia it carries can be machine readable, i.e., readable with optical character recognition techniques, magnetically detectable or optically detectable, where this is desired.

With further reference to FIG. **1**, the container **10** is arranged overall in three side-by-side sections **10***a*, **10***b* and **10***c*. The collection tube **12** is in an end section **10***a*, the chamber **14** is in the central section **10***b*, and the record panel **18** is in the other end section **10***c*.

One reason for this three-section arrangement of the container **10** is that it enables the chamber and record panel to be separated from the collection tube. The separation can be effected by cutting or otherwise severing the container into two parts along the dashed construction line **36** at the boundary between sections **10***a* and **10***b*. This separation may be desired to diminish the size of the container elements that are present during analysis of the collected sample, which may be of particular benefit where the analysis is performed with automated equipment. The showing in FIG. **4** in both solid and phantom illustrates the container elements that would remain intact after the container section **10***a*, bearing the collection tube, is thus removed by cutting along the construction line **36**.

With reference to FIG. **4** a conventional fluid coupling (not shown) can be inserted into the short length of collection tube **12***d* leading from the chamber to draw the collection sample out for the analysis.

Further, where the sample is to be openly available during analysis, the container chamber section **10***b* is severed along the dashed construction line **38**, shown in FIG. **1**, to remove the top portion of the chamber, including the collection tube entry therein, and leaving only the analysis container **40** shown in solid lines in FIG. **4**. The record panel **18** is preferably foreshortened relative to the other sections of the container **10**, as shown in FIG. **1**, so that when the container is cut along the construction line **38** to provide the analysis container **40** (FIG. **4**) the record panel **18** remains intact.

The analysis container **40** of FIG. **4**, with or without the upper section shown in phantom, can be placed in automatic analysis equipment and the sample stored therein analyzed according to instructions recorded on the record panel **18**.

Although the illustrated container **10** is described as fabricated with a collection tube and chamber encased between two panels, the invention can be practiced with other types of construction. Perhaps the lowest cost construction, at least for large volume manufacture, is to use panels that are molded to provide by themselves the passage for collecting the sample and the chamber for storing it. Each such panel is molded to form essentially half of the collection tube, or passage, and half of the chamber.

Also, alternative to bonding the tube **12** walls together to form the seal **22**, other construction can be employed. One such alternative is to conventional crimp or squeeze the tube

closed with a conventional clip or clamp applied from outside the container.

Further, the container system of the invention is of course not limited to collecting a sample from a finger puncture; this particular use is shown only by way of specific illustration.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above constructions without departing from the scope of the invention, all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative rather than in a limiting sense.

Having described the invention, what is claimed as new and secured by Letters Patent is:

1. In clinical sample collection and storage apparatus having a chamber resiliently maintaining a normal uncollapsed shaped and being resiliently collapsible to diminish the volume therein, and having a collection tube with a sample inlet end and feeding at the other end into said chamber, the improvement comprising
   A. a manually holdable frame mounting said tube and chamber, said frame including a planar cardlike casing joined to the walls of said tube along the tube length and joined to the walls of said chamber along a path encircling the chamber,
   B. at least one wall of said chamber bulging outwardly from said planar casing when in the normal uncollapsed shape and deflecting inward toward said casing to collapse said chamber, and
   C. said sample inlet end of said collection tube protruding from said casing frame to dispose said inlet end openly accessible relative thereto.

2. In apparatus as defined in claim 1, the further improvement wherein
   A. said collection tube defines a fluid volume therein between said ends thereof,
   B. said chamber is resiliently collapsible to expel therefrom at least twice said volume of fluid by way of said tube, and resiliently recovers said normal uncollapsed shape when said inlet end of said tube is open to aspirate fluid therein-to, and
   C. said frame casing carries a volume-measuring scale disposed along at least a portion of the length of said tube for indicating the volume of liquid aspirated into said tube from said inlet end thereof.

3. In apparatus as defined in claim 1 the further improvement comprising
   A. frangible fluidtight seal means for closing the fluid path of said tube between said ends thereof, said seal means being disposed adjacent said end of said tube feeding into said chamber, and
   B. manually manipulatable means for opening said seal to provide fluid communication between said chamber and said tube.

4. In apparatus as defined in claim 1, the further improvement wherein said frame casing has at least two side-by-side coplanar and conjoined sections a first of which carries said chamber and said end of said tube feeding into said chamber, and the second of which carries the rest of said tube.

5. In apparatus as defined in claim 4, the further improvement wherein said frame casing has a third section disposed side-by-side and coplanar with said first section and joined thereto, and forming an indicia-supporting panel.

6. In apparatus as defined in claim 5, the further improvement wherein said frame casing is severable along the juncture between said first and second sections for removing said second section with the tube length mounted thereon from the rest of said apparatus.

7. A container for the collection of a sample of a liquid and the storage thereof, said container comprising
   A. a generally rectangular flat casing having a small thickness relative to the length and width thereof and including at least first and second side-by-side and conjoined sections,
   B. means forming a serpentine-configured tubular passage on said casing second section with passage walls bulging from said casing along the direction of the casing thickness and having an inlet end, an outlet end, and a storage length therebetween with said inlet end protruding nozzlelike beyond the rectangular configuration of said casing, and
   C. means forming a pouchlike chamber
      1. having opposed walls joined together along a chamber-encircling path,
      2. mounted on said casing first section along said path to dispose said walls accessible from opposite sides of said casing,
      3. connected to said outlet end of said passage to provide fluid communication from the interior of said chamber through said passage to said inlet end thereof, and
      4. having said opposed walls resiliently collapsible to diminish the chamber volume and resiliently resuming a normal uncollapsed position where they bulge outwardly from said casing along the direction of the casing thickness.

8. A surgical container for the collection of a sample of animal body liquid and for the storage thereof, said container comprising
   A. a manually holdable flat cardlike body casing,
   B. sample collection means forming a tubular passage carried by said casing with an openly accessible inlet end extending outwardly from said casing, an outlet end, and a storage length therebetween,
   C. a volume-indicating scale carried by said casing having graduations arranged along said passage from said inlet end for indicating the volume of liquid in said passage measuring from said inlet end,
   D. means forming a pouchlike chamber
      1. carried by said casing,
      2. connected with said outlet end of said passage to provide fluid communication from the interior of said chamber through said passage to said inlet end thereof, and
      3. having opposed resilient walls engageable from opposite sides of said casing, and collapsible to diminish the chamber volume and resiliently resuming a normal uncollapsed position where they bulge outwardly from said casing, and
   E. means forming a record panel on said casing for bearing a readable message.

9. A container as defined in claim 8 in which said casing is arranged with first and second sections, said first section carrying said inlet end and said storage length of said passage and said scale associated therewith, said second section adjoining said first section along a first junction and carrying said chamber and said record panel, said casing sections being so arranged that severing said casing along said first junction separates said sections and severs said passage adjacent said outlet end thereof.

10. A container as defined in claim 8 further comprising
   A. means forming a frangible seal closing said passage along said outlet end thereof, thereby to seal said chamber closed, and
   B. seal-opening means carried on said casing and manually manipulatable for opening said seal, thereby to provide fluid communication between said chamber and said passage, said seal and said opening means being so arranged that said passage and chamber are fluidtight, except for the opening at said passage inlet end, when said seal is open.

11. A container as defined in claim 8 further characterized in that said casing has a peripheral edge that forms the peripheral edge of said container, except at said passage inlet end.

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