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REMEMBERING THE GALEN/COBE OPTIFLO BUBBLE OXYGENATOR

Galen Laboratories

Galen Laboratories was founded in Santa Ana, California in 1971 as a medical device company. Initial efforts focused on two key products - a kidney dialyzer and a blood oxygenator. The dialyzer, patented in 1973, was a fan-folded semipermeable membrane housed within a rectangular case (see Figure 1). Starting in 1964, plate-style dialyzers (which the Galen device resembled) were gradually supplanted by the sleek hollow-fiber design. As such, the Galen dialyzer fizzled and was ultimately shelved.

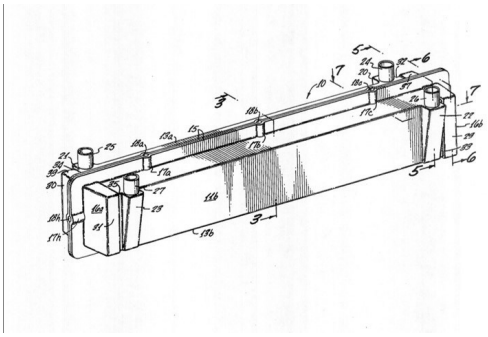

Figure 1. Schematic of the Galen kidney dialyzer developed in 1973.

Development of the Galen blood oxygenator commenced in 1972. Designated the OptiFlo, a 510(k) version of the device was on display at the AmSECT International Conference in Los Angeles in July 1973 (see Figure 2). Full market release occurred in early 1974. During the first 24 months of production, more than 15,000 OptiFlo oxygenators were sold throughout the United States. Included with each new OptiFlo device was an evaluation form that could also serve as a perfusion record (see Figure 3).

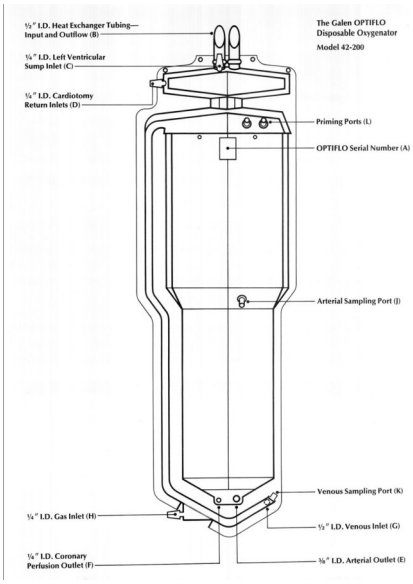

Figure 2. Schematic of the Galen OptiFlo bubble oxygenator developed in 1973.

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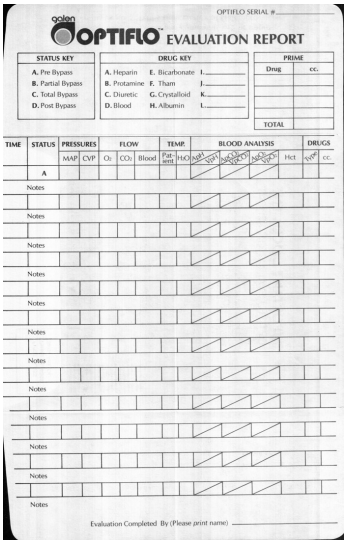
OPTIFLO SERIAL #

OPTIFLO EVALUATION REPORT

STATUS KEY	DRUG KEY		PRIME	
A. Pre Bypass	A. Heparin	E. Bicarbonate I.	Drug	cc.
B. Partial Bypass	B. Protamine	F. Tham J.		
C. Total Bypass	C. Diuretic	G. Crystalloid K.		
D. Post Bypass	D. Blood	H. Albumin L.		
			TOTAL	

TIME	STATUS	PRESSURES		FLOW			TEMP.	BLOOD ANALYSIS					DRUGS	
		MAP	CVP	O_2	CO_2	Blood	Patient	H_2O				Hct		cc.
	A													

Notes

Evaluation Completed By (Please print name)

Figure 3.Evaluation form packaged with each new Galen OptiFlo oxygenator (note resemblance to early perfusion records).

OptiFlo Description

The OptiFlo featured a radically different look from its contemporary Harvey H-series and Bentley Temptrol oxygenators. For example, once secured in its holder, the OptiFlo stood 3 feet tall (see Figure 4). The totally-visible oxygenating column traversed just one side of the device, ascending to the top of the unit and then emptying into a large polyurethane defoaming chamber. The integral aluminum-coated heat exchanger, located within the arterial reservoir, also served as a space-occupying component. The resulting blood path that surrounded the heat exchanger was just sixty thousandths of an inch thick. Moreover, from a safety and visibility standpoint, a blood volume of just 250 milliliters in the arterial reservoir would rise to a level of nearly 13 inches in height above the outlet. The most significant feature by far was the never-before-seen integrated cardiotomy reservoir with Swank Dacron filter. To clarify, the cardiotomy reservoir could not sequester volume as it was merely a rigid housing (with inlet connectors) for the filter media. This did not pose a problem however, because the arterial reservoir could hold a substantial 3500 milliliters. For users that preferred a separate cardiotomy reservoir as part of their system, an OptiFlo oxygenator without the integrated cardiotomy filter was also manufactured (see Figure 5).

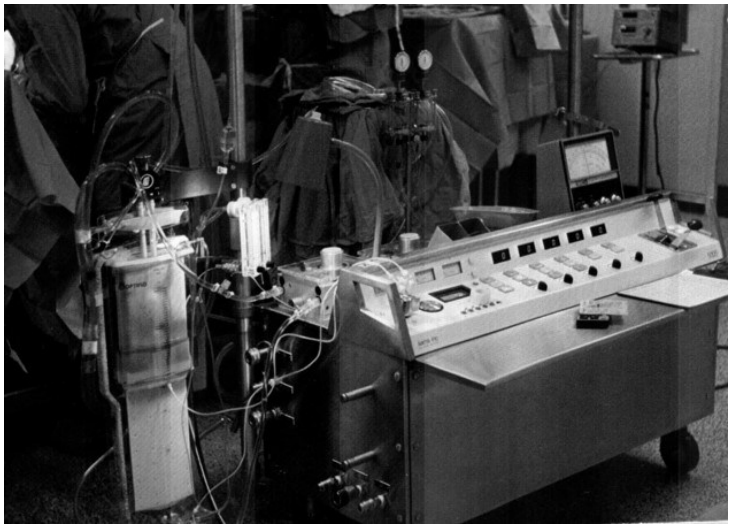

Figure 4.Photo depicting the height of the OptiFlo bubble oxygenator.

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Enter COBE Laboratories

In March 1974, COBE Laboratories acquired Galen in a cash advance and stock purchase agreement. For a time, Galen Laboratories was listed as a subsidiary of COBE. By early 1975, all product labeling and advertising material pertaining to the OptiFlo oxygenator had officially been converted to the COBE name. Despite this, the words "Galen OptiFlo" continued to appear in various journal articles until 1979. Bad luck befell the ever-reliable OptiFlo in the fall of 1976 when incidents of over-pressurizing were reported by users. An investigation by COBE revealed a most-hazardous problem, whereby the gas escape cap was cement-welded onto the oxygenator by assemblers in an upside-down position – effectively sealing off the vent port. A recall letter was sent to customers instructing them to quarantine all OptiFlo oxygenators in their possession until the units could be inspected by COBE personnel. The recall involved over 50,000 oxygenators worldwide.

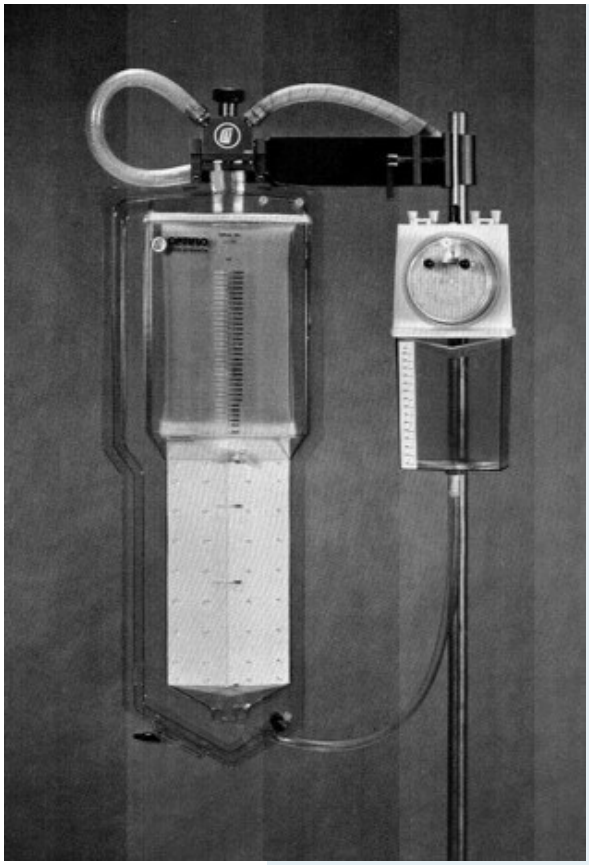

Figure 5. Photo of OptiFlo oxygenator without the integral cardiotomy filter (note separate cardiotomy reservoir to the right).

Summary

The OptiFlo oxygenator was an ingenious device for two reasons. First, it introduced the perfusion community to cardiotomy filter integration. COBE continued this unique feature in their second generation OptiFlo II oxygenator released in 1978. And secondly, the OptiFlo challenged the tightly-held notion that hard-shell bubble oxygenators had to be concentric in shape. Surely, in these instances, the folks at Galen Laboratories were visionaries and ahead of their time.

References

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