

**HAWAII HEALTH SYSTEMS CORPORATION
NOTICE OF AND REQUEST FOR EXEMPTION
FROM CHAPTER 103D, HRS**

EX 09-010

- 1. TO: Chief Procurement Officer
- 2. FROM: Maui Memorial Medical Center

Department/Division/Agency

Pursuant to §103D-102(b)(4), HRS, and Chapter 3-120, HAR, the Department requests a procurement exemption to purchase the following:

3. Description of goods, services or construction: Hamilton Medical Flow Sensors is the only flow sensor that has to be used with the Hamilton Ventilators. Item number 53120.	
4. Name of Vendor: Hamilton Medical Address: P.O. Box 30008 Reno Nevada 89520	5. Price: \$40,000.00
6. Term of Contract: From: 1 yr from signing To: w/1 additional year	7. Prior Exemption Ref. No.
8. Explanation describing how procurement by competitive means is either not practicable or advantageous to the State: Hamilton Medical flow sensor is the only sensor that would prevent a serious and potentially dangerous clinical condition. See attached.	
9. Details of the process or procedures to be followed in selecting the vendor to ensure maximum fair and open competition as practicable: The term of the exemption will be for (1) year period with an additional (1) year, at which time the hospital will re-evaluate the services and assess other options at which time a determination can be made if services should be continued, or if any other vendor can provide such services for the hospital. Based on available information and research the best procurement practice will be competed.	

10. A description of the agency's internal controls and approval requirements for the exempted procurement:
 This exemption shall be from section 103-302 all other guidelines, rules policies and procedures under Chapter 103D shall be upheld. HHSC policies and procedures will be followed and periodic reviews of contract action will be completed.


11. A list of agency personnel, by position, who will be involved in the approval process and administration of the contract:

Name	Position	Involvement in Process	
Pat Saka	COO	<input type="checkbox"/> Approval	<input type="checkbox"/> Administration
Wes Lo	CAO	<input type="checkbox"/> Approval	<input type="checkbox"/> Administration
		<input type="checkbox"/> Approval	<input type="checkbox"/> Administration
		<input type="checkbox"/> Approval	<input type="checkbox"/> Administration
		<input type="checkbox"/> Approval	<input type="checkbox"/> Administration
		<input type="checkbox"/> Approval	<input type="checkbox"/> Administration

12. Direct inquiries to:
 Department: Materials Management
 Contact Name: Lyle Kobashigawa
 Phone Number: 442 5467
 Fax Number: 242 2773

Agency shall ensure adherence to applicable administrative and statutory requirements

13. I certify that the information provided above is, to the best of my knowledge, true and correct.

 COO 11/24/08
 Department Head (Print: PATRICK SAKA) Date

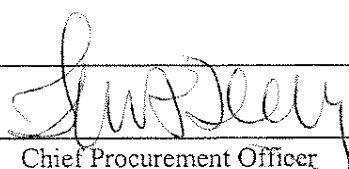
Reserved for CPO/Delegee Use Only

14. Date Notice Posted 11-6-08

The CPO is in the process of reviewing this request for exemption from Chapter 103D, HRS. Submit written objections to this notice to issue an exemption from Chapter 103D, HRS, within seven (7) calendar days or as otherwise allowed from the above posted date to: Chief Procurement Officer, HHSC, 3675 Kilauea Ave., Honolulu, Hawaii 96816

Chief Procurement Officer's comments:

15. APPROVED DISAPPROVED NO ACTION REQUIRED

 11/14/08
 Chief Procurement Officer Date



Rhazüns, 15 December 2003

IMPORTANT NOTICE

To all users of HAMILTON MEDICAL Ventilators

Dear valued Customer:

This is to inform you that a serious and potentially dangerous clinical condition may exist when unauthorized critical parts and accessories are used with your Hamilton Medical ventilators.

Background: Hamilton Medical's proximal flow sensors are an Application-Critical Component required for the safe and effective operation of the GALILEO, VEOLAR, AMADEUS and RAPHAEL ventilators. Hamilton Medical's flow sensors have been used for monitoring and control feedback of flow, volume and pressure applications since 1984. The required United States Food and Drug Administration (FDA) safety and performance verification and validation for each instrument is based on the precise flow sensor specifications of authorized Hamilton Medical flow sensors. If **Hamilton Medical ventilators are used with flow sensors that do not meet Hamilton Medical's design and performance specifications, the delivered tidal volume, minute volume, airway flow and pressure delivery may not be accurate.** Clinical conditions such as, hyper or hypo ventilation, hyper inflation, autoPEEP, high airway resistance, flow and pressure trigger problems and false detection of alarms may result if inaccurate flow sensor data are processed by Hamilton Medical ventilators.

It has recently been brought to our attention that third party companies such as ENVITEC and MAXTEC are distributing a flow sensor in the USA that looks like an authorized Hamilton Medical flow sensor. The flow sensor promotional information might imply that ENVITEC flow sensors are authorized for use with Hamilton Medical ventilators. Please be informed that Hamilton Medical has not received, nor submitted to the FDA for review, any of the required performance verification and validation data necessary to demonstrate the safety and effectiveness of any Hamilton Medical ventilator used in combination with any non-Hamilton Medical flow sensors per Pre-market notification 510(k) regulations. Hamilton Medical considers the substitution of any unauthorized critical components, such as the flow sensor to be a potentially dangerous and an Off -Label use of our ventilators.

The Warranty statement found in the Hamilton Medical Operator's Manual specifically defines exclusion of liability due to unauthorized or Off-Label use of Hamilton Medical products;

*"The user/owner of these products shall have sole responsibility and liability for any injury to persons or damage to property (including the Product) resulting from:
...E.) Use of damaged, unauthorized, or unapproved components and accessories."*

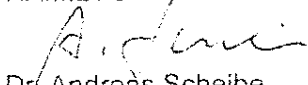
For critical safety reasons, we highly recommend that you evaluate the flow sensors in your institution and immediately discontinue the use of any unauthorized flow sensors being used with any Hamilton Medical ventilator.

To assist you in identifying and further ensuring that you are using only the correct and authorized flow sensors, we are enclosing a descriptive document with photographs and part numbers of both adult/pediatric and infant flow sensors authorized for use with Hamilton Medical ventilators.

If you have any questions or comments, please do not hesitate to contact the Hamilton Medical Quality Assurance and Regulatory Affairs office at 1 800 426 6331, Ext. 208.

Sincerely,

HAMILTON MEDICAL AG


Dr. Andreas Scheibe
Head of Quality Management

Enclosure:

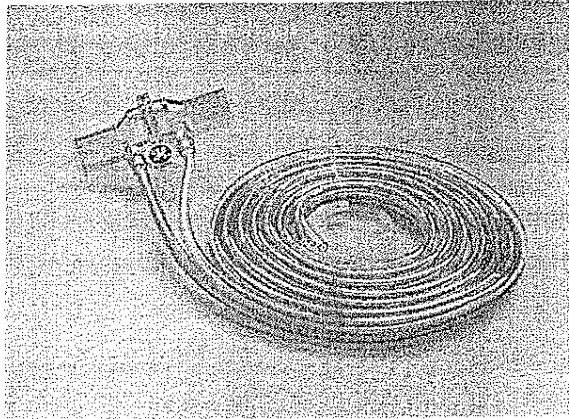
- Flow Sensor Identification Sheet

CC: FDA, CDRH, Office of Compliance, Division of Enforcement

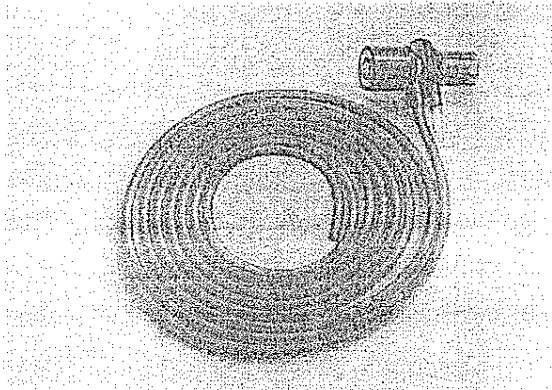
Identification of Authorized Hamilton Medical Flow Sensors

Authorized Hamilton Medical flow sensors are easily identified by the standard Hamilton blue color and product labeling. The Hamilton Medical trademark logo appears on all device labeling and is molded into the device housing. Unauthorized flow sensors will not contain the Hamilton Medical labeling or logo and the flow sensor housing is generally made from a clear/transparent plastic.

Hamilton Medical Authorized Flow Sensors



Adult/Pediatric Flow Sensor sold as
Part # 279331, boxed 10/ each case
Part # 155362, boxed 10/ each case
Part # 53120, boxed 50/ each case



Infant/Neonatal Flow Sensor sold as
Part # 155500, boxed 10/ each case