

K960168

OCT 25 1996

510(k) Summary for
Siemens Servo Screen 390

1. DATE THIS SUMMARY WAS PREPARED

January 11, 1996

2. SUBMITTER'S NAME AND ADDRESS

Siemens-Elema AB
Röntgenvägen 2
S-171 95 Solna
Sweden

3. CONTACT PERSON

Mr. Anders Lodin

Telephone 011-46 8 730 7228

Telefax 011-46 8 98 63 05

4. DEVICE NAME

Trade/Proprietary Name: Servo Screen 390 and Servo Computer Module 990

Common Name: Ventilator Monitoring System

Classification Name: (Accessories to) Ventilator, Continuous (Respirator)

5. PREDICATE DEVICES

The legally marketed devices to which equivalence is being claimed are:

- LEONARDO Patient Data Manager
Hamilton Medical
P.O. Box 30008
Reno, NV 89520

- 7202 DISPLAY OPTION MODULE
Puritan-Bennett International, Inc.
P.O. Box 25905
Overland Park, KS 66225
- EVITA Ventilator
Dräger
4101 Pleasant Valley Road
Suite 100
Chantilly, VA 22021

6. DEVICE DESCRIPTION

The Servo Screen 390 is a real time ventilatory monitor system that continuously reads and makes calculations from parameters measured or calculated by Servo Ventilators. It displays this information in a clear and logically organized manner. Parameters are listed in a numerical format and/or as waveforms and loops. All displayed parameters are trended in 3, 6, 12, or 24 hour intervals.

The device consists of a small, compact computer unit suitable for use in the clinical environment designed specifically for integration with existing ventilators Servo Ventilator 300 and Servo Ventilator 900. The flexible support arm makes it easy to place the screen in a wide array of positions; on the ventilator, on a cart, or even on a wall rail for maximum visibility. The front panel has an electro-luminescence monochromatic display screen and a single operator control in the form of a control-knob, which is simply turned or pressed.

The flat screen display unit measures 252 x 330 x 88 mm (not including control knob) and a flexible support arm. Weight including the support arm is 4.3 kg. When used with the Servo Ventilator 900, the Servo Computer Module 990 is required to interface the two devices. This interface mounts under the ventilator, adding 2.7 kg to the weight and 4.0 cm to the height.

7. INTENDED USE

The intended use of the Servo Screen 390 is to provide a central bedside location for the display of all parameter information from the ventilator in order to aid the clinician in quickly and accurately reviewing the operating state of the ventilator and the ventilatory

status of the patient. When review of the tabular or graphical data displayed on the Servo Ventilator 300 indicate that intervention may be required, it is the responsibility of the clinician to verify critical settings and measurements on the ventilator control panel and to obtain appropriate additional data from other sources before initiating changes in therapy.

The Servo Screen 390 does not control the ventilator, nor does it recommend specific changes in therapy or provide a diagnosis. It is a device for the formatting and display of data.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Servo Screen, Leonardo, 7202 Display Option Module, and Evita all provide for storage, trending, and graphing of data retrieved from the ventilator. All provide a video screen at the ventilator where the user can choose to view in real time a subset of the available parameters as tables, waveforms over time, or X-Y "loop" plots. Differences in the set of parameters available are due to differences in the ventilators, not the ventilatory monitoring system itself. Of the thirty parameters and graphs that can be displayed on the Servo Screen, fifteen are also available on the Leonardo. Of the fifteen not found on the Leonardo, three are found on the Puritan-Bennett 7202 Display Option Module (minute volume, tidal volume, and dynamic compliance), and one on the Dräger Evita (CO₂ concentration). The remaining twelve parameters represent unique capabilities of the Siemens Servo Ventilators, rather than a substantial difference in the monitoring systems.

Servo screen uses an Intel 80486SX microprocessor, MS-DOS operating system, and displays data on an electroluminescent flat-panel display. The hardware and software are designed, manufactured, and maintained under GMP controls. The Leonardo system is an application program that runs on an IBM compatible personal computer and displays data on a CRT display. The Puritan-Bennett 7202 Display Module displays data on an electroluminescent display. The details of the processor hardware are not known to this applicant. The Dräger Evita includes the equivalent functionality as an integral part of the ventilator and displays data on an LCD display.

The differences in user interface, size & weight, and data formatting among the four systems reflect differing implementations of systems with the common goal of providing the convenient and user-friendly presentation for the user. While some clinicians may

prefer one implementation over the others, we do not believe that these subjective differences have a significant effect on the clinical efficacy of the devices.

The SCM 990 Version 2 is a firmware upgrade to enable the data interface to provide a larger selection of ventilator parameters for display on the Servo Screen. The expanded list of available parameters is equivalent to the parameters which can be displayed on the predicate devices.

9. NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The design of the Siemens Model 390 Servo Screen has been thoroughly validated at the unit, integration and system level. Non-clinical tests were conducted of the Siemens Model 390 Servo Screen, interfaced to both the Servo Ventilator 900 and Servo Ventilator 300. These tests demonstrated that the data displayed by the servo screen is in agreement with the ventilator display when ventilator operation is simulated over the operating range of key ventilator parameters. The Servo Screen 390 and the SCM 990 have been tested and do meet the requirements for immunity to electromagnetic interference and emissions of electromagnetic energy as defined by EN60601-1-2

10. CONCLUSIONS FROM NONCLINICAL TESTING

Based on inspection of the Servo Screen and Servo Computer Module Requirements Specifications and review of the testing that demonstrates that these requirements are met, we conclude that the Servo Screen 390 and the SCM 990 are substantially equivalent to the predicate devices cited above.