Appendix 1: Intended Use/Indications for Use

Note: Products may not be available in all markets.

Device: Aisys CS2

The GE Datex-Ohmeda Aisys CS2 Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

Device: Avance CS2

The GE Datex-Ohmeda Avance CS2 is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

Device: Carestation 620/650/650c

The Carestation 620/650/650c anesthesia systems are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The anesthesia systems are suitable for use in a patient environment, such as hospitals, surgical centers, or clinics. The systems are intended to be operated by a clinician qualified in the administration of general anesthesia.

Device: Aisys

The GE Datex-Ohmeda Aisys Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation. The Aisys is not suitable for use in a MRI environment.

Device: Avance

The GE Datex-Ohmeda Avance Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.

Device: Aespire View

The Aespire View anesthesia system is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The device is intended for volume or pressure control ventilation.

Device: Aespire 7900

The family of GE Datex-Ohmeda Aespire anesthesia systems with 7900 ventilator (Aespire 7900 and Aespire View) is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The devices are intended for volume or pressure control ventilation.

Device: Aestiva MRI

The Aestiva/5 MRI Anesthesia System provides the functional feature set offered by the conventional Aestiva/5 to the clinician with the added ability to be used in the MR environment. Among those standard Aestiva/5 features is the Datex-Ohmeda user interface, all the ventilation parameters of the SmartVent along with Aestiva breathing circuit. The Aestiva/5 MRI Anesthesia System performed to specifications when tested directly next to 1.5 and 3.0 Tesla shielded MRI devices in a field strength that did not exceed 300 gauss.

Device: Aestiva 7900

This version of the Datex-Ohmeda 7900 Ventilator is used in Datex-Ohmeda Aestiva Anesthesia Systems. It is a microprocessor based, electronically controlled, pneumatically driven ventilator that provides patient ventilation during surgical procedures. The 7900 ventilator is equipped with a built-in monitoring system for inspired oxygen, airway pressure and exhaled volume. Sensors in the breathing circuit are used to control and monitor patient ventilation as well measure inspired oxygen concentration. This allows for the compensation of compression losses, fresh gas contribution and small leakage in the breathing absorber, bellows and system. User setting and microprocessor calculations control breathing patterns. User interface keeps settings in memory. The user may change settings with a simple and secure setting sequence. A bellows contains breathing gasses to be delivered to the patient. Positive End Expiratory Pressure

(PEEP) is regulated electronically. Positive pressure is maintained in the breathing system so that any leakage that occurs is outward. An RS-232 serial digital communications port connects to and communicates with external devices. Ventilatory modes for the device, include Volume Mode, Pressure Control Mode, Synchronous Intermittent Mandatory Ventilation (optional), Pressure Support with Apnea Backup Ventilation. (optional).

This device is to be used only by trained and qualified medical professionals.

Device: 9100c NXT**

**Not cleared or approved in the US or Canada.

The 9100c NXT anesthesia systems are intended to provide general inhalation anesthesia and ventilator support to a wide range of patients (neonate, pediatric and adult). The anesthesia systems are suitable for use in a patient environment, such as hospitals, surgical centers, or clinics. The systems are intended to be operated by a clinician qualified in the administration of general anesthesia.

Device: 9100c**

**Not cleared or approved in the US or Canada.

The 9100c anesthesia machine is a compact, integrated, and intuitive anesthesia delivery system. The 9100c anesthesia machine provides general inhalation anesthesia and ventilatory support for patients during surgery as well as monitoring and displaying various patient parameters. This anesthesia system is designed for mixing and delivering inhalation anesthetics, Air, O2 and N2O. This anesthesia system is not suitable for use in an MRI environment. This system must only be operated by medical personnel authorized and trained to use this product. It must be operated according to the instructions in this User's Reference Manual.