URGENT – Field Safety Notice
Philip's Anesthesia Machines
Negative Pressure Limiter (NPL) valve

Dear Customer,

A problem has been detected in the anesthesia machines manufactured by Philips Anesthesia Care A/S that, if it were to occur, could pose a risk for patients. This communication is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy of this Field Safety Notice with the equipment User Manual.

If the patient is connected to the anesthesia machine in a volume controlled ventilation mode and attempts a large spontaneous breath around the same time as a mandatory breath with a flow rate higher than 4.5 L/min, it is possible for the patient to create a high negative airway pressure. The higher the flow generated by the patient, the greater the risk of increased negative airway pressure, which can lead to discomfort for the patient.

This issue was discovered by Philips during an internal testing of SIMV mode. Philips has not received any reports of harm related to this issue.

Please refer to the following page, which provide instructions for actions to be taken. Follow the "Action to be taken by Customer/User" section of the instructions.

If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Peter Jørgensen
Senior Quality System Specialist

AFFECTED PRODUCTS	IntelliSave AX700 (P/N # 866205/10623-00) Dameca MRI 508 (P/N # 866203/10651MRI-00) Siesta i Whispa (P/N # 866202/10651-00) Siesta iTS (P/N # 866163/10653-00) Siesta Breasy (P/N # 866204/10652-00) All serial numbers are affected.
PROBLEM DESCRIPTION	If the patient is connected to the anesthesia machine in a volume controlled ventilation mode, and attempts a large spontaneous breath, it is possible for the patient to create a high negative airway pressure around the same time as a volume controlled breath (mandatory breath).This pressure will be limited by the mechanical Negative Pressure Limiter (NPL) valve. The NPL valve opens if the patient generates a negative pressure of -5 and -7.5 cmH_20 (hPa). This opening pressure of the NPL valve is defined at an inspiratory flow rate of 3.5-4.5 L/min. If the patient creates a higher flow rate than 4.5 L/min, the NPL valve will continue to function but due to the resistance of the flow and time taken to reach the patient, the airway pressure may decrease further. The higher the flow generated by the patient, the greater the risk of increased negative airway pressure. If the patient is breathing spontaneously, support ventilation modes (VSV, PSV) could be considered.
HAZARD INVOLVED	The higher the flow generated by the patient, the greater the risk of increased negative airway pressure, which can lead to discomfort for the patient.
HOW TO IDENTIFY AFFECTED PRODUCTS	All PHAC anesthesia machines are affected by this issue (IntelliSave AX700, Dameca MRI 508, Siesta i Whispa, Siesta iTS, and Siesta Breasy)
ACTION TO BE TAKEN BY CUSTOMER / USER	The customer should read the Field Safety Notice and the IFU addendum and ensure that they understand it – and then attach the addendum to the IFU.
ACTIONS PLANNED BY PHILIPS	Philips is voluntarily initiating this correction to affected IFU's of the above mentioned devices. Philips local representative will send out a letter (Field Safety Notice) to all Customers to ensure all users of Philips anesthesia machines are informed and understand the implications. The letter will include a copy of an addendum to the Instruction For Use (IFU) which needs to be attached to each customer IFU. The addendum to the Instruction For Use (IFU) will additionally be issued with all new systems that are shipped from factory.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.