Website Information on Identification, Performance and Safe Use of VISI
as required by 17/745 EUMDR section 23.1. 221219a.

Identification

As part of VISI Stowood manufactures three devices listed below with their respective GTIN (UDI-DI):

Device name	GTIN (UDI-DI)
Black Flash	05060504340052
Black Flash Plus	05060504340069
Black Shadow	05060504340076

Stowood has determined that for these devices the:

Global Medical Device Nomenclature (GMDN) code and term is
33843, sleep assessment device, and the

European Medical Device Nomenclature (EMDN) code and term is:
Z12100501, Polysomnographs

The three devices are similar and offer a different range of channels for recording physiological phenomena, with the Black Flash having the fewest and the Black Shadow the most.

Performance

Under EUMDR Article 2, definition 22 'performance' means the ability of a device to achieve its intended purpose as stated by the manufacturer.

The Black Series devices' intended purpose is to record human physiological phenomena which have or may have a connection to sleep disorders. These include: audio, SpO2, pulse rate, nasal airflow pressure, oral/nasal thermistry, sound level (dB), snoring, body position, body movement, patient event, pleth. signal, respiratory effort (2 inductance or PVDF), leg EMG/mvt (2 EMG or Pz), ECG, four auxiliary inputs for other phenomena as required, optional wireless (Bluetooth) transmission of some data.

In bench testing and in clinical use the Black Series consistently demonstrate their ability to fulfil their intended purpose.

Technical specification

Dimensions ..... 120 x 90 x 25 mm Weight including batteries
Weight including batteries .. <200 g
Power ..... Two AA standard or rechargeable NiMH batteries; virtually no power Consumption when 'Off'
Sensors ..... Disposable nasal cannulae, reusable or single use Masimo oximeter probes, reusable thermistors, inductance belts, leg sensors or EMGs
Data storage ..... Removable SD card
Setup & waveform check .... Bluetooth or wired setup
Software ..... Visi-Download including audio replay as used for oximeters & capnometers. Reports available in six languages
CE ..... CE 1639

Safe Use

Anyone using any of the devices should read the following sections from the instructions for use (IFU) on safety and correct use. An electronic copy of the IFU is available on request to support@stowood.com or by phoning +441865 358860:

13.0 Oximeter (any Black Series Device)

13.1 Specific Warnings in relation to use of the oximeter

Explosion hazard: Do not use in the presence of flammable anaesthetics or other inflammable substance in combination with air, oxygen enriched environment or nitrous oxide.

Apnoea monitors: A pulse oximeter should NOT be used as an apnoea monitor.

Pulse Rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. It should not be used as a replacement or substitute for ECG based arrhythmia analysis.

Alarms: There are no alarms or display implemented as this is a sleep recording device.

Operating personnel: Device to be operated by qualified personnel only. These Instructions for Use, accessory directions for use, all precautionary information, and specifications should be read before use.

Patient Cabling As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

Electric shock hazard: Do not remove equipment covers. There are no user defined operator procedures within the equipment. Refer any servicing to Stowood Scientific Instruments.

Interfering substances: Carboxyhaemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhaemoglobin present. Dyes or any substance containing dyes that change usual arterial pigmentation may cause erroneous readings.

MRI Scanners: Do not use during MRI scanning as it could potentially cause burns.

High Outside temperatures User is advised that if the room temperature reaches or exceeds 40C the temperature of the Black Shadow may be more than 41C but less than 43C.

14.0 Cautions

14.1.1 Cleaning of the oximeter probe:

- Do not autoclave, pressure sterilize, or gas sterilize.
- Do not soak or immerse in any liquid.
- Use cleaning solution sparingly. Excessive solution can flow into the product and cause damage to internal components.
- Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the product. These substances attack the device's materials and device failure can result.

14.1.2 Measurements

There is no display of saturation or pulse rate in Visi Black Shadow.

Inaccurate measurements may be caused by:

- incorrect sensor application or use

- significant levels of dysfunctional haemoglobins (e.g., carboxyhaemoglobin or methemoglobin) or Bilirubin
- intravascular dyes such as indocyanine green or methylene blue.
- exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material)
- excessive patient movement
- venous pulsations
- placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Nail varnish
- Sensors applied too tightly
- Low perfusion
- Venous congestion
- Use of tape which reduces blood flow

Loss of pulse signal can occur in any of the following situation:

- the sensor is too tight
- there is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight
- a blood pressure cuff is inflated on the same extremity as the one with a SpO2 sensor attached.
- the patient has hypotension, severe vasoconstriction, severe anaemia, or hypothermia
- there is arterial occlusion proximal to the sensor
- the patient is in cardiac arrest or is in shock

14.1.3 Sensors

Before use, carefully read the sensor directions for use.

Use only Masimo SET oximetry sensors for SpO2 measurements. Other oxygen transducers (sensors) may cause improper performance.

Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor 'Directions for Use' to ensure skin integrity and correct positioning and adhesion of the sensor.

Do not use damaged sensors. Do not use a sensor with exposed optical components. Do not immerse the sensor in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof). Do not sterilize by irradiation, steam, or ethylene oxide. See the cleaning instructions in the directions for use for reusable Masimo sensors.

Do not use damaged patient cables. Do not immerse the patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize by irradiation, steam, or ethylene oxide. See the cleaning instructions in the directions for use for reusable Masimo patient cables.