Device Essential Requirements Checklist

In Compliance With The 93/42/EEC Medical Device Directive

Product	PIPPA		**New product**	Yes
Part Number			**Existing Product**	No
Description	Breathing Monitor		**Introduced**	
Class	II(b)		**Main Standard**	IEC601

No	Essential Requirement	A/NA	Standard	Report
I	**General Requirements**			
1.	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	A	BS EN 60601-1 ISO9001 BS EN ISO 14971:2001 EN46001	Manufactured to ISO9000 quality standards. Non-Invasive device. Low battery voltage (E)Risk Assessment (E)Risk Analysis
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.	A	BS EN ISO 14971:2001 EN46001	No known Hazards. No known risks (E)Risk Analysis
	In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - Eliminate or reduce risks as far as possible (inherently safe design and construction),	A		(E)Risk Assessment
	- Where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	A		(E)Risk Analysis
	- Inform users of the residual risks due to any shortcomings of the protection measures adopted	A	EN1041 BS EN ISO 14971:2001	(F)User Manual
3.	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	A		(O2) Specification (O16) Validation (O26) Clinical trials (O21) Tests
4.	The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical	A	BS EN ISO 14971:2001	Portable, low voltage, non-invasive monitor.

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	conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.			(E) Risk Assessment
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	A		((L) Packaging Trials & Validation (UV) Manufacturers Data
6.	Any undesirable side effect must constitute an acceptable risk when weighed against the performances intended.	N/A	BS EN ISO 14971:2001	No known side effects (E) Risk Assessment
II	**Requirements Regarding Construction & Design**			
7.	**Chemical, physical and biological properties**			
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to:	A		Non Inflammable Non Toxic, Not in contact with the patient Medical grade materials used Manufacturers data (T) Material specifications
	-The choice of materials used, particularly as regards toxicity and, where appropriate, flammability,	A		(O18) Design Reviews (PSU protection) (T) Material specifications
	- The compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.	A		(O27) Biocompatibility
7.2	The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	N/A	BS EN ISO 14971:2001	Enclosure splash proof Manufacturers data(T) Material specifications (O18) Design Reviews (O27) Biocompatibility
7.3	The devices must be designed and manufactured	A		(O26) Clinical Trials

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	in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.			(T) Material specifications (O26) Biocompatibility (O21) & (O22) Test Reports
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may he considered to be a medicinal product as defined in Article 1 of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC.	A		(O21) & (O22) Test reports
7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.	A		(O21) & (O22) Test reports (O16) Validation
7.6	Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	A	BS EN 60601	Device splash proof IP43 rating. Manufacturers component specification (T) Material specifications
8	**Infection and microbial contamination**			
8.1	The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	A	ISO9001 EN46001 EN1041	Uses a standard facemask as an accessory Manufacturing procedures Cleaning Instructions in User manual Sensors for single patient use Manufacturers component specification (T) Material specifications
8.2	Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended	N/A		No animal origin components

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	use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.			
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	N/A		Non Sterile
8.4	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	N/A		Non Sterile
8.5	Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.	N/A		Non Sterile
8.6	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	A		(L) Packaging
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	N/A		Non Sterile
9	**Construction and environmental properties**			
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	A	BS EN 60601 ISO9001 BS EN ISO 14971:2001	Stand alone device ((F2) User manual
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: - The risk of injury, in connection with their physical features, including the volume/pressure	A		Hand held lightweight device (O1)Design Theory (O1) Design History (O26) Clinical Trials

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	ratio, dimensional and where appropriate ergonomic features,			
	- Risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,	A	BS EN 60601-1-2	(O25) EMC results
	- The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,	A	BS EN 60601-1-2	(O25) EMC results
	- risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	A		Not implantable An electronic circuit easily accessible (G) Maintenance manual
9.3	Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances, which could cause combustion.	A	EN1041 BS EN 60601	Not to be used in the presence of explosive gases (F3) Labels (F2)User Manual (O18) Design reviews
10	**Devices with a measuring function**			
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The manufacturer must indicate the limits of accuracy.	A		(O2)Specification (O1) Design history (O18) Design reviews (O26) Clinical trials (O21) & (O22) Test reports
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	A		(O2) Specification Digital readout approximately 10mm high
10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).	A		Breaths per minute (BPM) (O2) Specification
11	**Protection against radiation**			
11.1	***General***			
11.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of	N/A		No Ionizing radiation

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	appropriate specified levels for therapeutic and diagnostic purposes.			
11.2	***Intended radiation***			
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant parameters.	N/A		No Ionizing radiation
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	N/A		No radiation
11.3	***Unintended radiation***			
11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	N/A		No radiation
11.4	**Instructions.**			
11.4.1	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	N/A		No radiation
11.5	***Ionizing radiation***			
11.5.1	Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	N/A		No Ionizing radiation
11.5.2	Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	N/A		No Ionizing radiation
11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.	N/A		No Ionizing radiation

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12	**Requirements for medical devices connected to or equipped with an energy source**			
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	A		(O21) Pre clinical trials (HOPE Hospital)
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	A	EN1041	Information displayed on LCD when battery is low Audio alarm (O2) Specification (E) User manual
12.3	Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	N/A		Battery portable only (O2) Specification (E) User manual
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	N/A	EN1041	Measures only breaths/minute (O2) Specification (E) User manual
12.5	Devices must he designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	A	EN60601-1-2	(O25) EMC Report
12.6	***Protection against electrical risks***			
12.6.1	Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	A	EN60601-1	3 volt Battery used (O2) Specification
12.7	***Protection against mechanical and thermal risks***			
12.7.1	Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	A		Lightweight device (O2) Specification (E) User manual
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	A		No vibration
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible	A		No emitted noise except alarm

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	level the risks arising from the noise emitted taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.			
12.7.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	A		No external supplies Mask uses standard tubing (F) User manual (T) manufacturers specification (mask)
12.7.5	Accessible parts of the devices (excluding the parts or areas intended to supply or reach given temperatures) and their surroundings must not attain potentially danger temperatures under normal use.	N/A		No heat generated
12.8	***Protection against the risks posed to the patient by energy supplies or substances***			
12.8.1	Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	N/A		Does not supply energy
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate, which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	N/A		Is not used too control flow-rates
12.9	**The function of the controls and indicators must be clearly specified on the devices.** Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	A	BSEN980.	Graphic symbols for use in the labeling of medical devices All controls are marked (F) User manual, (F) Labels
13	**Information supplied by the manufacturer**			
13.1	Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on	A	EN1041	Information supplied by the manufacturer with medical devices (F) User manual, (F) sensor insert

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	the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or II(a) if they can be used safely without any such instructions.			
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colors must be described in the documentation supplied with the device.	A	BSEN980. EN1041	Graphic symbols for use in the labeling of medical devices All controls are marked (F) Labels
13.3	***The label* must bear the following particulars**	A	BSEN980.	Graphic symbols for use in the labeling of medical devices All controls are marked (F) labels
(a)	The name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14 (2) or of the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate;	A	BSEN980	(F) Label (F) Insert (F) User manual
(b)	The details strictly necessary for the user to identify the device and the contents of the packaging;	A	BSEN980 EN1041	(F) Label (F) Insert (F) User manual
(c)	Where appropriate, the word 'STERILE';			Not Sterile
(d)	Where appropriate, the batch code, preceded by the word 'LOT', or the serial number;	A	BSEN980 EN1041	(F) Label (F) Insert (F) User manual (F) Serial number label
(e)	Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;	N/A		Not required
(f)	Where appropriate, an indication that the device is for single use;	N/A		Not for single use (F) Insert

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				(F) User manual
(g)	If the device is custom-made, the words 'custom-made device';	N/A		
(h)	If the device is intended for clinical investigations, the words 'exclusively for clinical investigation';	N/A		
(i)	Any special storage and/or handling conditions;	A	BSEN980 EN1041	No special storage or handling conditions (F) User insert (F) User manual
(j)	Any special operating instructions;	A	BSEN980 EN1041	(F) User insert (F) User manual
(k)	Any warnings and/or precautions to take;	A	BSEN980 EN1041	(F) User insert (F) User manual
(l)	Year of manufacture for active devices other than those covered by (c). This indication may be included in the batch or serial number;	A	BSEN980 EN1041	(F) Label
(m)	Where applicable, method of sterilization.	N/A		No Sterilization
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	A	BSEN980 EN1041	Intended purpose is obvious (F)User Insert (F) User maual
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components	A	BSEN980 EN1041	(F) Label Serial number (F) Insert (F) User manual Accessory sensors LOT marked. Face masks have LOT numbers
13.6	**Where appropriate, the instructions for use must contain the following particulars:**	A	EN1041	Full Instruction leaflet supplied (F) User manual (F) Insert
A	The details referred to in Section 13.3, with the exception of (d)&(c);			
B	The performances referred to in Section 3 and any undesirable side-effects;	N/A		No side effects
C	If the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order	A		Full Instruction leaflet supplied F) User manual (F) Insert

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	to obtain a safe combination;			
D	All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;	A		Full Instruction leaflet supplied F) User manual (F) Insert
E	Where appropriate information to avoid certain risks in connection with implantation of the device;	A		Full Instruction leaflet supplied F) User manual (F) Insert
F	Information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	N/A		
G	The necessary instructions in the event of damage of the sterile packaging and, where appropriate, details of appropriate methods of re-sterilization;	N/A		Not sterile
H	If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses.	A		Full Instruction leaflet supplied F) User manual (F) Insert
	Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I;	N/A		Not Sterile
I	Details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);	N/A		No sterilisation
J	In the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:	N/A		No radiation

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K	Precautions to be taken in the event of changes in the performance of the device;	A		Full Instruction leaflet supplied F) User manual (F) Insert
L	Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influence, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	A		Full Instruction leaflet supplied F) User manual (F) Insert
M	Adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;	N/A		No medicinal products used except Oxygen or An oxygen air mix
N	Precautions to be taken against any special, unusual risks related to the disposal of the device;	A		No risks in disposable of the device
O	Medicinal substances incorporated into the device as an integral part in accordance with section 7.4;	N/A		No medicinal products used
P	Degree of accuracy claimed for devices with a measuring function.	A		(O2) specification
14	Where conformity with the essential requirements must be based on clinical data, as in Section I (6), such data must be established in accordance with Annex X.	A		(O26) Clinical trials