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iM 系列产品风险管理报告

iM Series Risk Management Report

文件修改记录 Revision History

文件版本 Version	日期 Date	作者 Author	修改描述 Description
1.0	2015-08-10	韦华彪 Weihuabiao	初始版本（TR0&TR1） Initial（TR0&TR1）
1.1	2016-4-26	韦华彪 Weihuabiao	增加措施（索引）和 验证与确认（TR2&TR3） Add control References and V&V references（TR2&TR3）
1.2	2016-5-23	韦华彪 Weihuabiao	试生产与确认阶段（TR4）升版 Pilot production and validation update（TR4）
1.3	2016-11-2	韦华彪 Weihuabiao	生命周期阶段更新，增加 CO2 风险 工程变更 ECR-S2_0000627 对 ETCO2 标准气体进行来料管控，对产品风险进行再次评审，增加风险条目：B6.1.14 Lifetime update ,add CO2 risk ECR-S2_0000627 control standard ETCO2 gas incoming, review Product Risk,added Risk Analysis Table: B6.1.14.

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1.4	2017-12-11	韩吉灯 Hanjideng	生命周期阶段更新. 工程变更 ECR-S2_0000767 增加开机自检故障自动恢复机制，对产品风险进行再次评审，刷新风险条目：4.1.22。 针对 Vista 120 抱怨（72005 MC-3530-20171024001）出现的 IBP 不正确校准问题，增加风险条目：6.1.15 Lifetime update. ECR-S2_0000767 Add audio self-test function,refreshed Risk Analysis Table: B4.6.17. For the Vista 120 complained （ 72005 MC-3530-20171024001）IBP measurement is abnormal after improper calibration,added Risk Analysis Table:6.1.15
1.5	2019-5-5	王敏 Wang Min	1. 模板更新 Template update 2. 年度升级 Annual update 3. 使用期限更改为 10 年 The expected Service life change to 10 years

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上述签名信息表明审核人已经审核、确认本文所记录的所有风险管理活动，且证明所有风险管理活已经满足了下述要求：With his/her signatures the signers confirm that the risk management activities have been reviewed and determined to be compliant. The review(s) further provide evidence that:

- 所有已识别出来的危害情形均已完成了风险评价及控制；Risks from all identified hazardous situations have been considered.
- 风险管理计划已经遵照执行 The Risk Management Plan has been appropriately implemented：
  - 风险管理活动已经满足了 QP38 风险管理控制程序的要求 The QP38 risk management control procedure has been followed.
  - 风险管理过程中相关活动和职责的执行与产品开发计划文件规定的一致 The actual responsibilities for the performed risk management activities agree with those defined in the DDP document.
  - 已经依照风险管理计划执行了风险控制措施的验证 Verification of risk control measures has been performed according to the Risk Management Plan.
- 综合剩余风险可接受 The overall residual risk is acceptable.

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iM 系列产品风险管理报告

iM Series Risk Management Report

1 说明 Introduction

1.1 目的与范围 Purpose and Scope

本文档是病人监护仪(型号：iM50、M50、iM60、iM70、iM80、M80)的风险管理报告。文档中记录了风险评估的对象及其相关的附件，风险评价的结果、风险控制措施和验证及风险控制措施实施后的综合剩余风险，风险评价结果不能满足风险可接受性判定标准时，给出必要的风险/受益分析。本文档的内容可作为证据证明风险管理过程已经满足 ISO 14971:2007、EN ISO 14971:2012、YY/T0316:2016 的要求。This document is the risk management report for Patient Monitor (Models:iM50,M50,iM60,iM70,iM80,M80).With respect to ISO 14971:2007、EN ISO 14971:2012、YY/T0316:2016, it covers results of the risk management process which are essential for approval purposes. The report further identifies the device(s) and accessories affected, the results of the risk evaluation and the overall residual risk after the implementation and verification of all risk control measures, including a risk/benefit analyses whenever risk exceeds the criteria for acceptability.

本文档在产品的整个生命周期内会不断的更新、升级，本文 1.2 节具体描述了每个版本适用的产品生命周期阶段。This document is continually updated during the life cycle of the device. See clause 1.2 for the specific project phase/milestone it is related to.

1.2 评价对象 Object covered by this document

型号 Model	名称 Product Name/description	阶段 Stage
iM50	Patient Monitor	Lifecycle
M50	Patient Monitor	Lifecycle
iM60	Patient Monitor	Lifecycle
iM70	Patient Monitor	Lifecycle
iM80	Patient Monitor	Lifecycle
M80	Patient Monitor	Lifecycle

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1.3 应用部分和准应用部分 Applied parts and quasi applied parts

1.3.1 应用部分 Applied part

正常使用中为了实现医疗设备或者医疗电气系统的功能而必须要与患者有物理接触的设备部分（定义引自 IEC60601-1:2005+A1 条目 3.8）。以及应用部分与患者接触时长“t” （引自 IEC60601-1:2005+A1 条目 11.1）

Parts of ME* equipment that in normal use necessarily comes into physical contact with the patient for ME equipment or an ME *system to perform its function (IEC60601-1:2005+A1 subclause 3.8). And Applied part having contact with the patient for a time “t” （From IEC60601-1:2005+A1 Clause 11.1.1 table 24）

ME*： Medical Electrical Equipment

功能/参数 Function/Parameter	**应用部分描述 Description of applied part**	**应用部分与患者接触时长 “ t” Applied part having contact with the PATIENT for a time “t ”**
ECG	Electrode 电极片	10 min ≤ t
TEMP	TEMP sensor 温度传感器	10 min ≤ t
SpO2	SpO2 sensor 血氧传感器	10 min ≤ t
NIBP	NIBP cuff 血压袖带	10 min ≤ t
CO	In-line Injection temperature probe C.O.温度探头	1 min ≤ t < 10 min
IBP	Disposable pressure sensor 一次性压力传感器	1 min ≤ t < 10 min
etCO2	Narial Sample line 鼻子采样管	10 min ≤ t
AG	Narial Sample line 鼻子采样管	10 min ≤ t

1.3.2 准应用部分 Quasi-applied parts

可能会接触患者不属于上述定义的应用部分、但是在使用中会接触患者、需要满足应用部分的要求的设备部件/部分（定义引自 IEC60601-1:2005+A1 条目 4.6）。

Parts that can comeinto contact with the patient but fall outside of the definition of applied parts shall be subject to the requirements for applied parts (IEC60601-1:2005+A1 subclause 4.6).

功能/参数 Function/Parameter	**准应用部分描述 Description of Quasi-applied part**	**准应用部分与患者接触时长 “ t” Quasi-applied part having contact with the PATIENT for a time “t ”**
ECG	ECG cable ECG 线缆	t < 1 min
TEMP	TEMP cable 体温线缆	t < 1 min
SpO2	SpO2 extension cable 血氧延长线	t < 1 min

NIBP	NIBP extension tube 血压延长管	t < 1 min
CO	C.O. transducer cable 心排转换电缆	t < 1 min
IBP	IBP transducer cable 无创血压转换电缆	t < 1 min
etCO2	CO2 sensor and cable CO2 适配器和线缆	t < 1 min
AG	Sidestream AG module and cable 旁流 AG 线缆	t < 1 min

1.4 预期用途 Intended use

The monitors are intended to be used for monitoring, storing, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.

The iM50 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO_2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO_2 and Quick Temperature (Quick TEMP).

The iM60 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO_2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP) and Expired CO_2.

The iM70 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO_2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO_2 and Anesthetic gas (AG).

The iM80 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO_2), Invasive or noninvasive blood pressure (2/4 channels IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO_2 and Anesthetic gas (AG).

The M50 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO_2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO_2 and Quick Temperature (Quick TEMP).

The M80 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO_2), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO_2 and Anesthetic gas (AG).

The arrhythmia detection and ST Segment analysis are intended for adult and pediatric patients.

The monitors are not intended for MRI environments.

产品性能结构以及组成：监护仪由主机和相应功能附件（心电电缆、无创血压袖带、血氧传感器、体温传感器、二氧化碳气体测量组件）组成。其中二氧化碳气体测量组件可选配 EDAN（理邦）G2 型或 Respironics（伟康）C5 型模块；无创血压测量组件可选配 EDAN

（理邦）或者 Omron（欧姆龙）模块；脉搏氧饱和度测量组件可选配 EDAN（理邦）或者 Nellcor 模块。

产品适用范围：适用于医疗单位对患者进行心电、心率、无创血压、脉搏氧饱和度、呼吸、体温、脉率和呼吸末二氧化碳的监测。

1.5 基本性能 Essential performance

1） 满足IEC 60601-2-49: 2011，（YY 0668-2008 ）对监护仪的基本性能要求。Compliant with essential performance requirements of IEC 60601-2-49。

Requirement	Specification
Defibrillator protection	Recovery Time After Defibrillation<5s
Electrosurgery interference	Electrosurgery interference recover time <10s

2） ECG、RESP：满足IEC60601-2-27:2005&2011、IEC60601-2-25：1999&2011、EC11、EC13（GB 9706.25-2005、YY 1079-2008）标准对心电的基本性能要求。ECG Compliant with essential performance requirements of IEC60601-2-27 、IEC60601-2-25 、EC11 and EC13；

除颤保护 Defibrillator protection	Recovery Time After Defibrillation<5s 除颤恢复时间<5s
Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT 网电源中断	支持内部电池和支持内部存储 suport battery and storage。
信号再现准确性 Accuracy of signal reproduction	符合 IEC 60601-2-27:2011 第 201.12.1.101.1 条款要求。 Comply with IEC 60601-2-27:2011 item 201.12.1.101.1
输入信号范围 Input signal range	±10mV PP
极化电压范围 Electrode Offset Potential Tolerance	±800mV
差分输入阻抗 Differential input impedance	>5 MΩ
系统噪声 System NOISE	<30uVp-p
多通道串扰 Multichannel crosstalk	符合 IEC 60601-2-27:2011 第 201.12.1.101.5 条款的要求 Comply with IEC 60601-2-27:2011 item 201.12.1.101.5
显示灵敏度 Display sensitivity	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), , 40 mm/mV (×4), AUTO gain
扫描速度 Sweep speed	6.25mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s
频率响应和脉冲响应 Frequency and impulse response	符合 IEC60601-2-27:2011 第 201.12.1.101.8 条款的要求 Comply with IEC 60601-2-27:2011 item 201.12.1.101.8

增益指示 GAIN INDICATOR	符合 IEC60601-2-27:2011 第 201.12.1.101.9 条款的要求 Comply with IEC 60601-2-27:2011 item 201.12.1.101.9
共模抑制比 Common mode rejection	Diagnosis 诊断模式：>95dB Monitor 监护模式：> 105dB Surgery 手术模式：> 105dB
基线复位时间 Baseline reset	< 3s
脉冲标识 Pulse Indicator	幅度 Amplitude: ±2 mV to ±700 mV 宽度 Width: 0.1 ms to 2.0 ms 上升时间 Ascending time: 10 µs to 100 µs
PACE 脉冲抑制 Rejection of pacemaker pulses	幅度 Amplitude: ±2 mV to ±700 mV 宽度 Width: 0.1 ms to2.0 ms 上升时间 Ascending time: 10 µs to 100 µs
除颤同步延时 Synchronizing pulse for cardioversion delay	< 35 ms
心率计算范围 HR Calculatio range：	ADU: 15 bpm to 300 bpm PED/NEO: 15 bpm to 350 bpm
心率计算精度 HR Calculatio Accuracy	±1% or 1 bpm, whichever is greater
QRS 检测范围	符合 IEC60601-2-27:2011 第 201.12.1.101.15 条款的要求 Comply with IEC 60601-2-27:2011 item 201.12.1.101.15
通道高度和比值 Channel height and aspect ratio	符合 IEC60601-2-27:2011 第 201.12.1.101.16 条款的要求
高大 T 波排斥能力 Tall T-wave rejection capability	符合 IEC60601-2-27:2011 第 201.12.1.101.17 条款的要求 IEC 60601-2-27:2011 item 201.12.1.101.17 minimum recommended 1.2mV T-Wave amplitude

RESP：

测量范围 RR Measuring Range	
成人 Adult	0 rpm to120rpm
小儿和新生儿 Neo/Ped	0 rpm to150rpm
分辨率 Resolution	1 rpm
精度 Accuracy	
成人 Adult	6 rpm to 120 rpm: ±2 rpm 0 to 5 rpm: not specified
小儿和新生儿 Neo/Ped	6 to 150 rpm: ±2 rpm 0 to 5 rpm: not specified
增益选择 Gain Selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
扫描 Sweep	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s
呼吸报警暂停 Apnea Alarm Time Setup	10s, 15s, 20s, 25s, 30s, 35s, 40s; default value is 20s.

3）TEMP：满足ISO 80601-2-56（YY 0785-2010）对体温的基本性能要求。TEMP Compliant with essential

performance requirements of ISO 80601-2-56；

精 度 Accuracy (without sensor)	±0.1 °C
报警 Alarm	provideT1、T2、TD alarm
	T1、T2 alarm ： 0~50℃； TD alarm limit：0.1℃~50℃；

4）SPO2：满足ISO 80601-2-61：2011、ISO9919：2005（YY 0784-2010）对血氧的基本性能要求。SPO2 Compliant with essential performance requirements of ISO 80601-2-61 and ISO9919；

EDAN Module：

数据更新周期 Data Update Period	1s
精度 Accuracy	
成人/小儿 Adult /Pediatric	±2 % (70% to 100% SpO_2)
	Undefined (0 to 69% SpO_2)
新生儿 Neonate	±3 % (70% to 100% SpO_2)
	Undefined (0 to 69% SpO_2)
报警范围 Adjustable Range of Alarm Limits	30 bpm to 300 bpm
脉率精度 Pulse Rate Accuracy	±2bpm

Nellcor Module：

数据更新周期 Data Update Period	1s
精度 Accuracy	DS-100A, OXI-A/N(Adult): ± 3% (70% to 100% SpO_2) OXI-A/N(Neonate): ± 4% (70% to 100% SpO_2)
脉率精度 Pulse Rate Accuracy	± 3bpm (20bpm to 250bpm)

5)NIBP: 满足IEC 80601-2-30：2009、IEC60601-2-30：1999（YY 0601-2009、YY 0667-2008、YY 0668-2008 、YY 0670-2008）对无创血压的基本性能要求。NIBP Compliant with essential performance requirements of IEC 80601-2-30 and IEC60601-2-30；

EDAN Module

Measuring Range	
成人模式 Adult Mode	SYS: 40 mmHg to 270 mmHg DIA: 10 mmHg to 215 mmHg MAP: 20 mmHg to 235 mmHg
小儿模式 Pediatric Mode	SYS: 40 mmHg to 230 mmHg DIA: 10 mmHg to 180 mmHg MAP: 20 mmHg to 195 mmHg
新生儿模式 Neonatal Mode	SYS: 40 mmHg to 135 mmHg DIA: 10 mmHg to 100 mmHg MAP: 20 mmHg to 110 mmHg
报警类型 Alarm Type	SYS, DIA, MAP
袖套压力测量范围 Cuff Pressure Measuring Range	0 mmHg to 300 mmHg
压力精度 Pressure Resolution	1mmHg
最大平均误差 Maximum Mean Error	±5mmHg
最大标准偏差 Maximum Standard Deviation	8mmHg

PR	
测量范围 Measuring Range	40 bpm to 240bpm
精度 Accuracy	±3bpm or 3.5%, whichever is greater

Omron Module

范围 PR Range	Adult/ Pediatric mode: 40bpm to 200bpm
	Neonatal mode: 40 bpm to 240bpm
PR 精度 Accuracy	± 2 bpm or 2% of the readings
测量范围 Measuring Range	
成人/小儿模式 Adult/ Pediatric Mode	SYS: 60 mmHg to 250 mmHg DIA: 40 mmHg to 200 mmHg MAP: 45 mmHg to 235 mmHg
新生儿模式 Neonatal Mode	SYS: 40 mmHg to 120 mmHg DIA: 20 mmHg to 90 mmHg MAP: 30 mmHg to 100 mmHg
报警类型 Alarm Type	SYS, DIA, MAP
压力分辨率 Pressure Resolution	1mmHg
测量精度 Measuring Accuracy	
最大平均误差 Maximum Mean Error	±5mmHg
最大标准偏差 Maximum Standard Deviation	8mmHg

SunTech Module

PR	
测量范围 Measuring range	30 bpm ~220bpm
精度 Accuracy	±3bpm or ±2%, whichever is greater
测量类型 Measuring Type	SYS, DIA, MAP
测量范围 Measuring Range	
成人模式 Adult Mode	SYS: 40 mmHg ~ 260 mmHg DIA: 20 mmHg ~ 200 mmHg MAP: 26 mmHg ~ 220 mmHg
小儿模式 Pediatric Mode	SYS: 40 mmHg ~ 230 mmHg DIA: 20 mmHg ~ 160 mmHg MAP: 26 mmHg ~ 183 mmHg
新生儿模式 Neonatal Mode	SYS: 40 mmHg ~ 130 mmHg DIA: 20 mmHg ~ 100 mmHg MAP: 26 mmHg ~ 110 mmHg
报警类型 Alarm Type	SYS, DIA, MAP
压力分辨率 Pressure Resolution	1mmHg
最大平均误差 Maximum Mean Error	±5mmHg
最大标准偏差 Maximum Standard Deviation	8mmHg

6）IBP: 满足IEC 60601-2-34: 2011&2001对有创血压的基本性能要求，Compliant with essential performance requirements of IEC 60601-2-34: 2011&2001；

IBP 测量 Measure	测量范围 Measuring Range	Art	0 to +300 mmHg
		PA	-6 to +120mmHg
		CVP/RAP/LAP/ICP	-10 to +40 mmHg
		P1/P2	-50 to +300 mmHg
	精度 Accuracy (not including sensor)		± 2 % or ±1 mmHg, whichever is greater ICP: 0mmHg to 40mmHg: ± 2 % or ±1 mmHg, whichever is greater; -10mmHg to 0mmHg: undefined
PR Measure	测量范围 Measuring Range		20bpm to 300bpm
	精度 Accuracy		30bpm to 300bpm: ± 2bpm or ± 2%,whichever is greater; 20bpm to 29bpm: undefined
生理报警信号延迟时间 delay time of physiological ALARM SIGNALS			报警延时符合 IEC60601-2-34：2011 T 条款 208.6.6.2.101
传感器故障报警 Detection of TRANSDUCER and TRANSDUCER cable fault			IBP 传感器或延长线发生故障 中级报警
导管脱落报警 Detection of disconnected catheter			IBP 动脉导管从患者动脉血管内脱落 高级报警

7)CO2、AG、RM: 满足IEC 80601-2-55：2011、ISO21647：2004（YY 0601-2009）对呼吸气体监护的基本性能要求。CO2、AG、RM Compliant respiratory gas monitors with essential performance requirements of ISO 80601-2-55 and ISO21647；

EDAN Module CO2

测量范围 Measuring Range	CO_2	0 mmHg to 150 mmHg (0 % to 20%)		
	AwRR	2 rpm to 150 rpm		
精度 Accuracy	$EtCO_2$	± 2mmHg, 0mmHg to 40mmHg	Respiratory rate ≤60rpm	Typical conditions: Ambient temperature: 25± 3℃ Barometric pressure: 760± 10mmHg Balance gas: N_2 Sample gas flowrate: 100ml/min
		± 5% of reading, 41mmHg to 70mmHg		
		± 8% of reading, 71mmHg to 100mmHg		
		± 10% of reading, 101mmHg to 150mmHg		
		±12% or ± 4mmHg of reading, whichever is greater	Respiratory rate >60rpm	
	AwRR	± 1 rpm		
报警 Alarm	$EtCO_2$, $FiCO_2$, AwRR			
报警延时 Apnea Alarm Delay	10s, 15s, 20s, 25s, 30s, 35s, 40s; default value is 20s.			

Respironics Module CO2

测量范围 Measuring Range	
$EtCO_2$	0 mmHg to 150 mmHg
$FiCO_2$	3 mmHg to 50 mmHg
AwRR	0 rpm to 150 rpm (Mainstream) 2 rpm to 150 rpm (Sidestream)

$EtCO_2$ Accuracy 精度	± 2 mmHg, 0 to 40 mmHg
	± 5 % of reading, 41 to 70 mmHg
	± 8 % of reading, 71 to 100 mmHg
	± 10 % of reading, 101 to 150 mmHg
	± 12% of reading, RR is over 80 rpm (sidestream)
AwRR Accuracy 精度	± 1 rpm
Alarm Type 类型	$EtCO_2$, $FiCO_2$, AwRR
Apnea Alarm Delay 报警延时	10s, 15s, 20s, 25s, 30s, 35s, 40s; default value is 20s.

ISA analyzer

标准条件的精度 Accuracy- Standard Conditions	Gas	Range	Accuracy
	CO_2	0 to 15 vol% 15 vol% to 25 vol%	±(0.2 vol% + 2% of reading) Unspecified
	N_2O	0 to 100 vol%	±(2 vol% + 2% of reading)
	HAL, ENF, ISO	0 to 8 vol % 8 vol% to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified
	SEV	0 to 10 vol % 10 vol% to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified
	DES	0 to 22 vol % 22 vol% to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified
	O_2	0 to 100 vol %	±(1 vol% + 2% of reading)
全范围精度 Accuracy- All Conditions	Gas	Accuracy	
	CO_2	±(0.3kPa + 4% of reading)	
	N_2O	±(2kPa + 5% of reading)	
	Agents	±(0.2kPa + 10% of reading)	
	O_2	±(2kPa + 2 of reading)	
AwRR Accuracy 精度	±1rpm		
Apnea Alarm Delay 报警延时	20s, 25s, 30s, 35s, 40s; default value is 20s.		
Alarm 报警	Providing alarms of $EtCO_2$, $FiCO_2$, EtO_2 , FiO_2 , EtN_2O , FiN_2O , EtAA , FiAA , AwRR		

Dräger Mini module

O_2	
范围 Range	0 to 100 Vol%
精度 Accuracy	±(2.5 Vol% + 2.5 % rel.)
CO_2	
范围 Range	0 to 13.6 Vol%
精度 Accuracy	±(0.43 Vol% + 8 % rel.)
N_2O	
范围 Range	0 to 100 Vol%
精度 Accuracy	±(2 Vol% + 8 % rel.)
Anesthetic Gases Range	
Halothane	0 to 8.5 Vol%
Isoflurane	0 to 8.5 Vol%
Enflurane	0 to 10 Vol%

Sevoflurane	0 to 10 Vol%
Desflurane	0 to 20 Vol%
精度 Accuracy	±(0.2 Vol% + 15 % rel.)
呼吸率 Respiratory Rate	
范围 Range	0 to 100/min
精度 Accuracy	0 to 60 /min: ±1 /min > 60 /min: not specified

IRMA module

标准条件下精度 Accuracy-Standard Conditions	Gas	Range	Accuracy
	CO_2	0 to 10 vol% 10 vol% to 15vol% 15 vol% to 25 vol%	±(0.2 vol% + 2% of reading) ±(0.3 vol% + 2% of reading) Unspecified
	N_2O	0 to 100 vol%	±(2 vol% + 2% of reading)
	HAL ISO ENF	0 to 8 vol% 8 vol% to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified
	SEV	0 to 10 vol% 10 vol% to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified
	DES	0 to 22 vol% 22 vol% to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified
全范围下精度 Accuracy-All Conditions	Gas	Accuracy	
	CO_2	±(0.3vol% + 4% of reading)	
	N_2O	±(2vol%+ 5% of reading)	
	Agents	±(0.2vol% + 10% of reading)	
AwRR Accuracy	±1rpm		
Apnea Alarm Delay 报警延时	20s, 25s, 30s, 35s, 40s; default value is 20s.		
Alarm 报警	Providing alarms of $EtCO_2$, $FiCO_2$, EtN_2O , FiN_2O , EtAA, FiAA, AwRR		

产品基本性能的符合性验证结果在产品标准，包括通标、并列标准、和专标的符合测试报告中给出，在产品需求跟踪文档中有汇总的结果，作为产品已经符合了基本性能要求的证据。Evidence of conformance to the requirements for essential performance captured under a general, collateral or particular standard, including the control description, is included in the verification trace for that respective standard.

1.6 软件安全等分类 Software Safety Classification

基于软件相关的风险及 IEC62304、YY/T 0664-2008 中定义的分类，病人监护仪(型号：iM50、M50、iM60、iM70、iM80、M80)的软件安全分类为 Class C Bassed on the risk related to software and the category defined in IEC62304 、 YY/T 0664-2008, the overall software safety classification of Patient Monitor (Models:iM50,M50,iM60,iM70,iM80,M80) is Class C,refer to IEC62304、YY/T 0664-2008compliance report for details.

1.7 预期使用寿命（使用期限）Expected Service Life

在规定的定期维护和保养条件都满足的条件下，病人监护仪(型号：iM50、M50、iM60、iM70、iM80、M80)由制造日期起计算的预期的使用寿命（使用期限）为< 10>年。预期使用寿命（使用期限）的估计值包含可能需要更换的元器件和附件，包括：电池，显示屏， 无创血压袖带，前置面板 e，依照维护/维修手册中规定的定期维护和安全检查可以确保设备在预期寿命（使用期限）周期内安全使用，一般情况下，预期的配附件使用寿命（使用期限）为一年。Patient Monitor (Models:iM50,M50,iM60,iM70,iM80,M80) have a Expected Service Life (ESL) of < 10> years from the date of manufacturer when regular maintenance and service requirements are fulfilled. The ESL includes the replacement of various components for EQUIPMENT as applicable, including：internal batteries, display backlights, non-invasive blood pressure pneumatics, front panel bezels, and accessories which are subject to degradation of performance over intervals less then the ESL. Therefore adherence to routine maintenance and safety checks as described in the Service Manuals insures the product will fulfill all essential performance and remain safe use throughout the ESL. Generally, Expected Service Life(ESL) of accessories is one year.

1.8 风险可接受性判定标准 Criteria for Risk Acceptability

所有识别到的风险均通过估计损害的严重程度和损害的概率两个因素来进行风险评价，具体的风险可接受性评价标准见 iM 系列风险管理计划第 5 章。
All identified risk have been evaluated by estimated two factors: the severity and probability of harm to persons, Refer to iM Series Risk management Plan chapter 5 for detailed criteria for risk acceptability

1.9 风险控制方法 Method for risk control

风险控制措施包括通过设计和制造尽可能消除或降低风险，在产品本身采取适当的保护措施，关于无法消除的风险，必要是报警，或提供必要的安全信息等均按照 iM 系列风险管理计划第 5 章所列的优先级顺序执行。详细的风险控制方法说明见 iM 系列风险管理计划第 5 章。Risk control measures including Eliminate or reduce risks as far as possible through safe design and manufacture, where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated，information for safety have been used in the priority order listed in iM Series Risk management Plan chapter 5.Refer to iM Series Risk management Plan chapter 5 for detailed information about risk control method.

2 风险管理团队 Risk management team

风险管理团队包括风险管理代表、执行具体风险管理任务的人和批准风险管理文件的人，详见 iM 系列风险管理计划第 4 章。Risk management team is consist of representative of the risk management team、personals responsible for performing specific risk management task and personals approve the risk managemet files.Refer to iM Series risk management plan chapter 4 for details.

3 风险管理结果 Results of Risk management

3.1 危害识别 Hazard Identification

参照ISO 14971:2007、EN ISO 14971:2012 、YY/T0316-2008附录C所列问题，对病人监护仪(型号：iM50、M50、iM60、iM70、iM80、M80)可能会影响安全性能的特征要素识别如下。The characteristics of Patient Monitor (Models:iM50,M50,iM60,iM70,iM80,M80) that could have an impact on safety are identified as follows, based on the questions in Annex C of ISO 14971:2007、EN ISO 14971：2012 、YY/T0316-2008.

ISO14971:2007/YY/T 0316-2008 附录 C 的问题 **Questions in Annex C of ISO14971:2007/YY/T 0316-2008**	**是否适用** **Applicable or Not**	**原因说明** **Explanation**	**相关危害** **Corresponding Hazards**
C.2.1医疗器械的预期用途是什么和怎样使用医疗器械？What is the intended use and how is the medical device to be used? 应当考虑的因素包括： Factors that should be considered include:	是 yes	预期用途见 1.4。 Refer to 1.4 for intended use	3 操作危害 Operating Hazards
-医疗器械的作用是与下列哪一项有关： - what is the medical device's role relative to	是 yes	医疗器械的作用是对疾病监护 The medical devices's role is relative to monitoring of disease	
- 对疾病的诊断、预防、监护、治疗或缓解diagnosis, prevention, monitoring, treatment or alleviation of disease,			
- 对损伤或残疾的补偿，或者 compensation for injury or handicap or	否 No	/	
- 解剖的替代或改进，或妊娠控制？ replacement or modification of anatomy, or control of conception?	否 No	/	
-使用的适应症是什么（如患者群体）？what are the indications for use (e.g. patient population)?	是 yes	使用的适应症是患者群体 The indications for use are the patient population	
-医疗器械是否用于生命维持或生命支持？ does the medical device sustain or support life?	否 No	不作为生命维持或生命支持 he medical device doesn't sustain or support life	
-在医疗器械失效的情况下是否需要特殊的干预？is special intervention necessary in the case of failure of the medical device?	否 No	在病人监护仪失效的情况下不用特殊的干预。 No special intervention needed in the case of failure of the medical device	

ISO14971:2007/YY/T 0316-2008 附录 C 的问题 Questions in Annex C of ISO14971:2007/YY/T 0316-2008	是否适用 Applicable or Not	原因说明 Explanation	相关危害 Corresponding Hazards
C.2.2医疗器械是否预期植入？**Is the medical device intended to be implanted?** 应当考虑的因素包括植入的位置、患者群体特征、年龄、体重、身体活动情况、植入物性能老化的影响、植入物预期的寿命和植入的可逆性。Factors that should be considered include the location of implantation, the characteristics of the patient population, age, weight, physical activity, the effect of ageing on implant performance, the expected lifetime of the implant, the reversibility of the implantation.	否 No	/	/
C.2.3医疗器械是否预期和患者或其他人员接触？**Is the medical device intended to be in contact with the patient or other persons?** 应当考虑的因素包括预期接触的性质，即表面接触、侵入式接触或植入以及每种接触的时间长短和频次。Factors that should be considered include the nature of the intended contact, i.e. surface contact, invasive contact, or implantation and, for each, the period and frequency of contact.	是 Yes	与患者表面接触（大于 24h，小于 30 天）：ECG 电极、SPO2 探头、NIBP 袖套、体表体温探头、快速体温探头、CO2 的采样管、AG 模块的采样管； Surface contact（more than 24h，less than 30days）：ECG electrodes 、 SpO_2 sensor、NIBP cuff、TEMP probe、Qiuck TEMP probe、CO_2 sampling cannula、AG sampling cannula； 侵入式接触（小于 24h）：IBP 传感器、体腔体温探头、CO 注射传感器导管； Invasive contact（less than 24h）：IBP trancducer、intracavitary TEMP probe、C.O. injection probe catheter；	2 生物学和化学危害 Biology and Chemistry Hazard 3 操作危害 Operating Hazards

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ISO14971:2007/YY/T 0316-2008 附录 C 的问题 Questions in Annex C of ISO14971:2007/YY/T 0316-2008	是否适用 Applicable or Not	原因说明 Explanation	相关危害 Corresponding Hazards
C.2.4在医疗器械中利用何种材料或组分，或与医疗器械共同使用或与其接触？**What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?** 应当考虑的因素包括Factors that should be considered include: - 和有关物质的相容性compatibility with relevant substances; - 与组织或体液的相容性compatibility with tissues or body fluids; - 与安全性有关的特征是否已知whether characteristics relevant to safety are known; - 医疗器械的制造是否利用了动物原材料is the device manufactured utilizing materials of animal origin?	是 Yes 是 Yes 是 Yes 是 Yes 否 No	外壳塑胶：PC+ABS（C2950）； 外壳五金：铝板+SPCC（冷扎钢板）； 血氧探头衬里：硅胶; 血压袖套：纺织品; 心电电极：Ag 或 Agcl; 心电、血氧、体温导联、血压导管：TPU 应用部分材料使用通过生物兼容测试的源材料。 Enclosure plastic: PC+ABS（C2950）； Enclosure metals: Aluminum board+ SPCC（ Cold-rolled steel board）； SpO2 sensor lining: Silicone; NIBP cuff: Textile; ECG electrodes: Ag or Agcl; ECG cable、SPO2 cable、TEMP Probe Cable、NIBP Extension Tube:TPU; Materials of the applied parts conform to the raw materials based on the biocompatibility test. 医疗器械的制造没有利用了动物原材料 No materials of animial origin utilized.	2 生物学和化学危害 Biology and Chemistry Hazard
C.2.5是否有能量给予患者或从患者身上获取**Is energy delivered to or extracted from the patient?** 应当考虑的因素包括Factors that should be considered include:	是 Yes	心电、呼吸测量有电能量传递； ECG measurse has electric energy transmission 漏电流要求满足	3 操作危害 Operating Hazards

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ISO14971:2007/YY/T 0316-2008 附录 C 的问题 Questions in Annex C of ISO14971:2007/YY/T 0316-2008	是否适用 Applicable or Not	原因说明 Explanation	相关危害 Corresponding Hazards
- 传递的能量类型the type of energy transferred; - 对其的控制、质量、数量、强度和持续时间its control, quality, quantity, intensity and duration; - 能量水平是否高于类似器械当前应用的能量水平whether energy levels are higher than those currently used for similar devices.	否 No	IEC60601-1-27，IEC60601-1； Leakage current conforms to EC13 and IEC60601-1 血氧测量有光能量传递；温升要求满足 ISO 80601-2-61； SpO2 measuring has light energy transmission; Temperature rise conforms to ISO80601-2-61; 能量水平满足安全标准。血压的机械能传输。 Energy level conforms to safety standard.	
C.2.6是否有物质提供给患者或从患者身上提取**Are substances delivered to or extracted from the patient?** 应当考虑的因素包括Factors that should be considered include - 物质是供给还是提取whether the substance is delivered or extracted; - 是单一物质还是几种物质whether it is a single substance or range of substances; - 最大和最小传递速率及其控制the maximum and minimum transfer rates and control thereof.	是 Yes	进行 CO 测量时需要对患者注射冷生理盐水 When measuring C.O., iced injecta needs to be injected to the patient.	3 操作危害 Operating Hazards

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ISO14971:2007/YY/T 0316-2008 附录 C 的问题 Questions in Annex C of ISO14971:2007/YY/T 0316-2008	是否适用 Applicable or Not	原因说明 Explanation	相关危害 Corresponding Hazards
C.2.7医疗器械是否处理生物材料用于随后的再次使用、输液/血或移植**Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?** 应当考虑的因素包括处理的方式和处理（一种或多种）物质的类型（如自动输液/血、透析、血液成分或细胞疗法处理Factors that should be considered include the type of process and substance(s) processed (e.g. autotransfusion, dialysis, blood component or cell therapy processing).	否 NO		
C.2.8医疗器械是否以无菌形式提供或预期由使用者灭菌，或用其它微生物学控制方法灭菌**Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?** 应当考虑的因素包括Factors that should be considered include - 医疗器械是预期一次性使用包装，还是重复使用包装whether the medical device is intended for single use or re-use packaging; - 储存寿命的标示shelf-life issues; - 重复使用周期次数的限制limitation on the number of re-use cycles; - 产品灭菌方法method of product sterilization; - 非制造商预期的其它灭菌方法的影响the impact of other sterilization methods not intended by the manufacturer.	是 Yes	CO2 附件为一次性附件，但不需要进行灭菌；IBP 传感器属于无菌附件。AG 采样管是一次性附件，不需要进行灭菌；血压和血氧部分附件是一次性附件，不需要进行灭菌； CO2 accessories are disposable, and need no sterilization; IBP transducer is sterile accessory; AG sampling cannula is disposable accessory; Part of the NIBP and SpO2 accessories are disposable.	2 生物学和化学危害 Biology and Chemistry Hazards

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ISO14971:2007/YY/T 0316-2008 附录 C 的问题 Questions in Annex C of ISO14971:2007/YY/T 0316-2008	是否适用 Applicable or Not	原因说明 Explanation	相关危害 Corresponding Hazards
C.2.9医疗器械是否预期由用户进行常规清洁和消毒**Is the medical device intended to be routinely cleaned and disinfected by the user?** 应当考虑的因素包括使用的清洁剂或消毒剂的类型和清洁周期次数的限制。医疗器械的设计可影响日常清洁和消毒的有效性。另外，应当考虑清洁剂或消毒剂对器械安全性和性能的影响Factors that should be considered include the types of cleaning or disinfecting agents to be used and any limitations on the number of cleaning cycles. The design of the medical device can influence the effectiveness of routine cleaning and disinfection. In addition, consideration should be given to the effect of cleaning and disinfecting agents on the safety or performance of the device.	是 Yes	按照说明书中说明的方式对清洁消毒工作进行控制。 Control the cleaning and disinfection work according to the methods described in the user manual. 能够耐受如下清洁剂The monitor has been tested to withstand the following recommended cleaning agents： 1. 温和的中性清洁剂 Mild near neutral detergent 2. 乙醇 75% Ethanol (75%)； 3. 异丙醇 70%；Isopropanol (70%) 消毒剂 Disinfection： 1. 乙醇 75% Ethanol (75%)； 2. 异丙醇 70%；Isopropanol (70%) 3. Cidex OPA（只针对腔内体温探头 Only intracavitary TEMP probe）。 每次使用后都需对设备和附件进行清洁及消毒。如设备和附件没有和病人接触的部分，设备和附件上没有明显的污垢，则应当每天对设备和附件进行清洁及消毒。 If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.	2 生物学和化学危害 Biology and Chemistry Hazards

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ISO14971:2007/YY/T 0316-2008 附录 C 的问题 Questions in Annex C of ISO14971:2007/YY/T 0316-2008	是否适用 Applicable or Not	原因说明 Explanation	相关危害 Corresponding Hazards
C.2.10医疗器械是否预期改善患者的环境**Is the medical device intended to modify the patient environment?** 应当考虑的因素包括Factors that should be considered include: - 温度temperature; - 湿度humidity; - 大气成分atmospheric gas composition; - 压力pressure; - 光线light.	否 NO		
C.2.11是否进行测量**Are measurements taken?** 应当考虑的因素包括测量变量和测量结果的准确度和精密度Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results.	是 Yes	测量变量和测量结果包括：心电波形、血氧波形、呼吸波形、温度数值、IBP 波形、CO2 波形等。 这些参数的准确度和精密度，具体指标参考用户手册中规格。Measured variables and measurement results include: ECG waveform, SpO_2 waveform, RESP waveform, TEMP value, IBP waveform, CO2 waveform, etc. Regarding the accuracy and precision of the parameter, you can refer to the specifications in the user manual for details.	3 操作危害 Operating Hazards 7 软件应用风险 Software Risk

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ISO14971:2007/YY/T 0316-2008 附录 C 的问题 Questions in Annex C of ISO14971:2007/YY/T 0316-2008	是否适用 Applicable or Not	原因说明 Explanation	相关危害 Corresponding Hazards
C.2.12医疗器械是否进行分析处理**Is the medical device interpretative?** 应当考虑的因素包括医疗器械是否由输入或获得的数据显示结论、所采用的计算方法和置信限。应当特别注意数据和计算方法的非预期应用Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data, the algorithms used, and confidence limits. Special attention should be given to unintended applications of the data or algorithm.	是 Yes	心电参数进行心率计算、计算心律失常， C.O.计算 The calculation of ARR The calculation of ST segment analysis The calculation of C.O.,	4 信息危害 Information Hazards
C.2.13医疗器械是否预期和其它医疗器械、医药或其它医疗技术联合使用**Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?** 应当考虑的因素包括识别可能涉及的任何其它医疗器械、医药或其它医疗技术和与其相互作用有关的潜在问题，以及患者是否遵从治疗 Factors that should be considered include identifying any other medical devices, medicines or other medical technologies that can be involved and the potential problems associated with such interactions, as well as patient compliance with the therapy.	是 Yes	存在护士呼叫系统、中央站系统、除颤仪、电刀配合使用，和护士呼叫系统和中央站系统连接，对监护仪没有影响，和除颤仪与电刀配合使用时，监护仪满足相关标准要求。It is intended to be used with nurse call , MFM-CMSsystem , defibrillator and electric scalpel. nurse call and MFM-CMS are not impacting to monitor, and comply with safe standard to connect with defibrillator and electric scalpel.	4 信息危害 Information Hazards
C.2.14是否有不希望的能量或物质输出**Are there unwanted outputs of energy or substances?**	是 Yes	包括电磁辐射、整机发热、漏电流等等； 这些都按照法规要求处	1 能量危害 Energy Hazards

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应当考虑的与能量相关的因素包括噪声与振动、热量、辐射（包括电离、非电离辐射和紫外/可见光/红外辐射）、接触温度、漏电流和电场或磁场Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing, and ultraviolet/visible/infrared radiation), contact temperatures, leakage currents, and electric or magnetic fields. 应当考虑的与物质相关的因素包括制造、清洁或试验中使用的物质，如果该物质残留在产品中具有不希望的生理效应Substance-related factors that should be considered include substances used in manufacturing, cleaning or testing having unwanted physiological effects if they remain in the product. 应当考虑的与物质相关的其它因素包括化学物质、废物和体液的排放Other substance-related factors that should be considered include discharge of chemicals, waste products, and body fluids.		理。 It includes electromagnetic radiation, heat, and leakage current. All above shall be handled according to the laws and regulations.	

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C.2.15医疗器械是否对环境影响敏感**Is the medical device susceptible to environmental influences?** 应当考虑的因素包括操作、运输和储存环境。它们包括光线、温度、湿度、振动、泄漏、对能源和致冷供应变化的敏感性和电磁干扰 Factors that should be considered include the operational, transport and storage environments. These include light, temperature, humidity, vibrations, spillage, susceptibility to variations in power and cooling supplies, and electromagnetic interference.	是 Yes	对异常情况，如高低温、电源干扰、无地线时，敏感，敏感的情况包括： 高温运行时主板稳定性降低，寿命降低； 低温运行时显示部件性能会降低； 振动可能导致结构上的损坏； 电源的干扰多大会导致心电干扰、呼吸干扰、血氧干扰、CO2 干扰； 无地线的情况可能会导致心电干扰过大； It is susceptible to the abnormal conditions, such as high/low temperature, power-supply interference, no ground wires: When it operates in high temperature, the stability and the shelf-life of the main board decrease; When it operates in low temperature, the performace of the display parts gets decreased; Vibrations might result in the damage to the structure; The power-supply interference may cause interference to ECG, RESP, SpO_2, and CO_2; Lack of ground might cause ECG measuring signal being greatly interrupted.	1 能量危害 Energy Hazards 5 初始事件和环境 Initial Event and Environment Hazards

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C.2.16医疗器械是否影响环境**Does the medical device influence the environment?** 应当考虑的因素包括Factors that should be considered include: - 对能源和致冷供应的影响the effects on power and cooling supplies; - 毒性物质的散发emission of toxic materials; - 电磁干扰的产生the generation of electromagnetic disturbance.	是 Yes	产生满足 EMC 标准的电磁干扰； 电池污染物，废弃物影响环境； It generates the electromagnetic interference that conforms to the EMC standard; The battery pollutants and wastes influence the environment; The consumed electric energy influences the environment.	2 生物学和化学危害 Biology and Chemistry Hazards 5 初始事件和环境 Initial Event and Environment Hazards
C.2.17医疗器械是否有基本的消耗品或附件 **Are there essential consumables or accessories associated with the medical device?** 应当考虑的因素包括消耗品或附件的规范以及对使用者选择它们的任何限制Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon users in their selection of these.	是 Yes	心电导联、血压袖套、血氧探头,CO2 采用管等，都是短期消耗品，CO2 的采样管、面罩，C.O.的注射器 ECG 电极片等部分是单次使用的。The ECG lead, NIBP cuff, and SpO_2 sensor are short-term consumables. CO2 Narial Sample line, C.O. Injection Probe Cannula, ECG Electrodes and so on are for single use.	2 生物学和化学危害 Biology and Chemistry Hazards
C.2.18是否需要维护和校准**Is maintenance or calibration necessary?** 应当考虑的因素包括Factors that should be considered include: - 维护或校准是否由操作者或使用者或专门人员来进行whether maintenance or calibration are to be carried out by the operator or user or by a specialist;	是 Yes 是 Yes	部分校准需要专门人员来完成，部分直接由使用者完成如 IBP 中的校零以及伟康 CO2 的大气压设定。按照说明书进行校准和维护操作。 触摸屏校准可以由用户校准；	3 操作危害 Operating Hazards 7 软件风险 Software Application Risk

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- 是否需要专门的物质或设备来进行适当的维护或校准are special substances or equipment necessary for proper maintenance or calibration?	是 Yes	Part of the calibration shall be performed by the specialist and others by the operator. Perform the calibration and maintenance according to the user manual. Screen calibration can be performed by the user.	
C.2.19医疗器械是否有软件**Does the medical device contain software?** 应当考虑的因素包括软件是否预期要由使用者或操作者或专家进行安装、验证、修改或更换Factors that should be considered include whether software is intended to be installed, verified, modified or exchanged by the operator or user or by a specialist.	是 Yes	软件的升级和更换需要由厂家专门人员在严格监控下执行。The software shall be updated or modified under strict supervision by authorized specialist.	3 操作危害 Operating Hazards 4 信息危害 Information Hazards
C.2.20医疗器械是否有储存寿命限制**Does the medical device have a restricted shelf-life?** 应当考虑的因素包括标记或指示和到期时对医疗器械的处置Factors that should be considered include labelling or indicators and the disposal of such medical devices when the expiration date is reached.	是 Yes	无菌附件的寿命需要在包装上注明 附件的储存寿命按照附件说明书要求。 按照说明书规定执行。The shelf-life of the sterile accessories shall be labeled on the packaging. The storage shelf-life of the accessories should conform to the requirements in the user manual. Carry it out according to the user manual.	6 失效模式和单一故障 Failure Mode and Single Fault Malfunction Hazards

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C.2.21是否有延时或长期使用效应**Are there any delayed or long-term use effects?** 应当考虑的因素包括人机工程学和累积的效应。其示例可包括含盐流体泵有随着时间推移的腐蚀、机械疲劳、皮带和附件松动、振动效应、标签磨损或脱落、长期材料降解Factors that should be considered include ergonomic and cumulative effects. Examples could include pumps for saline that corrode over time, mechanical fatigue, loosening of straps and attachments, vibration effects, labels that wear or fall off, long term material degradation.	是 Yes	包括附件、结构老化、电子器件老化、硅胶管腐蚀、丝印磨损、插座松动、螺丝松动、金属生锈、标签脱落等 It includes structure degradation, electron device, silicone tube corrosion, silk printing that wears off, loosening of plug and screw, metal rust, labels that wear or fall off, etc.	6 失效模式和单一故障 Failure Mode and Single Fault Malfunction Hazards
C.2.22医疗器械承受何种机械力**To what mechanical forces will the medical device be subjected?** 应当考虑的因素包括医疗器械承受的力是否在使用者的控制之下，或者由和其他人员的相互作用来控制Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user or controlled by interaction with other persons.	是 Yes	触摸屏承受用户触摸压力、模块插拔对插槽的拉力、插拔附件、拉扯或抓握时产生的拉力、手提机器时产生的拉力。 The touch screen will be subjected to the pressure from touch.	3 操作危害 Operating Hazards
C.2.23什么决定医疗器械的寿命**What determines the lifetime of the medical device?** 应当考虑的因素包括老化和电池耗尽Factors that should be considered include ageing and battery depletion.	是 Yes	器件、电池等外来物料的寿命限制。 The lifetime limitations of the foreign materials, such as components'.	5 初始事件和环境 Initial Event and Environment Hazards

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C.2.24医疗器械是否预期一次性使用**Is the medical device intended for single use?** 应当考虑的因素包括：器械使用后是否自毁？器械已使用过是否显而易见Factors that should be considered include: does the medical device self-destruct after use? Is it obvious that the device has been used?	是 Yes	监护仪的附件中存在一次性使用附件。例如 CO2 的采样管，IBP 的侵入式附件，C.O.的注射器，ECG 电极片使用后是很明显区分。 Some accessories are for single use, such as CO_2 sampling cannula, IBP invasive accessories，C.O. Injection Probe Cannula, ECG Electrodes and so on.	2 生物学和化学危害 Biology and Chemistry Hazards
C.2.25医疗器械是否需要安全地退出运行或处置**Is safe decommissioning or disposal of the medical device necessary?** 应当考虑的因素包括医疗器械自身处置时产生的废物。例如医疗器械是否含有毒性或有害材料， 或材料可再循环使用Factors that should be considered include the waste products that are generated during the disposal of the medical device itself. For example, does it contain toxic or hazardous material, or is the material recyclable?	是 Yes	医疗器械需要安全的退出运行和处置，内部五金部件，外壳塑胶件可以重复使用，PCB 板卡需要报废处理。 按照当地法规处理。 Safe decommission or disposal of the medical device is necessary. The internal metals and housing plastic are reusable. PCB board needs to be discarded. Dispose according to the local laws and regulations.	5 初始事件和环境 Initial Event and Environment Hazards
C.2.26医疗器械的安装或使用是否要求专门的培训或专门的技能**Does installation or use of the medical device require special training or special skills?** 应当考虑的因素包括医疗器械的新颖性，以及医疗器械安装人员的合适的技能和培训Factors that should be considered include the novelty of the medical device and the likely skill and training of the person installing the device.	是 Yes	操作人员需要拥有专业知识才可操作，和具体的检测参数相关。安装人员也需要有合适的技能和培训。The monitor shall be operated by professional personnel who have corresponding knowledge of the monitoring parameters. The installation personnel need appropriate skills anf training.	3 操作危害 Operating Hazards 7 软件应用风险 Software Application Risk

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C.2.27如何提供安全使用信息**How will information for safe use be provided?** 应当考虑的因素包括Factors that should be considered include: - 信息是否由制造商直接提供给最终使用者或涉及的第三方参加者，如安装者、护理者、卫生保健专家或药剂师，他们是否需要进行培训whether information will be provided directly to the end user by the manufacturer or will it involve the participation of third parties such as installers, care providers, health care professionals or pharmacists and whether this will have implications for training; - 试运行和向最终使用者的交付，以及是否很可能/可能由不具备必要技能的人员来安装commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills; - 基于医疗器械的预期寿命，是要求对操作者或服务人员进行再培训还是再鉴定based on the expected life of the device, whether re-training or re-certification of operators or service personnel would be required.	是 Yes	在使用说明书、维修手册、速查卡、标贴、丝印等中提供了安全信息。使用者需要按照要求操作。 It provides safety information in user manual, service manual, reference card, label, and silk pringting. The operator shall operate the monitor according to the requirements.	3 操作危害 Operating Hazards 4 信息危害 Information Hazards
C.2.28是否需要建立或引入新的制造过程**Will new manufacturing processes need to be established or introduced?** 应当考虑的因素包括新技术或新的生产规模 Factors that should be considered include new technology or a new scale of production.	否 NO		

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C.2.29医疗器械的成功使用，是否关键取决于人为因素，例如用户界面**Is successful application of the medical device critically dependent on human factors such as the user interface?**	是 Yes	本设备的使用受到人为因素影响。 用户界面可增强易用性，提高操作效率减少失误概率。 The medical device can be affected by human factors. The user interface is easier to use, which can improve the operating efficiency, and reduce the error probability.	3 操作危害 Operating Hazards 4 信息危害 Information Hazards 7 软件应用风险 Software Application Risk
C.2.29.1用户界面设计特性是否可能促成使用错误**Can the user interface design features contribute to use error?** 应当考虑的因素是可能促成使用错误的用户界面设计特性。界面设计特性的示例包括：控制和显示器、使用的符号、人机工程学特性、物理设计和布局、操作层次、驱动装置的软件菜单、警示的可视性、报警的可听性、彩色编码的标准化。适用性的附加指南见IEC 60601-1-6，报警的附加指南见IEC 60601-1-8 Factors that should be considered are user interface design features that can contribute to use error. Examples of interface design features include: control and indicators, symbols used, ergonomic features, physical design and layout, hierarchy of operation, menus for software driven devices, visibility of warnings, audibility of alarms, standardization of colour coding. See IEC 60601-1-6 for additional guidance on usability and IEC 60601-1-8 for guidance on alarms.	是 Yes	报警不明显可能使得使用者忽视了病人危险状态； 相邻的按键和菜单可能被混用； 病人类型设置可能被忽略而引起血压测量危险； 体温模块类型设置错误会引起测量值错误； Unobvious alarm could make the operator neglect the patient's dangerous situation. The neighbouring keys and menus can be confused. Patient type setting might be neglected, which can result in danger of NIBP measuring. Incorrect TEMP module type setting can result in measuring value error.	3 操作危害 Operating Hazards 4 信息危害 Information Hazards 7 软件应用风险 Software Application Risk

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C.2.29.2医疗器械是否在因分散注意力而导致使用错误的环境中使用**Is the medical device used in an environment where distractions can cause use error?** 应当考虑的因素包括Factors that should be considered include: - 使用错误的后果the consequence of use error; - 分散注意力的情况是否常见whether the distractions are commonplace; - 使用者是否可能受到不常见的分散注意力情况的干扰whether the user can be disturbed by an infrequent distraction.	是 Yes	出现概率较小。比如参数太多，单个参数异常变化可能被忽略。通过报警系统识别危险情况，降低风险。 It's less likely to happen. For instance, there are too many parameters, thus the change of individual parameter could be neglected. Recognize the dangerous situation by alarm system, so as to reduce the risk.	3 操作危害 Operating Hazards 4 信息危害 Information Hazards 5 初始事件和环境 Initial Event and Environment Hazards
C.2.29.3医疗器械是否有连接部分或附件**Does the medical device have connecting parts or accessories?** 应当考虑的因素包括错误连接的可能性、与其它的产品连接方式的相似性、连接力、对连接完整性的反馈以及过紧和过松的连接Factors that should be considered include the possibility of wrong connections, similarity to other products' connections, connection force, feedback on connection integrity, and over- and under-tightening.	是 Yes	监护仪的附件都是通过连接器同主机连接，存在过松、过紧的连接风险 The accessories are all connected to the monitor by connector, which exists connection risks of over- and under-tightening.	3 操作危害 Operating Hazards 5 初始事件和环境 Initial Event and Environment Hazards 4 信息危害 Information Hazards

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C.2.29.4医疗器械是否有控制接口**Does the medical device have a control interface?** 应当考虑的因素包括间隔、编码、分组、图形显示、反馈模式、出错、疏忽、控制差别、可视性、启动或变换的方向、以及控制是连续的还是断续的、和设置或动作的可逆性Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders,slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions.	是 Yes	用户软件界面上可以对仪器的使用方式进行配置，中央站也可以通过双向控制控制仪器。 控制是连续的可逆的。 The application method can be configured on the user's software interface. MFM-CMS can bilaterally control the device. The control is continuous and reversible.	6 失效模式和单一故障 Failure Mode and Single Fault Malfunction Hazards
C.2.29.5医疗器械是否显示信息**Does the medical device display information?** 应当考虑的因素包括在不同环境下的可视性、方向性、使用者的视力、视野和透视、和显示信息的清晰度、单位、彩色编码、以及关键信息的可达性Factors that should be considered include visibility in various environments, orientation, the visual capabilities of the user, populations and perspectives, clarity of the presented information, units, colour coding, and the accessibility of critical information.	是 Yes	本设备显示病人生理信号，包括波形，参数，技术提示信息，报警信息，需要充分考虑信息的可达性。 The medical device can display paitient's physiological signal, including waveform, parameter, technology prompts, and alarm information. The accessibility of critical information shall be fully taken into account.	4 信息危害 Information Hazards

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C.2.29.6医疗器械是否由菜单控制**Is the medical device controlled by a menu?** 应当考虑的因素包括层次的复杂性和数量、状态感知、路径设置、导向方法、每一动作的步骤数量、顺序的明确性和存储问题，以及有关其可达性的控制功能的重要性和偏离规定的操作程序的影响Factors that should be considered include complexity and number of layers, awareness of state, location of settings, navigation method, number of steps per action, sequence clarity and memorization problems, and importance of control function relative to its accessibility and the impact of deviating from specified operating procedures.	是 Yes	易用性的问题主要有：菜单层次多，操作复杂性高；菜单功能分类乱，使用者对常用功能的熟悉程度低。 The factors that affect the ease of use include: excessive menu layers, high operating complexity, disordered classification of function, less familiar of the common function for the operator.	7 软件风险分析 Software Application Risk
C.2.29.7医疗器械是否由具有特殊需要的人使用**Will the medical device be used by persons with special needs?** 应当考虑的因素包括用户、他们的精神和体能、技能和培训、人机工程学方面、使用环境、安装要求和患者控制或影响医疗器械使用的能力。对于有特殊需求的使用者，如残疾人、老人和儿童应当给予特别的关注。为能使用医疗器械，他们的特殊需要可能包括另一个人的帮助。医疗器械是否预期由具有各种技能和文化背景的人员使用Factors that should be considered include the user, their mental and physical abilities, skill and training, ergonomic aspects, the use environment, installation requirements, and the patient's capability to control or influence the use of the medical device. Special attention should be paid to users with special needs, such as handicapped persons, the elderly and children. Their special needs might include assistance by another person to enable the use of a medical device. Is the medical device intended to be used by individuals with various skill levels and cultural backgrounds?	是 Yes	对操作者需要专门培训和专业知识，不对残疾人等做特殊设计。 对患者有特殊设计，区分成人、儿童、新生儿等。 The operator shall have special training and specialized knowledge. There’s no special design for the disabled. There’re special designs for paitents, such as the design to differentiate the adult, children, and neonate.	3 操作危害 Operating Hazards 4 信息危害 Information Hazards

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C.2.29.8用户界面能否用于启动使用者动作 **Can the user interface be used to initiate user actions?** 应当考虑的因素包括：使用者启动了一个已准备的动作进入一个受控的运行模式的可能性，这种可能性增大了患者的风险，是否会引起使用者的注意Factors that should be considered include the possibility of initiating a deliberate action for the user to enter a controlled operation mode, which enlarges the risks for the patient and which creates awareness for the user for this condition.	是 Yes	病人类型、报警范围、C.O.，血压启动对患者的风险. Patient type, alarm range, C.O., and the start of NIBP measure risk to patient.	3 操作危害 Operating Hazards 7 软件风险分析 Software Application Risk
C.2.30医疗器械是否使用报警系统医疗器械是否使用报警系统？**Does the medical device use an alarm system?** 应当考虑的因素是错误报警、不报警、报警系统断开、不可靠的远程报警系统的风险和医务人员理解报警系统如何工作的可能性。IEC 60601-1-8[26]给出了报警系统的指南。Factors that should be considered are the risk of false alarms, missing alarms, disconnected alarm systems, unreliable remote alarm systems, and the medical staff's possibility of understanding how the alarm system works. Guidance for alarm systems is given in IEC 60601-1-8.	是 Yes	该设备使用了报警系统，存在错误报警，不报警或不可靠报警的风险。 The medical device uses an alarm system, which exist risks of false alarms, missing alarms, and unreliable alarms.	3 操作危害 Operating Hazards 4 信息危害 Information Hazards 7 软件风险分析 Software Application Risk

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ISO14971:2007/YY/T 0316-2008 附录 C 的问题 Questions in Annex C of ISO14971:2007/YY/T 0316-2008	是否适用 Applicable or Not	原因说明 Explanation	相关危害 Corresponding Hazards
C.2.31医疗器械可能以什么方式被故意地误用？**In what way(s) might the medical device be deliberately misused?** 应当考虑的因素是连接器的不正确使用、丧失安全特性或报警不能工作、忽视制造商推荐的维护。Factors that should be considered are incorrect use of connectors, disabling safety features or alarms, neglect of manufacturer's recommended maintenance.	是 Yes	不按照厂家要求使用导致误用。 误用可能有：病人类型错误、附件不配套、用到动物身上、附件超限使用。 Misuse the device because it is not used according to the manufacturer's requirements. The misuse includes: patient type error, accessory mismatch, applying on the animal, and using accessories beyond the limits.	3 操作危害 Operating Hazards 5 初始事件和环境 Initial Event and Environment Hazards
C.2.32医疗器械是否持有患者护理的关键数据？**Does the medical device hold data critical to patient care?** 应当考虑的因素包括数据被修改或被破坏的后果。Factors that should be considered include the consequence of the data being modified or corrupted.	是 Yes	这些数据包括生命体征的波形、数值、报警等。 按照厂家要求进行数据管理将降低风险，可通过CMS、外部存储设备、内部存储来备份存储数据。 无线方式传输数据时需要考虑数据完整性问题。 The data include waveforms, values, and alarms of the physiological parameters. Manage the data as the manufacturer specified, and it can reduce the risk. The user can back up the storage data by CMS, exterior and inner storage. Integrity of the data shall be taken into account when transferring data by Wi-Fi.	5 初始事件和环境 Initial Event and Environment Hazards 7 软件风险分析 Software Application Risk

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ISO14971:2007/YY/T 0316-2008 附录 C 的问题 Questions in Annex C of ISO14971:2007/YY/T 0316-2008	是否适用 Applicable or Not	原因说明 Explanation	相关危害 Corresponding Hazards
C.2.33 医疗器械是否预期为移动式或者便携式？Is the medical device intended to be mobile or portable? 应当考虑的因素是必要的把手、手柄、轮子、制动、机械稳定性和耐久性。Factors that should be considered are the necessary grips, handles, wheels, brakes, mechanical stability and durability.	是 Yes	便携式。需要考虑外壳破损带来的风险，把手承重的风险、插件模块的卡位牢固的风险。 Portable. The risks of housing wearout shall be taken into account.	1 能量危害 Energy Hazards 3 操作危害 Operating Hazards
C.2.34 医疗器械的使用是否依赖于基本性能？Does the use of the medical device depend on essential performance? 应当考虑的因素，例如声明支持器械的输出特征或报警的运行。有关医用电气设备和医用电气系统的基本性能的讨论见 IEC60601-1.Factors that should be considered are, for example, the characteristics of the output of life-supporting devices or the operation of an alarm. See IEC 60601-1 for a discussion of essential performance of medical electrical equipment and medical electrical systems.	是 Yes	各种参数的测试准确性，抗干扰性能，抗电刀抗除颤性能都属于基本性能的问题。 The measuring accuracy of the parameter, anti-interference performance, ESU-proof and defibrillator-proof performance all belong to essential performance problems.	3 操作危害 Operating Hazards 4 信息危害 Information Hazards 5 初始事件和环境 Initial Event and Environment Hazards

3.2 详细结果 Detailed results of risk management

基于ISO 14971:2007 和IEC60601-1:2005+A1的要求， iM50、M50、iM60、iM70、iM80、M80在正常使用和合理可预见的误用条件下的可能危害均进行了识别，每一种危害情形下的风险均依照风险管理计划中给出的方法和判定标准进行了估计和风险评价，对于风险评价结果为NACC 或者ALARP的，均采取了风险控制措施，并对风险控制措施实施后的剩余风险进行了估计和评价。

Hazards associated with iM50、M50、iM60、iM70、iM80、M80 in both normal use and reasonably foreseeable misuse condition were identified based on Annex E of ISO 14971:2007 and IEC60601-1:2005+A1. Risk for each hazardous situationhas been estimated and evaluated following the method and criteria specified in Risk Management Plan. For the hazards that have risk level of NACC or ALARP, risk control measures are implemented and risks are estimated and evaluated again after the implementation.

详细的结果记录在附件iM系列风险分析表。

The detailed results are shown in attachment iM Series Risk Analysis Table..

4 综合剩余风险 Overall residual risk

经过对 iM 系列产品的风险分析，并采用合理的技术手段后，以下风险项仍然无法降低到广泛可接受水平：

Through risk analysis of iM series，the following risk item not reach ACC by the Risk controls category: 1.1.1、1.1.2、1.1.3、1.1.4、1.1.5、1.1.7、1.1.8、1.1.9、1.1.10、1.1.12、1.1.14、1.1.18、1.2.4、1.2.5、1.2.6、1.2.7、1.2.8、1.2.9、1.3.1、1.3.2、1.3.3、1.3.4、1.3.5、1.3.6、1.3.7、1.3.8、1.3.9、1.3.12、1.3.13、1.4.1、1.4.2、1.4.3、1.4.4、1.4.5、2.1.4、2.3.1、2.3.2、3.1.1、3.1.2、3.1.3、3.2.3、3.2.4、3.2.5、3.2.6、3.2.7、3.2.8、3.2.9、3.2.13、3.2.14、3.2.15、3.2.18、3.3.1、3.3.2、3.3.4、3.3.6、3.3.7、3.3.8、3.3.10、3.3.12、4.1.1、4.1.2、4.1.3、4.1.4、4.1.5、4.1.8、4.1.9、4.1.10、4.1.11、4.1.12、4.1.13、4.1.14、4.1.19、4.1.20、4.1.24、5.1.1、5.1.2、5.1.3、5.1.7、5.1.9、5.1.10、5.1.11、5.1.12、5.1.13、5.1.14、5.1.15、5.1.16、5.1.17、5.1.18、5.1.19、6.1.1、6.1.2、6.1.3、6.1.4、6.1.6、6.1.10、6.1.11、6.1.12、6.1.13、7.1.1、7.1.2、7.1.4、7.1.5、7.1.6、7.1.7、7.1.8、7.1.9、7.1.10、7.1.11、7.1.12、7.1.13、7.1.14、7.1.15、7.1.16、7.1.17、7.1.18、7.1.19、7.1.27、7.1.28、7.1.32、7.1.33、7.1.34

通过与当前医疗市场上存在的各个医疗供应商提供的监护仪相比较，iM 系列所采用的技术手段与各个主流监护仪供应商所采用的技术手段在原理上基本一致。但是受制于当先医疗技术手段的限制，iM 系列与各个医疗供应商所提供的监护仪一样，当前还无法通过技术手段完全消除监护仪的使用风险。

iM series use the same risk controls category with other patient monitor of other manufacture in the current market，all risk anaysis of iM series cannot reach ACC by current medical technique .

与 iM 系列监护仪所带来的风险相比，给医疗人员提供的健康信息远远大于其产生的风险。

It is more benefit for medical person than the residual risk of iM series.

在预期使用情形下，每一个单一的剩余风险包括由风险控制措施可能的失效导致的剩余风险均评价为可忽略或者已尽可能降低，且所有剩余风险的综合的影响也是可以接受的，依照 iM 系列产品风险管理计划中给出的综合剩余风险评价标准，该产品的综合剩余风险可接受 Each of the single residual risks including risk arising from failure of risk control measures has been evaluated insignificant or as low as reasonably practicable for the intended use, their combination impact have been reviewed and evaluated as acceptable, the overall residual risk is acceptable according to the Acceptance Criteria for Overall Residual Risk defined in iM series Product Risk management Plan.

iM系列监护仪存在功能安全的是NIBP过压和致命报警（停搏，）失效，NIBP过压阻断血流超过40分钟会造成组织坏死，在监护仪有软件、硬件双层保护，对单一故障软、硬件导致过压风险进行分析，涉及硬件故障风险项：1.3.5、3.2.6、6.1.4。涉及软件故障风险项：1.3.6、1.3.7、3.2.15。致命报警失效超过4分钟会造成脑组织缺氧死亡。在监护仪中有指示灯指示，显示信息，音频报警，软件看门狗等保护，对多重故障包括导联探头故障、硬件故障、应用软件故障导致致命报警失效风险进行分析，涉及应用软件故障风险项：3.2.9、3.1.1、3.1.2、3.1.3、4.1.3；涉及应用硬件故障风险项：4.1.4，4.1.25，7.1.4；涉及导联探头故障风险项：7.1.8，7.1.15。

iM series patient monitor have NIBP over pressure and damage alarm (stop production、asphyxiate) fault，NIBP over pressure will stop the blood over 40 mins lead to Muscle necrosis.The patient monitor have software and hardware double protect,analysis the single fault risk with hardware and software ,hardware risk NO. 1.3.5、3.2.6、6.1.4,software NO. 1.3.6、1.3.7、3.2.15. The damage alarm disable over 4 mins will lead to brain lack of O2 and dead.The monitor have indicator message ,display information ,audio alarm software watchdog protection ,and do the risk analysis including sensor fault ,hardware fault ,software fault ,software risk NO. 3.2.9、3.1.1、3.1.2、3.1.3、4.1.3,hardware risk NO. 4.1.4，4.1.25，7.1.4, sensor fault risk NO. 7.1.8，7.1.15

在生产试制过程与确认过程中，未引入新的风险，现有的风险等级未发生变化。
In the process of pilot production and validation, there is no new risk, and the rank of existing risk has no change.

5 风险/受益分析 Risk/benefit analysis

依照QP38风险管理控制程序和iM系列产品风险管理计划风险管理计划，基于所有单一的剩余风险评价结果没有不可接受且综合剩余风险评价结果可接受，不需要进行风险/受益分析.
Since no single residual risk fall into N/ACC region and the overall residual risk is acceptable, no risk/benefit analysis is performed according to QP38 risk management control procedure and iM series Product Risk management Plan.

6 附件清单 Attachment list

序号 No.	附件名称 Attachment Name	所处章节 Section
1	iM Series Risk Analysis Table-1.5	/

7 缩略语/定义 Abbreviation/Difinitions

缩写/定义 Abbr. / Def.	描述 Description
ACC	ACCeptabale 可接受的
ALARP	as low as reasonably practicable without economic consideration 低至合理可行且不考虑经济因素
N/ACC	Not ACCeptable 不可接受的
Expected service life	Time period specified by the manufacturer during which the device is expected to remain safe for use 由制造商规定的医疗电气设备或医疗电气系统期望保持安全使用的时间（即保证基本安全和基本性能）
Rep.	Representative 代表
Safety	freedom from risk unacceptable risk 免除不可接受的风险的状态

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