INSTRUCTIONS FOR USE (IFU)

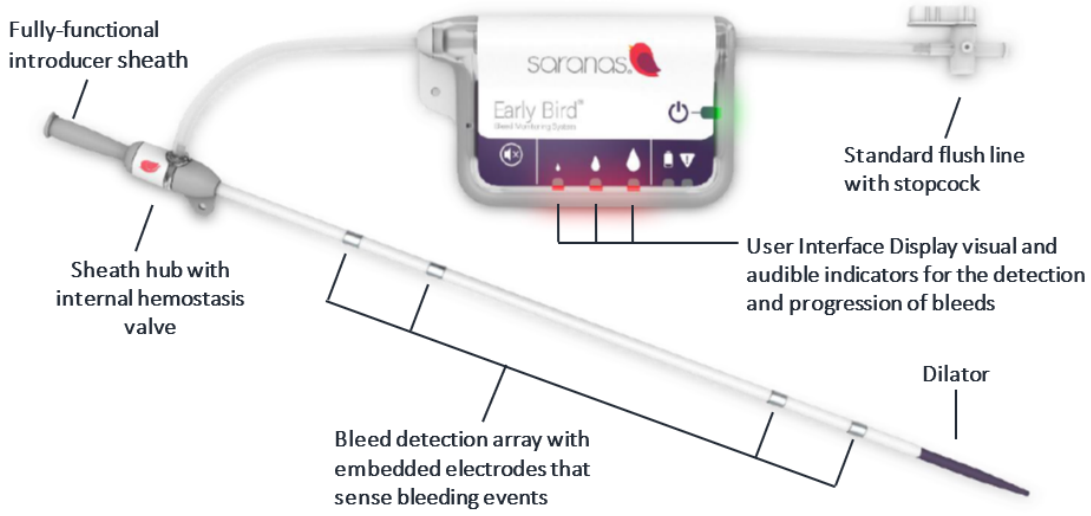
Saranas® Early Bird® Bleed Monitoring System

CAUTION: United States Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

1 DEVICE DESCRIPTION

FIGURE 1: Early Bird Bleed Monitoring System



The Early Bird consists of the following: introducer sheath, user interface display (UID), for the early detection and monitoring of potential internal bleeding complications (IBCs), and a dilator as shown in **Figure 1**. The introducer sheath contains four embedded electrodes on the cannula and a hemostasis valve located within the sheath hub. The distal end of the sheath has a tapered leading edge which transitions smoothly to the tapered dilator, forming an atraumatic device. The dilator is radiopaque to aid in visibility under fluoroscopy during insertion.

TABLE 1: Sizing Table for Choosing Early Bird Introducer Sheath

Size (French)	Minimum Sheath Internal Diameter, inches (mm)	Working Length (cm)	Working Length w/ Dilator (cm)
6	0.085 (2.16)	20	23
8	0.110 (2.79)	20	23

2 PACKAGE CONTENTS

- Early Bird Bleed Monitoring System
- Dilator
- Directions for Accessing IFU

3 INTENDED USE

The Early Bird is intended:

- to be inserted into the femoral artery or femoral vein to provide a conduit for the insertion of diagnostic and interventional endovascular devices.
- to provide physicians with an early indication of extravascular fluid accumulation, which may be due to a potential internal bleeding complication.
- to detect and monitor changes in bioimpedance due to extravascular fluid accumulation, and to provide physicians with indications that a potential internal bleeding complication is progressing.

The Early Bird is intended to provide physicians and other healthcare providers with additional information to aid in their clinical assessment of the patient during and after endovascular procedures. As such, it is not intended to diagnose or replace clinical judgment of healthcare professionals.

The Early Bird can be used in endovascular procedures such as percutaneous coronary intervention (PCI), transcatheter structural heart procedures (such as balloon valvuloplasty, valve repair, or valve replacement), hemodynamic support device procedures (such as intra-aortic balloon pump (IABP) insertion, percutaneous ventricular assist device (PVAD) implantation, and extracorporeal membrane oxygenation (ECMO)), endovascular aneurysm repair (EVAR), thoracic endovascular aneurysm repair (TEVAR), or other similar procedures which utilize introducer sheaths to gain vascular access.

Physicians are encouraged to follow accepted clinical practices when treating a potential internal bleeding complication, including cessation or reversal of anti-coagulants, application of pressure near the site of vascular access, or any other endovascular or surgical interventions deemed clinically appropriate.

4 INDICATIONS FOR USE

The Early Bird is indicated for the introduction of catheters, catheter balloons, and other diagnostic and interventional devices into the femoral artery or femoral vein while maintaining hemostasis during diagnostic and interventional endovascular procedures.

The Early Bird provides physicians with an early indication of a potential internal bleeding complication by initial detection and monitoring of extravascular fluid accumulation.

5 CONTRAINDICATIONS

There are no known contraindications for the Early Bird.

6 WARNINGS

- Insertion of more than one Early Bird device in the same vessel or in the adjoining vessel is not recommended due to potential interaction between the two bioimpedance measurement signals. If more than one introducer sheath is required simultaneously to perform a procedure, use a standard introducer sheath in the secondary position.
- Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

- This device is not MRI compatible.
- The Early Bird may not detect an internal bleeding complication if internal bleeding has already occurred prior to insertion of the introducer sheath or prior to initial bioimpedance measurement.
- The Early Bird should not be exposed to organic solvents.
- Do not alter this device, including cutting to alter the length. Alterations may impair device function.
- Do not attempt to place a guidewire with a maximum diameter greater than 0.035” (0.89 mm) through the dilator.
- Do not attempt to insert a catheter or interventional device having a diameter larger than the Early Bird introducer sheath size (Table 1). Device damage or breakage may result.
- Do not attempt to insert multiple catheters or devices when the combined diameter is larger than the Early Bird introducer sheath size (Table 1). Device damage or breakage may result.
- Do not attempt sheath advancement or withdrawal without guidewire and dilator in place. Major bleeding, vessel damage or serious injury to the patient, including death, may result.

- Adequate vessel access is required to introduce the sheath into the femoral artery or femoral vein. Careful evaluation of vessel size, anatomy, tortuosity, and disease state (including calcification, plaque, and thrombus) is required to ensure successful sheath introduction and subsequent withdrawal. If the vessel is not adequate for access, major bleeding, vessel damage, or serious injury to the patient, including death, may result.
- Difficulties with sheath insertion at the insertion site may result in kinking of the device. If the Early Bird is kinked, remove the device and replace with a new one.
- Do not advance the sheath if the dilator is not snapped in the hemostasis valve housing. When the dilator is not snapped into the valve housing, the tip of the introducer sheath may not be fully supported by the cylindrical section of the dilator. Therefore, advancement of the unsupported tip of the introducer sheath may result in major bleeding, vessel damage, or serious injury to the patient, including death.
- Do not attempt to advance or withdraw a guidewire, catheter, or other device through the introducer sheath or dilator if resistance is felt. Use fluoroscopy to determine the cause. Continued advancement or retraction against resistance may result in major bleeding, vessel damage, serious injury to the patient, or damage to/breakage of the guidewire, catheter, or other device.
- Advance the dilator and sheath assembly together with a gentle rotation/twisting motion to minimize vessel trauma.
- Advance the sheath only under fluoroscopic guidance.
- Use an appropriate wire guide to introduce additional guidewires through the hemostasis valve alongside the previously placed guidewire, catheter, or other interventional device. Advancement of guidewires without the appropriate wire guide through the valve may result in damage to the guidewire or the valve. Damage to the valve could result in major blood loss.

7 PRECAUTIONS

- Do not attempt to advance sharp objects/instruments through the hemostasis valve. Sharp objects/instruments could cause damage to the valve and could result in major blood loss.
- Do not puncture the hemostasis valve. Puncturing the valve could result in major blood loss.
- Examine the packaging and device before use. Do not use if either the packaging or device is damaged, or if the sterile barrier has been compromised.
- Do not use after the use by (expiration) date printed on the label.
- Do not re-sterilize; for single use only.
- The Early Bird is designed for single use only; do not re-use this device. Saranas does not have data regarding re-use of this device. Re-use may cause device failures or procedural complications, including device damage, compromised

device biocompatibility, and device contamination. Re-use may result in blood loss, infection, serious injury, or patient death.

- To prevent or reduce the risk of clot formation, consider using systemic anticoagulation and keeping the introducer sheath filled with an appropriate heparinized flushing solution when it is in the vessel.
- Verify sheath, device, catheter, and accessory components size compatibility prior to use.
- Individual patient anatomy and physician techniques may require procedural variations.
- The Early Bird requires special precautions regarding Electromagnetic Compatibility (EMC) and must be used according to the EMC information provided in this IFU.
- Electronic equipment, including portable and mobile Radio Frequency (RF) communications equipment, and RF emitters such as diathermy, electrocautery, RFID, and security systems, can affect the operation of the Early Bird. Operating non-essential equipment in the vicinity of the Early Bird should be avoided. If interference is suspected, the responsible equipment and associated cables should be moved away from the Early Bird.
- The emissions characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A).

8 POTENTIAL ADVERSE EVENTS

Adverse events related to the Early Bird that may occur include, but are not limited to:

- Bleeding, possibly leading to major blood loss
- Hematoma
- Embolization (micro or macro) of thrombus or plaque, possibly resulting in transient or permanent ischemia
- Infection
- Vascular trauma (e.g., dissection, rupture, perforation, or tear)
- Nerve injury
- Arterio-venous fistula
- Pseudoaneurysm
- Deep vein thrombosis
- Death

9 HOW SUPPLIED

The Early Bird is supplied sterile and non-pyrogenic.

10 STORAGE AND HANDLING

Store in a cool, dry place.

11 REQUIRED ACCESSORIES

- 0.035” (0.89 mm) Guidewire
- Heparinized Saline

12 DIRECTIONS FOR USE

12.1 Sheath Preparation

12.1.1 Verify that the proper size Early Bird introducer sheath (6F or 8F) is selected for the catheter or device to be introduced.

12.1.2 Verify that the vessel is of adequate diameter and tortuosity to accommodate the Early Bird introducer sheath.

12.1.3 Remove the Early Bird introducer sheath and dilator from their packaging and examine the contents for possible damage or defects.

Caution: In endovascular procedures in which 9-25F sheaths and/or devices are inserted into the femoral artery, the Early Bird introducer sheath should be inserted either into the femoral artery and adjacent to the procedural sheath or device in the femoral artery, or into the adjacent femoral vein.

Caution: Do not use if damaged or defective.

Caution: <u>Do not pull the UID battery pull tab</u> prior to insertion of the sheath into the femoral artery or femoral vein and prior to suturing the sheath in place. Once the battery pull tab is pulled, the device automatically powers on and allows up to five (5) minutes for the bleed monitor to detect a bioimpedance signal before the device locks into an error state, after which, the device will not function as intended. To ensure that the device will not error out, suture the sheath in place and try to minimize sheath movement. Refer to Section 13 if the device is in an error state.

12.1.4 Prior to insertion, wipe down the introducer sheath and dilator with heparinized saline. Do not wipe the surface with dry gauze.

12.1.5 Flush the sheath through the stopcock with heparinized saline. Close the stopcock.

12.1.6 Flush the dilator through the proximal hub with heparinized saline.

12.1.7 Carefully insert the dilator tip through the hemostasis valve and into the sheath until the dilator hub is adjacent to the valve. Gently snap the dilator hub into the valve housing to ensure the tapered portion of the dilator is beyond the distal end of the introducer sheath making a smooth, atraumatic transition.

12.2 Sheath Introduction and Use

12.2.1 Using standard Seldinger technique, access the target vessel with the appropriate needle.

12.2.2 Insert a 0.035” (0.89 mm) guidewire through the needle and into the vessel, then remove the needle ensuring the guidewire remains positioned within the vessel.

12.2.3 Advance the distal end of the dilator over the guidewire.

12.2.4 Advance the assembly (sheath/dilator) as a unit over the guidewire under fluoroscopic guidance; do not allow the dilator to back out of the sheath while advancing. Use a slight twisting motion to advance the assembly through the tissue and into the target vessel. Stop advancement of the assembly if resistance is felt. Investigate the cause of resistance before proceeding. Carefully advance the assembly until it is fully inserted.

Caution: Do not attempt advancement of the sheath without the dilator and guidewire in place. Major bleeding, vessel damage, or serious injury to the patient, including death, may result.

12.2.5 Hold the sheath steady and maintain guidewire position while withdrawing the dilator from the sheath until it is completely removed from the guidewire.

12.2.6 Aspirate and flush the introducer side-arm.

12.2.7 Carefully suture the sheath in place to minimize device movement during use.

12.2.8 Pull the battery pull tab to activate the Early Bird.

Do not press the power button at this time. The power button is only used to turn off the device within the first five (5) minutes.

12.2.9 Carefully support all guidewires, catheters, and other devices while advancing through the hemostasis valve and sheath.

12.2.10 Advance the selected diagnostic or interventional device over a guidewire through the hemostasis valve and sheath. Follow manufacturer’s recommendations for use of the selected diagnostic or interventional device.

Caution: Do not advance or retract diagnostic or interventional devices into or out of the sheath if resistance is felt. Determine the cause of resistance before proceeding.

Caution: Do not attempt to advance sharp objects/instruments through the hemostasis valve. Damage to the valve may result in major blood loss.

Caution: Advancement of guidewires without an appropriate wire guide through the hemostasis valve may result in damage to the guidewire or the valve. Damage to the valve could lead to major blood loss.

12.3 Sheath Removal

12.3.1 Gently rotate the sheath to ensure the sheath is free from the vasculature.

12.3.2 While applying pressure, pull the sheath proximally until the sheath is fully removed. The yellow Device Error indicator will illuminate, and the audible indicator will momentarily beep. During removal of the sheath, precautions should be taken to prevent excessive blood loss, vessel damage, or other serious injury.

12.3.3 Follow standard clinical procedure to close the vessel puncture site after device removal.

12.3.4 Follow standard hospital procedure for device disposal.

13 FUNCTIONALITY

The Early Bird provides early detection of potential internal bleeding complications and monitors for internal bleeding progression based on baseline bioimpedance measurements and bioimpedance changes throughout the course of a procedure. The device correlates the bioimpedance signal to changes in extravascular fluid accumulation and displays bleeding status to the physician through a series of Light-Emitting Diodes (LED's) located on the UID (as shown in **Figure 2**). Please note, triggering of the early bleed indicator levels is not directly related to specific volume targets of extravascular blood accumulation as the device does not directly measure blood volume.

After the device powers on, the system performs a series of self-tests to ensure proper functionality, followed by initiation of the bleed monitoring algorithm. The Early Bird's intelligent IBC detection and monitoring system involves a microprocessor and utilizes digital filters to collect, transform, and calculate regional changes in bioimpedance.

Upon vessel trauma, leading to extravascular fluid accumulation, the bioimpedance begins to decrease at a given rate. If the rate of bioimpedance decline reaches a prescribed slope threshold, the bleed monitoring algorithm will trigger the Level 1 IBC audible and visible indicator (as described in **Table 2**). At this time, the algorithm will save the current bioimpedance as a datum for which bleed progress will be measured against. If the progression of the bleed persists and the impedance continues to fall, then after a fixed percent change from the datum, the Early Bird will trigger the audible and visible Level 2 IBC indicator. Still further, if bleeding continues to progress and the next predetermined percent change from the datum

is met, the Early Bird will trigger the audible and visible Level 3 IBC indicator.

FIGURE 2: Early Bird UID

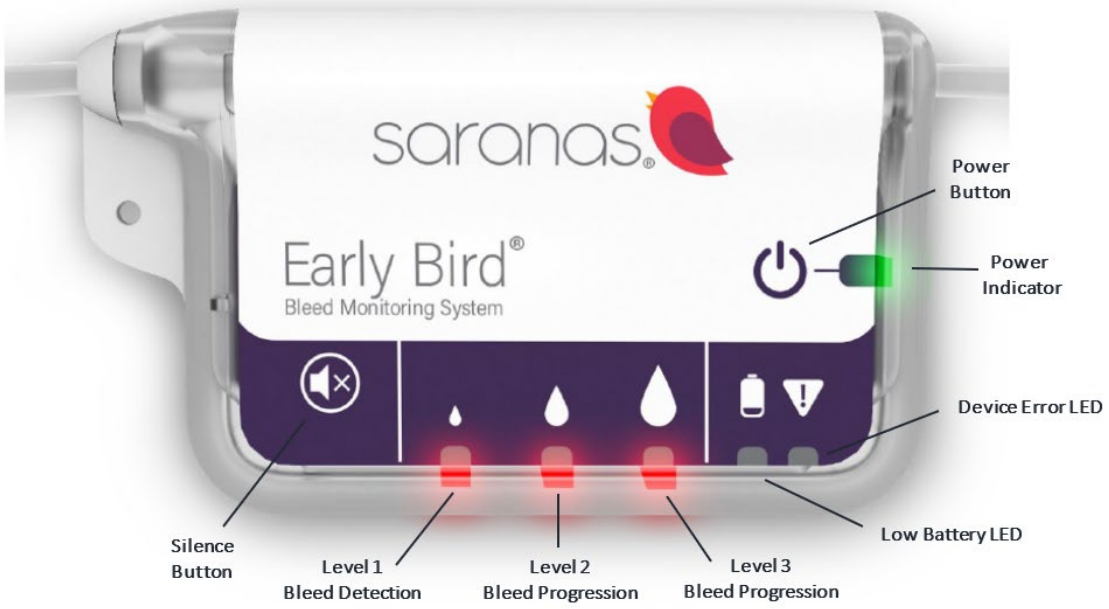


TABLE 2: Indicator Descriptions

LED/Indicator	Description
Bleed Monitoring (Red) 	The red Bleed Monitoring indicators are a series of three (3) LEDs that sequentially illuminate as bioimpedance continues to change over the course of a procedure, indicating a possible internal bleeding complication. • Level 1 indicator (1st LED) is triggered by the early onset of a bleed. An audible alert is momentarily activated once this level is triggered. • Level 2 indicator (2nd LED) is triggered as the bleed progresses when a bioimpedance threshold is reached. An audible alert, longer in duration than the 1st LED, is momentarily activated once this level is triggered. • Level 3 indicator (3rd LED) is triggered as the bleed continues to progress further when a higher bioimpedance threshold is reached. An audible alert is activated once this level is triggered and requires the attending physician to silence the device by pressing the silence button.

Low Battery (Blue) 	The blue Low Battery indicator will blink when the battery is near end of life. The audible indicator will momentarily beep. If the system shuts down due to a low battery, the device has reserved enough power so that the system can be powered on to observe the last state of bleed monitoring indicators.
Device Error (Yellow) 	The yellow Device Error indicator will illuminate when an internal system error has been detected. The audible indicator will momentarily beep. If the yellow Device Error is illuminated, press and hold the Power button to turn off the device and turn the device back on for one additional attempted use of bleed detection and monitoring. If the yellow Device Error illuminates again, the device cannot be used. Once the procedure is completed, report the event to Saranas.
Power (Green) 	The green Power indicator will blink after the device is first turned on and until it detects a bioimpedance signal which is in an acceptable range. Then, the indicator will stop blinking and remain illuminated throughout the procedure.
Button	**Function**
Silence 	This button is used to silence the audible indicator.
Power 	After the battery pull tab is pulled, the system will run through a series of self-tests which will illuminate all indicators. The audible indicator will momentarily beep. If required, press and hold the button to turn off the device. Note that the device can be turned off only within the first five (5) minutes after powering on the device.

14 EARLY BIRD STUDY SUMMARY

A prospective, self-controlled acute animal investigation was conducted to evaluate the safety and efficacy of the Early Bird in detecting extravascular fluid accumulation via simulated IBC. The primary endpoint was sensitivity of Level 1 bleed detection, and the secondary endpoint was bleed progression performance.

Twenty (20) female Yorkshire Cross swine underwent femoral vessel cannulation with the Early Bird. After preparation of the access site, the Early Bird was introduced into the target vessel. To simulate a bleed, 500 ml of blood solution was infused at 10 ml/min in the subcutaneous tissue near the access site. Blood volumes and fluoroscopic images were collected upon triggering of the Early Bird bleed indicators. Systemic gross necropsy was performed to study the end-organ effects of the Early Bird. Level 1 bleed detection resulted in 100% sensitivity and 100% specificity (as described in **Table 3**).

TABLE 3: Sensitivity and Specificity at Level 1 Detection

Early Bird Level 1 Bleed Detection	**Bleed Status**	
	Bleed Simulations or Access Site Bleeds	**No Bleed Simulations or No Access Site Bleeds**
Detection	40 = True Positive*	0 = False Positive
Non-Detection	0 = False Negative	30 = True Negative
Sensitivity/Specificity	**Sensitivity = 100%**	**Specificity = 100%**

* 10 true bleeds that occurred prior to bleed simulation and 30 bleeds that were detected during bleed simulation (40 total)

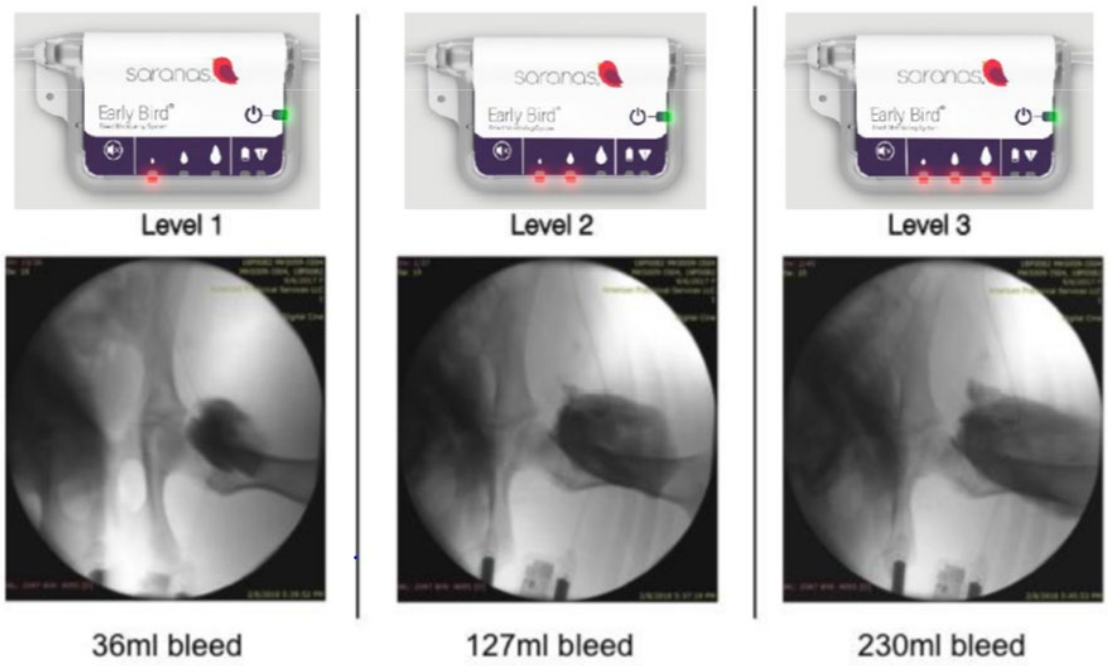
The Early Bird successfully identified bleed progression with a statistically significant increase in volume detected at each bleed indicator level (as described in **Table 4**, Wilcoxon Signed Rank Test $P<0.001$). No vessel trauma related to the Early Bird was detected by histopathology.

TABLE 4: Volume of Blood Infused and Detected at Each Level

	Level 1	**Level 2**	**Level 3**
Median, ml [IQR]	28.5 [26.0,35.8]	64.0 [52.8,79.8]	111.0 [85.3,154.0]
Mean, ml (SD)	31.5 (±12.7)	77.80 (±53.5)	145.50 (±100.5)
Range, ml	5.0 – 74.0	17.0 – 315.0	44.0 – 488.0
IQR=interquartile range; SD=standard deviation			

The activation of level 1, 2 and 3 bleed indicators resulted in clinically significant hematoma development as bleed simulation progressed (as shown in Figure 3).

FIGURE 3: Bleed Progression with Early Bird Indicator Levels



15 TECHNICAL DESCRIPTION

Battery

Battery Type:	Alkaline 1.5V AAA
Battery Life:	Up to 12 hours

The Early Bird battery is non-serviceable.

Electrical Safety

ME Equipment Class:	Internally Powered
Patient Connection:	Type BF

The Early Bird Bleed Monitoring System (User Interface Display module and introducer sheath) is considered to be the Applied Part.

IBC Audible Indicator Volume 50dBA @ 1m

Electromagnetic Compatibility (EMC)

The Early Bird meets the requirements of IEC 60601-1-2 for a Group 1, Class A device. Specific levels for the Early Bird device appear below.

TABLE 5: Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Early Bird is intended for use in the electromagnetic environment specified below. The customer or the user of the Early Bird should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR II	Group 1	The Early Bird uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF Emissions CISPR II	Class A	The Early Bird is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Essential Performance

The Early Bird Bleed Monitoring System maintains stable impedance measurement in the specified environmental conditions.

TABLE 6: Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Early Bird is intended for use in the electromagnetic environment specified below. The customer or the user of the Early Bird should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge IEC 61000-4-2	No false indications, error mode allowed: 8 kV Contact 15 kV Air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	Complies	If abnormal operation occurs, it may be necessary to position the Early Bird further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended location of use to assure that it is sufficiently low.
Conducted RF IEC 61000-4-6	3V 0.15 to 80 MHz 6V in ISM bands between 0.15 and 80 MHz 80% AM at 1 kHz	Refer to TABLE 7	Portable and mobile RF communications equipment should be used no closer to any part of the Early Bird, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2 √P 150 kHz to 80 MHz d = 1.2 √P 80 MHz to 800 MHz d = 2.4 √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Refer to TABLE 7	

NOTE 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Early Bird is used exceeds the applicable RF compliance level above, the Early Bird should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating to an alternate site. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TABLE 7: Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Early Bird			
The Early Bird is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Early Bird can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Early Bird as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz d = 1.2 √P	**80 MHz to 800 MHz** d = 1.2 √P	**800 MHz to 2.5 GHz** d = 2.4 √P
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.76
1	1.2	1.2	2.4
10	3.8	3.8	7.6
100	12	12	24

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Impedance Measurement

Applied signal waveform:	10.0 kHz, sinusoidal
Applied signal amplitude:	250 µA peak to peak
Impedance sampling rate:	0.25 seconds
Impedance measurement range:	10 to 95 ohms, -20 to +20 degrees phase

Maximum Delay of Bleed Detection Notification 398 seconds

Permissible Environmental Conditions

Temperature:	Transportation and Storage: 5°C to 50°C
Relative Humidity:	Transportation and Storage: 0% to 85%
Atmospheric Pressure:	Transportation and Storage: 50kPa to 106kPa

Operating Conditions: Typical operating room / catheterization laboratory environment

WARNING: No modification of this equipment is allowed.

16 PATENTS AND TRADEMARKS

This product and/or its use may be covered by one of more of the following United States Patents: 8,273,023; 8,366,615; 8,961,417; 9,078,627; 9,700,216; 10,264,981. Other U.S. patents pending. Other patents issued and/or pending outside of the U.S.

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17 DEVICE-RELATED ADVERSE EVENT REPORTING

Any adverse event involving the Saranas Early Bird Bleed Monitoring System should be reported to Saranas, Inc. immediately. To report an event in the United States, please call 1-833-ERLYBRD (833-375-9273), e-mail info@saranas.com, or write to:

Saranas, Inc.
2450 Holcombe Boulevard
Suite X
Houston, TX 77021-2039
USA.

TABLE 8: Symbol Descriptions

SYMBOL	DESCRIPTION
	**Catalog Number**
	**Batch Code**
	**Use by Date**
	**Quantity**
	**Manufacturer**
	**Maximum I.D. (French Size)**
	**Guidewire Compatibility**
	**Do Not Re-use**
	**Do Not Use if Package is Damaged**
	**Keep Dry**
	**Do Not Re-sterilize**
	**Temperature Limit**

SYMBOL	DESCRIPTION
	**Humidity Limitation**
	**Atmospheric Pressure Limitation**
	**Consult Electronic Instruction for Use (www.saranas.com/IFU)**
	**Caution**
	**Keep Away from Sunlight**
	**Caution: U.S. Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.**
	**Sterilized using Ethylene Oxide**
	**Type BF Applied Part**
IP41	**Ingress Against Water or Particulate Matter (IP) Classification** **Protected against solid foreign objects of 1.0 mm Ø and greater and protection against vertically falling water drops**
RoHS 	**Restriction of Hazardous Substances**
	**General Prohibition Sign, i.e., Do Not…**
	**General Warning Sign, i.e., Caution…**
	**MR Unsafe**