

## **Potential for Radio Frequency Interference on Device Operation**

Both portable and mobile RF communications equipment can affect medical electrical equipment, including SLS PCS. SLS PCS is intended for use in the electromagnetic environment specified in the guidance and manufacturer's declaration section.

## **Potential for Radio and Television Interference**

SLS PCS generates and uses radio frequency energy, and if not installed and used properly, that is, in strict accordance with the manufacturer's instructions, may cause interference to radio and television reception. **This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.** SLS PCS is not intended for use in a residential Class A environment. SLS PCS requires a medical power/ground. If your SLS does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna
- Relocate SLS PCS with respect to the receiver

If necessary, you should consult Codonics Technical Support or an experienced radio/television technician for additional suggestions. You may find the following booklet prepared by the Federal Communications Commission helpful: *How to Identify and Resolve Radio-TV Interference Problems*. This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402, Stock No. 004-000-00345-4.

*Le présent appareil numérique n'émet pas de bruits radio-électriques dépassant les limites applicables aux appareils numériques de la Classe B prescrites dans le Règlement sur le brouillage radioélectrique édicté par le ministère des Communications du Canada.*

This product is in conformity with the protection requirements of EC Council directive MDR 2017/745/EU(CE) on the approximation of the laws of the Member States relating to medical devices. This product satisfies the Class A limits of IEC 60601-1-2 for Professional Healthcare Facilities and CISPR 11. A declaration of conformity with the requirements of the Directive has been signed by a Codonics vice president.

### **Potential for Operator Exposure to Radio Frequency Energy**

The Safe Label System, when equipped, emits radio frequency energy for the purpose of reading and writing to radio frequency identification (RFID) tags. The device transmits momentarily after scanning a drug barcode at the front cover and also when printing labels equipped with RFID functionality. The radio transmitters are disabled at all other times. The Safe Label System meets the radio frequency exposure requirements of the U.S. 47CFR 1.1310 and Canada RSS-102 standards. The time-averaged power of emitted radio energy is well below the SAR exemption thresholds for human exposure set forth by the United States and Canada.

### **Potentiel d'Exposition de l'Opérateur à l'Énergie des Radiofréquences**

Le Safe Label System, lorsqu'il est équipé, émet de l'énergie radiofréquence dans le but de lire et d'écrire sur des étiquettes d'identification par radiofréquence (RFID). L'appareil transmet momentanément après avoir scanné un code-barres de médicament sur l'étiquette avant et également lors de l'impression d'étiquettes équipées de la fonctionnalité RFID. Les émetteurs radio sont désactivés à tout autre moment. Le Safe Label System répond aux exigences d'exposition aux radiofréquences des normes U.S. 47CFR 1.1310 et Canada RSS-102. La puissance moyenne dans le temps de l'énergie radio émise est bien inférieure aux seuils d'exemption SAR pour l'exposition humaine établis par les États-Unis et le Canada.



**WARNING** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SLS600i, its cables, or accessories. Otherwise, degradation of the performance of this equipment could result.



**ATTENTION** The Safe Label System contains authorized radio equipment that has been tested and approved as a system. Changes or modifications to the Safe Label System that are not expressly approved by Codonics could void the user's authority to operate this equipment in the field.

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Test/Standard	Compliance
<b>Electrical Fast Transient/Burst</b>	AC Port: $\pm 2$ kV, 100 kHz repetition frequency
IEC 61000-4-4	SIP/SOP Ports: $\pm 1$ kV, 100 kHz repetition frequency
<b>Surge</b>	Line-to-Line: $\pm 0.5$ kV, $\pm 1.0$ kV
IEC 61000-4-5	Line-to-Ground: $\pm 0.5$ kV, $\pm 1.0$ kV, $\pm 2.0$ kV
<b>Conducted Immunity</b>	AC Port and SIP/SOPs:
IEC 61000-4-6	3 V, 0.15 MHz – 80 MHz
	6 V, in ISM bands between 0.15 MHz and 80 MHz
	80% AM at 1 kHz
<b>Magnetic Field Immunity</b>	30 A/m, 50 Hz or 60 Hz
IEC 61000-4-8	
<b>Voltage Dips</b>	0% UT, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
IEC 61000-4-11	0% UT, 1 cycle AND 70% UT, 25/30 cycles, Single phase: at 0°
<b>Voltage Interruptions</b>	0% UT, 250/300 cycle
IEC 61000-4-11	
<b>Radiated fields in close proximity</b>	134.2 kHz: 2.1-kHz pulse modulation, 65 A/m
IEC 61000-4-39	13.56 MHz: 50-kHz pulse modulation, 7.5 A/m
<b>Exposure to Radio Frequency ID Readers</b>	Table 3 test levels
AIM 7351731	

# B

## Specifications

### Specifications (English)

System:	Integrated capacitive touch screen computer, 2D barcode scanner, color ink jet printer, audio feedback, and provision for a network interface
Ink Cartridges:	One color cartridge (CMY)
SmartDrive:	USB flash drive for storing configuration data, formulary database, log files
Readable Barcodes:	GS1 DataBar Limited (RSS Limited), GS1 DataBar Stacked (RSS-14 Stacked), GS1-128, UPC-A, Data Matrix, Code 128, Code 128 barcodes with GS1-128, Code 39, Code 32, IFT-14, Interleaved 2 of 5, EAN-8, EAN-13
Writable Barcodes:	Data Matrix
Network Interfaces:	Ethernet (RJ-45), included standard Wi-Fi (USB-2 adapter), optional, available from Codonics
Network Speeds:	Ethernet, full duplex 100 Base-T only Wi-Fi, 802.11 b/g/n (2.4 GHz) and 802.11 a/n/ac (5.0 GHz)
Network Protocols:	SSH (Secure Shell) and SCP (Secure Copy) Used to access SLS PCS from Codonics-authorized applications
Dimensions:	Height: 16.5 in. (41.9 cm) Width: 10.43 in. (26.5 cm) Depth: 15.67 in. (39.8 cm)
Weight:	14.5 lbs (6.6 kg)

Power: Universal Input: 100-240 VAC, 50/60 Hz

**Intentional Transmitters:** When equipped, SLS transmits radio frequency energy at 13.56 MHz using ASK modulation: Effective Radiated Power: -43.14 dBm (48.5 nW).

When equipped, SLS transmits radio frequency energy within the band of 902–928 MHz using PR-ASK modulation: Peak Effective Radiated Power: 21.94 dBm (156 mW).

Environmental: *Operating:*  
Temperature: 15–30°C (59–86°F)  
Humidity: 20%–80% noncondensing

*Shipping and Storage:*  
Altitude: Sea Level to 5790 m  
Temperature (Hardware): -22.2–51°C (-8–123.8°F)  
Temperature (Ink Cartridge and Label Media): 1–43°C (34–110°F)  
Humidity (Hardware): 5%–85% noncondensing  
Humidity (Ink Cartridge and Label Media): 5%–80% noncondensing

Medical Compliance and Regulatory: FDA cleared to market per 510(k) K101439 Class II, MDR CE (Class I), GMP/QSR ISO 13485:2016, Safety IEC 60601-1 and EMC IEC 60601-1-2 for Professional Healthcare facilities

Classification: Class II equipment, Product Code BSZ, Regulation Number 868.5160



**CAUTION** Federal law restricts this device to be sold for use by or on the order of a physician.

## Specifications (French)

<i>Système :</i>	<i>Ordinateur à écran tactile capacitif intégré, 2d barcode scanner, imprimante à jet d'encre, feed-back audio, et prestation d'un network interface</i>
<i>Cartouches :</i>	<i>Une cartouche couleur (CMY)</i>
<i>Smart Drive :</i>	<i>USB flash drive pour garder data du configuration, database de formulaire, dossiers du registre</i>
<i>Barcodes livrable :</i>	<i>RSS, UPC-A, B, C, Data Matrix</i>
<i>Barcodes inscriptible :</i>	<i>GS1 DataBar Limited (RSS Limited), GS1 DataBar Stacked (RSS-14 Stacked), GS1-128, Code 128 barcodes with GS1-128, Code 39, Code 32, IFT-14, Interleaved 2 of 5, EAN-8, EAN-13</i>
<i>Interfaces réseau :</i>	<i>Ethernet (RJ-45), inclu en standard Wi-Fi (USB-2 adaptateur), en option, disponible à partir Codonics</i>
<i>Vitesses réseau :</i>	<i>Ethernet, full duplex 100 Base-T seulement Wi-Fi, 802.11 b/g/n (2,4 GHz) et 802.11 a/n/ac (5,0 GHz)</i>
<i>Protocoles réseau :</i>	<i>SSH (Secure Shell) et SCP (Secure Copy) Permet d'accéder SLS PCS d'applications autorisées par Codonics</i>
<i>Dimensions :</i>	<i>Hauteur: 41.9 cm (16.5 in.) Largeur: 26.5 cm (10.43 in.) Profondeur: 39.8 cm (15.67 in.)</i>
<i>Poids :</i>	<i>14.5 lbs (6.6 kg)</i>
<i>Puissance :</i>	<i>Universel Input: 100-240 VAC, 50/60 Hz</i>

### *Transmetteurs intentionnels :*

*Lorsqu'il en est équipé, SLS transmet l'énergie radiofréquence à 13,56 MHz en utilisant la modulation ASK. Puissance rayonnée effective : -43,14 dBm (48,5 nW)*

*Lorsqu'il en est équipé, SLS transmet l'énergie des radiofréquences dans la bande de 902 à 928 MHz en utilisant la modulation PR-ASK. Puissance rayonnée efficace maximale : 21,94 dBm (156 mW)*

<i>Conditions du travail :</i>	<i>Opération:</i>	
	<i>Température:</i>	15–30°C (59–86°F)
	<i>Humidité:</i>	20%–80% non condensation
	<i>Transport et Stockage:</i>	
	<i>Altitude:</i>	Niveau de la mer to 5790 m
	<i>Température (appareil):</i>	-22.2–51°C (-8–123.8°F)
	<i>Température (les cartouches et les et étiquettes):</i>	1–43°C (34–110°F)
	<i>Humidité (appareil):</i>	5%–85% non condensation
	<i>Humidité (les cartouches et les et étiquettes):</i>	5%–80% non condensation
<i>Conformité Médical/ Réglementaire :</i>	<i>Conformité Médicale/Réglementaire: Autorisé par la FDA sur le marché selon 510 (k) K101439 Classe II MDR CE (Classe I), GMP/QSR ISO 13485:2016, Conformité IEC 60601-1 and EMC IEC 60601-1-2 pour les établissements de santé professionnels</i>	
<i>Classification :</i>	<i>Class II équipement, code de produit BSZ, numéro de règlement 868.5160</i>	



**CAUTION** Conformément à la loi, il est interdit de vendre cet appareil par l'ordre d'un médecin.