TITLE: WS SIGNATURE PRO OPERATOR'S MANUAL ADDENDUM (ENGLISH), CE MARK

SPECIFICATIONS:

1. **BINDER:** N/A
2. **TEXT:**
   - 2.1 **DIMENSIONS:** 8 1/2" X 11" THREE RINGS, WHITE LASER PAPER
     NOTE: DIMENSIONS ARE FOR REFERENCE DIMENSION ONLY.
   - 2.2 **TYPE OF PAPER:** 60# OFFSET, WHITE, 3 RING PUNCHED
   - 2.3 **INK COLOR:** BLACK ON WHITE PAPER. PRINTING TO BE CLEAR AND LEGIBLE WITH NO INK SMEARS.
     NOTE: COLOR VARIATION DUE TO COLOR BANDING INHERENT IN DIGITAL PRINTING OF SOLID COLORS IS ALLOWABLE
   - 2.4 **TYPE OF COPY:** SINGLE COPY, PRINT 2 SIDES.
3. **COVER & SPINE:** N/A
4. **TAB PAGES:** N/A
5. **ASSEMBLY / PACKAGING:** Shrink-wrap assembled binder with copy of first page of document (cover page) between shrink and outside of binder. Manual identify from cover page (version, part number, etc.) must be facing out and visible for warehouse identification.
6. **LANGUAGES:** English
7. **POINTS OF USE:** AMO Santa Ana, CA, AMO Milpitas, CA

CHANGE SUMMARY

REVISION	DESCRIPTION OF CHANGE
A	Initial release of WHITESTAR SIGNATURE PRO Operator's Manual Addendum.

ADDENDUM

The Warning and Symbol definitions are in addition to those same lists in:

- **WHITESTAR SIGNATURE PRO** Operators Manual NGPZ370500 Chapter 1.

WARNINGS:

WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the **WHITESTAR SIGNATURE PRO** System or shielding the location.

WARNING: WHITESTAR SIGNATURE PRO System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

WARNING: Portable and mobile RF communications equipment can affect **WHITESTAR SIGNATURE PRO** System.

WARNING: The use of accessories, transducers and cables other than those specified by AMO, may result in increased EMISSIONS or decreased IMMUNITY of the **WHITESTAR SIGNATURE PRO** System.

WARNING: The **WHITESTAR SIGNATURE PRO** System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the **WHITESTAR SIGNATURE PRO** System should be observed to verify normal operation in the configuration in which it will be used.

WARNING: Do not replace the Advanced Linear Pedal (ALP) battery when the pedal is attached to a power source.

WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the **WHITESTAR SIGNATURE PRO** System or shielding the location.

WARNING: WHITESTAR SIGNATURE PRO System may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

Additional information for Wireless Setup - Foot Pedal and Remote Control in the **WHITESTAR SIGNATURE PRO** System Manual NGPZ370500 Chapter 6.

Note: If you have problems pairing the Advanced Control Pedal (ACP) and the remote control, remove any other BLUETOOTH devices from the area. Multiple BLUETOOTH devices can affect the pairing process.

The Electromagnetic Information is in addition to the specifications in:

- **WHITESTAR SIGNATURE PRO** Operators Manual NGPZ370500 Chapter 10.

Electromagnetic Information

Table 1 – Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The **WHITESTAR SIGNATURE PRO** System is intended for use in the electromagnetic environment specified below. The customer or the user of the **WHITESTAR SIGNATURE PRO** System should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The **WHITESTAR SIGNATURE PRO** System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions	Complies	
The **WHITESTAR SIGNATURE PRO** System 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.		

Table 2 – Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The **WHITESTAR SIGNATURE PRO** System is intended for use in the electromagnetic environment specified below. The customer or the user of the **WHITESTAR SIGNATURE PRO** System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
ElectroSurge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% *U*T (>95% dip in *U*T) for 0,5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	<5% *U*T (>95% dip in *U*T) for 0,5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **WHITESTAR SIGNATURE PRO** System requires continued operation during power mains interruptions, it is recommended that the **WHITESTAR SIGNATURE PRO** System be powered from an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: *U*T is the a.c. mains voltage prior to application of the test level.			

Table 3 – Electromagnetic Immunity

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration - electromagnetic immunity</th></tr>
<tr><td colspan="4">The WHITESTAR SIGNATURE PRO System is intended for use in the electromagnetic environment specified below. The customer or the user of the WHITESTAR SIGNATURE PRO System should assure that it is used in such an environment</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td colspan="3"></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the WHITESTAR SIGNATURE PRO System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz

3 V/m
80 MHz to 2,5 GHz</td><td>3 Vrms

3 V/m</td><td>Recommended separation distance:
$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 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:

  </td></tr>
<tr><td colspan="4">Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity
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 **WHITESTAR SIGNATURE PRO** System is used exceeds the applicable RF compliance level above, the **WHITESTAR SIGNATURE PRO** System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **WHITESTAR SIGNATURE PRO** System. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 4 – Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the WHITESTAR SIGNATURE PRO System

The **WHITESTAR SIGNATURE PRO** System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **WHITESTAR SIGNATURE PRO** System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **WHITESTAR SIGNATURE PRO** System 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	5.7	7.4
100	12	12	23

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

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

System Cables

Table 5 – System Cables

Manufacturer	Manufacturer Part Number	Description	Maximum Length
AMO	2410-0049-L	Power cord, hospital grade, 20 ft., 6.1 meters	6.1 meter
AMO	0100-0055	Cable Assy, **WHITESTAR** Series Foot Pedal	3.7 meter
AMO	0100-6303	Cable Assy, Advanced Linear Foot Pedal to Console, Signature	3.7 meter
AMO	690697	**WHITESTAR** Phaco Handpiece, Coaxial	2.2 meter
AMO	690880	**ELLIPS FX** Phaco Handpiece	2.2 meter
AMO	SCP680600	Diathermy Cord	3.6 meter

RF Wireless Technology

Table 6 – RF Wireless Technology Used on the WHITESTAR SIGNATURE PRO System

Devices	RF Wireless Technology	Part Number	Operating Frequencies	Operating Distances	Industry Standard	Device System Wireless Functions, Capabilities, and Limitations
NGP680703 **WHITESTAR SIGNATURE PRO** Advanced Linear Pedal (ALP)*	BLUETOOTH Low Energy (two individual chips)	Texas Instruments CC2541F256RHAT	2.402 to 2.480 GHz, Adaptive Frequency Hopping GFSK (Gaussian Frequency-Shift Keying) over 37 Channels 2 MHz apart, 3 advertising Channels	Class 2 - 3 meters	BLUETOOTH Specification version 4.0 FCC CFR47, Part 15, sections 15.205, 15.209, 15.247 and 1.249	ALP Wireless Technology: Wirelessly and uniquely connects the ALP to the console to facilitate full functional control of the **WHITESTAR SIGNATURE PRO** System the same as if connected by cord. Function is limited to a 3 meter range. The ALP is a BLUETOOTH 4.0 (BLUETOOTH Low Energy) device that utilizes two TI CC2541 chips that communicates with the console through a transceiver that also utilizes two CC2541 chips. Functional ability: Consists of four programmable switches and a treadle that allows the operator to activate different functionalities at its corresponding pitch zone. Limitations during device operation: The device must be used within the specified operating range.

Devices	**RF Wireless Technology**	**Part Number**	**Operating Frequencies**	**Operating Distances**	**Industry Standard**	**Device System Wireless Functions, Capabilities, and Limitations**
NGP680701 **WHITESTAR SIGNATURE** ACP* and NGP680137 **WHITESTAR SIGNATURE PRO** Remote Control*	BLUETOOTH 2.0 (three individual chips, two for foot pedal, one for remote)	Texas Instruments LMX9830SM/ NOPB	2.402 to 2.480 GHz, Adaptive Frequency Hopping over 79 Channels, 1 MHz Apart	Class 2 - 3 meters	BLUETOOTH Specification version 2.0 + EDR FCC CFR47, Part 15, Sections 15.205, 15.209, 15.247 and 15.249	ACP Wireless Technology: Wirelessly and uniquely connects the ACP to the console to facilitate full functional control of the **WHITESTAR SIGNATURE PRO** System the same as if connected by cord. Function is limited to a 3 meter range. The ACP is a BLUETOOTH 2.0 device that utilizes two TI LMX9838 BLUETOOTH modules, which communicate with the console through a wireless transceiver that utilizes two TI LMX9830 BLUETOOTH modules. Functional ability: The ACP consists of several linear controls and digital switches to activate different functionalities at its corresponding pitch zone. Limitations during device operation: The device must be used within the specified operating range. Remote Control Wireless Technology: Wirelessly and uniquely connects the Remote Control to the console to navigate the GUI display. Function is limited to a 3 meter range.

Devices	RF Wireless Technology	Part Number	Operating Frequencies	Operating Distances	Industry Standard	Device System Wireless Functions, Capabilities, and Limitations
						The remote control is powered with an internal rechargeable NiMH battery, and has a BLUETOOTH 2.0 device that utilizes a TI LMX9830 BLUETOOTH module for its RF communication. It communicates with the system via a BLUETOOTH dongle residing in the system, which also utilizes a LMX9830 BLUETOOTH module. The remote control is an accessory that provides an alternative method for the operator to navigate through the different surgical modes, set various parameters, and perform IV pole height adjustment. Functional ability: The Remote Control consists of 12 buttons with their functionality described below: • IV Pole Up/Down: IV pole height adjustment. • Mode: for operator to select preprogrammed surgeon mode. • Navigator Up, Down, Left, Right, and Enter: navigate to access different functional icons on the screen within the surgical mode. • Up, Down, Enter: for operator to navigate to desired surgical mode. • Back-light: for operator to turn on Remote control back-light. Limitations during device operation: The device must be used within the specified operating range.

Devices	RF Wireless Technology	Part Number	Operating Frequencies	Operating Distances	Industry Standard	Device System Wireless Functions, Capabilities, and Limitations
NGP680301 **WHITESTAR SIGNATURE PRO** Console*	Wireless PCIe-M Card 802.11b/g/n	Advantech EWM-W142H01E	2.4 to 2.483 GHz, DSSS and OFDM modulation over 16 Channels 5MHz apart	Up to 3 meters	IEEE 802.11N-2009	Console Wireless Technology: The **WHITESTAR SIGNATURE PRO** Phacoemulsification System console downloads surgery case data via Wi-Fi to iPad for formatting/ printing/ presentation. The system has a Wi-Fi adapter that allows the surgical data to be downloaded to an iPad with our proprietary application, using IEEE 802.11 b/g/n standard Functional ability: it provides the operator with an ability to download data from the system to an iPad. Please note that the console does not store any patient information. The iPad connection to the system is password-protected and data flow is unidirectional from the console to the iPad. Limitations during device operation: The device must be used within the specified operating range.

* All devices are on the 2.4 GHz ISM band.

Table 7 – Wireless Technologies Used for Each of the Wireless Devices

Devices	RF Wireless Technology	Operating Distances	Quality of Service and Security	Device System Wireless Function, Capabilities, and Limitations
NGP680703 **WHITESTAR SIGNATURE PRO** Advanced Linear Pedal (ALP)*	BLUETOOTH Low Energy (two individual chips)	Class 2 - 3 meters	In addition to the inherent data integrity by using the BLUETOOTH technology, the system design also incorporated redundant BLUETOOTH channels (2 channels) to further improve the quality of service for this wireless device, and reduce the chance of losing wireless connection between the foot pedal and the console. The wireless communication is secured by BLUETOOTH encrypted data technology.	ALP Wireless Technology: Wirelessly and uniquely connects the ALP to the console to facilitate full functional control of the **WHITESTAR SIGNATURE PRO** System the same as if connected by cord. Function is limited to a 3 meter range. The ALP is a BLUETOOTH 4.0 (BLUETOOTH Low Energy) device that utilizes two TI CC2541 chips that communicates with the console through a transceiver that also utilizes two CC2541 chips. Functional ability: Consists of four programmable switches and a treadle that allows the operator to activate different functionalities at its corresponding pitch zone. Limitations during device operation: The device must be used within the specified operating range. .
NGP680701 **WHITESTAR SIGNATURE** Advanced Control Pedal (ACP)*	BLUETOOTH 2.0 (two individual chips)	Class 2 - 3 meters	In addition to the inherent data integrity by using the BLUETOOTH technology, the system design also incorporated redundant BLUETOOTH channels (2 channels) to further improve the quality of service for this wireless device, and reduce the chance of losing wireless connection between the foot pedal and the console. The wireless communication is secured by BLUETOOTH encrypted data technology.	ACP Wireless Technology: Wirelessly and uniquely connects the ACP to the console to facilitate full functional control of the **WHITESTAR SIGNATURE PRO** System the same as if connected by cord. Function is limited to a 3 meter range. The ACP is a BLUETOOTH 2.0 device that utilizes two TI LMX9838 BLUETOOTH modules, which communicate with the console through a wireless transceiver that utilizes two TI LMX9830 BLUETOOTH modules. Functional ability: The ACP consists of several linear control and digital switches to activate different functionalities at its corresponding pitch zone. Limitations during device operation: The device must be used within the specified operating range.

Devices	RF Wireless Technology	Operating Distances	Quality of Service and Security	Device System Wireless Function, Capabilities, and Limitations
NGP680137 **WHITESTAR SIGNATURE PRO** Remote Control*	BLUETOOTH 2.0 (one chip)	Class 2 - 3 meters	The quality of service is ensured by the BLUETOOTH technology. The **WHITESTAR SIGNATURE PRO** System uses the touchscreen as the primary user interface device. In the rare event of losing communication between the remote control and the console, the user can continue to operate all system functions by using the touchscreen. The wireless communication is secured by BLUETOOTH encrypted data technology.	Remote Control Wireless Technology: Wirelessly and uniquely connects the Remote Control to the console to navigate the GUI display. Function is limited to a 3 meter range. The remote control is powered with an internal rechargeable NiMH battery, and has a BLUETOOTH 2.0 device that utilizes a TI LMX9830 BLUETOOTH module for its RF communication. It communicates with the system via a BLUETOOTH dongle residing in the system, which also utilizes a LMX9830 BLUETOOTH module. The remote control is an accessory that provides an alternative method for the operator to navigate through the different surgical modes, set various parameters, and perform IV pole height adjustment. Functional ability: The Remote Control consists of 12 buttons with their functionality described below: • IV Pole Up/Down: IV pole height adjustment. • Mode: for operator to select preprogrammed surgeon mode. • Navigator Up, Down, Left, Right, and Enter: navigate to access different functional icons on the screen within the surgical mode. • Up, Down, Enter: for operator to navigate to desired surgical mode. • Back-light: for operator to turn on Remote control back-light. Limitations during device operation: The device must be used within the specified operating range.

Devices	RF Wireless Technology	Operating Distances	Quality of Service and Security	Device System Wireless Function, Capabilities, and Limitations
NGP680301 **WHITESTAR SIGNATURE PRO** Console*	Wireless PCIe-M Card 802.11b/g/n	Up to 3 meters	The quality of service is ensured by the Wi-Fi technology.RO Downloading data from the **WHITESTAR SIGNATURE PRO** System to the iPad application does not interfere with system surgical functions. In the rare event of losing communication between the iPad and the console while downloading data, the application will notify the user to retry. The wireless communication is secured by Wi-Fi connection password.	Console Wireless Technology: The **WHITESTAR SIGNATURE PRO** Phacoemulsification System console downloads surgery case data via Wi-Fi to iPad for formatting/ printing/ presentation. The system has a Wi-Fi adapter that allows the surgical data to be downloaded to an iPad with our proprietary application, using IEEE 802.11 b/g/n standard Functional ability: The Wi-Fi adapter provides the operator with an ability to download data from the system to an iPad. Please note that the console does not store any patient information. The iPad connection to the system is password-protected and data flow is unidirectional from the console to the iPad. Limitations during device operation: The device must be used within the specified operating range.

* All devices are on the 2.4 GHz ISM band.