Wi-Box™

Instructions for Use

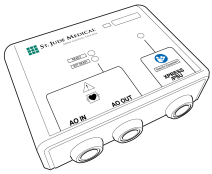
St. Jude Medical
More control. Less risk.

ENGLISH

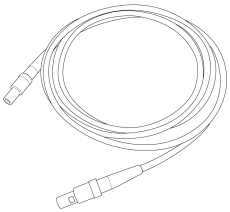
1. PRODUCT NAME
Wi-Box™

2. CONTENT

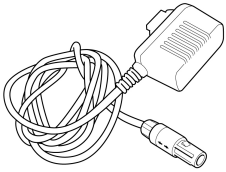
Wi-Box



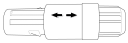
Wi-Box Xpress Cable
(Ordered separately.)



Wi-Box External Power Supply
(Ordered separately.)



Wi-Box Excitation plug
(Ordered separately.)



3. DESCRIPTION
Wi-Box is used for measurement of pressure from an external connected pressure transducer.

It has an eavesdropping function such that a hemodynamic recording system can be directly connected to the pressure transducer at the same time as Wi-Box measures the pressure and transmits it on a specific radio interface.

An isolated interface provides the measured pressure as an analog output signal.

4. INDICATION FOR USE
Wi-Box is indicated to condition and transmit a physiological signal via radiofrequency.

5. GENERAL WARNINGS
Wireless transmitter and RadiAnalyzer™ Xpress pressure output ports are not designed nor intended for vital signs monitoring.

Modification of this equipment is not allowed.

6. GENERAL PRECAUTIONS

Federal (USA) law restricts distribution and sales of Wi-Box to sale by or on the order of a physician.

Handle Wi-Box in accordance with medical practice and applicable local, state and federal laws and regulations.

Do not use Wi-Box if it has been subject to damage.

If Wi-Box has been subject to accidental wetting, wipe off and perform leakage current measurement and functional test.

Software upgrade shall not be performed during a clinical procedure.

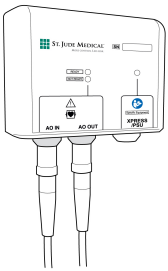
7. INSTALLATION

7.1 Normal Operation

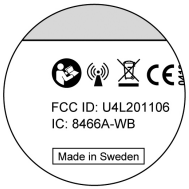
NOTE: Wi-Box needs to be installed in a place that ensures adequate radio transmission with receiving unit.
Radio range is reduced by objects and walls, keep Wi-Box and receiving unit in line of sight wherever possible.

NOTE: High frequency surgical equipment shall not be used in the close proximity of the device since this could influence the performance of the device.

a. Mount Wi-Box vertically on or close to the cathlab table using the enclosed mounting details. The cable connectors shall be facing downward to minimize stress on cabling and connectors and to protect the unit from ingression of fluids.



NOTE: After mounting, Wi-Box is securely fastened and may be very difficult to remove. If Wi-Box needs to be repositioned, be careful not to damage Wi-Box by bending.



CAUTION: The used pressure transducer must have excitation impedance larger than 270 Ω.

CAUTION: All equipment connected to AO OUT must be CF classified and defibrillation proof. Failure to comply to these requirements will void the CF classification and defibrillation protection on AO IN.

CAUTION: The person performing the connections of Wi-Box is responsible for forming a medical electrical system and the total system and patient leakage currents thereof.

NOTE: The test below shall be performed when changing type of blood pressure transducer.

b. Connect the AO OUT connector on Wi-Box to a blood pressure channel on the ANSI/AAMI-BP22 compatible hemodynamic recording system using the corresponding St. Jude Medical monitor cable.

c. Connect the blood pressure transducer to the AO IN using the corresponding St. Jude Medical adapter cable. For appropriate handling of the external pressure transducer (calibration, removing possible entrapped air, sterility, time limit before use, warm-up time or volume displacement) refer to its operating instructions.

NOTE: Transducers marked for single-use may not be reused.

d. Make sure that the blood pressure channel is powered.

e. To verify correct pressure, apply a known pressure on the blood pressure transducer using a blood pressure simulator.

If the green READY light is lit and the AO pressure is correctly displayed on the hemodynamic recording system, Wi-Box is ready to use.

If the red NOT READY light is lit or the AO pressure is incorrectly displayed on the hemodynamic recording system, Wi-Box External Power supply needs to be connected to provide adequate power to the unit (see Wi-Box External Power Supply below).

If the red NOT READY light is blinking, internal fail has occurred.

Contact your St. Jude Medical representative.

7.2 Wi-Box External Power Supply (for low power hemodynamic recording systems)

CAUTION: The only approved power supply to connect is C12785/ FW7333SM.

CAUTION: The power supply shall be mounted at a location where it is protected from fluids.

CAUTION: Mains power is disconnected by removing Wi-Box External Power Supply from the wall socket. Place Wi-Box External Power Supply such that it easily can be removed from the wall socket.

a. Connect Wi-Box External Power Supply cable to the PSU connector on Wi-Box.

b. Connect Wi-Box External Power Supply to a free wall socket using the appropriate wall socket adapter.
The white light on Wi-Box shall now be lit indicating that Wi-Box is powered.

c. To verify correct pressure, apply a known pressure on the blood pressure transducer using a blood pressure simulator.
If the green READY light is lit and the AO pressure is correctly displayed on the hemodynamic recording system, Wi-Box is ready to use.

If the red NOT READY light still is lit, an internal error has occurred. Try to reconnect Wi-Box External Power Supply. If the problem remains contact your St. Jude Medical representative. If the AO pressure is incorrectly displayed on the hemodynamic recording system, do not use the Wi-Box.

Contact St. Jude Medical representative.

d. If Wi-Box is intended to be used stand-alone without hemodynamic recording system, Wi-Box Excitation Plug shall be inserted in the AO OUT connector.

7.3 Use with RadiAnalyzer Xpress

NOTE: Using Wi-Box in combination with RadiAnalyzer Xpress affects the performance of AO measurements in RadiAnalyzer Xpress, see 13 Technical specifications, Performance below.

NOTE: Wi-Box cannot be used together with RadiAnalyzer Xpress if connected to a low power hemodynamic recording system and a Wi-Box External power supply is needed.

a. Connect Xpress connector on Wi-Box to the AO IN connector on RadiAnalyzer Xpress using Wi-Box Xpress cable.

b. Open the transducer to air and Zero AO on the RadiAnalyzer Xpress.
   The white light on Wi-Box shall now be lit indicating that Wi-Box is powered.

   The AO pressure presented on the hemodynamic recording system shall be equal to the AO pressure presented on RadiAnalyzer Xpress.

8. DIRECTION FOR USE

WARNING: Do not touch AO IN or AO OUT connectors during a clinical examination.

a. Establish a radio connection between Wi-Box and the receiving unit via the user interface. See instructions for use for receiving unit.
   AO pressure shall now be visible for use on the user interface and hemodynamic recording system.

9. DISPOSAL

Dispose Wi-Box in accordance with medical practice and applicable local, state and federal laws and regulations.

10. CLEANING AND MAINTENANCE

Wi-Box shall only be cleaned with regular cleaning agents.

CAUTION: Do not immerse in liquid.

Do not use Wi-Box if it has been immersed in liquid.

Perform leakage current measurement on Wi-Box yearly. See Classifications below for information.

CAUTION: Perform leakage current measurement and functional test on Wi-Box if it has been subject to mechanical damage.

CAUTION: Do not sterilize Wi-Box. Do not use Wi-Box if it has been subject to sterilization.

Software upgrade shall be performed by St. Jude Medical representative.

11. TECHNICAL SPECIFICATIONS

Electrical interface compatibility

ANSI/AAMI BP22 – 1994	
Power Input:	2.4 to 8 VDC (for 2.4 to 4 VDC, use Wi-Box External Power Supply)
Transducer impedance:	>270 Ω
Wi-Box External Power Supply input:	100 to 240 VAC, 50-60 Hz

Performance

Accuracy:	<±1 mmHg or ±1% of reading whichever greatest
Resolution:	≤0.2 mmHg

Performance (cont'd.)

Bandwidth:	0-50 Hz
Xpress output bandwidth:	0-25 Hz

Physical

Weight:	130 g
Dimensions:	108 x 83 x 33 mm
Material:	Housing of PC.

Radio

Frequency range:	2.4000-2.4835 GHz (ISM-band)
Type:	Frequency Hopping Spread Spectrum
Range:	0 - 4 m

Environmental conditions

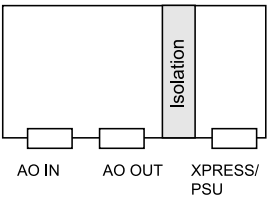
Temperature:	10-40°C
Air humidity:	30-75%
Ambient pressure:	525-795 mmHg

Transport and storage

Transportation temperature:	-20°C to +70°C
Air humidity:	10%-95%
Ambient pressure:	375- 795 mmHg
Store at room temperature in a dry place.	

Classifications

Wi-Box External Power Supply	Electrical safety Class II
AO IN, AO OUT	Galvanically connected together. CF, Defibrillation Proof
EXPRESS/PSU	CF, Defibrillation Proof



12. COMPLIANCE WITH REGULATORY REQUIREMENTS

Hereby, St. Jude Medical Systems AB, declares that the Wi-Box is in compliance with the essential requirements and other relevant provisions of Medical Device Directive (93/42/EEC), Radio and Telecommunications Terminal Directive (1999/5/EC) and Quality System Regulation (US).

This device complies with part 15 of the FCC Rules and RSS-210 of the IC 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.

Guidance and manufacturer's declaration – electromagnetic emissions

<table>
<tr><td colspan="3">Wi-Box is intended for use in the electromagnetic environment specified below. The customer or the user of Wi-Box should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>Wi-Box 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">Wi-Box is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity

Wi-Box is intended for use in the electromagnetic environment specified below. The customer or the user of Wi-Box 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 n/a for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode n/a for 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 Wi-Box requires continued operation during power mains interruptions, it is recommended that Wi-Box be powered from an uninterruptible power supply or battery.
Power frequency (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.

Guidance and manufacturer's declaration – electromagnetic immunity

Wi-Box is intended for use in the electromagnetic environment specified below. The customer or the user of Wi-Box should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Comp-liance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of Wi-Box, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance $d = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2 \sqrt{P}$ 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,[1] should be less than the compliance level in each frequency range.[2] Interference may occur in the vicinity of equipment marked with the following symbol. 

NOTE: At 80MHz and 800 MHz, the higher frequency range applies.

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

1) 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 Wi-Box is used exceeds the applicable RF compliance level above, Wi-Box should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Wi-Box.

2) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and Wi-Box

Wi-Box is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Wi-Box can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Wi-Box 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	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
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.

13. WARRANTY DISCLAIMER

Although Wi-Box, hereafter referred to as "product", have been manufactured under carefully controlled conditions, St. Jude Medical Systems AB has no control over the conditions under which the product is used. St. Jude Medical Systems AB, therefore disclaims all warranties, both express and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. St. Jude Medical Systems AB shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise no person has any authority to bind St. Jude Medical Systems AB to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

St. Jude Medical Systems AB
Palmbladsgatan 10
Box 6350, 751 35 Uppsala, SWEDEN
+46 (0) 18 16 10 00
www.sjm.com

14. EXPLANATION OF SYMBOLS

	Follow instructions for use.
	Equipment includes RF transmitter.
	Electronic waste bin. Disposal according to WEEE.
	Complies with Medical Device Directive 93/42/EEC and Radio Telecommunication Terminal Equipment Directive 1999/5/EC.
FCC ID:U4L 201106	FCC identifier for the transmitter.
IC-8466A-WB	Industry Canada RF.
	cETLus valid for Canada and US. Conforms to UL 60601-1.Certified to CAN/CSA STD C22.2 NO 601.1 –M90.
SN	Serial number.
READY	Unit ready for use.
NOT READY	Unit not ready for use.
	Caution, (Attention, consult accompanying documents).
	Defibrillation-proof Type CF equipment.
Specific Equipment	Only connect specified power supply equipment.
	Manufacturer.
RX only	Caution: Federal law restricts this device to sale by or on the order of a physician.
REF	Product number.
QTY	Quantity.
LOT	Lot number.
	Consult instructions for use.
	Date of manufacture.
Made in Sweden	Made in Sweden.
INSTRUCTIONS FOR USE	Instructions for use.

St. Jude Medical is focused on reducing risk by continuously finding ways to put more control into the hands of those who save and enhance lives.

ATRIAL FIBRILLATION CARDIAC RHYTM MANGEMENT CARDIOVASCULAR NEUROMODULATION

Global Headquarters
One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

Cardiovascular Division
177 East County Road B
St. Paul, Minnesota 55117
USA
+1 651 756 4470
+1 651 756 4466 Fax

St. Jude Medical Systems AB
Box 6350
SE-751 35 Uppsala
Sweden
+46 18 161000
+46 18 161099 Fax

U.S. Division
6300 Bee Cave Road
Building Two, Suite 100
Austin, TX 78746
USA
+1 512 732 7400
+1 512 732 2418 Fax

St. Jude Medical Coordination Center BVBA
The Corporate Village
Avenue Da Vinci laan 11 Box F1
B-1935 Zaventem
Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Japan Co., Ltd.
Shiodome City Center 15F
1–5–2, Higashi-Shinbashi,
Minato-ku
Tokyo 105–7115
Japan
+81 3 6255 6370
+81 3 6255 6371 Fax

St. Jude Medical (Hong Kong) Ltd.
Suite 1608, 16/F Exchange Tower
33 Wang Chiu Road
Kowloon Bay, Kowloon
Hong Kong SAR
+852 2996 7688
+852 2956 0622 Fax

St. Jude Medical Brasil Ltda.
Rua Frei Caneca, 1380
7º ao 9º andares
01307-002 - São Paulo (SP)
Brazil
+55 11 5080 5400
+55 11 5080 5423 Fax

SJMprofessional.com

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

RX only

CE 0413

22023 Rev. A 2011-06