Operational Description

1.0 Operating Principle

The principle of neuromuscular electrical stimulation (NMES) is to stimulate nerve fibers by means of electrical impulses transmitted by electrodes. The electrical pulses generated by the Compex® Wireless USA stimulate motor nerves to stimulate a muscular response. The quantity and benefits obtained depend on the stimulation parameters.

In voluntary activity, the order for muscular work comes from the brain, which sends a command to the nerve fibers in the form of an electrical signal. This signal is then transmitted to the muscular fibers, which contract. The principle of NMES accurately reproduces the process that occurs during a voluntary contraction. The Compex® Wireless USA electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, and total session duration), different types of muscle work can be imposed on the stimulated muscles. The Compex® Wireless USA may therefore be considered a technique of muscle training.

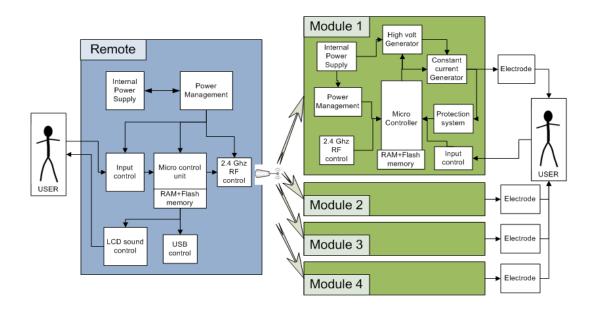
2.0 System Description

The Compex® Wireless USA system consists of the following components.

- A. 1 Remote Control
- B. 4 Stimulation Modules
- C. 1 Docking Station
- D. 1 Charger
- E. 2 Bags of Small Electrodes (5x5 cm; 2x2 inch)
- F. 2 Bags of Large Electrodes (5x10 cm; 2x4 inch 2 snap connections)
- G. 2 Bags of Large Electrodes (5x10 cm; 2x4 inch -1 snap connection)
- H. 1 Carrying case
- I. 1 Instructions for Use
- J. 1 Quick Start Guide

The remote control, stimulation modules, and electrodes are stored and shipped within the docking station. The relationship between the components and the user are illustrated in Figure 2.0 below.

Figure 2.0 User/Device Diagram



3.0 Remote Control

Figure 3.0 Compex® Wireless USA Remote Control



A – On/Off button (press briefly to switch on and press

And hold longer than 2 seconds to switch off)

- B-4 Multi-functions buttons:
- a.) Functions associated with the icons shown on the screen (e.g. info, main menu, electrode placement, etc.)
- b.) Selection of stimulation channel to increase or decrease the stimulation energy level
- C Multi-directional pad (up-down-left-right) to select items.
- D Validation button (to accept selected functions)
- E Port for docking station connector

3.1 Remote Control General Description

The remote control is the interface between the stimulation modules and the user. It sends and receives information to and from the modules via a wireless network. The remote control allows the user to navigate through the user interface (UI), select stimulation program or objectives, set desired options and control the four (4) module intensities independently. The remote control is powered by a rechargeable battery.

4.0 Stimulation Modules

The Compex® Wireless USA stimulation module set is composed of 4 independent stimulation modules that are controlled via the remote control by a wireless connection. Each module is composed of two "pods" (1 battery "pod" and one stimulation "pod") linked by an electrical connection (cable). Two proprietary Compex standard snap gel electrodes are also needed to connect each "pod" to the body. The modules are powered by a Lithium Polymer (LiPo) rechargeable $3.7[V] / \ge 450$ [mAh] battery.

Figure 4.0 Stimulation Module

One stimulation module is made of 2 "pods" with one electrical connection.

MODULE

A On/Off button (press briefly to switch on but press and hold longer than 2 seconds to switch off)

- · LED blinking green: ready for use
- LED blinking yellow: stimulating

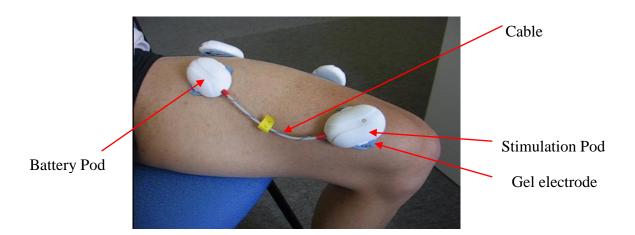
B Groove to wind up the cable



Figure 4.1 Stimulation Pod Bottom View



Figure 4.2 Electrical impulses travel from one "pod" to the skin through gel electrodes. The loop is closed by the electrical connection between the "pods".



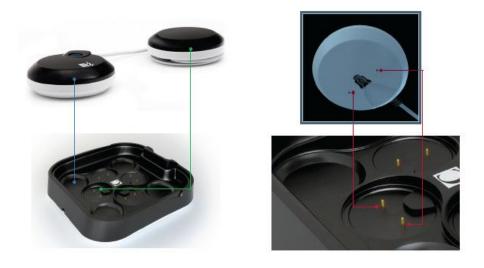
5.0 Radio Frequency (RF) Communication

The remote control and modules communicate through a wireless network. Networks from different remote controls do not interfere with each other.

Broadcast range:

- Up to 2 meters continuous transmission in a room
- Up to 1 meter continuous transmission in a multi-sport gym (remote control and module shall be used in line of sight)
- The Compex® Wireless USA is not intended to be used outdoors

Figure 5.0 Module Charge Connections



5.1 Stimulation Power Output Characteristics

- Square, symmetrical, compensated waveforms, current controlled
- Maximum current of an impulse: 120 mA under a charge (body load)
- Impulse width: from 50 to 400 [us]
- Maximum Energy output of: $120^2 = 5760000$ [mA2µs]
- Impulse frequency: from 1 to 150 Hz
- In any case, the maximum power output is 1 Watt

5.2 Performance around the Maximum Power Limit

The limitation around the maximum power shall be achieved by limiting the current intensity. The power shall increase normally up to the limit and then stop.

Information/feedback given to the user: When the user reaches a limit, the intensity shall stop increasing and a visual feedback (icon, text, symbol on the remote) shall be given.

Figure 5.1 Compex® Wireless USA Docking Station

DOCKING STATION A Connector for charging the remote control B Notch for opening the top of the docking station C Slot for positioning the modules to be recharged

D Socket for the AC adaptor





Figure 5.2 Docking Station During Charge Function



6.0 Compex® Wireless USA -Wireless Configuration

6.1 General Information

The wireless protocol of the Compex® Wireless USA Device is a proprietary design of a Radio-Frequency protocol operating the 2.4 GHz ISM band. It is used to:

- Send particular information from remote control to stimulation modules like stimulation settings (start/stop/increase intensity, decrease intensity, etc...)
- Send particular information from stimulation modules to remote control, like current stimulation level and stimulation module subsystem status
- Transfer binary data to stimulation modules (from 100[B] to more than 100 [kB])
- Allow synchronization (clock sharing) from stimulation modules to remote control clocks.

The wireless protocol is a proprietary design of a star network of up to 8 slaves for 1 master. Bidirectional communications are allowed in this topology between:

- The master which is the remote control
- The slave(s) which is the stimulation module (1 to 8 slaves per 1 master).

The Compex® Wireless USA product doesn't make use of more than 4 slaves. Each of the slaves remembers the master with which they are paired, and the master remembers which slaves can be paired with him.

Each of the manufactured Compex® Wireless USA devices (master or slave) has a unique identifier, which allows coexistence of several Compex Wireless products in the same RF area.

The protocol is using 6 RF channels in the 2.4 GHz band. The master will hop every 1.5 [ms] to another RF channel. The hopping sequence is pseudo-randomly generated from the master's unique identifier.

6.2 Summarized Wireless Protocol Characteristics

- EIRP: measured max -6.2 dBm (0 dBm configured as theorical maximum output power).
- Network topology: star
- Maximum network size: 1 master + 8 slaves
- Compex Wireless network size: 1 remote control + 4 stimulation modules
- Protocol type: proprietary, frequency hopping
- Frequency range: 2.4 GHz
- Duty cycle: < 5%
- Frequency modulation : GFSK (Gaussian Frequency Shift Keying)
- Frequency deviation: +/- 320 kHz

- Channel width: 2 MHz
- Channel occupation: 1.5ms, hopping sequence generated through master's network ID.
- Channel definition:
 - o Ch 1: 2403 MHz
 - o Ch 2: 2414 MHz
 - o Ch 3: 2423 MHz
 - o Ch 4: 2440 MHz
 - o Ch 5: 2461 MHz
 - o Ch 6: 2475 MHz
- Data rate : 2 Mbps
- Device identification: 32 bits, shared only with devices using the same wireless protocol (actually, only Compex® Wireless USA uses this wireless protocol)
- Data integrity checks: each data frame is protected by a 16[b] length CRC.

6.3 Wireless Protocol Design Information

At least every 500 [ms], the master will send "synchronization" frames, allowing slaves to compensated local clock drifts against master's clock. Synchronizations are repeated broadcasted to all the network members, sent twice per channel and once per RF channel. Between synchronization frames, the master will have a two-way communication with each of the slaves, allowing slave to send information to the master (polling).

Each communication is acknowledge, which will allow generating "feedbacks" on point to point communications:

- When the master sends an order to a slave, a feedback (positive or negative) will be given to the remote control in less than 50 [ms] (typical).
- When the slave sends an order to the master, a feedback will be given to the stimulation module only when the frame is sent to the remote control (can take time)

Finally, each of the slave and the master will monitor the other side presence:

- The slave will keep the simulation module informed about the duration from last master communication
- The master will keep the remote control informed about the network status, for example if a slave was out of range for more than maximum 500 [ms].

Both Stimulation modules and remote control can transmit up to 0 dBm EIRP. The network of 1 remote control and 4 stimulation module can operate indoor typically from 2-4 [m] and up to 10 [m]. The wireless network is not designed to operate outdoor.

Based on the monitoring feature of the wireless protocol, the stimulation module will stop stimulation if no contact was received from the remote control (out of range) for more than 500 [ms]. As opposite, the remote control will send a « stop order » to the other

stimulation modules if one stimulation module went out of range, or if it detected that a stimulation module stopped stimulation for any reason.

If other devices are operating on the 2.4 GHz ISM band (like 802.11, 802.15.1, other Compex Wireless Devices, etc...), the worst effect will be loosing of orders or acknowledge frames. And based on the monitoring feature, the stimulation will stop as a worst consequence.

During the 1.5 [ms] channel occupation, there is enough time reserve for 1 sending of the master, repeated once if lost, and 1 ACK including additional information from slave. The master can send up to 32 B, slave up to 14 B.

Note that the implementation of the wireless protocol is a software stack running on the top of a highly integrated transceiver which offers the following features (hardware implemented):

- Frame constitution and demodulation
- CRC generation and control
- ACK sending

6.4 Modes of Operation of the RF Wireless Emissions

The wireless protocol sends regularly "synchronization" frames (broadcasted to the network members) which allow slave to synchronize to master's clock.

Between two "synchronization frames", the wireless protocol allows "single point communications":

- The master sends communication to slaves in range, and potentially pairing ones
- The slave in range have the opportunity to add an payload together with the acknowledgement sent to the master
- If the master receives information from slave, it will send ACK to the slave.

6.5 Required Wireless Quality of Service

When the system is under stimulation, the remote control and all the stimulation modules shall have a bidirectional point-to-point communication more than once every 500 [ms]. In addition to this point-to-point communication, synchronization frame shall be sent every 500 [ms].

This minimal quality of service shall be satisfied with 2[m] range between stimulation modules and the remote control.

6.6 Required Security Measures

• **Data Integrity / Redundancy:** Data integrity checks are required in order to prevent wireless order to be interpreted from noise or other system operating on

the same RF channel / data rate (minimizes cross-talk). The implementation of the data integrity is made with a 16[b] CRC (cyclic redundancy check) protecting the content of data frame.

- **Target Identification:** Each wireless frame has a target ID coded on 32[b]. For broadcast frames, the target ID is the one of the master.
- **Acknowledgement:** Each point-to-point communication will be acknowledged in order to give feedback to the communication from an application level.
- Lost Packet / Out of Range Behavior Main Principle: If the quality of service is not sufficient (out of the range wireless members, or presence of perturbation), the security principles is:
 - Stimulation modules stops stimulation automatically when out of range from the remote control
 - Remote control stops the entire network stimulation when it detects one of its stimulation modules is out of range.

6.7 Coexistence with other Compex Wireless Devices

The wireless protocol is designed to allow coexistence with at least 3 other Compex Wireless Products, with no cross-talk between the 3 networks. Coexistence is assured through:

- Time Division Multiple Access (TDMA): data are transferred in encapsulated frame (with target identification and CRC). With a high air data rate, the time one Compex Wireless is transmitting power is pretty low. That means even if several Compex Wireless devices are present on the same RF channel, collisions may not necessarily occur.
- Frequency Division Multiple Access (FDMA): frequency hopping protocols over several RF channels, will reduce the probability of having several Compex Wireless Devices at the same time on the same RF channel.
- Hopping sequence generated through Remote Control ID (not the same between Compex® Wireless USA Devices), which means two Compex Wireless can collision on one RF channel, but they shouldn't collision to the same network channel after hopping.
- Unique Identifier assignment plan to guarantee no Compex Wireless will share the same identity and control members of another Compex wireless network.

6.8 Coexistence with Other 2.4 GHz Wireless Technologies

The Design principles against coexistence with other 2.4 GHz Wireless Technologies are:

• Compex® Wireless USA shall be used in an environment with other devices (medical and non-medical) operating on the 2.4 GHz band.

- Compex Wireless is conform to the 2.4 GHz ISM band regulations (EMI/EMC) thus shall not disturb other 2.4 GHz wireless products.
- The Compex Wireless product is working in the PAN (personal area network), which means the SNR ratio shall be always better than the one of a device located in other buildings.
- The RF channels of the Compex® Wireless USA can be all saturated by the addition of lots of other Wireless Products. But the principle is all the stimulation modules will stop stimulating if such situation occurs (failsafe).

6.9 General Requirements

Compex® Wireless USA protocol is design to coexist with other RF wireless products operating in the same RF band (2.4 GHz/ISM).

Well-known coexistence principles are setup to allow such coexistence:

- FDMA: Frequency Division Multiple Access. Compex® Wireless USA Protocol uses frequency hopping techniques and will hop every 1.5 [ms] to one of the 6 RF channels used in the 2.4 GHz band. With this strategy, Compex Wireless protocol is robust enough to operate even if one or more RF channel is permanently occupied by another transmitter.
- TDMA: Time Division Multiple Access. Compex Wireless Protocol only uses the RF channel during the transmission of data frames. With a low duty cycle, both Remote Control and stimulation modules are more in Receiving Mode than Transmitting Mode.
- Protocol: with a proprietary communication protocol cross-talk effects are minimized (acknowledged communication, unique identifier as frame target, etc.).

6.10 Specific Coexistence Need with Bluetooth / IEEE 802.15.1

The Compex® Wireless USA protocol is designed to coexist with Bluetooth (IEEE 802.11) network in the same range. Bluetooth and Compex® Wireless USA share all of the Compex® Wireless USA RF Channels. Bluetooth is based on adaptive frequency hopping spread spectrum, with hop every 625 [us]. It means:

- If the Compex Wireless introduces perturbation on Bluetooth Protocol, the Bluetooth protocol will ban the Compex® Wireless USA Frequency channels
- As Bluetooth hop every 625 [us], perturbation will be short enough for the Compex Wireless to detect the frame has been corrupted, repeat it and have the time to receive the ACK during the same 1.5 [ms] time slot.

6.11 Specific Coexistence Need with Wi-Fi / IEEE 802.11

The Compex® Wireless USA protocol is designed to share some channels with Wi-Fi (IEEE 802.11). Wi-Fi networks uses 13 channels of 22 MHz wide over the whole 2.4 GHz band. In the typical case, a single Wi-Fi network will share from 1 to 3 Compex Wireless RF Channels. That means 1 Wi-Fi network will be able to block the usage of up

to 3 Compex® Wireless USA RF channels, but the other Compex® Wireless USA RF channel won't be disturbed by this Wi-Fi network.

6.12 Claims for the Device Wireless Function

The Wireless technology is only active when the device is in standard mode. When in charge mode, stimulation modules shall be off, and remote control disables the RF part.

7.0 Wireless Security Measures Implemented on the Wireless Protocol

7.1 Data Integrity Checks on All Wireless Information Sent

All wireless information is protected by at least one CRC (additional for binary data transfer). As a result:

- Demodulating an understandable frame from noise has very low probability
- Demodulating an understandable frame from other Wireless System has also very low probability

7.2 Acknowledgement of All Security Related Commands

All the commands that are related to any security concerns are sent as single-target communication (repeated to each stimulation module). As a result:

- No cross-talk is possible with other Compex® Wireless USA devices
- Acknowledgement allows the system to remain safe even if the communication was not successful
- It also allows the system to take safe action if the communication was successful, but took too long.

7.3 Network Members Monitoring and Behavior

As defined in previous chapters, all Compex® Wireless USA device members are able to monitor if they are in range of their associated remote control or stimulation modules. Both remote control and stimulation module has a feature that will stop the stimulation output of the whole network if any member is out of range:

- The out of range member will stop stimulation autonomously
- The members in range will detect the out of range member and come to a safe state through the remote control

7.4 Reduced Function Set and Stimulation Start Process

Lots of intelligence is placed in the stimulation module, and the stimulation module handles most of the safety measures.

All the functions that have a stimulation start or intensity modification are under several controls, and those to gain a safe state are straight-forward.

- **Specific Stimulation Start Behavior:** To start a stimulation program, there is a specific command sequence to be received by the stimulation modules in order to authorize stimulation generation.
- **Specific Stimulation Stop Behavior:** To stop the stimulation (emergency stop), no specific frame shall be sent, because the bit containing the "emergency stop" information is transmitted in every RF frame (broadcast, single-order, answer, etc.). The emergency stop information is transferred:
 - o With a minimal of delay
 - Redundantly (both through synchronization frames and single-target frames)
- **Specific Intensity Modification Behavior:** When the stimulation module receives an order to change its output intensity, the differential value is controlled by the stimulation module. In this way, the stimulation module can't suddenly jump to an intensity level neither come to this level too quickly.

8.0 Evaluating Compex® Wireless USA Essential Performance for Coexistence in a Shared Environment

Because the Compex® Wireless USA has been tested for Electromagnetic Compatibility according to IEC 60601-1-2 (Refer to Appendices G and H), the remaining concerns to be evaluated are related to the performance of the Compex® Wireless USA System.

The essential performance requirements for the Compex® Wireless USA System are:

- 1) Continues stimulating according to the defined parameters, as long as Performance #2 is not invoked;
- 2) Stop stimulation when the RF wireless channels are saturated by activities of other devices or after any event intended to stop stimulation (stop button pressed, end of program, low battery, error, etc.)

Coexistence performance testing was conducted. Refer to Section 19, Performance Testing – Bench for the test plan and test results.

2.45 GHz High Gain SMD Chip Antenna

P/N 2450AT45A100

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General Specifications				
Part Number	2450AT45A100	Input Power	3W max. (CW)	
Frequency Range	2400 - 2500 Mhz	Impedance	50 Ω	
Operating Temp	-40°C to +125°C	Reel Quanity	1,000	

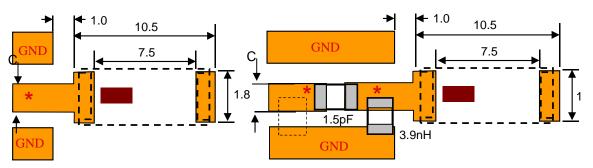
Me	Mechanical Specifications			Т	erminal Configuration
	In	mm	†	No.	Function
L	0.374 ± 0.008	9.50 ± 0.20	w l	1	Feeding Point
W	0.079 ± 0.008	2.00 ± 0.20	←	2	NC
Т	0.047 +.004/008	1.20 +0.1/-0.2	_		
а	0.020 ± 0.012	0.50 ± 0.30	→ ^a ←	ſ	
			<u></u>	2	1

Typical Electrical Specs for "Vertical Orientation" (T=25°C)				
Frequency Range	2400 - 2500 Mhz	Peak Gain	3.0 dBi typ. (XZ-V)	
Return Loss	9.5 dB min.	Average Gain	1.0 dBi typ. (XZ-V)	

Mounting Considerations 1: "Vertical Orientation"

Mount these devices with red mark facing up. Units: mm

* Line width should be designed to provide 50Ω impedance matching characteristics.



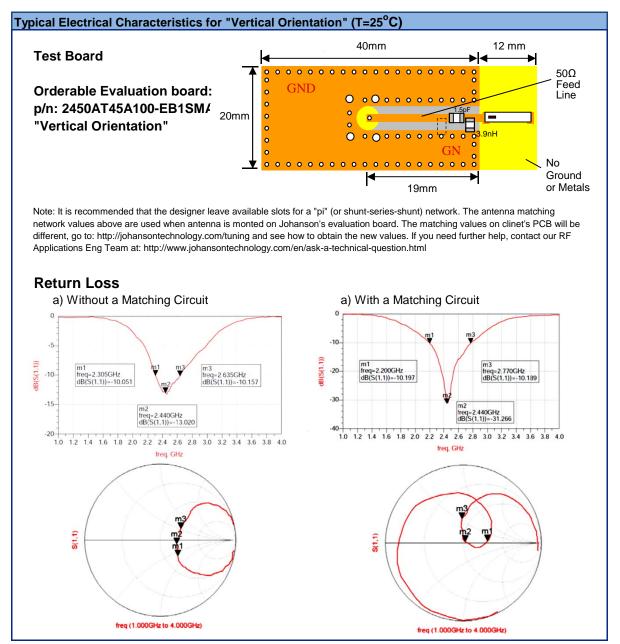
- a) Without Matching Circuit (moderate bandwidth)
- b) With Matching Circuit* (wide bandwidth)
 These matching circuit values only apply to Johanson's
 evluation board, they will be different on the client's PCB, see
 pages 2 and 10 for details.
- "C" Dimmension will depend on the width of the trace required for it to have a 50ohm characteristic impedance (i.e. coplanar waveguide theory)



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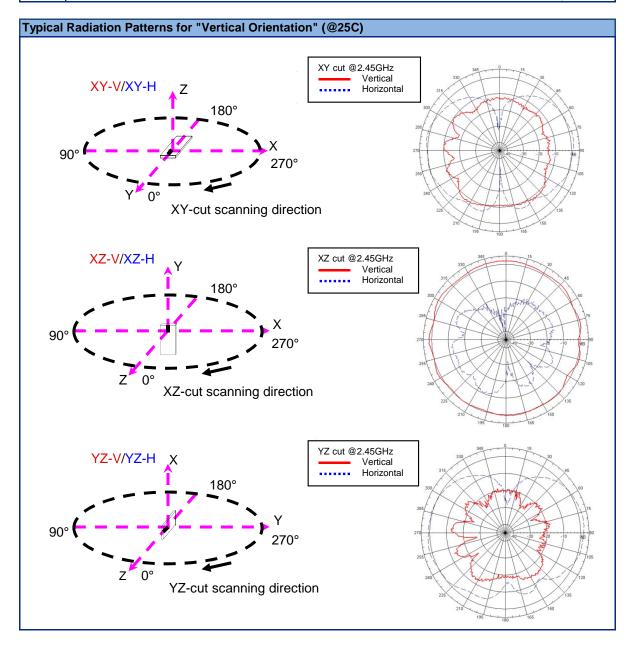




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P/N 2450AT45A100

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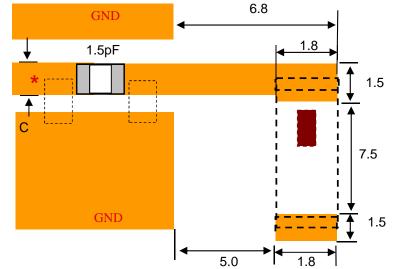
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Typical Electrical Specs for "Horizontal Orientation_1" (T=25°C)				
Frequency Range	2400 - 2500 Mhz	Peak Gain	1.5 dBi typ. (XZ-V)	
Return Loss	9.5 dB min.	Average Gain	0.0 dBi typ. (XZ-V)	

Mounting Considerations 2 - Horizontal Orientation_1

Mount these devices with brown mark facing up. Units: mm

*Line width should be designed to provide 50Ω impedance matching characteristics. Units in mm



EVB p/n: 2450AT45A100-EB2SMA Horizontal Orientation_1

"C" Dimmension will depend on the width of the trace required for it to have a 500hm characteristic impedance (i.e. coplanar waveguide theory)

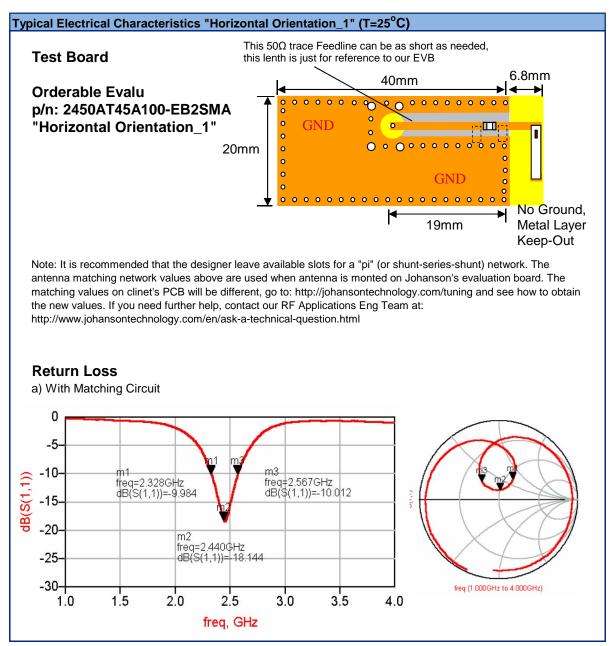


^{*}These matching circuit values only apply to Johanson's evluation board, they will be different on the client's PCB, see pages 5 and 10 for

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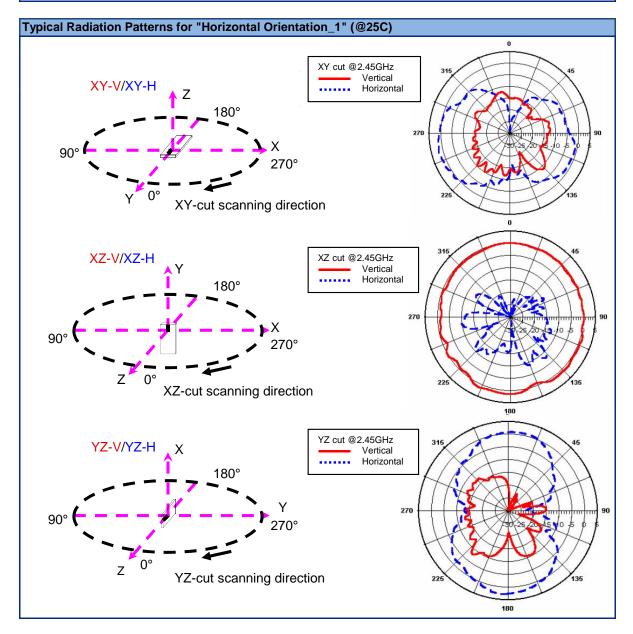




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Typical Electrical Specs for "Horizontal Orientation_2" (T=25°C)				
Frequency Range	2400 - 2500 Mhz	Average Gain	0.6 dBi typ. (XZ-V)	
Return Loss	9.5 dB min.	Peak Gain	1.3 dBi typ. (XZ-V)	

Mounting Considerations 3 - Horizontal Orientation_2

Mount these devices with brown mark facing up. Units: mm

* Line width should be designed to provide 50Ω impedance matching characteristics.

GND 0.5 10.5 7.5 1.8 Units in mm

EVB p/n: 2450AT45A100-EB2SMA Horizontal Orientation_2

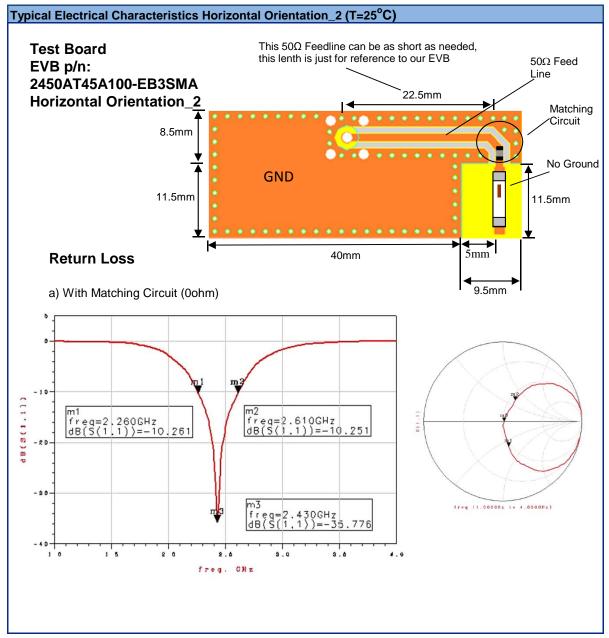
Note: It is recommended that the designer leave available slots for a "pi" (or shunt-series-shunt) network. The antenna matching network values above are used when antenna is monted on Johanson's evaluation board. The matching values on clinet's PCB will be different, go to: http://johansontechnology.com/tuning and see how to obtain the new values. If you need further help, contact our RF Applications Eng Team at: http://www.johansontechnology.com/en/ask-a-technical-question.html



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P/N 2450AT45A100

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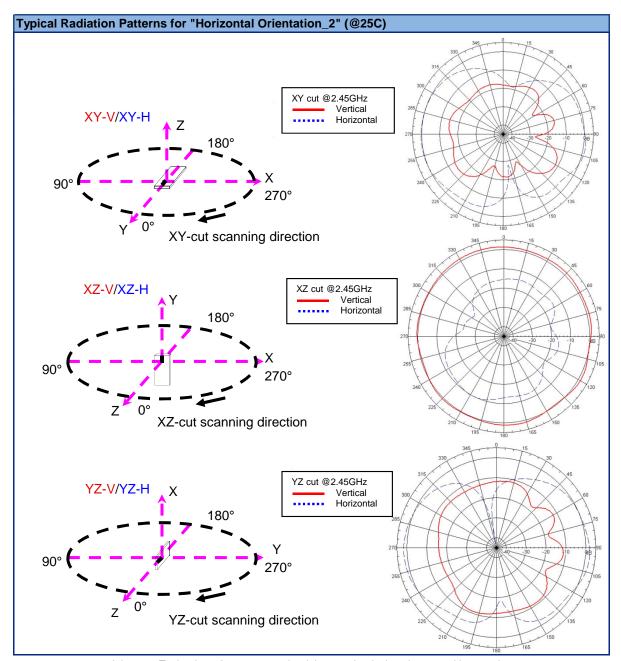




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Part Number Explanation					
		Bulk (loose pieces)	Suffix = S	Eg. 2450AT45A100S	
Pool	Packaging Style*	T&R	Suffix = E	Eg. 2450AT45A100E	
	Packaging Style	T & R (Reverse)	Suffix = R	Eg. 2450AT45A100R (MOQ Applies	
P/N Suffix		100% Tin	Suffix = None	Eg. 2450AT45A100(S, E, R)	
F/N Sullix	Termination style	Tin / Lead	Please consult Factory		
	Evaluation Boards	2450AT45A100-EB1SMA (Page 2)			
	(1-port SMA antenna	2450AT45A100-EB2SMA (Page 5)			
test boards)		2450AT45A100-EB3SMA (Page 8)			

Storage Conditions and Shelf Life (On T&R or Bulk)			
Temperature: +5C to +35°C	Shelf Life: 18 months max.		
Relative Humidity: 45 to 75%			

Packaging information	
	www.iohansontechnology.com/ipcpackaging.html

Soldering Information	
	www.johansontechnology.com/ipcsoldering-profile

Antenna layout and tuning techniques	
www.iohan	sontechnology.com/tuning

Antenna layout review, tuning, and characterization services	
www.johansontechnology.com/ipcantennaservices	

