



BioJVA Wireless

Safety and User Manual

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Table of Contents

1. Safety	Page
1.1. Intended Use	5
1.2. Indications for Use	5
1.3. User Profile	5
1.4. Contraindications	5
1.5. Adverse Effects	6
1.6. Device Validation	6
1.7. Distributor Information	6
1.8. Warnings	7
1.9. Cautions	8
1.10. Technical Specifications	10
1.11. Symbols	11
1.12. Device Indicators	13
1.13. Reuse Conditions	13
1.14. Storage Conditions	14
1.15. Cleaning	14
1.16. Disposal	14
1.17. Technical Assistance	15
1.18. Warranty	15
1.19. Intentional Radiator Statement	16

Continue to next page for table of contents of Instructions for Use.

Table of Contents

2. Instructions for Use	Page
2.1. Creating an Account	17
2.2. Adding a Patient	17
2.3. Editing a Patient	17
2.4. Connecting the Device	18
2.5. Placing the Headset	18
2.6. Recording a Trace	19
2.7. Analyzing a Trace	19
2.8. Understanding the Data	20
2.9. General Troubleshooting	21
2.10. Connecting the Device with a USB Adapter	21

Read this Safety Manual before attempting to use the device.

Key



WARNING

Identifies conditions or practices that could result in harm.



CAUTION

Identifies conditions or practices that could result in damage to the device or to other properties.



Important

Indicates information considered important but not hazard or injury related.

1. Safety

1.1. Intended Use

The BioJVA Wireless is intended to record joint vibrations to be used as evidence for diagnosis of temporomandibular joint disorders. The device is intended to collect vibrational data representing the temporomandibular joint function with respect to the patient's dynamic jaw motion; the data shall then be transmitted via wireless transmission to be displayed for the medical or dental professional to analyze.

1.2. Indications For Use

- Intended patients include people who experience jaw pain, noise in the temporomandibular joint, headaches or cranio-facial pain, and/or limited jaw movement.
- Intended patients include people who engage in activities where the temporomandibular joint is at risk of harm or have undergone are or expected to undergo a medical or dental procedure which could affect the temporomandibular joint.

1.3. User Profile

The BioJVA Wireless is intended to be used by trained medical and dental professionals. Lay-persons should not use the BioJVA Wireless.

1.4. Contraindications

The BioJVA Wireless must not be used on any patients with an allergy to silicone or PLA plastics. The BioJVA Wireless must not be placed on any compromised skin, infected skin, mucosal membranes, or open sores.

1.5. Adverse Effects

There have been no known adverse events related to the device. The device is a low-risk of harm when used as intended.



If anyone is harmed by the device in any way, contact the distributor or BioRESEARCH after receiving appropriate medical attention.

1.6. Device Validation

BioRESEARCH Associates Inc. validates all medical devices according to ISO 13485 clause 7.3.7. The presented medical device is validated.

1.7. Distributor Information

BioRESEARCH Associates Inc. shall, upon request, make any circuit diagram, components list, description, work instruction, or other information available to approved service personnel.

If you are not located in the United States or Canada, contact us by phone at (414) 357-7525 or e-mail at support@bioresearchinc.com. BioJVA Wireless is a medical device; purchasing and servicing availability is subject to your nation's specific regulations.

1.8. Warnings



If the device is removed or placed on the head, hair may be caught in the adjustment mechanism causing pain.

Make any sizing adjustments prior to placing the device on the patient's head. Do not make sizing adjustments while the device is on the patient.



If the device moves across a patient's face without the sensors attached, abrasions to the face may occur.

Ensure that the sensors are attached to the Velcro before placing the device on the patient's head. Lift the sensors off the patient's skin to adjust their location; do not rub the sensors on the patient's skin.



If the back or side band of the device breaks due to an excessive force, the fractured side may cause lacerations to the back of the head or face.

Do not apply excessive force to the device while the device is on the patient. Do not use a device with a broken headband.



If there is unintended movement, the back of the device may cause scratches and discomfort to the back of the neck.

Ensure the patient is in good posture with their shoulders in a comfortable position. Instruct the patient to keep their shoulders and neck still during the procedure. Restrict patient movement if necessary.



If the device is not properly cleaned between patients, infections may spread between patients.

Ensure the device is cleaned and disinfected by cleaning the device prior to each use.



If a user uses the device outside of the expected or intended use, the device may not provide effective evidence for a diagnosis or false cause for a diagnosis of a temporomandibular joint disorder.

Ensure that all staff are properly trained to use the device. Do not use the device outside of the intended use.

1.9. Cautions



If the device is not correctly calibrated, the device may report inaccurate or unreadable data. The erroneous data may be used as justification for medical decisions.

Ensure that the device is within the calibration window before use. Do not use the device if the device's calibration has expired.



If the device is positioned improperly, there may not be any meaningful data recorded by the device to provide evidence of any diagnosis.

Ensure that the device is positioned correctly before using the device. Contact your sales representative or clinical integration specialist for any questions relating to device positioning.



If the battery is not maintained properly, the capacity and function of the battery may deteriorate over time.

Ensure the device is stored in a controlled environment. Do not hold the power button for more than 30 seconds. Do not leave the device charging for more than 24 hours. Charge the device if the battery is below 10%. If you suspect there is an issue with the device’s battery, or if you have questions regarding best practices for preventing battery degradation, contact your sales representative.



The device may be susceptible to electromagnetic interference.

Do not place the device adjacent or stacked with other equipment, and do not use portable RF communication equipment within 30cm of the device.



The device may not be compatible with third-party supplied components.

Use the device with the cables provided in the device packaging.



Use of the device in residential environments might not offer adequate protection to RF communication services.

Only use the device in an industrial area or medical facility.



Do not use the device while the device is charging. The device will not function.

1.10. Technical Specifications











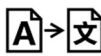


Standards	Basic Medical Device Safety	EN IEC 60601-1:2020
	Basic Medical EMC	EN IEC 60601-1-2:2020
	Design and Development	EN ISO 13485:2016
	Risk Management	EN ISO 14971:2019











Standards are dated to the standards active and in-use at the time of initial product development.

Category	Specification	Units	Min	Typ/Nom	Max
Device	Data Transmission	sm ^p /s	2500	5000	5000
	Noise (Interference)	mV	–	11.5	36.5
	Standby Current	μA	–	10	20
	Working Voltage	V	3.4	3.7	4.2
	Power Consumption	mW	–	30	35
	Shelf Life	years	1	8	–
	Calibration Period	years	–	1	1.2
Power Input	Input Voltage	V	-0.3	5	5.8
	Input Current	mA	10	100	250
Radio	Effective Radiated Power	mW	–	3.2 Nom	3.16
	Radiated Frequency	GHz	2.402	2.4 Nom	2.480
Packaging	Package Dimensions	cm	–	37x27x9	–
	Package Weight	g	–	840	1000

EMC/EMI Specification	Standard	Result
Conducted Emissions	CISPR 11 & CISPR 32	Compliant
Radiated Emissions	CISPR 11 & CISPR 32	Compliant
Electrostatic Discharge	IEC 61000-4-2	Compliant
Radiated Immunity	IEC 61000-4-3	Compliant
Conducted RF Disturbance	IEC 61000-4-6	Compliant
Magnetic Fields Immunity	IEC 61000-4-8	Compliant
Proximity RF Immunity	IEC 61000-4-39	Compliant



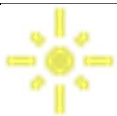




1.11. Symbols

Symbol	Meaning	Location
	Serial Number ISO 7000-2498	Device Label and Packaging Label
	Batch Code ISO 7000-2492	Packaging Label
	Date of Manufacture ISO 7000-2497	
	Catalog Number ISO 7000-2493	
	Unique Device Identifier ISO 15223-1 [5.7.10]	
	Manufacturer Address ISO 7000-3082	
	Medical Device ISO 15223-1 [5.7.7]	Device Label
	Refer to Instruction Manual ISO 7000-1641	
	Caution ISO 7000-0434	Packaging Label
	Distributor Address ISO 7000-3724	
	Translation ISO 7000-3728	Translated Distributor Labels
	FCC Compliance KDB 784748 D01	Packaging Label
	Class II ME Equipment IEC 60417-5172	

Symbol	Meaning	Location
	Type B Applied Part IEC 60417-5840	Packaging Label
	Fragile / Handle with Care ISO 7000-0621	
	Keep Dry ISO 7000-0626	
	Temperature Range ISO 7000-0632	
	Humidity Range ISO 7000-2620	
	DC Port IEC 60417-5031	Device Label
	Charging Port No Specific Standard	
	Power-Standby Toggle IEC 60417-5009	Device Backplate
	Non-Sterile ISO 7000-2609	Packaging Label
	Electronic DO NOT THROW IN TRASH (WEEE) EN 50419	

1.12. Device Indicators

When the device is first turned on, a solid color will appear to indicate the state of battery charge. Afterwards, the device shall enter “Pairing Mode” and seek connection. When the device is charging, a breathing-colored light indicates the state of charge for the device. If the battery is too low to operate, the indicator shall blink red before returning to the “Off” state.

Indicator	Conditions	Definition
	Pairing Mode	The device is on without a sustained wireless connection.
	Charging Complete, or Recording Mode	The device either has completed charging the battery (over 97%), or the device is actively recording and transmitting data.
	Medium Battery Charging	The device is charging with a battery charge between 15% and 97%.
	Low Battery Charging, or Dead Battery	The device is charging with a battery charge below 15%, or the device battery is too low to operate the device.
	Full Battery Charge, or Connected	The device battery has greater than 55% charge.
	Medium Battery Charge	The device battery has a charge between 55% and 20%.
	Low Battery Charge	The device has a charge below 20%.
No Light	Off	The device is powered off.

1.13. Reuse Conditions

The device may be reused after the device is cleaned provided the device is within the allotted calibration period. The device must be recalibrated before the end of each calibration period. Seek technical assistance if the device is out of calibration.

1.14. Storage Conditions

The BioJVA Wireless and its accessories should be stored within the following temperature and humidity ranges:

Operation Environment	Temperature	+8°C to +35°C
	Relative Humidity	10% to 90% RH non-condensing
Transportation and Storage	Temperature	+8°C to +35 °C
	Relative humidity	10% to 90% RH non-condensing

1.15. Cleaning

This device has been designed and manufactured for safe use and easy maintenance. The device must be cleaned before use. To clean the device, use a clean cloth dampened with non-alcoholic and non-flammable disinfectant detergents or a low-level disinfectant wipe and clean over the sensors and inside of the headband. Dry it afterwards with a clean cloth or clean synthetic leather.



Disconnect from power before cleaning. Do not use water or conductive materials to clean the charging port.

1.16. Disposal

The device must be disposed of in an appropriate manner, not in general garbage. The device must be disposed of as e-waste, alternatively the device may be returned to BioRESEARCH to be scrapped.

1.17. Technical Assistance



Do not modify the device. In the event of a fault or malfunction, contact the distributor or BioRESEARCH as soon as possible.

For a rapid solution to the problem, give the technical assistance service the following data: serial number (found on the back of the unit), customer identification and contact details, description of the fault or malfunction, and details of the purchase.



For technical assistance or to send your device in for calibration, please visit www.bioresearchinc.com or call the office at 414-357-7525.

1.18. Warranty

Your BioJVA Wireless has warranty for one year from the date of purchase against any defect in material or workmanship. If, for any reason, it becomes necessary to return this unit to BioRESEARCH, prior authorization must be obtained. Please make a note of the serial number on the back of the unit before contacting us. **Any unauthorized modification of the device shall result in a voided warranty.**

Contact us by phone at (414) 357-7525 or e-mail at support@bioresearchinc.com. After receiving authorization, return BioJVA Wireless prepaid to:

BioRESEARCH Associates, Inc.
12308 Corporate Parkway, Suite 450
Mequon, WI 53209 USA

The unit should be packaged carefully with adequate padding to avoid being damaged in shipment. Your repaired unit will be returned to you by BioRESEARCH prepaid.

1.19. Intentional Radiator Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/TV technician for help.

The FCC requires the user to be notified that any changes or modifications made to this device that are not expressly approved by BioRESEARCH Associates, Inc. may void the user's authority to operate the equipment.

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.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. The device has been evaluated to meet general RF exposure requirements. The device can be used in portable exposure conditions without restriction.

2. Instructions for Use

2.1. Creating an Account



Please contact your sales representative or call the office at 414-357-7525 before creating an account to ensure you have an active subscription to be able to connect to the BioJVA Wireless device.

To create an account, visit <https://biojva.com/> and select “Get Started” in the top right corner. Enter all the fields prompted; ensure that the email used is the same as the email associated with your subscription.



If you would like to change the email address on your account, or if there are any issues with your subscription, please contact your sales representative or call the office at 414-357-7525.

If you would like to change accounts, select “Sign Out” in the top right corner, then sign into the account you wish to use.

2.2. Adding a Patient

To add a patient to your patient list, select “New Patient”. Then, enter the patient’s information. For using the BioJVA Wireless, measure the patient’s range of motion, and enter the patient’s range of motion in the Initial ROM field.

2.3. Editing a Patient

To edit a patient, select the patient from the patient list. Then, select “Edit Profile” in the patient ribbon. Select “Edit Profile” in the bottom of the session notes to modify the fields.



If this is the first time you have seen a patient in one day, measure the patient’s range of motion.

2.4. Connecting the Device



Verify that your computer has LMP version 9 or newer. Search “how to check Bluetooth version” in your favorite search engine for instructions. If your device does not have LMP version 9 or newer, see 2.10: Connecting Device with a USB Adapter.

To connect your BioJVA Wireless device to the BioPAK software, power on the BioJVA Wireless by holding the power button for 5 seconds. Select “Connect Device” at the top right corner. If the device has not been previously paired, a pop-up window shall appear. Select the device which matches the serial number on the label on the top of the BioJVA Wireless device. Then select “Pair”.

2.5. Placing the Headset



Read 1.8: Warnings relating to handling the device on the patient to avoid illness, abrasions, and pulling hair.

Place the headset onto the patient such that the sensors rest over the temporomandibular joint. To find the temporomandibular joint, place your fingers on the patient 1–2 centimeters anterior to the patient’s ears. Instruct the patient to open and close their jaw. Feel for the condyles and follow their motion to where the patient’s jaw is closed. This is the location where the BioJVA Wireless sensors are to be placed. Remember the location or use a skin-safe marker to mark the location before placing the BioJVA Wireless sensors onto the patient. Allow the back of the BioJVA Wireless to rest on the patient’s neck.



Ensure the patient is in good posture with their shoulders in a comfortable position. Instruct the patient to keep their shoulders and neck still during the procedure.

2.6. Recording a Trace



If this is the first time you have seen a patient, measure the patient's range of motion. This number will be prompted when a recording is started.

To start a recording, select “Start New Recording”. Enter the measured range of motion in the Range of Motion field. Select “Start Recording”. Instruct the patient to move their jaw in-line with the sinewave (also called ROM Guide). Allow the jaw to move up and down for 10 seconds to collect enough samples. If there are any errors in starting the trace, continue the procedure for 10 seconds. The final 10 seconds of the recording is what is saved. Select “Stop Recording” or press either the spacebar or the “s” key before instructing the patient to stop moving their jaw. If the recording is invalid in any way, select “Rerecord” on the top left to repeat the recording. After recording, the session enters analysis-mode for the recording. See 2.7: Analyzing a Trace for how to mark a trace. Select “Save Notes & Selections” and enter any notes in the “Session Notes” field. Select “Save Notes” to save the recording.

2.7. Analyzing a Trace

To view a previously recorded trace, navigate to the patient dashboard. On the bottom of the dashboard, select the desired session from the “Recent Sessions” at the bottom of the page. To select vibrations, sweep your cursor across the vibration data. If a vibration is found, select the vibration. Ensure that only the desired vibration is within the live preview, any additional vibration may lead to inaccurate calculations. If the vibration occurs at the same location relative to jaw position, select “Mark All Similar” to mark the same jaw location. To add in notes related to the trace, select “Edit Notes” in the top right of the Session Notes field.

For screening assistance, select “Screening Assists” to provide suggestions related to the joint's characteristics. To record the screening results, select the “Left/Right Screening Result” drop down, and select an option. If no option is applicable, or there are additional details, record them using the “Session Notes” field. Select “Save Notes & Selections”. To save selections and notes, select “Save Notes & Selections”. If a new analysis is to be created on the same trace, select “New Summary”.



If a new summary is created without saving the notes and selections, the notes and selections will be lost. Always select “Save Notes & Selections” after any changes.

2.8. Understanding the Data

The device is intended to collect vibrational data representing the temporomandibular joint function with respect to the patient's dynamic jaw motion to serve as evidence for diagnosis. Interpretation and diagnosis are to be made by trained and licensed dental or medical professionals who make a diagnosis with evidence collected from patient history, other general methods of examination, and further imaging. For training regarding integration of joint vibration into screening practices, visit <https://bioresearchinc.com/dental-education/> or contact your sales representative for scheduling training.

2.9. General Troubleshooting

For a tutorial of basic functions of the software, select the help icon located at the center-top of the screen. For more detailed questions and answers, select the help icon at the right-bottom of the screen to open the BioPAK Support module. To use the BioPAK Support module, enter your question in the textbox and select the send icon.



If you would like human assistance, or your question is not being resolved by the BioPAK Support module, please call the office at 414-357-7525 or email us at support@bioresearchinc.com.

2.10. Connecting the Device with a USB Adapter

To connect to the BioJVA Wireless using the adapter, follow the instructions in the UB500 Quick Installation Guide. For an instructional video, visit:

<https://www.tp-link.com/us/support/download/ub500/v3.60/#video>.

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UM-05-EN BioJVA Wireless Safety and User Manual v1
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