VQ OrthoCare is not liable for misuse or misunderstanding of the BioniCare product or operating manual. In the US, please call VQ OrthoCare’s Patient Care Department at 800.444.1456 if any additional assistance is required regarding this product and its operating instructions. Outside the US, please contact your BioniCare System provider or your healthcare practitioner.
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How much relief of my osteoarthritis will I receive with the BioniCare Knee System? The answer, in large part, will depend on......you.

You are one of tens of thousands of patients whose doctor has prescribed the BioniCare® Knee System to treat osteoarthritis of the knee. Some patients benefit more than others from this non-drug, non-invasive treatment. What are they doing to get better results? They understand that improvement in their knee won’t happen overnight, since their osteoarthritis likely developed over many years. To be successful, they commit to using their device for at least 6-10 hours each day over many months. Your commitment to long-term daily use is the key to your success. Like many users, you may begin to feel an improvement within a few weeks. Clinical studies show that in the short term, you may experience pain relief and improvement in knee function. With continued use, researchers found that many users’ need for pain medications decreased or ended entirely. Over the long term, a major four-year study demonstrated that BioniCare-treated patients had significantly fewer total knee replacements. Relief of pain, improved function, and decreased drugs are common benefits. These are some of the many reasons to commit today to faithfully follow your doctor’s prescription for daily treatments. For more data from these medical studies and to read encouraging success stories from actual BioniCare patients like you, please visit our web site at www.bionicare.com.
Prescribing Information

Caution: Federal law restricts this device to sale by, or on the order of, a practitioner licensed by the law of the State in which he/she practices to use or order the use of this device.

Indication
The BioniCare Knee System is indicated “for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician’s global evaluation (clinical studies).”

Contraindications
• Do not use the BioniCare Knee System for any electrode placement that applies current to the carotid sinus (neck) region.
• Do not use the BioniCare Knee System for any electrode placement that causes current to flow transcerebrally (through the head).
• Do not use the BioniCare Knee System whenever pain syndromes are undiagnosed, until etiology is established.

Warnings
• The BioniCare Knee System must be used only as prescribed and applied only to the knee.
• Patients with demand type cardiac pacemakers should consult with their physician prior to use of this system.
• The safety of the BioniCare Knee System for use during pregnancy has not been established.
• The BioniCare Knee System is not effective for pain of central origin (including headache).
• Use only under the continued supervision of a physician.
• Keep out of reach of children.
• Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the BioniCare Knee System is in use.

Precautions
• Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.

Adverse Reactions
• Skin irritation and electrode burns are potential adverse reactions. Patients with skin irritation / reactions should be monitored.
Introducing the BioniCare Knee System

The BioniCare Knee System is prescribed by physicians and other medical professionals to treat osteoarthritis of the knee. It is a non-drug, noninvasive therapy delivering a unique electrical impulse that mimics the impulse created naturally within a healthy knee. The BioniCare Generator (BioniCare Generator) sends this low voltage impulse to the knee joint via electrodes that are held in place by the OActive® or Eagle® OA braces, or the BioniCare Night-Wrap.

People diagnosed with osteoarthritis of the knee who regularly use the BioniCare Knee System experience significant reduction of pain and improvement in overall function, and may avoid costly, riskier treatments over the long term. For more information, visit our web site at www.bionicare.com.
System Components

System Components
(1) Knee Wrap (OActive® and Eagle® OA Systems)
(1) Thigh Liner (OActive® and Eagle® OA Systems)
(1) Night-Wrap
(1) Knee Electrode
(1) Thigh Electrode
(1) BioniCare Generator
(1) Lead Wire
(1) Battery Charger
(1) Bluetooth Dongle
(2) Rechargeable Batteries
General Operating Instructions

This section describes the operation of the BioniCare Knee System for the treatment of osteoarthritis of the knee. Each patient should read and become completely familiar with the written operating instructions. Special attention should be given to the sections on “Contraindications” and “Cautions”.

Preparation and Treatment

Charging the Battery for the BioniCare Generator:
The BioniCare Generator is powered by a single rechargeable Lithium Ion battery. The battery charger can be used at 110 or 220 volts and fully charges the battery in four hours. Use only the charger supplied by VQ OrthoCare as improper charging can cause heat damage or even high pressure rupture. Do not use any battery that shows any signs of corrosion, leaking or other damage. Replace corroded, leaking or damaged batteries.

Preparation:
Prior to applying electrodes to the skin, the skin must be washed with soap and water and completely dried. Electrodes are held in place by the liners and knee wrap of the OActive® or Eagle® OA brace, or by the BioniCare Night-Wrap. To prepare your brace or Night-Wrap for application and use, please refer to the application instructions that were supplied with your BioniCare Knee System. You may request a copy of the application instructions by contacting our Patient Services Center toll-free at 800.444.1456 or by visiting our website at www.bionicare.com.

BioniCare OActive Application Guide:

STEP 1. Attach knee wrap to brace. With the wrap extending out toward the front of the brace, place the condyle cup/pad into the slit in the wrap. Make sure the condyle cup/pad is completely covered by the wrap.

STEP 2. Replace thigh liner by removing the standard OActive liner from the brace and replacing it with the one included in the BioniCare kit.

Note: These steps may have been done for you by a technician.
**Preparation and Treatment (cont.)**

**STEP 3. Apply thigh electrode to thigh liner.** Peel the white backing from the thigh electrode. Adhere electrode to the thigh liner, centering it in the outlined area. Make sure that the wire extends toward the top of the liner. The white side of the electrode should be against brace or liner and black side goes against the skin.*

**STEP 4. Peel clear plastic gel backing.** Keep plastic backing for protection of electrode when not in use.

**STEP 5. Apply Brace to leg,** as detailed in brace application instructions. Leave knee wrap Velcro tabs unattached.

**STEP 6. Apply knee electrode.** Peel clear plastic backing from knee electrode. With knee at 45°, adhere electrode to knee by first placing center section over kneecap with wire extending towards medial (inside) side of knee as shown. Then press entire electrode firmly to skin. Peel white backing off electrode. The white side of the electrode should be against brace or liner and black side goes against the skin.*

**STEP 7. Apply knee wrap** by stretching it snugly around the knee and attach Velcro tabs on the center of the thigh and calf straps, as shown. Make sure to route wire upward towards thigh.

*For demonstration purposes, electrodes are shown here in a contrasting color.*
**BioniCare Eagle OA Application Guide:**

**STEP 1. Attach knee wrap to brace.** Front side of the knee wrap has a tag on it.

With front of brace and knee wrap facing toward you, place one loop of knee wrap over the plastic condyle cup on the brace as shown.

Pull knee wrap around back of brace, then around the outside of the other hinge. Secure the remaining loop around the plastic condyle cup.

*Note: Tag side should be facing the front of the brace.*

**STEP 2. Replace thigh liners with BioniCare liner.** Install BioniCare liner in the same position as the original side-liners with the thigh cuff covered as shown in **STEP 3.** The softer protruding area on the liner should face toward the skin.

**STEP 3. Install thigh electrode.** Remove white backing from the thigh electrode. Adhere electrode to the thigh liner, centering as shown. Electrode wire should top of the brace. The white side of the electrode should be against brace or liner and black side goes against the skin.*

**STEP 4. Install knee electrode.** Temporarily place the brace on the leg backwards with center of knee wrap over center of the kneecap. Hinges should sit on the sides of the knee.

Remove white backing from knee electrode and adhere it to knee wrap as shown with wire extending downward. The white side of the electrode should be against brace or liner and black side goes against the skin.*

*For demonstration purposes, electrodes are shown here in a contrasting color.
Preparation and Treatment (cont.)

STEP 5. Apply the brace (See application instructions for Eagle OA).
Remove the clear backing from both electrodes. With the knee bent at
45 degrees, gently push the knee wrap over the knee to create a “reverse
bubble”. Be sure the center of the knee wrap and center round part of the
electrode are directly over the center of the kneecap.

Fasten straps in numerical order and continue applying the brace per the Eagle OA application instructions.

BioniCare Night-Wrap Application Guide:

STEP 1. Install Electrodes on the BioniCare Night-Wrap

- Lay the Night-Wrap on the leg with the longer strap closer to the waist, and so that the graphics of the wrap are visible. Ensure that the kneecap (patella) is centered beneath the patella marking.

- Apply the thigh electrode by peeling off the white paper backing and adhering the electrode to the wrap within the markings. The wire should extend up toward the waist. The white side of the electrode should be against the wrap and black side goes on the skin.*

- Apply knee electrode by peeling off the white paper backing and adhering the electrode to the wrap within the markings as pictured. The wire should extend downward. The white side of the electrode should be against the wrap and black side goes on the skin.*

*For demonstration purposes, electrodes are shown here in a contrasting color.
STEP 2. Apply the BioniCare Night-Wrap

• Remove the clear backing from both electrodes. Position the wrap so that the electrodes are facing leg (keep long strap closer to the waist).

• Center the small round area of the electrode over the patella, and gently press the knee electrode to the knee while keeping the thigh portion of the wrap away from the leg.

• While grasping the top edge of the wrap, gently tension it, and then adhere the thigh electrode to the skin.

• Wrap the straps around the leg and secure hook-tabs to the wrap. Straps may be trimmed as needed. Best performance is achieved when the lower strap crosses over the patella, wrapping the patella in two layers.

STEP 3. Connecting the Device:
The lead wire connects the BioniCare Generator to the knee and thigh electrodes. The single end of the Wire inserts into the female connector on the generator and the other end divides into two ends with color-coded tips. See Figure 1 and 2, to attach this Wire:

1. Connect the two color coded lead wire ends to the electrode wires. Make sure the BioniCare Generator is turned off. Attach red (knee) electrode to the red lead wire tip and the black (thigh) electrode to the black lead wire tip.

2. Now connect the single lead wire end to the BioniCare Generator as seen in figure 2.
Preparation and Treatment (cont.)

STEP 4. Starting Your Treatment

1. Check that the electrodes are in place and all connections and adjustments are correct.

2. Turn the BioniCare Generator on by pressing the Select/Power button until BioniCare appears on the screen. Unlock the device by pressing the lock on the screen or the button. The screen will then advance to the main treatment menu.

3. Press the play button.

4. Increase the stimulation by pressing the Increase Button on the touch screen or the corresponding manual button. Increase until you feel a tingling sensation in the thigh or knee.

5. Press the Decrease Button on the touch screen or the corresponding manual button a few times to reduce the stimulation just enough so you no longer feel the tingling sensation. You have now begun your treatment.

Note: The BioniCare Generator must be set at 2.0V or greater. If the voltage is set below 2.0 V, the device will begin to beep after 5 minutes and will turn off after 10 minutes.

Note: Optimal Treatment time is 6 - 10 hours per day (minimum) or as much as possible.

BioniCare System Removal Steps:

STEP 1. Unhook knee wrap from straps and carefully peel from knee. Place clear plastic backing onto knee electrode for protection when not in use.

STEP 2. Remove brace. Place clear plastic backing onto thigh electrode.

Note: There is no need to remove the electrodes from the Night-Wrap upon removal. Leave the electrodes in place and cover the electrodes with the clear backing to keep the electrodes clean and to prevent them from prematurely drying.
BioniCare Generator Features & Functions

The BioniCare Generator is a small, portable and battery-powered FDA Class II medical device that produces a unique, patented electrical signal to treat osteoarthritis of the knee.

Manual Buttons

There are 3 manual push buttons that control functions on the device.

Select ( ) Button functions:
- Turns the power on or off (4 second hold to turn off)
- Enters the selected function or value from the highlighted icon in the touch screen
- Unlocks the device

Navigation (outer buttons) functions:
- Allow scrolling through the menus and icons (icons are highlighted when they’re active)
- Control stimulation level

Touch Screen Display

The Touch Screen Display allows the user to control the device and provides information regarding its operation and status. Virtually all of the functions of the device can be viewed and controlled via a finger touch on the touch screen.

Main functions:
- Start treatment
- Set/view stimulation (measured in volts)
- View overall hours of treatment
- Check battery charge
- Unlock device
- Control settings of device parameters
Basic Use Screens

1. Main Display Screen

1. **Back Button** (press to return to previous screen)
2. **Menu Button** (press to advance to settings menu)
3. **Battery Level** (press for full screen reading)
4. **Clock**
5. **Start Button** (press to set voltage and begin treatment)
6. **Usage time**

2. Voltage Setting Screen

- **Increase Button** (press to increase voltage)
- **Decrease Button** (press to decrease voltage)

Quick Tip: Navigation buttons may also be used to adjust voltage

**00.0 v** Voltage from 00.0 to 12.0

3. Treatment Running Screen

- **Voltage** (press to adjust stimulation level)
- **Usage time** (press for full screen reading)
- **Running indicator**

4. Locked Mode Screen

- **Unlock button** (press to unlock)

Quick Tip: Select button may also be used to unlock
5. Settings Menu Screen

![Settings Menu Screen](image)

**NOTE:** This display can only be accessed when amplitude is 0 Volts.

<table>
<thead>
<tr>
<th>Display Settings</th>
<th>General Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language, Screen Orientation, Color and Brightness</td>
<td>Progress Survey Questions, Clock Format, Time Zone, Audible and Idle Mode Settings</td>
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<tr>
<td>Time Settings</td>
<td>Bluetooth Connection</td>
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<tr>
<td>Calendar Settings</td>
<td>Technician Settings</td>
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</tbody>
</table>

**Understanding Special Display Messages**

Special messages may appear on the display screen during use to report a low battery condition or other operational conditions that require attention.

**Low Battery:** When the device determines the battery is approaching the end of its usable charge, the device will continue to operate but the battery icon on the main display screen will flash and audible beep will sound. When this occurs, recharge the battery or replace it with a freshly charged battery.

**Open (circuit):** An “Open” circuit message will be displayed and an audible beep will sound if 1) the lead wire is disconnected from the generator (“Open” does not flash in this case) or 2) an electrode either loses skin contact or the wire is disconnected (“Open” will flash in these cases).

**Advance Device Functions**

The BioniCare Generator has data recording and Bluetooth communication capabilities to allow it to capture patient data input and transmit it automatically to the BioniCare website. The patient can then access the website to see how their progress compares to that of all other BioniCare users. For information and instructions for the website, go to www.bionicare.com.
Description of data collection and transmitting functions:

- Record patient progress via simple survey questions on the generator display

- Automatic upload of patient progress data to BioniCare website to track performance and outcome measurements

⚠️ BIONICARE GENERATOR CAUTIONS

- Do not connect the BioniCare Generator to any electrical outlet.
- Remove the battery from the BioniCare Generator during long-term storage to prevent battery leakage. Failure to do so may damage the BioniCare Generator.
- Replace batteries immersed in water or liquid. Failure to do so may damage the BioniCare Generator.
- Do not store batteries with their terminals touching. Batteries may be damaged or their charge drained.
- When using rechargeable batteries, carefully read and follow all instructions provided with the batteries and the battery charger.
- Dispose of batteries according to current federal, state and local regulations.
Six Keys to Treatment Success

Complying with your doctor’s prescription of daily treatments is the most important key to your success. These Six Keys to Success will help you receive maximum benefit from your BioniCare Knee System.

1. Use daily. Take a treatment with your BioniCare Knee System for a minimum 6-10 hours each day, averaging about 8 hours. Results are seen sooner when worn with an OActive or Eagle OA unloading brace.

2. Use over many months. Studies support using your System for at least 4-6 months to obtain the best results.

3. Charge the batteries. Use a fully charged battery each day. Two batteries are supplied so that one can be charging for 4 hours while the other is in use.

4. Replace electrodes every 10-14 days or when they show signs of excessive wear.

5. Adjust the signal for each treatment. Turn the BioniCare Generator on and increase the voltage until you feel a tingle under the knee electrode or thigh electrode. Then, slowly turn the voltage down until you feel no tingle.

6. Renew supplies. Order replacement electrodes every month or as needed.
Frequently Asked Questions

Q. Is it harmful to wear my Device more than 10 hours a day?
A. No. There has been no evidence that it is harmful to wear the device more than 10 hours a day. In fact, studies show that the more the device is worn, the sooner you will see significant results. (See below FAQ regarding break-in schedule.)

Q. What is the recommended break in schedule for a new brace with BioniCare?
A. It’s important that you allow your body to adjust to a new brace (or new brace with BioniCare) by starting out slowly and gradually increasing your wear time. On day one, wear the brace for one hour, and each day going forward, double the amount of time until you reach your optimal daily wear time. For example, on the first day wear it for one hour, on the second day for two hours, on the third day for four hours, and the fourth day for eight hours. This will allow your body to more easily adapt to the new corrective pressures and improved biomechanics that are provided by the brace.

Q. How often do I need to recharge the battery?
A. Since your BioniCare system comes with two batteries, you have the ability to charge one battery while the other is in use. Use a fully charged battery for every treatment. Do not use any other battery with the BioniCare system.

Q. What are the side effects, if any?
A. There are no serious side effects associated with the BioniCare system. Some patients develop a mild rash under the Electrodes or Wrap.

Q. I have a rash under an electrode. How do I treat it?
A. A skin rash may be caused by the electrode. If you develop a rash, stop treatment for a few days. Many users find it helpful to apply an over-the-counter topical hydrocortisone cream to the rash; you may choose to check with your doctor. If the rash persists, check with your doctor.

Q. What can I do to prevent a skin rash?
A. Take special care of the skin underneath the electrodes and Knee Wrap. After a treatment, wash the skin with warm water and mild soap. Then rub in a quality moisturizing lotion, preferably with aloe vera, or an over-the-counter hydrocortisone cream. Make sure to completely wash the lotion/cream from skin before re-applying the electrode.
BioniCare® Knee System

Q. How frequently should I reorder electrodes?
A. You should reorder your electrodes before you need them so you can continue your regular treatment. Electrodes should be replaced after 7 to 10 days of use at 8 hours per day. This time may vary. Routine visual inspection of electrode condition is recommended, and changing electrodes in a timely manner ensures optimum performance.

Q. How do I get new supplies of electrodes and batteries?
A. In the US, just call our Patient Services Center toll-free at 1.800.444.1456, Monday-Friday, 7 a.m. - 6 p.m. Pacific Time or log online to www.bionicare.com/supplies. Outside the US, please contact your BioniCare provider or your healthcare practitioner.

Q. Can the knee wrap and liners be washed and dried?
A. Yes. You can hand wash and air dry the knee wrap. Make sure to remove electrodes before washing. Use only mild soap, such as Ivory® or Woolite®; never use bleach, detergent or fabric softener. Air dry. Never run any of the System’s component through the washer or dryer. Never place your Wire, BioniCare Generator, battery or battery charger in water; these items can be wiped clean with a damp cloth or cotton swab. Electrodes may be rehydrated with water by dabbing them with a wet, lint-free cloth.

Q. I can’t feel the tingle during setup, what do I do?
A. It’s OK and quite normal to not feel the tingle. If this occurs, set the voltage to 8.4 volts. This will provide your BioniCare treatment while maintaining battery life. Your voltage level to produce a tingle may also vary daily. Ramp up the voltage until you feel it, and then back it down a few tenths of a volt until you don’t feel it. Run it at this level. You should not feel a constant tingle when treating.

Q. Once symptoms improve, can I stop using my Knee Device?
A. Once you have been pain free for three months, we recommend a maintenance regimen where BioniCare is used for 8 hours per week.

Q. How long will my symptoms remain improved?
A. Symptom improvement varies, so it’s best to use the recommended maintenance regimen of one 8 hour treatment per week.
Frequently Asked Questions (cont.)

Q. Will my insurance cover the costs, and will VQ OrthoCare bill my insurance company for me?

A. Insurance coverage varies. VQ OrthoCare reimbursement professionals will help determine your insurance coverage, submit claims and follow up for reimbursement. They will bill you if there is a co-pay or deductible amount. In the case of no insurance coverage, they will work with you to discuss payment options. They will answer any questions you have about this process and your responsibilities. Outside the US, please contact your BioniCare provider.

Q. Who do I contact if I have an insurance or billing question?

A. In the US, call VQ OrthoCare at 1.800.444.1456. Outside the US, please contact your BioniCare provider.
Troubleshooting

Problem: BioniCare Generator displays the “OPEN” message.
This is a common occurrence that can be easily corrected. The OPEN message is an indication that there is an incomplete circuit within the electrical system. The circuit consists of the BioniCare Generator, Wire and electrodes and connection to your skin. If one piece of this circuit is not connected, the BioniCare Generator will read OPEN. The likely suspects are the Wires or electrodes.

1.  Check all connections to the electrodes and BioniCare Generator.

2.  Be sure the correct side (clear backing side) of the electrodes is facing the skin.

3.  Check the Wires to be sure there are no frayed ends and that they are secured to the electrodes. If your Wire is frayed, in the US, contact Patient Services for a replacement. Outside the US, please contact the provider that delivered your BioniCare System.

4.  Consider the last time you replaced the electrodes; if they no longer adhere to your skin, it is probably time to order new ones. If after you’ve checked these solutions the BioniCare Generator still reads OPEN, phone Patient Services.

Problem: Your skin has a rash or irritation.
To prevent escalation of the rash, immediately stop using the device until the rash or irritation clears up. If possible, determine the source of the problem. The electrode is the most likely cause in nearly all cases. Many patients find relief by treating the area with an over-the-counter hydrocortisone cream until the rash is gone, usually in 5-7 days; you may choose to check with your doctor. Some patients may be allergic to the Wrap or brace liner fabric. In all cases, stop using the device until the rash is gone. Once your rash has completely healed, resume treatment. If the rash re-appears, in the US, call our Patient Services Center toll-free at 1.800.444.1456. Outside the US, please contact your BioniCare provider or your healthcare practitioner. Warning: Continued use of the device with a rash may worsen the condition to the point of causing blisters, open sores or infection. Notify your physician if your rash has worsened even after you’ve stopped using the device.
Troubleshooting (cont.)

**Problem: Battery will not hold a charge.**
Your BioniCare Generator may display a “Low Battery” indication. Keep track of how long the battery lasts during one treatment session. If the battery lasts eight hours or more, the battery is functioning normally. Remember to charge both batteries initially for at least 4 hours; be sure the battery charger is not plugged into an outlet controlled by a light switch. In order to hold their maximum charge, the batteries must be cycled (fully charged and fully drained) 4 to 5 times. If you’re travelling overseas be sure to get a converter adapter for the charger.

**Problem: Display is blank and the BioniCare Generator shuts off.**
If your Generator shuts off, you may have accidentally turned it off or unplugged the Wire. If you can turn on the Generator normally then this is most likely the problem. If the Generator does not turn back on, it might mean the battery has completely discharged and has turned off normally. Plug in a charged battery and check the battery percentage. A fully charged battery should say “100%”. One last thing; be sure to hold down the On/Off button for about one second; if the button is not pressed long enough the Generator will not turn on. The best way to know you’re doing it right is to wait for BioniCare logo to display, then let go of the On/Off button.

**Problem: You can’t feel the tingle when you increase the signal. There are a few reasons for this to occur.**

1. Your setting is too low. Increase the output until the signal is felt. It’s normal for the voltage setting to change from day to day, depending on how long the electrodes have been used and the condition of your skin.

2. Your skin might be too dry. Use moisturizer after each therapy session on the area of the skin under the electrodes.

3. It is quite common for some patients to not feel the tingle even at the highest voltage setting. Do not worry as this is normal. Set the voltage to 8.4 volts to receive your treatment. Remember to ramp up the voltage for each treatment as your sensitivity may change over time.
Care and Cleaning

**BioniCare Generator**
The case of the BioniCare Generator may be cleaned with a cloth and cotton swab. The BioniCare Generator should be turned “OFF” and not connected to the Wire when cleaning. Do not use liquids for cleaning; the BioniCare Generator is not waterproof. The BioniCare Generator case must not be opened by removing the screws, because there are no operator serviceable components inside. Always store the BioniCare Generator in a clean, dry area between 0° and 140°F.

- Do not use the BioniCare Generator with a battery other than the original battery supplied or an exact replacement battery.
- Do not use any Wire or cord if the insulation is damaged or if the conductive strands are exposed.
- Do not immerse the BioniCare Generator, batteries, battery charger or Wires in water or any other liquid.
- Do not wear and use the Device while bathing, swimming or any other activity that would get the Device wet.
- Do not use the BioniCare battery charger with extension cords or adaptor plugs.
- Do not use the BioniCare Generator or its battery charger in the presence of flammable liquids.
- Do not use the BioniCare Generator or the battery charger in the presence of explosive atmospheres.
- Do not leave the battery charger plugged into an electrical outlet between charges.
- The BioniCare Generator has no field serviceable components. If you suspect a malfunction, discontinue use and in the US, call VQ OrthoCare at 1.800.444.1456 toll free. Outside the US, please contact your BioniCare provider or your healthcare practitioner.

**Brace Knee Wrap/Thigh Liner and Night-Wrap**
To clean the above soft goods, the electrodes should first be removed and the brace liner/wrap should be removed from the brace. They should be hand washed in cold water with mild detergent. Rinse thoroughly and air-dry (do not machine dry). Never machine wash the soft goods. Never use bleach, fabric softener, or harsh detergents. The other brace liners and straps should be washed in the same manner.
Care and Cleaning (cont.)

Electrodes
- Factory manufactured electrodes have been designed and authorized specifically for use with this product and must not be manipulated or altered in any way.
- Do not use alcohol to clean skin surface.
- Apply electrodes to dry, clean, unbroken skin surfaces only, checking all edges for proper adhesion. Prior to electrode application, the skin should be washed with soap and water and completely dried.
- Do not apply skin lotion prior to application of electrodes.
- Electrodes should always be placed at least one inch apart.
- Do not trim electrodes, as cut edges may affect the even distribution of stimulation.
- Remove electrodes before showering.
- Place clear plastic backing onto knee and thigh electrode for protection when not in use.
- If you experience symptoms of skin irritation while using the BioniCare® Knee System, discontinue use immediately and in the US, contact VQ OrthoCare’s Patient Care department at 1.800.452-7993, or consult your healthcare practitioner. Outside the US, please contact your BioniCare provider or your healthcare practitioner.

CAUTION
Electrodes should be discarded and replaced if damaged or when proper adhesive tack can no longer be obtained, the gel has separated, or you sense a change in stimulation intensity. If in doubt about the integrity or proper function of any electrode, replace it before proceeding with treatment. If using pain medication and/or other pain management devices, exercise caution when increasing amplitude on the BioniCare device.

Service
Do not return the BioniCare Knee Device to your physician’s office.

This BioniCare Generator contains no user serviceable parts and must be returned to VQ OrthoCare or its representatives for service, repair or calibration at its factory.
## Basic Specifications

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<tr>
<th>Specification*</th>
<th>BioniCare Knee System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>100Hz ± 5 Hz, fixed digital</td>
</tr>
<tr>
<td>Waveform</td>
<td>Monophasic spike-shaped pulse analog generated</td>
</tr>
<tr>
<td>Voltage Output Range</td>
<td>0-15 volts peak - digital</td>
</tr>
<tr>
<td>Voltage Pulse Width</td>
<td>1.8 ms @ 10% pt. of peak  + 0.64 ms @ 50% pt. of peak</td>
</tr>
<tr>
<td>Current Pulse Range</td>
<td>0-30 mA peak @ 500 ohms resistive load</td>
</tr>
<tr>
<td>Current Pulse Width</td>
<td>1.8 ms @ 10% pt. of peak @ 500 ohms resistive load  + 0.64 ms @ 50% pt. of peak @ 500 ohms resistive load</td>
</tr>
<tr>
<td>Maximum Output Charge</td>
<td>25 µC into a load of 500 ohms</td>
</tr>
<tr>
<td>Display</td>
<td>LCD</td>
</tr>
<tr>
<td>Power Source</td>
<td>3.7V Li-Ion battery</td>
</tr>
<tr>
<td>Standard: ANSI/AAMI NS4-1985</td>
<td>Compliant</td>
</tr>
<tr>
<td>Dimensions</td>
<td>3.56” (90.5mm) X 2.13” (54.0mm) X 0.59” (15.0mm)</td>
</tr>
<tr>
<td>Weight</td>
<td>0.152lb or 2.45oz or 69g (With battery)  + 0.110lb or 1.75oz or 50g (Without battery)</td>
</tr>
<tr>
<td>Electrical Protection Rating</td>
<td>Type BF Equipment, Battery Operated</td>
</tr>
</tbody>
</table>

*Electrical specifications are +/- 10% into a 500 ohm load unless otherwise noted.

**Output Waveform**
The signal is a spiked shape, monophasic, asymmetrical, DC output.

**Output Waveform**

---

**Output**

[Diagram showing output waveform with width at 10% Peak = 1.8ms and width at 50% Peak = 0.64ms]
Normalized Symbols
This device is a FDA Class II device with its own internal electrical power, with type BF applied sections. IMPORTANT: The information in this manual must be strictly observed. The ON/OFF switch is a multi-function key.

Operating Conditions
- Temperature: 5° C - 40° C
- Relative Humidity: 15% - 93%
- Atmospheric Pressure: 700 to 1060 hPa (0.69 to 1.05 atm)

Storage and Transport
- Temperature: -25°C - +70°C
- Relative Humidity: 30 - 93%
- Atmospheric Pressure: 700 to 1060 hPa (0.69 to 1.05 atm)

The BioniCare is rated IP22 in accordance with IEC60529. This rating means that the device is protected against ingress of foreign objects larger than 12.5mm and against ingress of water with harmful affects when exposed to dripping at 15 degree tilt.
EMC Compliance Table

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Use of lead wires and other accessories other than those supplied by VQ OrthoCare may result in increased emissions or decreased immunity of the BioniCare Knee System.

### Guidance and manufacturer’s declaration - electromagnetic emissions

The BioniCare Knee System is intended for use in the electromagnetic environment specified below. The customer or user of the BioniCare Knee System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions</td>
<td>Group 1</td>
<td>The BioniCare Knee System uses RF energy only for its internal function. Therefore it RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF Emissions</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Complies</td>
<td>The BioniCare Knee System 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>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

### Guidance and manufacturer’s declaration - electromagnetic immunity

The BioniCare Knee System is intended for use in the electromagnetic environment specified below. The customer or user of the BioniCare Knee System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 6 kV contact</td>
<td>± 6 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>± 8 kV air</td>
<td>± 8 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient / burst</td>
<td>± 2 kV for power supply lines</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>± 1 kV for input / output lines</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>
## EMC Compliance Table (cont.)

<table>
<thead>
<tr>
<th>Guidance and manufacturer’s declaration - electromagnetic immunity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Immunity test</strong></td>
</tr>
<tr>
<td>Surge</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
</tr>
<tr>
<td>(&gt;95 % dip in U&lt;sub&gt;a&lt;/sub&gt;)</td>
</tr>
<tr>
<td>40 % U&lt;sub&gt;a&lt;/sub&gt;</td>
</tr>
<tr>
<td>70 % U&lt;sub&gt;a&lt;/sub&gt;</td>
</tr>
<tr>
<td>&lt; 5 % U&lt;sub&gt;a&lt;/sub&gt;</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
</tr>
</tbody>
</table>

NOTE: U<sub>a</sub> is the a.c. mains voltage prior to application of the test level.

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### Guidance and manufacturer’s declaration - electromagnetic immunity

The BioniCare Knee System is intended for use in the electromagnetic environment specified below. The customer or the user of the BioniCare Knee System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th><strong>IEC 60601 Test Level</strong></th>
<th><strong>Compliance level</strong></th>
<th><strong>Electromagnetic environment - guidance</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Portable and mobile RF communication equipment should be used no closer to any part of the BioniCare Knee System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
</tbody>
</table>
## EMC Compliance Table (cont.)

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conduction RF</td>
<td>IEC6100-4-6</td>
<td>3 Vrms</td>
<td>Recommended Separation Distance</td>
</tr>
<tr>
<td></td>
<td>150KHz to 80MHz</td>
<td>3 Vrms</td>
<td>d = 1.2 √P</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 610004-3</td>
<td>3 V/m</td>
<td>80 MHz to 800MHz</td>
</tr>
<tr>
<td></td>
<td>80MHz to 2.5GHz</td>
<td>3 V/m</td>
<td>d = 1.2√P</td>
</tr>
<tr>
<td></td>
<td>(continued)</td>
<td></td>
<td>800 MHz to 2.5GHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = 2.3√P</td>
</tr>
</tbody>
</table>

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, should be less than the compliance level in each frequency range b.

Interference may occur in the vicinity of the 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 reflection from structures, objects and people.

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 BioniCare Knee System is used exceeds the applicable RF compliance level above, the BioniCare Knee 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 BioniCare Knee System.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
U.S. and International Safety Standards

When traveling with the BioniCare Knee System, users may be requested to provide documentation identifying it as a medical device and substantiating its electrical safety. The following facts are provided for this purpose.

The BioniCare Knee System, is a FDA Class II Medical Device prescribed by a licensed physician or other medical professional for the treatment of osteoarthritis of the knee. This Device has been cleared by the U.S. Food and Drug Administration under 510(k) K030332.

In Europe, the BioniCare Hand System is a Class IIa Medical Device for the treatment of the Rheumatoid Arthritis of the hand. This Device has been cleared to be sold in the EU under CE certificate # 567144.

The BioniCare Knee System meets or exceeds federal and international standards for electrical safety, including:


- ANSI/AAMI NS4-1985 American National Standards for Transcutaneous Electrical Nerve Stimulator; Environmental Testing

- IEC60601-1-2:2007 Medical electrical equipment - General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

- IEC60601-1-11:2010 General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Further information regarding this medical device may be obtained directly from VQ OrthoCare at 1.800.444.1456 (inside the US) or 949.261.3000 (outside of the US).
One year limited warranty

VQ OrthoCare warrants that the electronic BioniCare Generator of the BioniCare Knee System (hereafter referred to as the “Device”) is free from defects in material and workmanship and will perform within applicable specifications for a period of one (1) year from the date of purchase.

Who is protected by this warranty?
This warranty is valid only to the original purchaser and is void if the device was damaged as a result of accident, misuse, or negligence, or if repair or modification is made by an unauthorized service center or anyone other than VQ OrthoCare. VQ OrthoCare reserves the right to determine whether the defects of the device in question are the results of accident, misuse, or negligence.

What is covered?
VQ OrthoCare’s obligation under this warranty is limited to repairing or replacing the device. The warranty described herein shall only apply if the owner contacts VQ OrthoCare Patient Services within one year of the date of purchase and returns the device within thirty (30) days of contacting VQ OrthoCare Patient Services. Transportation and insurance charges will be prepaid by the owner, and the device must prove to be defective. Sewn goods, batteries, electrodes, wires, and battery chargers are not covered under this warranty. VQ OrthoCare reserves the right to determine whether to repair or replace the returned device. VQ OrthoCare also reserves the right to replace the device with the same model or a comparable model.

How to obtain warranty service?
If the device should become unusable or unsafe due to materials, workmanship, or any other reason, the user agrees to immediately cease using the device and in the US, contact VQ OrthoCare Patient Services at: 1.800.444.1456 toll free or by mail at:

VQ OrthoCare
18011 Mitchell South
Irvine, CA 92614

Outside the US, please contact the provider that delivered your BioniCare System.
VQ OrthoCare makes no claim, warranties, or representations regarding the suitability of this type of medical treatment nor assumes any responsibility for the success, failure, or outcome of any treatment administered using VQ OrthoCare equipment. **FURTHERMORE VQ OrthoCare MAKES NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON INFRINGEMENT WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERWISE.**

The above limited warranty takes the place of all other warranties, expressed or implied and correction of such defects by replacement or repair shall constitute a fulfillment of all obligations under the terms of the warranty, which specifically EXCLUDES any incidental or other indirect damages caused by or associated with the system or its use, including transient skin irritation associated with use of this system or specific patient allergies to components used to manufacture the system. No warranty or representation not contained herein shall be binding. This warranty gives the owner specific legal rights, and the owner may also have other rights that vary from state to state.
Notes:
BioniCare® Knee System

Notes
VQ OrthoCare is not liable for misuse or misunderstanding of the BioniCare product or operating manual. In the US, please call VQ OrthoCare’s Patient Care Department at 800.444.1456 if any additional assistance is required regarding this product and its operating instructions. Outside the US, please contact your BioniCare System provider or your healthcare practitioner.