Caution: Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

Description: The XpandOrtho XO[1] knee balancing system provides the surgeon with a method for assessing ligament balance during Total Knee Arthroplasty.

The XpandOrtho XO[1] knee balancing system consists of a controller with an attached tibiofemoral distractor (XO[1] Device) and the XpandOrtho Graphic User Interface (GUI).

The XO[1] Device is supplied as a sterile, single use disposable device that employs a wireless communication link to the GUI to display information regarding the tibiofemoral gap.

The GUI requires a tablet PC with the XpandOrtho GUI software installed an XpandOrtho Wireless Receiver and an external CD drive, which is supplied separately. The PC, GUI software, XpandOrtho Wireless Receiver and external CD drive are non-sterile and reusable.

Each single use XpandOrtho XO[1] package contains:

1. Instructions for Use (IFU).
2. The XO[1] device sterile package consisting of:

    (1 each) XO[1] controller/ tibiofemoral distractor device.

    (1 each) Battery assembly.

    (1 each) Extension line.

    (1 each) Dual check valve.

3. The syringe sterile package consisting of:

    (1 each) 20 mL syringe.

4. The leg strap sterile package consisting of:

    (1each) leg strap.

Additionally, each shipment of an XO[1] device is accompanied by an "XpandOrtho Calibration Data" CD. This CD contains the necessary calibration data for the supplied XO[1] Device.

Indications: The XO[1] knee balancing system is intended for use as a tool for adjustment of a knee implant to reduce instability from flexion gap asymmetry.

Contraindications:

- Use of the XpandOrtho XO[1] knee balancing system is contraindicated in the presence of any active or suspected latent infection in or around the knee joint.
- The XpandOrtho XO[1] knee balancing system is contraindicated in non-standard total knee arthroplasty in which atypical bone cuts or custom component shape preclude its use.

- The XpandOrtho XO[1] knee balancing system is contraindicated in partial knee replacements such as unicompartmental arthroplasty.
- The XpandOrtho XO[1] knee balancing system may not be used in cases with severe deformity: for example; a residual varus or valgus greater than 5° even after making bone cuts and ligament releases.
- The XpandOrtho XO[1] knee balancing system may not be used in cases with severe mismatch in the gap at flexion and that at extension (flexion-extension gap mismatch greater than 5 mm).
- The XpandOrtho XO[1] knee balancing system is contraindicated in cases in which the minimum gap between tibiofemoral surfaces is less than 8 mm.
- The XpandOrtho XO[1] knee balancing system may not be used when the controller cannot be safely anchored to the thigh: for example, when the distance between the superior edge of the incision and the inferior margin of the tourniquet is too small to place the controller securely.

Precautions:

- Read and follow Instructions for Use (IFU) for the correct application of the XO[1] Device, GUI and displayed data.
- Data displayed is for reference purposes only and should be used at the surgeon's discretion and should not be the sole basis for surgical decisions.
- Check that the gap between the femur and tibia is at least 8mm.
- Insert the tibiofemoral distractor in a fully deflated condition only.
- Do not forcibly insert the tibiofemoral distractor between the femur and tibia. Do not forcibly strike any part of the XO[1] Device or the attached tibiofemoral distractor with any instrument (such as a mallet).
- The XO[1] Device is intended to be used for approximately 15 minutes during surgery. The device will not operate properly once the Controller Status Light flashes red.

-  If the Controller Status Light flashes red stop using the device immediately.
- The XO[1] Device is intended to be used by surgeons; skilled, trained and knowledgeable in the performance of total knee arthroplasty (TKA).
- The XO[1] Device should be used in a sterile operating room environment only.
- Use only the provided computer, software, CD ROM, and wireless receiver with the XO[1] Device.
- Ensure the PC is in Airplane Mode and the Wi-Fi is turned off

Warnings

- WARNING: No modification of this equipment is allowed.
- Do not attempt to inflate the XO[1] device with any means other than those supplied with the XpandOrtho XO[1] knee balancing system.
- Do not use The XO[1] device with components other than those supplied in the XpandOrtho package.
- Do not attempt to inflate the XO[1] device with any liquid.
- Do not attempt to re-process or re-sterilize the XO[1] device.
- The pouch containing the tray is not a sterile barrier.

-  The XO[1] device contains ferro-magnetic materials and is not to be used with Magnetic Resonance (MR) imaging equipment.

User and Patient Safety:

- The XO[1] device is intended for single use: do not re-use.
- Do not use after expiration date on the package labeling.
- The XO[1] device is provided sterile. Do not use if lidded tray is damaged or opened outside of the sterile field.
- Do not use if there is any evidence of damage, fracture, cracks, breaches in the system, separation of component parts, or exposure of internal surface or components.
- Do not pressurize over 30 psi.

Instructions for Use:

1. PC and GUI Preparation:

1.1. The PC and GUI should be prepared prior to the start of the TKA procedure.

1.2. Connect the PC to an AC power source.

1.3. Place the PC on a secure surface that will allow the display to be visible to the surgeon during the procedure.

1.4. Verify that the PC is in the following configuration. Set these parameters as required:

1.4.1. The PC is in “AIRPLANE MODE”.

1.4.2. The Wi-Fi is turned “OFF”.

1.4.3. An external CD Drive is attached to the PC via a USB port.

1.5. Insert the CD labeled “XpandOrtho Calibration Data” into the external CD drive. A calibration data CD is provided with each shipment of XO[1] devices.

1.6. From the XpandOrtho Calibration Data CD:

1.6.1. Download the file "TrialCalData.xml"

1.6.2. Save the file "TrialCalData.xml" in the directory C:\Xpand Ortho\Calibration Data.

1.6.3. Once the Calibration Data is saved on the PC, eject the CD and remove it from the external CD drive.

1.6.4. If desired, the external CD drive may be removed from the PC.

1.7. Start the XpandOrtho Graphical User Interface (GUI) software program.

1.8. Connect the Wireless Receiver Assembly to the PC via the USB cable.

2. Transferring the XO[1] Device to the sterile field:

2.1. Remove the XO[1] device sterile components from the shipping carton in preparation for transfer to the sterile operating field (sterile field).

2.1.1. Open and discard the non-sterile pouch containing the XO[1] device. <u>DO NOT OPEN THE XO[1] DEVICE STERILE TRAY, STERILE SYRINGE POUCH OR THE STERILE LEG STRAP POUCH AT THIS TIME.</u>

2.2. Prepare a surface within the sterile field to receive the XO[1] device and components.
2.3. Using sterile technique, open the leg strap pouch and place the leg strap onto the prepared surface within the sterile field.
2.4. Using sterile technique, open the syringe pouch and place the syringe onto the prepared surface within the sterile field.
2.5. Using sterile technique, open the XO[1] device and place the contents onto the prepared surface within the sterile field.

3. Preparation of the XO[1] device for use:

3.1. Preparation of the XO[1] Device is to be completed when the surgeon is ready to begin the assessment of the ligament balance. The XO[1] Device is intended to be used for approximately 15 minutes during surgery. The device will not operate properly once the Controller Status Light flashes red. (see "Precautions")
3.2. Preparation of the XO[1] device is to be performed within the sterile field using appropriate techniques.
3.3. Attach the female end of the dual check valve to the 20ml syringe and seat the luer fitting by turning it clockwise.
3.4. Attach the female end of the extension line to the dual check valve and seat the luer fitting by turning it clockwise.
3.5. Remove the luer cap from the XO[1] device. Attach the male end of the extension line to the XO[1] device and seat the luer fitting by turning it clockwise.
3.6. Place the battery into the XO[1] device with the dot and "+" on the battery cap facing up. Push the battery in until it stops. Rotate the battery clockwise approximately one quarter turn to lock.
3.6.1. When the battery is correctly seated the Controller Status Light appears:
3.6.1.1. Momentarily red when the battery is first seated. (1 second or less)
3.6.1.2. Flashing green continuously.
3.7. At this point the preparation of the XO[1] device is complete.
3.8. If any of the operations fails to perform as described, refer to the "Troubleshooting" section.

4. Activation of Communication and GUI.

4.1. Ensure that the GUI is displayed on the PC.
4.2. Verify that the "Radio" display located in the upper left of the GUI screen indicates at least one bar.
4.3. Choose the knee that the procedure is to be performed on, then choose "Next".
4.4. In the "Trial Serial Number" box, choose the serial number that corresponds with the XO[1] device being activated, then choose "Next".
4.5. In the "Trial Serial Number" box, choose "Select" to confirm the previously highlighted device serial number. At this point the preliminary activation of the XO[1] device is complete.
4.6. If any of the operations fails to perform as described, refer to the "Troubleshooting" section.

5. Placement of the device on the patient.

5.1. If a tourniquet is being applied, ensure that there will be at least 127mm (5inches) of space between the inferior margin of the tourniquet and the proximal extent of the incision. Cover the patient's lower thigh with a sterile barrier film or drape. Wrap the leg strap around the patient's thigh, on top of the sterile barrier film or drape, and tighten firmly. Ensure that the Velcro patch on the leg strap is positioned anteriorly on the thigh.

5.2. Orient the XO[1] device such that it's long axis is aligned with that of the patient's thigh, and the attached tibiofemoral distractor is facing the surgical site.

5.3. While maintaining the orientation of the XO[1] device as described in 5.2, locate the controller above the Velcro patch on the leg strap. Ensure that the keypad is in the anterior position, and firmly attach the controller box to the Velcro patch on the leg strap.

5.4. Drape the XO[1] device controller with sterile barrier film.

6. Placement of the tibiofemoral distractor.

6.1. Confirm that the tibiofemoral distractor is fully deflated before inserting in the knee.

6.2. If the tibiofemoral distractor is pressurized outside the knee, disengage the extension line from the dual check valve on the end of the syringe and allow the XO[1] device to deflate. Reattach the extension line to the dual check valve when the XO[1] device is fully deflated.

6.3. Insert the tibiofemoral distractor into the knee between the cut tibial and femoral surfaces. The bottom surface of the tibiofemoral distractor is flat and should be in contact with the tibial bone cut. The upper surface is contoured to articulate with the femoral condyles and should be in contact with femoral surface.

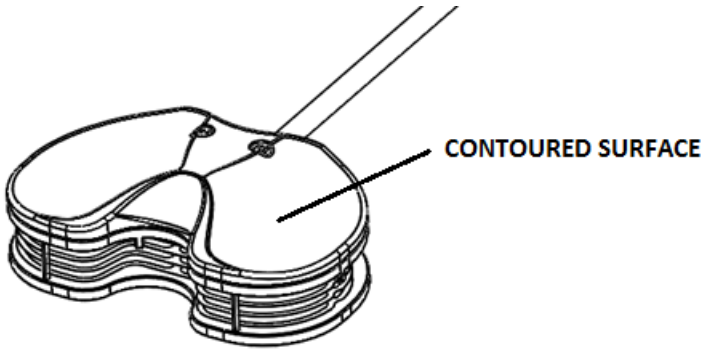
6.4. The tibiofemoral distractor should fit comfortably and be centered on the tibial cut surface. Check that the curved upper surfaces articulate with the femoral condyles.

6.5. Do not force the tibiofemoral distractor or attempt to hammer the tibiofemoral distractor into the knee.

6.6. If the tibiofemoral distractor cannot be inserted easily check that it is fully deflated and that the gap between the tibial cut surface and the femoral condyles is at least 8mm (0.31").

6.7. Note: The XO[1] device is contraindicated in cases in which the gap between tibiofemoral surfaces is less than 8 mm (0.31").

6.8. If the distance between the tibial cut surface and the femoral condyle is at less than 8mm (0.31")., abandon the use of the XO[1] device.



7. Pressurize the XO[1] device:

7.1. Pump the piston of the 20mL syringe to pressurize the tibiofemoral distractor to 20psi (approximately 5 to 6 full strokes). The pressure will be displayed on the GUI. If the pressure is greater than 25psi, disengage the extension line from the dual check valve on the end of the syringe and allow the XO[1] device to deflate. Reattach the extension line to the dual check valve and inflate to the desired pressure.

7.2. Do not pressurize the XO[1] device with the tibiofemoral distractor outside the knee.

7.3. Do not pressurize the XO[1] device with the tibiofemoral distractor with any device other than the supplied 20mL syringe.

7.4. Do not attempt to pressurize the XO[1] device with any liquids or in any other means other than as described in these instructions.

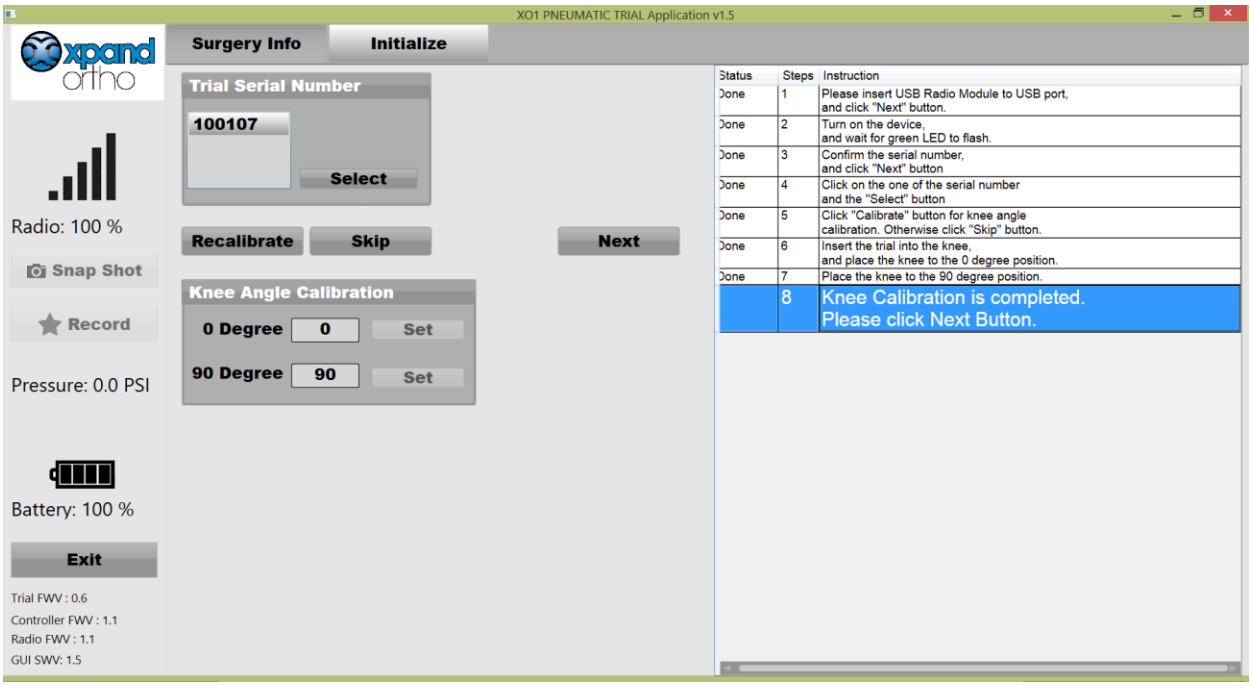
7.5. If the tibiofemoral distractor is pressurized outside the knee, disengage the extension line from the dual check valve on the end of the syringe and allow the XO[1] device to deflate.

7.6. Confirm that the tibiofemoral distractor is fully deflated before inserting in the knee.

8. Calibrate knee flexion:

8.1. To confirm proper positioning of the XO[1] device controller relative to the tibiofemoral distractor, hold the knee in 0° flexion and at 90° flexion and monitor the flexion reading on the display. If the GUI display is different from the knee position, use the "**Calibrate**" tab on the GUI and follow the instructions on the GUI to calibrate knee flexion. Note: once a calibration has been performed, the "**Calibrate**" tab will change to read "**Recalibrate**".

8.2. If during the procedure, the XO[1] device is removed, or repositioned, the user may recalibrate by repeating the instructions in the previous step.



9. Controller Buttons:

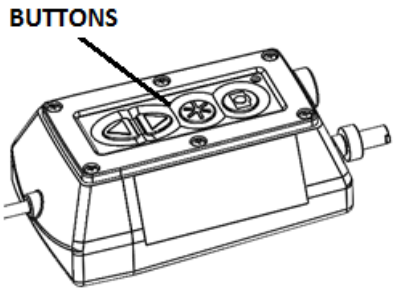
9.1. The XO[1] device controller has four physical buttons on the top surface. The buttons function as:

9.1.1. **Forward Arrowhead:** Moves the highlighted tab selection in a clockwise direction around the GUI display.

9.1.2. **Back Arrowhead:** Moves the highlighted tab selection in a counter-clockwise direction around the GUI display.

9.1.3. **Asterisk (*):** Equivalent to a mouse click on the highlighted tab.

9.1.4. **Camera icon:** Takes a snapshot of the data in the graphs shown on the GUI.



10. **GUI Data Display:**
    - **10.1.** There are two display tabs available on the GUI.
    - **10.2. View 1:** View 1 displays a live axial image of the tibiofemoral distractor with a cross-hair in the center. The location of the cross-hair provides a visual indication of the tilt between the top and bottom surfaces of the tibiofemoral distractor. For example, if the medial compartment is tight, the top surface will tilt medially relative to the bottom surface and the cross-hair will move towards the medial side of the knee. The net tilt between the top and bottom surfaces, the gap distance between the top and bottom surfaces, and the flexion angle are displayed numerically. Two live graphs are also displayed in View 1.
        - **10.2.1. MedioLateral Tilt Graph:** The mediolateral tilt between the tibial and femoral surfaces over the range of flexion that the knee is flexed.
        - **10.2.2. Tibiofemoral Gap Graph:** The gap between the tibial and femoral surfaces over the range of flexion as the knee is flexed.
    - **10.3. View 2:** View 2 displays three axial images of the tibiofemoral distractor with cross-hairs in the center. View 2 also displays 3 graphs.
        - **10.3.1.** The image on the left displays the data recorded when the knee was at 0° flexion.
        - **10.3.2.** The image in the center displays the same live data as in View 1.
        - **10.3.3.** The while the image on the right displays the data recorded when the knee was at 90° flexion.
        - **10.3.4. MedioLateral Tilt Graph:** Displays the mediolateral tilt between the tibial and femoral surfaces over the range of flexion that the knee is flexed.
        - **10.3.5. Tibiofemoral Gap Graph:** Displays the gap between the tibial and femoral surfaces over the range of flexion as the knee is flexed.
        - **10.3.6. AnteroPosterior Tilt Graph:** Displays the anteroposterior tilt between the tibial and femoral surfaces over the range of flexion that the knee is flexed.
11. **Flexion-Extension Gap Balance:** The GUI will display the net gap between the tibial and femoral surfaces in real time. The information may be referenced from either the View 1 or View 2 tabs.
    - 11.1. To check gap in flexion and extension: hold the knee in 0° and read the gap off the Tibiofemoral Gap Graph. Then flex the knee to 90° and read the gap off the Tibiofemoral Gap Graph.

11.2. This process can be repeated as many times as needed. If the surgeon desires to recut the bones or reposition the components, tibiofemoral distractor can be deflated and removed.

11.3. If the surgeon desires to perform soft-tissue releases and there is adequate surgical access, the surgeon can perform the soft-tissue releases with the tibiofemoral distractor in place and monitor the tibiofemoral gap in real-time on the Tibiofemoral Gap Graph.

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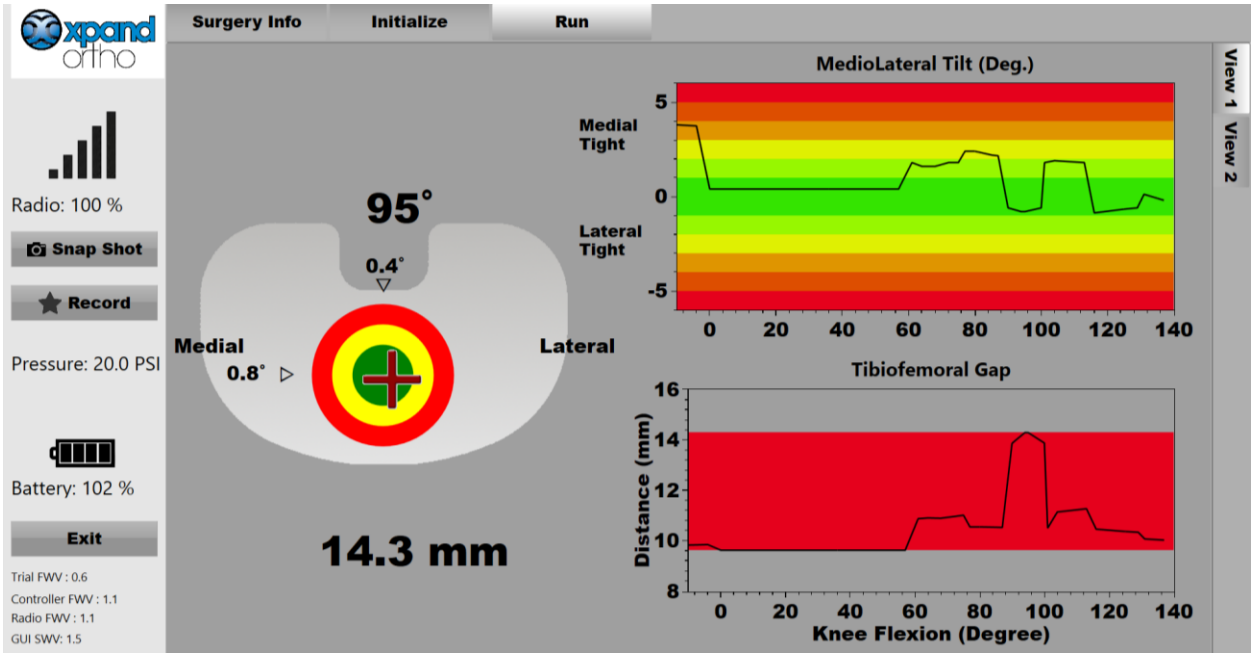
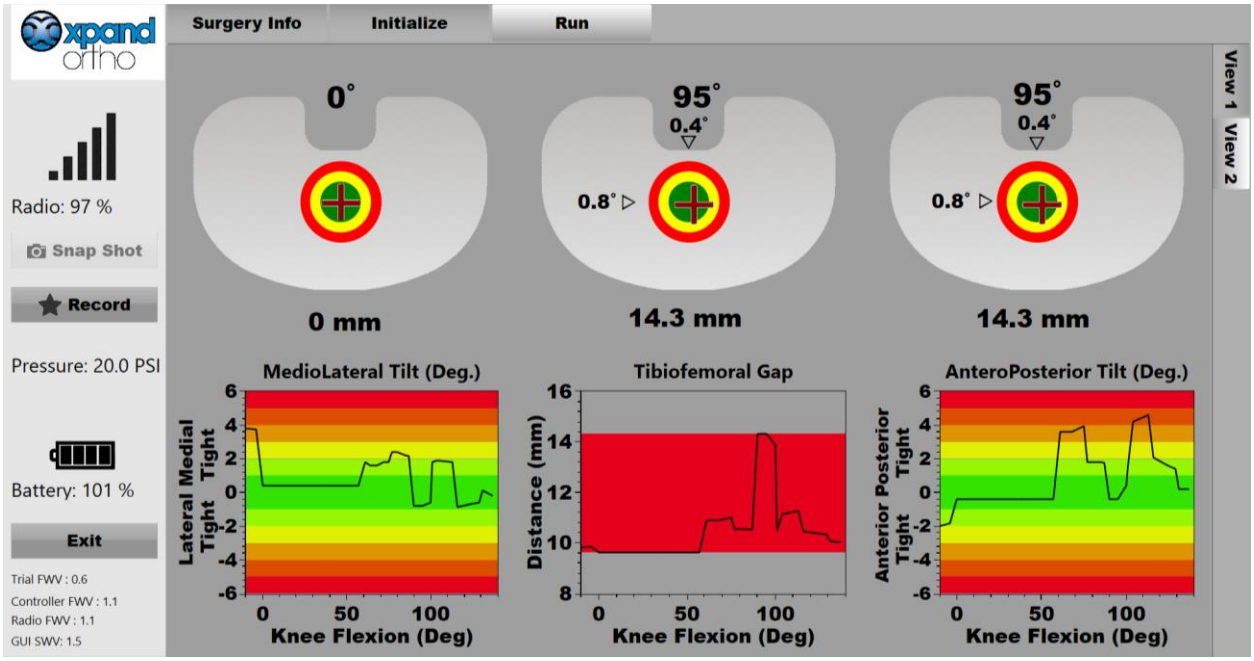


View 1



View 2

12. **Measure Dynamic Knee Balance:** The GUI will display the net gap between the tibial and femoral surfaces in real time as well as record the gap and show a plot of the tibiofemoral gap against knee flexion. The information may be referenced from either the View 1 or View 2 tabs.
    - **12.1.** Flex the knee gently between full extension and full flexion. To record the gap, flex and extend the knee again.
    - **12.2.** Changing knee flexion updates the plot to display the newly recorded gap.
13. **Deflation and Removal**: Disengage the extension line from the dual check valve on the end of the syringe and allow the tibiofemoral distractor to deflate. Remove the tibiofemoral distractor from the knee joint space.
14. **Device Disposal:** Click the Exit button to end the wireless communication between the controller and the PC.
    - 14.1. Remove the battery from the device by turning the battery knob counterclockwise one quarter turn and pulling out.
    - 14.2. Dispose of the device, leg strap, and battery according to facility policies and procedures.

15. **Wireless Technology:** XO[1] Knee Balancing System uses a point-to-point network configuration.
    1. The controller board of the XO[1] Knee Balancing System contains a radio that transmits the data from the balancing device to the display computer. The radio is an A2500R24A (Anaren, NY) low power transceiver operating at 2.4GHz frequency. See certification ID and FCC compliance statement below.

2. A wireless USB integrated radio receiver assembly is connected to the computer display. The assembly connects an A2500R24A-EZ4E Anaren Integrated Radio to a USB interface.
3. Total output power output is 1.5 mW maximum, and range is a maximum of 10m.
4. The wireless technology is used primarily in the operating room during knee surgery.
5. The controller firmware transmits data at 115,200 baud at frequency of 10 Hz.
6. The Quality of Service (QoS) needed for the XO[1] Knee Balancing System is data transmission at 10Hz within a range of 10 feet. This is achieved by communicating within the 2400.9 MHz channel which does not interfere with BlueTooth or WLAN frequencies.
7. The wireless data transmission has been tested for data throughput, latency, and data integrity at up to 10 Hz data rate.
8. 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. Changes or modifications not expressly approved by XpandOrtho Inc. void the user's authority to operate the equipment.
9. Compliant with IEC 61000-4-3 per ETSI EN 301-489-1

16. Wireless Security and Precautions:

1. Please ensure that Wi-Fi is kept disabled on the provided PC computer. This prevents any unauthorized wireless access to the XO[1] Knee Balancing System or the display computer. Use the provided computer only for communication and display with the XO[1] Knee Balancing System. Do not use for any other application. Do not attempt to access the internet or email.
2. Do not enter any patient-identifiable information in the graphic user interface of the provided PC computer.
3. 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:
    a. Reorient or relocate the receiving antenna.
    b. Increase the separation between the equipment and receiver.
    c. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
    d. Consult the manufacturer.

17. Troubleshooting:

1. Controller LED does not light up. Make sure the battery assembly is inserted and turned clockwise.
2. ⚠ Controller LED is red. Battery is low, stop using the device.

3. Device does not communicate with the computer. Remove and re-insert the USB of the Wireless Receiver. If this doesn't work, restart the PC. If this doesn't work, replace the USB receiver. If this does not work replace the device.
4. Device does not communicate with the computer. Check for and turn off all other wireless devices in the vicinity. If the XO[1] Knee Balancing System begins to communicate, turn on the other wireless devices sequentially to identify the source of interference. Either keep the interfering device turned off, or move it away from the vicinity of the XO[1] Knee Balancing System
5. Controller and USB receiver LEDs light up but PC does not display the data. Check that the serial number on the controller label matches the serial number selected on the PC display and that the appropriate COM Port is selected. If the serial numbers match, restart the PC. If the PC does not display data after restarting, replace the device with a new one.

Device Accessories (detachable parts):

Leg Strap
Control Syringe, 20 ml
Computer with GUI Software
Wireless Tool, Programmed

Detachable Parts:

Vented Male Luer Lock Cap
Battery Cap Assembly
Dual Check Valve
Bonded Pressure Monitoring Extension Line

Device Specifications:

IP rating for the device: IPX2

Applied Parts: Type B

FCC ID: 2ALBY-XO1

Storage Conditions:

Products must be stored in a clean, dry environment.
Temperature Limits: -20°C to 60°C

Manufactured for XpandOrtho, Inc.
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