Ultraflex ONE™
Dynamic Assist™
Orthotic Components
Instruction Manual

UNIVERSAL TECHNOLOGY:
KNEE, ELBOW, WRIST,
ANKLE, FLEXION,
EXTENSION
A note on this manual
This manual is meant to serve as a reference to the clinical team but particularly to orthotists and therapists. Both professions are best served by reading this manual in its entirety however sections 1.0, 3.0, 4.0, 5.0, 6.0, and 10.0 are of most importance to orthotists. The remaining sections are relevant to both orthotists and therapists. Section 11.0 is particularly important for therapists. The Patient Wear Schedule and Success Stickers are intended to be given to the patient or the patient’s caregiver. The clinical team should use its best judgment with regard to furnishing the patient with this manual.
# Table of Contents

1.0 Scope of Delivery  
2.0 Intended Use/General Description  
3.0 Safety Information  
4.0 Visual Identification and Function of Product Features  
  4.1 Platform  
  4.2 Power Unit  
  4.3 Hardware and Accessories for Large Components  
  4.4 Hardware and Accessories for Small Components  
5.0 Initial Setup for Specific Joint Orientation  
  5.1 Initial setup for Left Knee or Right Elbow  
  5.2 Initial setup for Right Knee or Left Elbow  
  5.3 Initial setup for Wrist or Ankle  
6.0 Fabrication Guidelines  
  6.1 Use of the Ultraflex ONE™ Jig  
  6.2 Finding Joint Axis  
  6.3 Metal Work  
  6.4 Adaptor Struts  
7.0 Using the Lock-Out Handle to Lock the Platform  
8.0 Fine Tuning Range of Motion Limits  
  8.1 Adjusting Range of Motion Gear Position  
9.0 Using the Power Unit  
  9.1 Attaching the Power Unit  
  9.2 Removing the Power Unit  
  9.3 Reversing the Assist Direction of the Power Unit  
  9.4 Adjusting the Tension of the Power Unit  
10.0 Maintenance of the Ultraflex ONE™ Components  
11.0 Guidelines for Caregivers  
  11.1 Wear Times  
  11.2 Tension Settings  
  11.3 General Brace Care  
12.0 Learning More About Ultraflex  
Patient Wear Schedule  
Insert
1.0 Scope of Delivery

Ultraflex ONE™ Large Components – Model # UF ONE LG
Ultraflex ONE™ Small Components – Model # UF ONE SM

Herein after called Large Components and Small Components

In addition to this manual, for each Ultraflex ONE™ Component order placed the customer can expect the following contents to be delivered:

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultraflex ONE™ Orthotic Joint “Platform”</td>
<td>1</td>
</tr>
<tr>
<td>Ultraflex ONE™ Adjustable Assist Unit “Power Unit”</td>
<td>1</td>
</tr>
<tr>
<td>Adaptor Screw</td>
<td>2</td>
</tr>
<tr>
<td>Adaptor Post</td>
<td>2</td>
</tr>
<tr>
<td>Joint Pad</td>
<td>1</td>
</tr>
<tr>
<td>WHFO Distal Adaptor Strut “J Bar”</td>
<td>1</td>
</tr>
<tr>
<td>AFO Distal Adaptor Strut “T Bar”</td>
<td>1</td>
</tr>
<tr>
<td>End Range Screw</td>
<td>2</td>
</tr>
<tr>
<td>#7 Drill Bit</td>
<td>1</td>
</tr>
<tr>
<td>1/8” (3.2mm) Drive Ball Driver</td>
<td>1</td>
</tr>
<tr>
<td>5/64” (2mm) Allen Key*</td>
<td>1</td>
</tr>
</tbody>
</table>

* This item is only included with the Small Components

Fabrication jigs must be ordered separately. For Ultraflex Genuine Fabricated™ Orthoses, the quantity of Ultraflex ONE™ components supplied shall be according to the design specified by the orthotist.

2.0 Intended Use/General Description

Orthotic braces which incorporate Ultraflex ONE™ components are intended for therapeutic use to manage loss of motion associated with various neurological and orthopedic indications for both adults and pediatrics.

<table>
<thead>
<tr>
<th>Neurological Indications</th>
<th>Orthopedic Indications</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebral Palsy</td>
<td>Ligament Tears</td>
<td>Fixed Deformities</td>
</tr>
<tr>
<td>Cerebral Vascular Accident</td>
<td>Tendon Rupture/Repair</td>
<td></td>
</tr>
<tr>
<td>Spina Bifida</td>
<td>Toe Walking</td>
<td></td>
</tr>
<tr>
<td>Traumatic Brain Injury</td>
<td>Burns</td>
<td></td>
</tr>
<tr>
<td>Brachial Plexus Injury</td>
<td>Limb Loss</td>
<td></td>
</tr>
<tr>
<td>Spinal Cord Injury</td>
<td>Rheumatoid Arthritis</td>
<td></td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>Severe Fractures/Trauma</td>
<td></td>
</tr>
<tr>
<td>Reflex Sympathetic Dystrophy</td>
<td>Arthrogryposis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Muscular Dystrophy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total Knee Arthroplasty</td>
<td></td>
</tr>
</tbody>
</table>
The two primary components of the Ultraflex ONE™ system are the Ultraflex ONE™ Orthotic Joint and Ultraflex ONE™ Adjustable Assist Unit herein after referred to as the “Platform” and “Power Unit” respectively. When incorporated into an orthosis the Platform serves as an orthotic hinge or joint with features to statically control motion. The Power Unit mounts to the Platform and provides continuous tension to the limb to restore range of motion to the affected joint. It is recommended that the Ultraflex ONE™ components are combined with an Ultraflex Range of Motion (ROM) hinge on the contralateral side.

The components are intended to be fitted by an orthotist and used under the supervision of the orthotist, therapist, and prescribing physician. The components are for orthotic use only and are designed for resting use although they can be used for limited household ambulation, standing, and transfers to increase compliance. The components are not intended for community ambulation. Warranty information may be obtained from the Ultraflex web site http://www.ultraflexsystems.com.

3.0 Safety Information

The information in this section is addressed to orthotists. The content related to safety is confined to the features of the components. It does not contain any notes regarding the risks associated with orthotics in general which are obvious to orthotists. The orthotist should verify correct functioning of the components prior to the delivery of the orthosis to the patient. To ensure proper use, please demonstrate to the patient and caregivers how to use and maintain the product correctly.

It should be made clear that the settings of the joints including the tension and static controls should not be changed by anybody other than the orthotist or therapist unless the overseeing physician decides otherwise. The components should not be immersed in water or be exposed to the elements for prolonged periods of time. Particular safety or product performance concerns will be addressed within the relevant sections of this manual and will be accompanied by the ⚠ symbol.
4.0 Visual Identification and Function of Product Features

4.1 Platform

Figure 4.0a

(1) Proximal Strut
(2) Lock Out Handle
(3) Power Unit Catch
(4) Spline
(5) Range of Motion Gear
(6) Stop Angle Mark
(7) Worm
(8) Distal Strut

Figure 4.0b

(1) Proximal Strut
(9) Power Unit Release Button
(11) End Range Tapped Holes
(10) Platform Retainer
(8) Distal Strut
# 4.1 Platform

<table>
<thead>
<tr>
<th>#</th>
<th>NAME</th>
<th>QUANTITY</th>
<th>FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Proximal Strut</td>
<td>1</td>
<td>Aluminum upright bar to be contoured and fastened to the orthotic shell proximal to the anatomical joint</td>
</tr>
<tr>
<td>2</td>
<td>Lock Out Handle</td>
<td>1</td>
<td>Blue-colored handle used to lock the Platform</td>
</tr>
<tr>
<td>3</td>
<td>Power Unit Catch</td>
<td>1</td>
<td>Spring loaded latch which inserts into the Catch Receiver of the Power Unit. It serves to maintain engagement between the Platform and Power Unit.</td>
</tr>
<tr>
<td>4</td>
<td>Spline</td>
<td>1</td>
<td>Centrally located grooved shaft which mates with the Spline Receiver of the Power Unit</td>
</tr>
<tr>
<td>5</td>
<td>Range of Motion Gear</td>
<td>1</td>
<td>Circular ridged gear whose position can be adjusted to change extension or flexion range of motion limits</td>
</tr>
<tr>
<td>6</td>
<td>Stop Angle Mark</td>
<td>2</td>
<td>One of two red colored reference marks located on the Range of Motion Gear used to gauge the angle to which the Range of Motion Gear stops at a particular Range of Motion of the Platform</td>
</tr>
<tr>
<td>7</td>
<td>Worm</td>
<td>1</td>
<td>A gear which, when turned, will change the position of the Range of Motion Gear and Stop Angle Marks so as to set a range of motion stop</td>
</tr>
<tr>
<td>8</td>
<td>Distal Strut</td>
<td>1</td>
<td>Aluminum upright bar to be contoured and fastened to the orthotic shell distal to the anatomical joint</td>
</tr>
<tr>
<td>9</td>
<td>Power Unit Release Button</td>
<td>1</td>
<td>Allows for the Power Unit to be detached from the Platform when pressed in a upward direction</td>
</tr>
<tr>
<td>10</td>
<td>Platform Retainer</td>
<td>1</td>
<td>Pivot point and central fastener for the Platform. The Ultraflex ONE™ jig also locates on the Platform Retainer to facilitate proper alignment of the orthotic joints to one another.</td>
</tr>
<tr>
<td>11</td>
<td>End Range Tapped Holes</td>
<td>4</td>
<td>Four tapped holes located on the reverse profile of the platform. Each End Range Tapped Hole is designed to receive an End Range Screw to set up the Platform with the normal anatomical range of the joint it is intended to treat and to ensure proper functioning of the Power Unit.</td>
</tr>
</tbody>
</table>
4.2 Power Unit

Figure 4.0c

- (1) Catch Receiver
- (2) Tension Level Indicator
- (3) Spline Receiver
- (4) Assist Direction Indicator
- (5) Tension Adjustor

PROXIMAL END
FRONT PROFILE

DISTAL END

REVERSE PROFILE

reverse profile
## 4.2 Power Unit

<table>
<thead>
<tr>
<th>#</th>
<th>NAME</th>
<th>QUANTITY</th>
<th>FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Catch Receiver</td>
<td>1</td>
<td>Through feature on the proximal aspect of the Power Unit designed to interface with the Power Unit Catch</td>
</tr>
<tr>
<td>2</td>
<td>Tension Level Indicator</td>
<td>1/ side</td>
<td>Indicates current tension setting of the Power Unit. Tension settings range from a minimum of 0 to a maximum of 7 in increments of 0.5. Initial factory setting is 1.</td>
</tr>
<tr>
<td>3</td>
<td>Spline Receiver</td>
<td>1</td>
<td>Grooved feature which mates with the Spline of the Platform</td>
</tr>
<tr>
<td>4</td>
<td>Assist Direction Indicator</td>
<td>1/ side</td>
<td>One of two markings, one of which is clockwise and the other counterclockwise. These serve to indicate the direction of the assist generated by the Power Unit.</td>
</tr>
<tr>
<td>5</td>
<td>Tension Adjustor</td>
<td>1</td>
<td>Mechanism used to increase/decrease tension generated by the Power Unit</td>
</tr>
</tbody>
</table>
4.3 Hardware and Accessories for Large Components

Figure 4.0d

(1) Adaptor Screw
(2) Adaptor Post
(3) Joint Pad
(4) WHFO Distal Adaptor Strut “J Bar”
(5) AFO Distal Adaptor Strut “T Bar”
(6) Drill Bit
(7) End Range Screw
(8) Ball Driver
### 4.3 Hardware and Accessories for Large Components

<table>
<thead>
<tr>
<th>#</th>
<th>NAME &amp; PART NUMBER</th>
<th>QUANTITY</th>
<th>FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adaptor Screw 119-28-082</td>
<td>2</td>
<td>Used with Adaptor Post to fasten Adaptor Strut to Distal Strut</td>
</tr>
<tr>
<td>2</td>
<td>Adaptor Post 234-38-042</td>
<td>2</td>
<td>Used with Adaptor Screw to fasten Adaptor Strut to Distal Strut</td>
</tr>
<tr>
<td>3</td>
<td>Joint Pad 467-54-050</td>
<td>1</td>
<td>Adhesive pad applied to the Platform. Retainer post fabrication for cushioning of the patient's skin</td>
</tr>
<tr>
<td>4</td>
<td>WHFO Distal Adaptor Strut &quot;J Bar&quot; 401-62-005</td>
<td>1</td>
<td>For use with WHFO fabrication to facilitate attachment to hand piece. Can also be used to facilitate difficult bends.</td>
</tr>
<tr>
<td>5</td>
<td>AFO Distal Adaptor Strut &quot;T Bar&quot; 401-62-055</td>
<td>1</td>
<td>For use with AFO fabrication to facilitate attachment to the foot plate. Can also be used to facilitate difficult bends.</td>
</tr>
<tr>
<td>6</td>
<td>Drill Bit 300-03-010</td>
<td>1</td>
<td>#7 drill bit supplied for drilling the correct hole size for attaching either of the Adaptor Struts to the Distal Strut of the Platform</td>
</tr>
<tr>
<td>7</td>
<td>End Range Screw 253-62-001</td>
<td>2</td>
<td>Screw which threads into one of the End Range Tapped Holes of the Platform to establish the normal anatomical range of the joint it is intended to treat. Shipped attached to the Platform</td>
</tr>
<tr>
<td>8</td>
<td>Ball Driver 300-03-008</td>
<td>1</td>
<td>Used to adjust the tension of the Power Unit and the position of the Range of Motion Gear. It also serves as a driver for the End Range Screws.</td>
</tr>
</tbody>
</table>
4.4 Hardware and Accessories for Small Components

Figure 4.0e

(1) Adaptor Screw

(2) Adaptor Post

(3) Joint Pad

(4) WHFO Distal Adaptor Strut “J Bar”

(5) AFO Distal Adaptor Strut “T Bar”

(6) Drill Bit

(7) End Range Screw

(8) Ball Driver

(9) Allen Key
## 4.4 Hardware and Accessories for Small Components

<table>
<thead>
<tr>
<th>#</th>
<th>NAME &amp; PART NUMBER</th>
<th>QUANTITY</th>
<th>FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adaptor Screw 119-28-062</td>
<td>2</td>
<td>Used with Adaptor Post to fasten Adaptor Strut to Distal Strut</td>
</tr>
<tr>
<td>2</td>
<td>Adaptor Post 234-38-022</td>
<td>2</td>
<td>Used with Adaptor Screw to fasten Adaptor Strut to Distal Strut</td>
</tr>
<tr>
<td>3</td>
<td>Joint Pad 467-54-050</td>
<td>1</td>
<td>Adhesive pad applied to the Platform Retainer post fabrication for cushioning of the patient’s skin</td>
</tr>
<tr>
<td>4</td>
<td>WHFO Distal Adaptor Strut “J Bar” 401-64-005</td>
<td>1</td>
<td>For use with WHFO fabrication to facilitate attachment to hand piece. Can also be used to facilitate difficult bends.</td>
</tr>
<tr>
<td>5</td>
<td>AFO Distal Adaptor Strut “T Bar” 401-64-055</td>
<td>1</td>
<td>For use with AFO fabrication to facilitate attachment to the foot plate. Can also be used to facilitate difficult bends.</td>
</tr>
<tr>
<td>6</td>
<td>Drill Bit 300-03-010</td>
<td>1</td>
<td>#7 drill bit supplied for drilling the correct hole size for attaching either of the Adaptor Struts to the Distal Strut of the Platform</td>
</tr>
<tr>
<td>7</td>
<td>End Range Screw 253-64-001</td>
<td>2</td>
<td>Screw which threads into one of the End Range Tapped Holes of the Platform to establish the normal anatomical range of the joint it is intended to treat. Shipped attached to the Platform</td>
</tr>
<tr>
<td>8</td>
<td>Ball Driver 300-03-008</td>
<td>1</td>
<td>Used to adjust the tension of the Power Unit and the position of the Range of Motion Gear</td>
</tr>
<tr>
<td>9</td>
<td>Allen Key 300-60-002</td>
<td>1</td>
<td>Driver for the End Range Screws</td>
</tr>
</tbody>
</table>
5.0 Initial Setup for Specific Joint Orientation

Figure 5.0a

PROXIMAL

DISTAL

End Range Screws shipped pre-installed from the factory in these locations

Figure 5.0b

Use only these holes for ankle or wrist applications

Use only this hole for right knee and left elbow applications

Use only this hole for left knee and right elbow applications
Depending on the type of brace to be fabricated, the Platform must have either one or two End Range Screws installed correctly at all times. The End Range Screws provide the correct anatomical range for the joint to be treated. They also assure proper functioning of the Power Unit. If the Power Unit is attached and used without the End Range Screw(s) installed in the correct position(s), damage can occur to the Power Unit rendering it inoperable and voiding the warranty. The Power Unit is shipped attached to the Platform and set up for a right ankle/wrist dorsiflexion assist.

To setup the Platform for its specific joint orientation, follow these steps:

1. Remove the Power Unit (reference section 9.2)
2. Unscrew the two preinstalled End Range Screws (Figure 5.0a)
3. Note the significance of the markings on the Platform (Figure 5.0b):

   A / W = Ankle or Wrist  
   RK / LE = Right Knee or Left Elbow  
   LK / RE = Left Knee or Right Elbow

4. Refer to the following subsections for specific joint setup

   These initial setups assume a lateral placement of the Platform with the exception of the wrist which is assumed to be placed on the medial (ulnar) side of the hand.
Figure 5.1a

End Range
Screw position
left knee or
right elbow

Figure 5.2a

End Range
Screw position
right knee or
left elbow

Figure 5.3a

End Range
Screw position
ankle or wrist
5.1 Initial Setup for Left Knee or Right Elbow
Allows motion from 135° of flexion to 15° of hyperextension. Use LK/RE Hole.

1. Apply a small amount of semi-permanent thread-locker (such as Loctite 243®) to the threads of one End Range Screw.

2. With the Platform positioned as pictured in Figure 5.1a, thread the screw into the hole where indicated. Tighten using 1/8" (3.2mm) Ball Driver for Large Platforms; use 5/64" (2mm) Allen Wrench for Small Platforms.

3. Ensure the joint moves from 135° of flexion to 15° of hyperextension.

5.2 Initial Setup for Right Knee or Left Elbow
Allows motion from 135° of flexion to 15° of hyperextension. Use RK/LE Hole.

1. Apply a small amount of semi-permanent thread-locker (such as Loctite 243®) to the threads of one End Range Screw.

2. With the Platform positioned as pictured in Figure 5.2a, thread the screw into the hole where indicated. Tighten using 1/8" (3.2mm) Ball Driver for Large Platforms; use 5/64" (2mm) Allen Wrench for Small Platforms.

3. Ensure the joint moves from 135° of flexion to 15° of hyperextension.

5.3 Initial Setup for Wrist or Ankle
Allows motion from 75° of plantar (palmar) flexion to 75° of dorsiflexion. Use both A/W Holes.

1. Apply a small amount of semi-permanent thread-locker (such as Loctite 243®) to the threads of both End Range Screws.

2. Thread End Range Screws into positions shown in figure 5.3a. Tighten using 1/8" (3.2mm) Ball Driver for Large Platforms; use 5/64" (2mm) Allen Wrench for Small Platforms.

3. Ensure the joint moves from 75° of dorsiflexion to 75° of plantar (palmar) flexion.
6.0 Fabrication Guidelines

Figure 6.2a

BRASS TUBE PLACEMENT
6.1 Use of the Ultraflex ONE™ Jig

An Ultraflex ONE™ Jig is required (sold separately) for proper alignment of the orthotic joints. Use part # UF ONE JIG LG for Large Platforms and part # UF ONE JIG SM for Small Platforms.

6.2 Finding Joint Axis

Proper alignment of the orthotic joints to one another as well as to the anatomical axis is vital for optimum performance.

1. Precisely locate the anatomical joint axis in the positive patient model.

2. Drill a 7/32" (5.6mm) hole through the joint axis of the positive model.

3. Insert the 7/32" (5.6mm) brass tube included with the jig kit through the hole (Figure 6.2a). Brass tube may also be placed in the negative cast at the joint axis before it is filled with plaster.

4. Trim tubing so that it is flush with the positive patient model.
Figure 6.3a
Plastic trimmed away from Brass Tube

Figure 6.3b
Jig inserted into Brass Tube

Figure 6.3c
Platform fixtured on Jig
6.3 Metal Work

The Proximal and Distal Struts should be contoured to the positive patient model after the plastic shells are thermoformed.

1. After thermoforming shells, cut plastic away from brass tubing used in previous section (Figure 6.3a).

2. Insert the shaft of the jig into the brass tube on the lateral side of the positive patient model with the exception of the wrist which is placed medially (Figure 6.3b). The washers included with the jig kit can be stacked onto the jig shaft to vary the joint spacing from the anatomy.

3. Remove Power Unit from Platform (Reference Section 9.2), if not done already.

4. Set the Platform angle to correspond to the anatomical angle of the positive patient model. Use the Lock Out Handle to lock the Platform (Reference Section 7.0).

5. Insert the Platform Retainer into the recessed surface of the jig head. This will ensure proper alignment to the anatomical axis (Figure 6.3c).

6. Do not bend the struts anywhere within the region shown in figure 6.3d.

7. Contour struts using standard industry bending irons suitable to the strut thickness. Fasten struts to the outside of the plastic shells using posts and screws or rivets.

8. Ensure orthosis has full range of motion in both directions and Platform articulates smoothly.
6.4 Adaptor Struts

Figure 6.4a

Figure 6.4b
6.4 Adaptor Struts

The adaptor struts are included to facilitate bending to the footplate of an AFO or handpiece of a WHFO. The T Bar is used for an AFO; the J Bar is used for a WHFO. Either bar may be used in other applications as well to facilitate difficult bends.

1. The Distal Strut should be trimmed to the extent necessary to allow for optimal placement of the Adaptor Strut.
2. Use the holes in the Adaptor Strut to mark the location of the drill holes on the Distal Strut.
3. Use #7 (4.8mm) drill bit (supplied) to drill holes where marked.
4. Contour Adaptor Struts using standard industry bending irons suitable to strut thickness.
5. Wick Adaptor Screws (supplied) with a small amount of Loctite 243®.
7. Fasten all struts to outside of the plastic shells.
8. Figure 6.4a shows a finished AFO using a T Bar. Figure 6.4b shows a finished WHFO using a J Bar.
7.0 Using the Lock-Out Handle to Lock the Platform
The Lock Out Handle is used to immobilize or “lock-out” the Platform primarily for donning and doffing the orthosis with the Power Unit attached and tensioned. The Platform is shown in this section without the Power Unit to better illustrate the mechanics of the locking mechanism. To use the Lock Out Handle follow these steps:

1. To lock, press the Lock Out Handle downward until it is fully engaged.

2. To unlock, pull the Lock Out Handle upward.

An audible ‘snap’ will be heard when the Lock Out Handle is successfully locked or unlocked. Figure 7.0a shows the locked position; figure 7.0b shows the unlocked position. Note the engagement/disengagement of the teeth in the locked and unlocked positions.

The patient should not ambulate in an orthosis with the Platform locked. This may cause the lock to break leading to falling and will void the warranty.
8.0 Fine Tuning Range of Motion Limits

Figure 8.1a

From this position there is approximately 35° of motion remaining in the direction indicated.

= SAM POSITION

Figure 8.1b

35°

Figure 8.1c

90°

From this position there is approximately 90° of motion remaining in the direction indicated.

= SAM POSITION
The Platform may be fine tuned to block excessive or unwanted flexion or extension allowing for infinite positioning options between the fixed limits established by the End Range Screws (reference section 5.0). There are two red colored Stop Angle Marks (SAMs) within the teeth of the Platform’s Range of Motion Gear; the SAMs are most clearly visible from a side view of the Platform (Reference Section 4.0A). One SAM corresponds to extension range limitation and the other to flexion range limitation. The key to success with fine tuning the Platform’s range of motion lies in understanding the relationship between the SAMs and the Proximal Strut. Specifically the Platform’s motion will stop at the angle where a SAM intersects the midline of the Proximal Strut.

Please be aware that while the Platform may be fine tuned to limit range of motion in either the flexion or extension direction it is not possible to limit both directions simultaneously. Therefore only one SAM will have any significance with respect to the Platform’s range of motion — this will become more apparent in the section that follows. The illustrations in the following section appear with the Power Unit detached from the Platform in order to better illustrate the mechanics involved, however the Platform’s range of motion may be fine tuned with or without the Power Unit attached.

8.1 Adjusting Range of Motion Gear Position

1. Unlock the Platform (reference section 7.0).

2. The initial factory position of the Platform is illustrated in figure 8.1a. Note the position of the Proximal and Distal Struts at a 180° relationship and the red Stop Angle Marks (SAM) at the 5 and 7 o’clock positions. At the initial factory position the Range of Motion Gear does not influence the range of motion of the Platform.

3. The Range of Motion Gear position is adjusted by turning the Worm with the included Ball Driver (pictured in figures 8.1b and 8.1c). The Worm may be turned in either direction.

4. Starting with the initial factory position, depending on the direction the Worm is turned, one of the SAMs will move into closer proximity to the Proximal Strut compared to the other SAM. This “closer” SAM represents the stop point. The Platform will not be moveable past the region where the SAM intersects the midline of the Proximal Strut; free range of motion will be available in the other direction. Figures 8.1b and 8.1c illustrate two possible settings of the Range of Motion Gear.
9.0 Using the Power Unit

Figure 9.1a

Platform locked out in 15° of hyperextension for right elbow or left knee.

Figure 9.1b

Assist Direction Indicator points in the direction of an extension force for right elbow or left knee.
9.1 Attaching the Power Unit

1. Set the Range of Motion Gear to its initial factory position (see section 8.1).

2. Move the Distal Strut of the Platform into the maximum end range of the direction to be assisted.
   For example, to assist ankle dorsiflexion move the Distal Strut to its maximally dorsiflexed position (+75° dorsiflexion).
   If the Platform is not moved to the maximum end range of the direction to be assisted the Power Unit’s internal stops will limit the range of motion of the Platform and its assist output will be diminished. This can also damage the Power Unit and void the warranty.

3. Lock the Platform in this position (refer to section 7.0). Figure 9.1a shows the Platform oriented for right elbow extension assist (left knee extension assist). Recall from section 5.0 the maximum extension end range for an elbow setup is 15° of hyperextension.

4. Orient the Power Unit so that the Assist Direction Indicator on the side facing you points in the direction of the motion you wish to assist. Figure 9.1b shows the Power Unit oriented to assist right elbow extension (left knee extension).
5. Line up the Spline and Power Unit Catch of the Platform with the Spline Receiver and Catch Receiver of the Power Unit as shown in figure 9.1c. Press the Power Unit onto the Platform. You should hear the Power Unit Catch ‘click’ into place once the Power Unit is successfully attached.

6. Figure 9.1d shows a successfully attached Power Unit from a top profile; Figure 9.1e is from the side profile.

7. Unlock the Platform and test your assembly to ensure the range of motion is correct. For an elbow or knee assembly as discussed in the examples above, the Platform should have range of motion from 135° of flexion to 15° of hyperextension; ensure resistance is felt in the correct direction.
Figure 9.2a

Push Power Unit Release Button upward to remove Power Unit

Figure 9.3a

Platform locked out in 135° of flexion for right elbow or left knee.
9.2 Removing the Power Unit

1. Move the Lock Out Handle of the Platform to the unlocked position (reference Section 7.0).

2. Platform must be at the end range of the assisted direction for the Power Unit to be removed. For example, if the Power Unit is set up to assist elbow extension you would move the Platform to its maximum extension end range. Lock the Platform in this position.

3. Push the Power Unit Release Button upward (figure 9.2a). While holding the Power Unit Release Button upward, lift the Power Unit off the Platform.

   Power Unit cannot be removed with the Platform in a mid-range position.

9.3 Reversing the Assist Direction of the Power Unit

The assist of the Power Unit can be reversed to assist the opposite direction. For example, a power unit oriented for knee extension assist could be reversed for knee flexion assist; a power unit oriented for wrist extension assist could be reversed for wrist palmar flexion assist, etc. In section 9.1, setting the Power Unit up for extension assist of the right elbow was demonstrated. In this section (9.3), setting the Power Unit up for flexion assist of the right elbow will be demonstrated.

1. Remove the Power Unit (see section 9.2) and set the Range of Motion Gear to its initial factory position (see section 8.1).

2. Move the Distal Strut into maximum flexion range which for an elbow is 135°.

   See warning under section 9.1

3. Lock the Platform in this position (figure 9.3a).
Figure 9.3b
Assist Direction Indicator points in the direction of a flexion force for right elbow or left knee.

Figure 9.4a
Initial Factory Setting of Power Unit
4. Orient the Power Unit so that the Assist Direction Indicator on the side facing you points in the direction of the motion you wish to assist. Figure 9.3b shows the Power Unit oriented to assist right elbow flexion (left knee flexion).

5. Follow steps 5, 6, and 7 in section 9.1.

9.4 Adjusting the Tension of the Power Unit

1. The Power Unit can be adjusted for tension between a minimum level of 0 and a maximum level of 7. In its initial factory setting the Power Unit has the tension set at the level of 1 (see figure 9.4a).
2. The Power Unit may be adjusted for tension on or off the Platform. Use the included Ball Driver to turn the Tension Adjustor to increase/decrease the tension of the Power Unit. The Tension Adjustor can be approached from either side with the Ball Driver. Depending on the side of the Power Unit chosen to make the adjustment as well as the direction of the assist selected, you may need to turn the tension adjustor either toward you or away from you to increase (decrease) the tension. Figure 9.4b shows the possibilities for increasing the tension.

3. To decrease the tension, simply turn the Tension Adjustor in the opposite direction.

⚠️ Do not attempt to force the tension past the 0 or 7 settings. Doing so may damage the unit and void the warranty.
10.0 Maintenance of the Ultraflex ONE™ Components

The Power Unit has its spring lubricated during its factory assembly and should require no further lubrication. It is recommended to check the Platform and Power Unit at least once every six months. The orthotist can also alter the maintenance schedule as needed for particular patient cases.

11.0 Guidelines for Caregivers

The key to success with Ultraflex Therapeutic Bracing is for the patient to be compliant with recommended wear times. This is done not only by ensuring good fit and function of the brace but by also emphasizing the priority of wear time over the amount of tension on the Power Unit. There can be a tendency to substitute higher tension settings on the Power Unit in exchange for sub-optimum wear times. This should be discouraged as the best evidence suggests higher wear times at lower tension settings deliver the best results. Benefits of this approach may include greater range of motion and less pain thereby improving posture and/or function. Patients who achieve good wear times often notice the correlation between brace wear and these improvements which further reinforces compliance.

11.1 Wear Times

Ultraflex recommends wearing the brace(s) from 4 to 8 (or more) hours per day. The brace(s) is intended to be worn at rest. Night time wear during sleep is encouraged but not required. The braces can be used for limited household ambulation, standing, and transfers to increase compliance but are not intended for ambulation over and above this. An effective approach is to begin with one hour of wear the day the patient receives the brace(s) then wear for one additional hour each subsequent day until the recommended wear time is achieved. A 26-week patient wear schedule with stickers for tracking compliance is included with this manual for the patient’s use.
11.2 Tension Settings

Initial tension settings on the Power Unit should be low (defined as a setting of 2 or less) to allow the patient to become accustomed to the wear program. Acceptance in the first two weeks is the main indicator of successful long-term compliance and positive functional outcomes. Tension only needs to be increased if range of motion is not improving. The nature of the patient’s condition must be taken into consideration to determine the amount of the increase. An increase of .5 to 1 is a good general guideline. It is recommended that the therapist track range of motion as part of a comprehensive program.

⚠️ The Power Unit must not be turned up to a setting which triggers a spasm (stretch reflex) in a patient with spasticity.

⚠️ If tension goes up and wear times go down it is likely too much tension is being used. Ultraflex recommends turning the tension down by a setting of at least 0.5 if this happens.

11.3 General Brace Care

The surfaces of the brace should be cleaned periodically with a damp cloth and soapy water. Leave the brace to air dry before your patient wears it again. The orthosis should be checked by the orthotist every 6 months.

12.0 Learning More About Ultraflex

To learn more about Ultraflex consider attending one of our live or online courses. Go to https://ultraflexsystems.webex.com to view a listing of online courses and times and to sign up. Contact us at http://www.ultraflexsystems.com/askusprofessional.asp to receive a listing of courses in your area or to see about hosting a course at your facility.