CYMEDICA
orthopedics

PROFESSIONAL ATHLETE REHABILITATION FOR EVERY PATIENT

The CyMedica QB1 NMES capitalizes on revolutionary energy delivery to alter the spectrum of treatment for muscle atrophy following ACL Reconstruction and Total Knee Replacement.

The QB1 NMES delivers:

- **HIGH-INTENSITY NMES with COMFORT**
  - Due to its unique waveform and novel closed-loop power control, the QB1 delivers HIGH-INTENSITY NMES at lower power levels than competitive systems for ultimate patient COMFORT and compliance.

- **SMART System**
  - SMART system provides feedback based on the body's impedance changes and adjusts stimulation pulses real-time, delivering energy efficiently for quad activation.

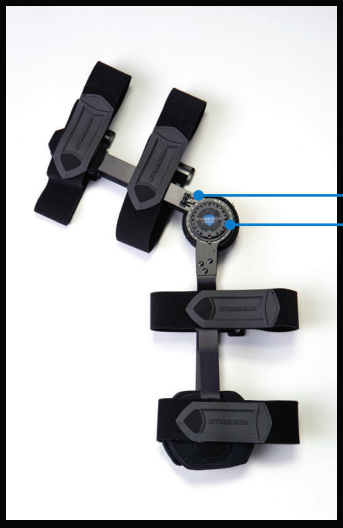
The CyMedica Orthopedics post-op system combines three best-in-class products to facilitate patient compliance.

Conductive Garment
High compression, breathable wrap houses & pre-positions NMES electrodes

Post-Op Knee Brace
Low-profile, hinged post-operative knee brace provides ROM adjustment & simple drop-lock capabilities

Stimulation Control Unit
Easy-to-use User Interface to control NMES and TENS sessions

Conductive Garment and Brace



Form-Fitting Wrap with Non-Slip Silicone

Extension Drop Lock

Hinge with Flexion & Extension ROM Adjustments

Gorilla-Grip Compression Technology

Ordering Information

Full ordering information may be found at www.cymedicaortho.com.

Reference #	Description
QB-1000-030 to QB-1000-045	QB1 NMES System (Small-XL; Regular or Short; Right or Left)
QB-1000-046 to QB-1000-061	QB1 Post-Op Brace & NMES System (Small-XL; Regular or Short; Right or Left)
QB-1000-002	QB1 TENS System (1 TENS Pod & 2 Size 2x2" Electrodes)
QB-1000-004	QB1 TENS Electrodes Set (2 Size 2x2" Electrodes)
QB-1000-005	QB1 NMES Electrode Set (1 Size 2x2" & 2 Size 2x4" Electrodes)
QB-1000-006	QB1 Electrode Gel (2oz. Gel Tube)
Refer to QB1 User's Manual for indications for use and safety information.	

CYMEDICA orthopedics

To find out more about the latest advancements in treating muscle atrophy, log on to **www.cymedicaortho.com**.

CyMedica Orthopedics Inc. / 19120 N. Pima Rd., Ste. 135 / Scottsdale, AZ 85255 U.S.A. / customerservice@cymedicaortho.com / Fax: (866) 296-2772 / Phone: (844) CYM-2014 or (844) 296-2014

QB-0065-001, Rev. A

510(k) Summary

CyMedica Orthopedics, Inc.

QB1 NMES and TENS Systems

1- SUBMITTER

Manufacturer Name:	CyMedica Orthopedics, Inc. 19120 N. Pima Rd. Suite 135 Scottsdale, AZ 85255 Telephone (480) 664-1282 FAX (866) 296-2772
Official Contact:	Kereshmeh Shahriari 19120 N. Pima Rd. Suite 135 Scottsdale, AZ 85255 kereshmeh@cymedica.net Telephone (480) 664-1282 FAX (866) 296-2772
510(k) Summary Preparation Date	February 13th, 2015
510(k) Number	K150413

2- DEVICE

Trade/Proprietary Name:	QB1 Powered Muscle Stimulator System (NMES) & Transcutaneous Electrical Nerve Stimulator System (TENS); QB-1000
Common Name:	Muscle stimulator
Classification Names:	Powered muscle stimulator (21 CFR 890.5850)
Product Code:	NMES device; IPF TENS device: GZJ
Device Class:	2

These devices are reviewed by the Division of Neurological and Physical Medicine Devices.

3- PREDICATE DEVICE

Name & 510(k) Number:	Kneehab XP, K110350 MediStim XP (AvivaStim XP), K082011
Manufacturer:	Bio-Medical Research, Ltd.

4- DEVICE DESCRIPTION

The CyMedica Orthopedics QB1 System is a multifunctional electrotherapy device with two stimulation channels and two treatment modes that allows for neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS). The principles of electrotherapy emulate the process observed during a voluntary muscle contraction. The QB1 system delivers stimulation based on the principles of NMES and TENS. NMES pulses stimulate motor points of target muscles, causing a muscle contraction. This can help re-educate and strengthen muscles following an injury or surgery. TENS blocks the pain signal sent from the affected area on nerve pathways.

The QB1 NMES and TENS systems are prescription devices in the USA and are intended to be used following the directions of a healthcare provider. The device may be used in a healthcare facility setting or by a patient or lay operator in a home environment.

In NMES mode, the QB1 system provides two therapeutic treatment programs: Post-Operative and Strength. Its simplified programming makes the device convenient for home use; after placing the electrodes and selecting the program as prescribed by a healthcare professional, the patient only needs to increase the intensity to a comfortable level to begin therapy. The QB1 NMES Post-Operative and Strength programs utilize an electrical stimulus that, when properly applied, activates specific muscles or muscle groups to help treat disuse muscle atrophy and to reeducate muscles. This is achieved via a closed loop feedback system that minimizes energy delivery to the targeted treatment areas.

In NMES mode, the QB1 system consists of a Conductive garment with an incorporated NMES pod, User Interface device with a battery charger, NMES electrodes, and electrode gel.

The QB1 device also offers a TENS program for pain management. The QB1 TENS system consists of a TENS pod, User Interface device with a battery charger, TENS electrodes, and electrode gel.

The QB1 User Interface is programmed with an embedded software to manage the treatment programs and communicate with the User Interface touchscreen, NMES conductive garment, and TENS pod. The User Interface allows the user to select a treatment from the available treatment programs stored in the memory component of the NMES conductive garment and TENS pod. The User Interface utilizes a touchscreen and tactile buttons for user control. The User Interface device is powered by an internal rechargeable 3.7 V Lithium Ion battery that, when fully charged, can deliver at least three-20 minute treatments before requiring a recharge. The QB1

USB charger can fully recharge the battery in approximately five hours.

The QB1 system accessories include:

- QB1 electrodes for NMES application
- QB1 electrodes for TENS application
- QB1 electrode gel

5- INDICATIONS FOR USE

The QB1 System is a multifunctional electrotherapy device with two treatment modes that allow for neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS).

The intended use of QB1 NMES device, including any indications for use, is limited to use in rehabilitation, including providing adjunctive therapy in rehabilitation for medical purposes.

Indications for Use:

As an NMES device, indications are for the following conditions:

1) Relaxation of muscle spasms
2) Retardation or prevention of disuse atrophy
3) Increasing local blood circulation
4) Re-educating muscles
5) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6) Maintaining or increasing range of motion

Programs NMES Post-Op and NMES Strength provide the above indications.

Treatment Program	**Pulse shape**	**Duration**	**Frequency**	**Pulse width**	**Duty cycle**	**Work cycle**	**Relaxation time**	**Contraction time**	**Rest time**	**Indications numbers**
NMES Post-Op	Monophasic	20 min	50 pps	5 ms	25%	13 s	10 s	3 s	3.4 s	1, 2, 3, 4, 5, 6
								2 cycles		
NMES Strength	Monophasic	20 min	50 pps	5 ms	25%	12 s	10 s	1 s	1.4 s	1, 2, 3, 4, 5, 6
								5 cycles		

The QB1 TENS device is intended for pain relief.

As a TENS device, indications are for the following conditions:

7) Symptomatic relief and management of chronic intractable pain
8) Adjunctive treatment for post-surgical and post-trauma acute pain

Program TENS pain management provides the above indications.

Treatment Program	Pulse shape	Duration	Frequency	Pulse width	Duty cycle	Work cycle	Interphase interval time	Indications numbers
TENS Pain Management	Biphasic, symmetrical	20 min	100 pps	1 ms	20%	Continuous	4 ms	7, 8

6- COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

CyMedica Orthopedics, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the QB1 System is substantially equivalent in indications and design principles to predicate devices, which have been determined by FDA to be substantially equivalent to preamendment devices: Bio-Medical Research, Ltd, Kneehab XP device, K110350 and MediStim XP (AvivaStim XP), K082011. The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

The intended use, design, materials and functional characteristics of the QB1 System and the predicate devices are substantially the same. The subject device and predicate devices are for prescription use, portable, hand-held, and home healthcare environment devices. The power in QB1 device Kneehab XP device is derived from a rechargeable battery that is pre-installed in the unit. There are two channels of stimulation in all three devices. In all three devices the user needs to select the desired treatment program and adjust the intensity. All three devices employ a ramp-up, work, and rest phases.

The following table summarizes the technological characteristics of the subject device and predicate devices:

Parameter		QB1 NMES POST-OP	QB1 NMES STRENGTH	QB1 TENS	Kneehab XP-NMES	Kneehab XP-NMES	Kneehab XP-TENS	MediStim XP- NMES	MediStim XP- TENS
510(k) Number		K150413	K150413	K150413	K110350	K110350	K110350	K082011	K082011
Mode or Program Name		POST-OP	STRENGTH	TENS	Program 1	Program 5	Program 7	Program 1	Program 9
Waveform (e.g., pulsed monophasic, biphasic)		Pulsed Monophasic	Pulsed Monophasic	Symmetric Biphasic	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic	Pulsed, Symmetrical, Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Complex	Complex	Complex	Square	Square	Square	Square	Square
Maximum Output Voltage (volts, rms) (+/- ____%)		3.4 @500Ω	3.4 @500Ω	0.18 @500Ω	25.5 @500Ω	25.8 @500Ω	40 @500Ω	33.5 @500Ω	20.9 @500Ω
		6.1 @ 2 k Ω	6.1 @ 2 k Ω	0.19 @ 2 k Ω	46.8 @ 2 kΩ	50.3 @ 2kΩ	61.7 @ 2kΩ	Error message for high load	Error message for high load
		8.5 @10 k Ω	8.5 @10 k Ω	0.20 @10 k Ω	34.0 @10 k Ω	34.2 @10k Ω	25.7 @10k Ω	Error message for high load	Error message for high load
Maximum Output Current (mA, rms) (+/- ____%)		6.8 @500Ω	6.8 @500Ω	0.36 @500Ω	51.0 @500Ω	51.6 @500Ω	80.0 @500Ω	67 @500Ω	41.8 @500Ω
		3.0 @ 2 k Ω	3.0 @ 2 k Ω	0.10 @ 2 k Ω	23.4 @ 2k Ω	25.2 @ 2k Ω	30.8 @ 2k Ω	Error message for high load	Error message for high load
		0.9 @10 k Ω	0.9 @10 k Ω	0.02 @10 k Ω	3.4 @10k Ω	3.4 @10k Ω	2.6 @10k Ω	Error message for high load	Error message for high load
Duration of primary (depolarizing) phase (µsec)		5000	5000	N/A (Continuous)	300	300	N/A (Continuous)	400	150
Pulse Duration (µsec)		5000	5000	1000	640	640	300	800	300
Frequency (Hz) [or Rate (pps)]		50	50	100	50	50	99	50	99
For interferential modes only: Beat Frequency (Hz)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	Yes	Yes	Yes	Yes	Yes	Yes
	Phase duration	N/A	N/A	1 ms	300 µs	300 µs	0.3 ms	400 µs	150 µs

Net Charge (microcoulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)		126 @500Ω	126 @500Ω	0 @500Ω (Symmetric Biphasic)	0 @500Ω (Symmetric Biphasic)	0 @500Ω (Symmetric Biphasic)	0 @500Ω (Symmetric Biphasic)	0 @500Ω (Symmetric Biphasic)	0 @500Ω (Symmetric Biphasic)
Maximum Phase Charge, (μC)		126 @500Ω	126 @500Ω	43.0 @500Ω	25.2 μC @500Ω	25.2 μC @500Ω	19.8 μC @500Ω	23.4 μC @500Ω	0.14 μC @500Ω
Maximum Current Density (mA/cm², r.m.s.)		0.27 @500Ω	0.27 @500Ω	0.014 @500Ω	0.61 @500Ω	0.62 @500Ω	0.964 @500Ω	2.63 @500Ω	1.64 @500Ω
Maximum Average Current (average absolute value), mA		6.8 @500Ω	6.8 @500Ω	0.36 @500Ω	51.0 @500Ω	51.6 @500Ω	80.0 @500Ω	67 @500Ω	41.8@500Ω
Maximum Average Power Density, (W/cm²), (using smallest electrode conductive surface area)		0.001 @500Ω	0.001 @500Ω	2.6 E-6 @500Ω	0.016 @500Ω	0.016 @500Ω	0.039 @500Ω	0.088 @500Ω	0.034 @500Ω
Burst Mode	(a) Pulses per burst	150	50	N/A (Continuous Pulse)	250	250	N/A (Continuous Pulse)	250	N/A (Continuous Pulse)
	(b) Bursts per second	0.087	0.23		0.10	0.10		0.10	
	(c) Burst duration (seconds)	3	1		5	5		5	
	(d) Duty Cycle: Line (b) x Line (c)	0.26	0.23		0.50	0.5		0.5	
ON Time (seconds)		312	276	Continuous	600	600	Continuous	900	Continuous
OFF Time (seconds)		888	924	Continuous	600	600	Continuous	900	Continuous
Additional Features (specify, if applicable)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

QB1 system differs from the Kneehab XP and MediStim XP devices in the following areas:

	Difference Area	Equivalence Discussion
1	Output Regulation: QB1 system is a power regulated stimulator while Kneehab XP and MediStim XP are current regulated stimulators	Various voltage, current, and power regulated stimulators exist which indicate the control methodology used. The QB1 power controlled stimulator monitors both voltage and current. As shown in Section 18, the system has been fully tested per IEC 60601-1, 60601-1-2, 60601-1-6, 60601-1-11, 60601-2-10, IEC 62366 and meets all standard requirements and FDA guidance requirements. It adequately controls the stimulator outputs to the allowable ranges and within the tolerance limits provided in the standards and guidance, evidenced in IEC 60601-2-10. The QB1 output power levels are lower than Kneehab XP and MediStim XP as evidenced in Tables 2-4 of QB1 Design Verification & Validation, QB-0030-034, Section 018 of this submission. Accordingly, the QB1 power regulated stimulator poses no new safety risks and is substantially equivalent to the predicate.
2	Number of Electrodes: QB1 system uses three electrodes for NMES application while Kneehab XP uses 4 electrodes for NMES application.	Various electrical stimulation systems use two or more than two electrodes to deliver the stimulation energy. The choice of three electrodes versus the four electrodes is purely to target the thigh muscle regions desired. The main safety concern with number of electrodes is to have sufficient surface area and appropriate power output levels to prevent potential skin burns. As tested in QB1 Design Verification & Validation, QB-0030-034, Section 018 of this submission and evidenced in Tables 2-4, the maximum current densities of QB1 are lower than Kneehab XP. Accordingly, the difference in electrodes in the QB1 system poses no new safety risks and is substantially equivalent to the predicate.
3	Electrode Sizes: QB1 electrode sizes are 25.86, 51.61, and 51.61 cm^2 while the Kneehab XP electrode sizes are 194, 74, 83, and 66 cm^2. Three MediStim XP electrode sizes are 20.25 cm^2, 25 cm^2, 49 cm^2.	Various electrical stimulation systems use different sizes of electrodes to deliver the stimulation energy. The choice of the QB1 electrodes is to have sufficient area for stimulation but to be sufficiently small to target the thigh muscle regions desired. The main safety concern with number of electrodes is to have sufficient surface area and appropriate power output levels to prevent potential skin burns. As tested in QB1 Design

		Verification & Validation, QB-0030-034, Section 018 of this submission and evidenced in Tables 2-4, the maximum current densities of QB1 are lower than Kneehab XP and MediStim XP despite the smaller electrode sizes. Accordingly, the difference in electrode sizes in the QB1 system poses no new safety risks and is substantially equivalent to the predicate.
4	Waveform and Shape: QB1 NMES treatment waveform is a pulsed, monophasic and complex shape. QB1 TENS treatment waveforms is pulsed, symmetrical, biphasic, and complex shape. Kneehab XP and MediStim XP are pulsed, symmetrical, biphasic and rectangular shape with interphase interval.	Various electrical stimulation systems use various waveforms and shapes to deliver the stimulation energy. The design philosophy of the QB1 waveforms was to produce sufficient muscle contractions while maintaining comfort for the user. The QB1 waveforms are generally lower in amplitude and wider in pulse width to minimize the power required for muscle activation and maximize the comfort. The main safety concern with the waveform and shape is that the power output does not produce skin burns or other user health risks. As tested in QB1 Design Verification & Validation, QB-0030-034, Section 018 of this submission and evidenced in Tables 2-4, the QB1 waveforms are at lower voltage and current and therefore power levels than the Kneehab XP and MediStim XP. Accordingly, the difference in waveforms in the QB1 system poses no new safety risks and is substantially equivalent to the predicate.

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

7- PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence.

To demonstrate the safety, the QB1 system was tested for electrical safety, electromagnetic compatibility, usability, biocompatibility, and risk management requirements.

To demonstrate the safety, the QB1 System was tested per the following standards:

- IEC 60601-1, Medical electrical equipment- General requirements for basic safety and essential performance
- IEC 60601-1-2, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility requirements

- IEC 60601-2-10, Medical electrical equipment- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulator

- IEC 60601-1-11, Medical electrical equipment- Part 1-11: 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

- IEC 60601-1-6, Medical electrical equipment- Part 1-6: General requirements for basic safety and essential performance- Collateral standard: Usability including IEC 62366: Application of usability engineering to medical devices

- IEC 62366: 2007, Medical devices -- Application of usability engineering to medical devices

- ISO 10993-1: 2009, Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process

- ISO 10993-5: 2009, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10: 2010, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization

- ISO 14971: 2007, Application of risk management to medical devices

In addition, to demonstrate the QB1 system effectiveness and performance substantial equivalency of the subject device, QB1 NMES and TENS system and the predicate devices Kneehab XP (K110350) and MediStim XP (K082011) were tested according to the following FDA guidance documents:

- FDA Final Guidance Document for Powered Muscle Stimulator 510(k), June 9, 1999
- FDA Draft Guidance Document, Class II special controls guidance document: Transcutaneous electrical nerve stimulator for pain relief, April 5, 2010

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the QB1 system, consisting of the User Interface, battery charger, conductive garment, and electrodes. The system compiles with the IEC 60601-1, IEC 60601-2-10, and 60601-11 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification & Validation Testing

The device's software has been validated in accordance with the requirements set forth in the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical

Devices (May 11, 2005). The software validation tests demonstrated that the software version meets its design requirements.

Human Factors and Usability

The human factors and usability study was conducted to validate the usability of the QB1 system in the home environment. The results of the study support the instructions for successfully using the device as intended. The results of human factors and usability study substantiates the acceptability of the risks identified during the risk assessment activities. The QB1 system complies with the IEC 60601-1-6: 2010 for usability and IEC 62366: Application of usability engineering to medical devices.

8- CONCLUSION

Based on the performance testing and the supporting documentation, it can be concluded that the QB1 NMES and TENS system is safe, effective, and substantially equivalent to the predicate devices. The QB1 device output pulse parameters provide a safe and effective treatment for the NMES and TENS applications.

Based on the acceptable bench test results, QB1 compliance with the applicable standards, and low current and voltage values, the QB1 device is considered safe and as effective as the predicate devices, Kneehab XP (K110350) and MediStim XP (K082011) for its intended uses and indications for use. The QB1 NMES and TENS pulse parameters and waveform are selected and designed so they would provide a safe and effective treatment for the indications for use.

SALES PRESENTATIONS

CYMEDICA
orthopedics

SALES PRESENTATION

CYMEDICA STORY

- **Dr. Coleman HSS recognized Quadriceps Weakness as a huge problem in their practice.**
- **Idea to combine a brace with NMES.**
- **Tasked a group in Cambridge. The asylum!**
- **Cambridge Group dismantled a NMES system and found the technology to be from 1985.**
- **Group develops Revolutionary Cymedica Technology**

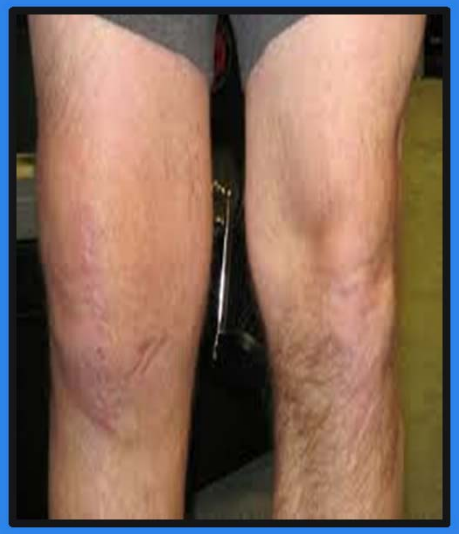
CYMEDICA orthopedics

SALES PRESENTATION

2 QUADICEPS LOSS

- **Mizner, Petterson et al, Journal of Bone and Joint, 2005,**
  20 TKR patients 27 days post surgery.
  62 % decrease in Quadriceps strength,
  17% decrease in voluntary activation

- **Stevens, Snyder-Mackler, et al, University of Delaware**
  28 TKR patients days 30 days post op.
  60% loss in Quadriceps strength
  17% decrease in voluntary activation



CYMEDICA orthopedics

SALES PRESENTATION

2 PROFESSIONAL ATHLETE REHAB

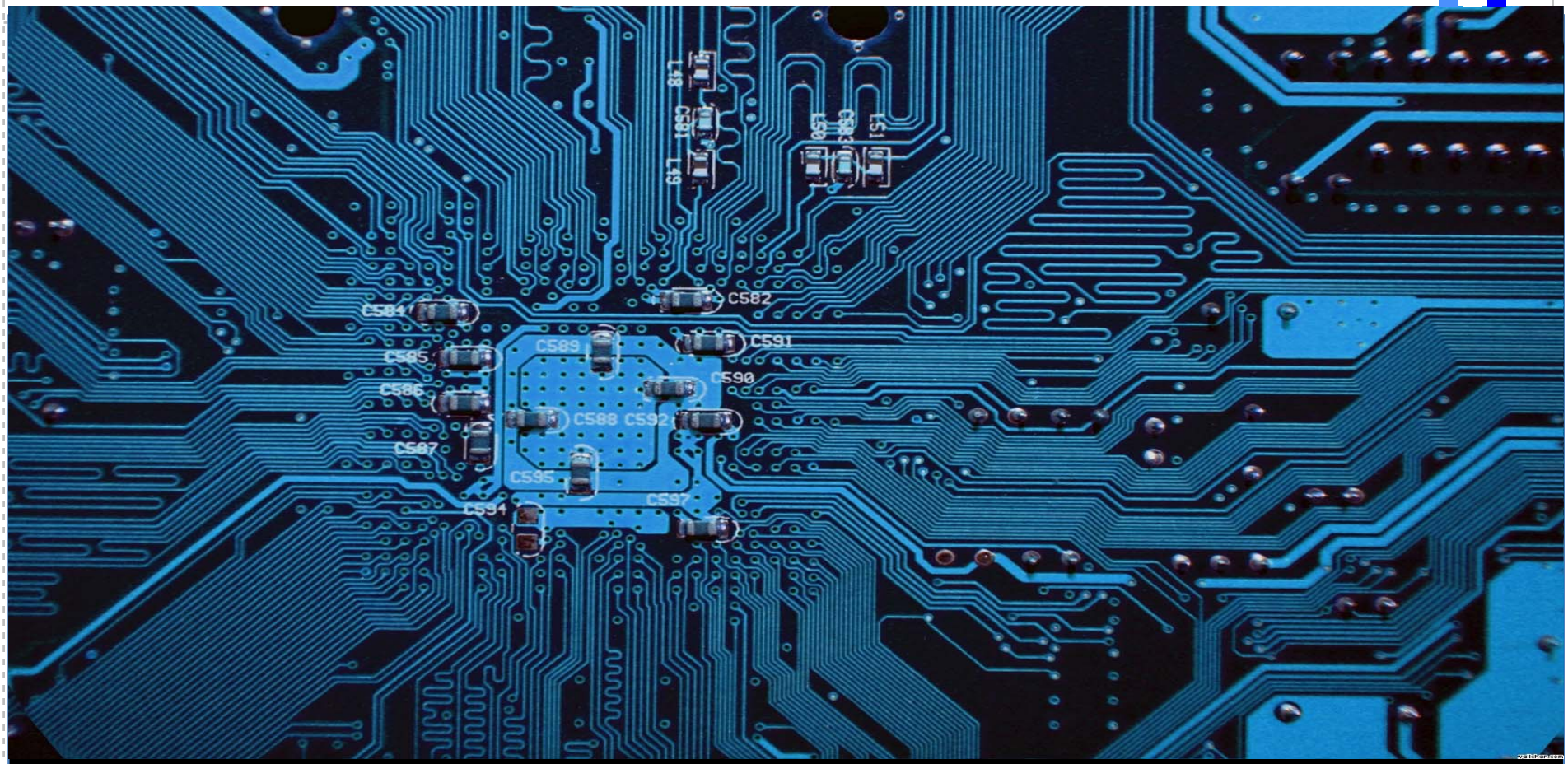
Current Treatment

- Currently patients go 1-2 times a week to PT Clinic.
- Standard stimulation technology.

Cymedica Rehab

- Professional Athlete level rehab.
- Combined brace and wrap provides reimbursement avenue to allow patients to take system home.
- Quad strengthening 3 times a day (18 /week) for 20 minutes.
- Significant strength gains documented with this amount of usage.

CYMEDICA orthopedics

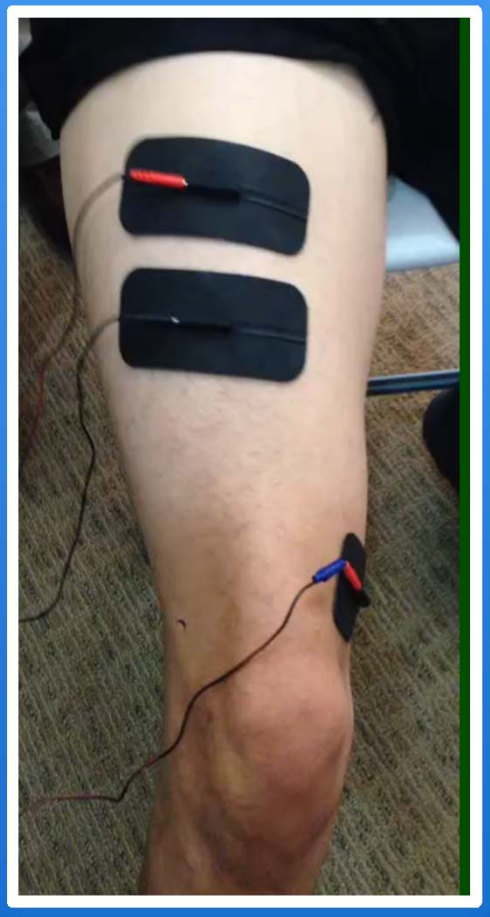


CORE TECHNOLOGY

CYMEDICA
orthopedics

SALES PRESENTATION

ELECTRODES & NMES VIDEO



CYMEDICA orthopedics

SALES PRESENTATION

ELECTRODE PLACEMENT

- **Electrodes are placed on the VMO and the mid rectus directly to stimulate the motor point and create ideal muscle activation. KEVIN WILK! Standard placement.**
- **Electrodes alternate pulse on same channel and are individually controlled to maximize comfort and activation of each muscle.**
- **Competitors cover whole thigh area and stim across muscle groups as well as nerves creating activation of unnecessary muscles (Lateralis) and increasing patient discomfort.**

CYMEDICA orthopedics

SALES PRESENTATION

TECHNOLOGY SIMPLE

LOWER POWER

- QB1 operate at 10-25% of the power of our competitc
- Details- power is volts x current

CLOSED LOOP SYSTEM

- System is smart and provides feedback based on the signal it receives from the body.
- As body's resistance changes, the system automatically adjusts in real time.

POWER DISSIPATION

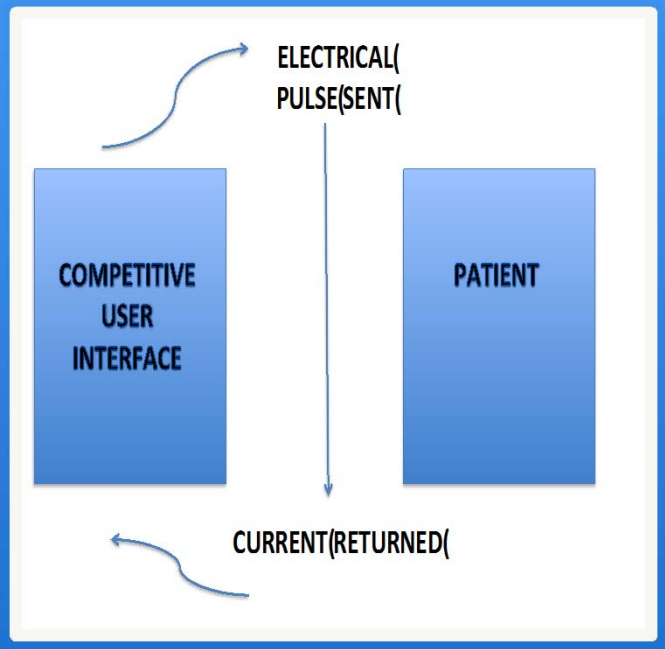
- The pulse initiates at a high level then quickly dissipates to minimum levels, which greatly improves comfort.
- Details- the closed loop feedback system is what allows our pulse to lower and change dramatically.

CYMEDICA orthopedics

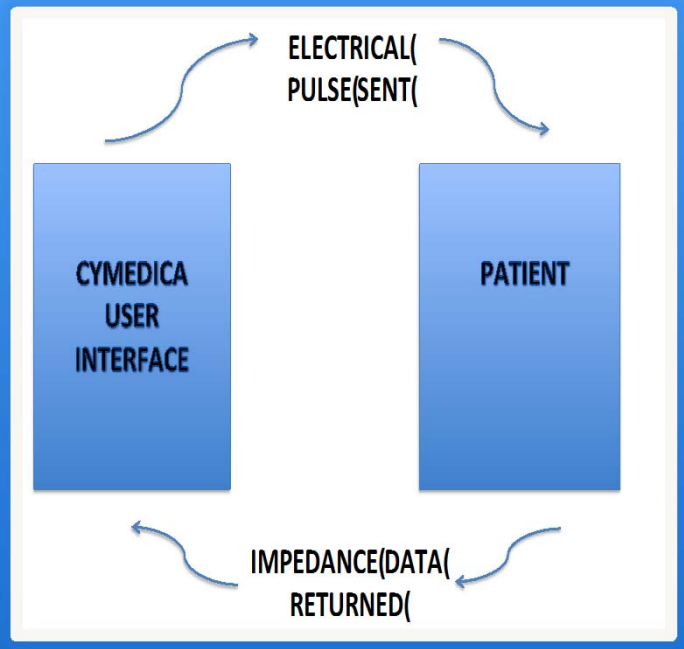
SALES PRESENTATION

TECHNOLOGY COMPARISON

Modulation of Current



Competitive Technology

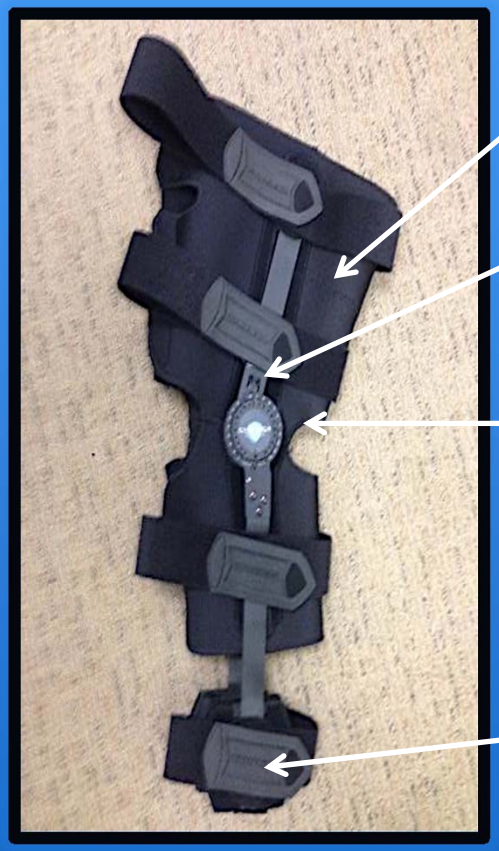


Cymedica Technology

CYMEDICA orthopedics

SALES PRESENTATION

CONDUCTIVE GARMENT AND BRACE



FORM-FITTING WRAP W/NON-SLIP SILICONE

EXTENSION DROP LOCK

HINGE WITH FLEXION & EXTENSION ROM ADJUSTMENTS

GORILLA-GRIP COMPRESSION TECHNOLOGY

FIXED LENGTH WRAP & BRACE (REGULAR & SHORT)

CYMEDICA orthopedics

SALES PRESENTATION

PRODUCT OVERVIEW

Conductive Garment

- Compressive Breathoprene to house the NMES and TENS electrodes.

Post Op Brace

- Hinged knee brace combined with Conductive
- Garment delivering NMES and TENS.

Control Unit

- Easy to use User Interface to control NMES and TENS sessions.

CYMEDICA orthopedics

SALES PRESENTATION

LOAD SCREENS AND SELECT

SALES PRESENTATION

NMES - CONTROL

CYMEDICA orthopedics

SALES PRESENTATION

REIMBURSEMENT

Current HCPCS codes describe the CyMedica QB1 Orthopedic System components, subject to PDAC verification

	**Payment Ceiling	**Payment Floor
L1833 Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf	$715	$536
E0731 Form fitting conductive garment for delivery of tens or NMES (with conductive fibers separated from the patient's skin by layers of fabric)	$390	$332
Total if both devices are covered (based on Medicare 2014 DME rates)	$1,105	$868
NMES unit is reported with E0745 Neuromuscular stimulator, electronic shock unit. If paid separately, it will be rented at between $83 and $98/mo. for up to 13 months or until the device cost for purchase is met and the patient owns the device.		

Private payer payments vary based on their contracts with DME suppliers. Medicare payments generally serve as a benchmark; private payers typically fall within 20% +/- Medicare fees.

CYMEDICA orthopedics

SALES PRESENTATION

REIMBURSEMENT - TENS

- **E0720** — ***Transcutaneous Nerve Stimulation (TENS) - 2 Leads***
- **EO730** — ***Transcutaneous Nerve Stimulation (TENS) – 4 Leads***
  Medicare Fee $350

CYMEDICA orthopedics

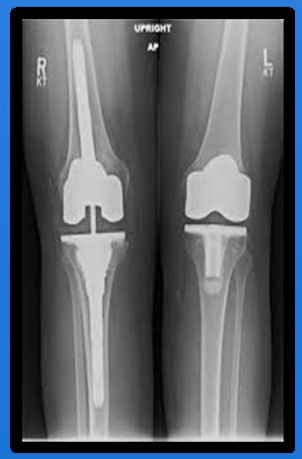
SALES PRESENTATION

CLINICAL STUDIES TKR

QUAD WEAKNESS POST TKR

- **Mizner, Petterson et al, Journal of Bone and Joint, 2005,**
  20 TKR patients 27 days post surgery.
  62 % decrease in Quadriceps strength,
  17% decrease in voluntary activation

- **Stevens, Snyder-Mackler, et al, University of Delaware**
  28 TKR patients days 30 days post surgery.
  60% loss in Quadriceps strength
  17% decrease in voluntary activation



CYMEDICA orthopedics

SALES PRESENTATION

CLINICAL STUDIES TKR

EARLY NMES TO IMPROVE QUADRICEPS MUSCLE AFTER TOTAL KNEE ARTHROPLASTY. A RANDOMIZED CLINICAL TRIAL.

- **Stevens-Lapsey, Balter, Wolfe, Eckhoff, Kohrt.**
- **66 Patients assigned to two groups.**
- **At the 3.5-week visit, the NMES group had significantly greater improvements than the control group in quadriceps and hamstring muscle strength.**
- **Functional performance for the NMES group at 1 year began to approach outcomes for older adults who were healthy**

CYMEDICA orthopedics

SALES PRESENTATION

CLINICAL STUDIES ACL

A SYSTEMATIC REVIEW OF EVIDENCE FOR ACL REHABILITATION

- **Risberg, Lewek, and Snyder Mackler. February 2004**
  33 Randomized Clinical Trials (RCT's) were examined.
  Low level NMES ineffective.
  High Intensity NMES very effective.

- **Results**
  High Intensity NMES vs. Low-Intensity NMES
  40% greater restoration of strength in High Intensity NMES group

CYMEDICA orthopedics

SALES PRESENTATION

CLINICAL STUDIES - SUMMARY

- **Patients lose a significant amount of quadriceps strength both pre and post operatively.**
- **Clinical studies have demonstrated that quadriceps weakness can persist up to 2 years. (Risberg et al., 1999).**
- **Quadricep strength is a significant outcome measure for patient's satisfaction following ACL reconstruction (Risberg et al., 1999).**
- **If gains are to be made with NMES, then a high-intensity stimulation is required to achieve an adequate stimulus to the large quadriceps muscle.**

CYMEDICA orthopedics

SALES PRESENTATION

CLINICAL STUDIES - SUMMARY

- **There is a direct correlation in the timeline of post surgical physical therapy and the strength of the quadriceps. For every day you don't have sufficient quad strength it costs you a week on the back end.**

- **"Immediate quadriceps strengthening allows the patient to progress faster and much more effectively through the rehabilitation program." -Kevin Wilk, PT, DPT, James Andrews, MD et al. Journal of Orthopedic and sports therapy.**

CYMEDICA orthopedics