KNEESUP Compact of

KNEESUP Care

Instructions for Use

Conzian

TABLE OF CONTENTS

KNEESUP Care Instructions for Use

Please read the manual thoroughly and follow the instructions. DO preserve the manual for future use. If you have any problem or doubts with **KNEESUP Care**, please contact our customer service: **KNEESUP** Support (+886 2 2382 1935 / service@conzian.com)

DESCRIPTION

KNEESUP Care is constituted of **KNEESUP Smart Core** and **KNEESUP** application.
KNEESUP Smart Core needs to be installed on a suitable functional knee brace. (**Smart Core** refers to **KNEESUP Smart Core** in the following manual)

The **Smart Core** can synchronize with knee movements and collect angle measurements to be used on **KNEESUP** App to assist with post-surgery rehabilitation.

INTENDED USER PROFILE

The intended user should be the patient, the patient's caretaker, or a family member providing assistance. The user should be able to read, understand and be physically able to perform and follow the directions, warnings, and cautions provided in the information for use. This product is not applicable to be used on the patient age 17 or below.

INTENDED USE / INDICATIONS

KNEESUP Care consists of a measuring device and a mobile application that can demonstrate real-time movement of knee joint during exercise, record rehabilitation history and prepare future rehabilitation plan, which can further assisting medical professionals to manage patient's overall rehabilitation progression. This system is used to optimize the rehabilitation experience for patients not only in the pre-surgical and post-surgical phases of reconstructive knee surgery, but also in the recovery and monitoring phases of non-surgically treated knee injuries and knee functional deficit.

KNEESUP Smart Core is a device able to record and transmit the knee range of motion and motion data to the compatible application during rehabilitation.

KNEESUP is an application able to receive and display the data of rehabilitation and the rehabilitation program.

⚠ Notice, Our system **DOES NOT** involve in any rehabilitation program designing, all rehabilitation programs are created by patient's medical provider.

CONTRAINDICATIONS

None

⚠ CAUTIONS

- **THE PRODUCT COULD ONLY BE OPERATED UNDER THE INSTRUCTIONS OF A MEDICAL PROFESSIONAL.**
- **TO RECEIVE THE PROPER MOTION DATA OF KNEE JOINTS, PLEASE READ THE FOLLOWING BEFORE OPERATING KNEESUP SMART CORE.**
- **STORE SMART CORE IN A COOL, DRY AND CLEAN ENVIRONMENT, AVOID DIRECT EXPOSURE TO SUNLIGHT AND KEEP OUT OF REACH OF CHILDREN.**
- **DO NOT DROP, DISLOCATE, CRUSH OR BEND THE PRODUCT AS THE ABOVE MENTIONED BEHAVIOR COULD RESULT IN DEVICE MALFUNCTION AND SAFETY CONCERNS.**
- **AVOID RAIN, WATER OR ANY LIQUID DAMAGE.**
- **IN CASE OF DAMAGE OR ANOMALY, PLEASE CONTACT KNEESUP SUPPORT.**
- **THE DATA AND INFORMATION PROVIDED BY KNEESUP CARE CAN ONLY BE USED AS A REFERENCE, AND CANNOT REPLACE PROFESSIONAL OPINION FROM MEDICAL PROVIDER. IF YOU HAVE FURTHER QUESTIONS, PLEASE CONSULT WITH YOUR MEDICAL PROVIDER.**
- **IF YOU HAVE ACUTE OR UNSTABLE CARDIOPULMONARY CONDITIONS, ACUTE INFECTIONS, CHRONIC DISEASES WITH POOR CONTROL, PLEASE CONSULT WITH YOUR MEDICAL PROVIDER BEFORE USE.**
- **IF YOU FOLLOW DEDICATED REHABILITATION PLAN AND FEELING UNWELL DURING OR AFTER USING THE PRODUCT, PLEASE STOP IMMEDIATELY AND CONTACT YOUR MEDICAL PROVIDER FOR MORE INFORMATION.**

SYMBOLS

	Read and understand all warnings and Instructions for Use before using this device.	REF	Product catalog number
	CAUTION! This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.	LOT	Lot number
	Non-ionizing radiation: a type of electromagnetic radiation that is commonly seen on mobile phone, radio, microwave, radar, and laser etc.	SN	Serial number
	Crossed out wheelie bin		Temperature range
	Manufacturer		Atmospheric pressure range
IP22	Protected against solid foreign objects of 12.5 mm and greater. Protected against vertically falling water drops when tilted up to 15º.		Humidity range

KNEESUP SMART CORE BRIEF
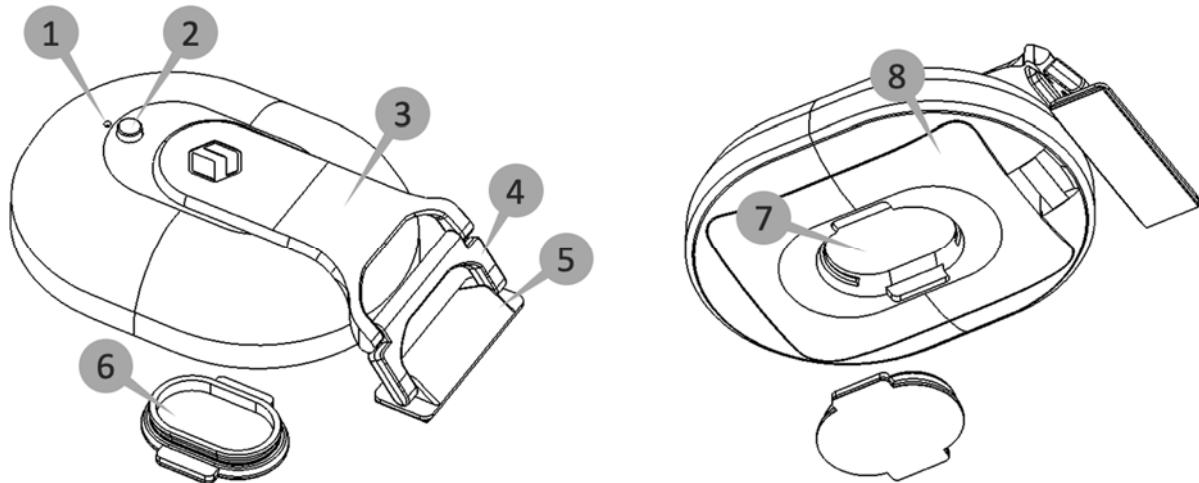
Serial	Component	Function
1	LED	Flashing Disconnected from **KNEESUP** app, waiting to connect. Steady Connected with **KNEESUP** app, fully functional. Off Power off
2	Button	Hold for 3 seconds On / Off
3	Shaft	Drives the angle measurement
4	Belt Module	Connects **Smart Core** with Strap Base
5	Clip	Fix the straps onto the functional knee brace
6	Bottom Base	Fix **Smart Core** onto the functional knee brace
7	Bottom Base Socket	Fix **Smart Core** on the base
8	Bottom(Battery Cover)	Protect the battery

Notice: Under the long term spinning motion, it is normal to have scratches on the surface of **Smart Core**.

CONTENT

Upon obtaining KNEESUP Care, authorized distributor or sales will install your Smart Core onto compatible functional knee brace. If any part of the product is missing or damaged, please contact **KNEESUP** Support.

The package contains Smart Core, Bottom Base, Belt Module and Clip in a total of 6 pieces, along with an user manual. (as illustrated below)

Smart Core

Bottom Base

Belt Module × 3

Clip
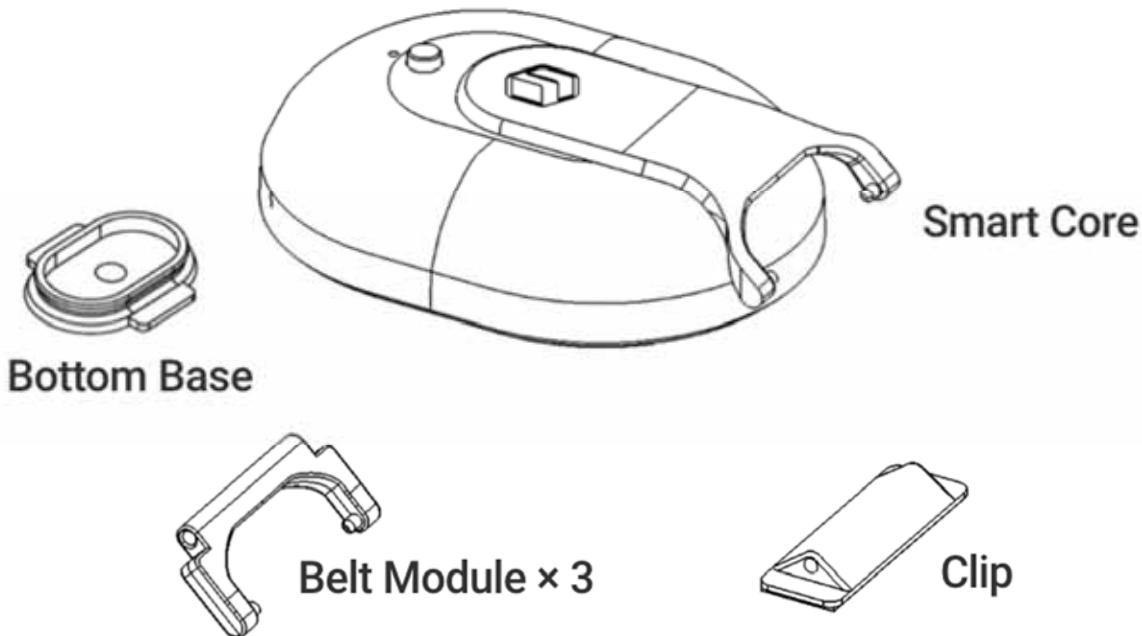
ENVIRONMENTAL CONDITIONS

Operation Environment	Temperatures (　)	+5~+40
	Relative Humidity (%)	15%~90%
	Atmospheric Pressure (kPa)	70~106
Delivery & Storage Environment	Temperatures (　)	-25~+55
	Relative Humidity (%)	10%~90% (+5　 to +35　 at relative humidity up to 90%, non-condensing)
	Atmospheric Pressure (kPa)	70~106

KNEESUP APPLICATION BRIEF

Notice: The Application illustration may differ from the actual application, due to the updates or the difference between various mobile brands.
You will be notified to update when your KNEESUP application is outdated or major update release while launching.

COMPATIBILITY

- Android requires 5.0 or above, Bluetooth requires 4.0 or above.
- iOS requires 10.0 or above, Bluetooth requires 4.0 or above.

DOWNLOAD KNEESUP APPLICATION

- With Android, please go to Google Play and search for KNEESUP to download **KNEESUP** application.
- With iOS please go to App Store and search for KNEESUP to download **KNEESUP** application.
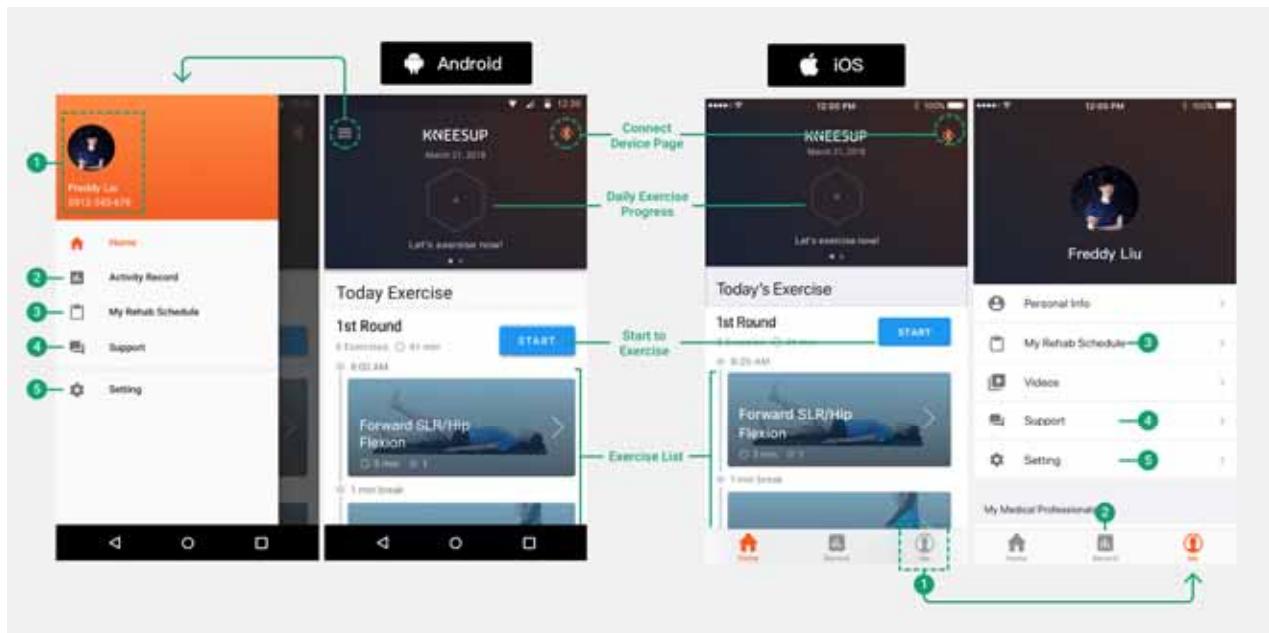
Profile: Showing your personal information, ability, achievement and other personal data.

Activity Record: You can review your rehabilitation record in the calendar to review your rehab history.

My Rehab Schedule: Showing the rehabilitation schedule arranged by medical providers, you can also review your current level and goal.

Support: In case of problem, you can search for support with the customer service here.

Setting: Page to show the details of the application, you can also look up the version and log out here.

OPERATIONS

APPLICATION SET UP AND PAIRING

Cautions & Notice：

⚠

- Please make sure Smart Core is installed correctly onto the functional knee brace by authorized local distributor or sales.
- If **Smart Core** has not yet been installed onto the functional knee brace, please contact the local distributor for installation assistance.
- Do not wear the functional knee brace after your first pairing, there will be an angle calibration instruction following up.

1. Download and Install **KNEESUP** Application
   a. If the App has not yet been downloaded, please go to *KNEESUP APPLICATION BRIEF* for more instructions.

2. Please turn on the **Bluetooth** on your phone or tablet
   a. Go to **Setting** > **Bluetooth** > **On** *(Figure 1)*
   b. Please keep the **Bluetooth ON** while **Smart Core** is operating

Figure 1

3. Activate **KNEESUP Smart Core**
   a. Hold on to the power button for 3 seconds till the light starts flashing, which indicates **Smart Core** is operating. *(Figure 2)*
   b. If **Smart Core** can not be activated, please check if the battery is installed correctly or out of electricity. (Please go to *SMART CORE BATTERY REPLACEMENT* for more instructions)
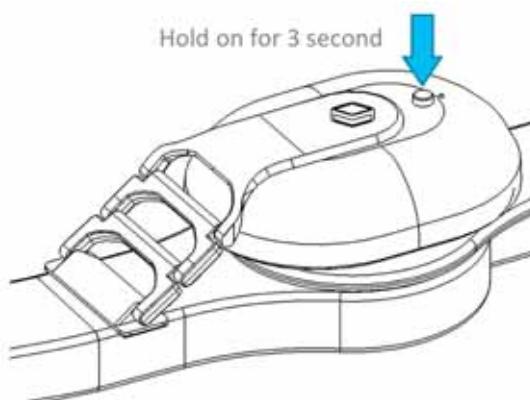
Figure 2

4. Start **KNEESUP** App and tap on **PAIR NOW**. *(Figure 3a and 3b)*
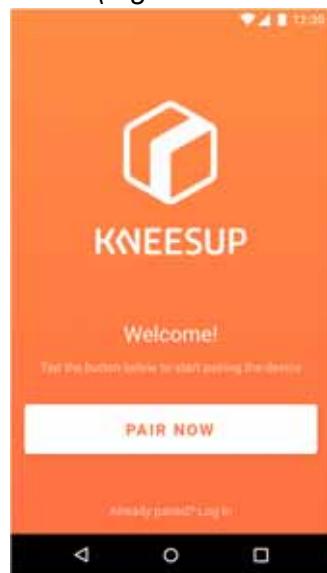
| Figure 3a | Figure 3b |

5. Scan the QR Code on the instruction manual to start pairing. *(Figure 4a and 4b)* (Note: 1 QR code is only valid for 1 account)

| Figure 4a | Figure 4b |

6. When paired, the LED on the **Smart Core** will change from **flashing** to **steady** and the App will enter the Sign Up page.

Notice : To prevent unexpected linkage, there will be a dedicated code for each individual **Smart Core.** There is no need to worry about data leakage.

SIGN UP

Notice :
There will be a text message for verification, please stay in a environment with good reception to receive text messages. Each phone number can only sign up once.

1. Enter your phone number. *(Figure 5)*

Figure 5

2. Please tap on the **PRIVACY POLICY & TERMS of SERVICE** to read the full statement, after reading please CHECK to agree. *(Figure 5* and *6)*

Figure 6

3. Tap on the **SIGN UP** button. *(Figure 6)*

4. You will receive a text message with six digits verification code, enter the verification code and tap on the **VERIFY** button. *(Figure 7a* and *7b)*
   a. If you haven't receive the verification code after 60 seconds, tap on **RESEND**.
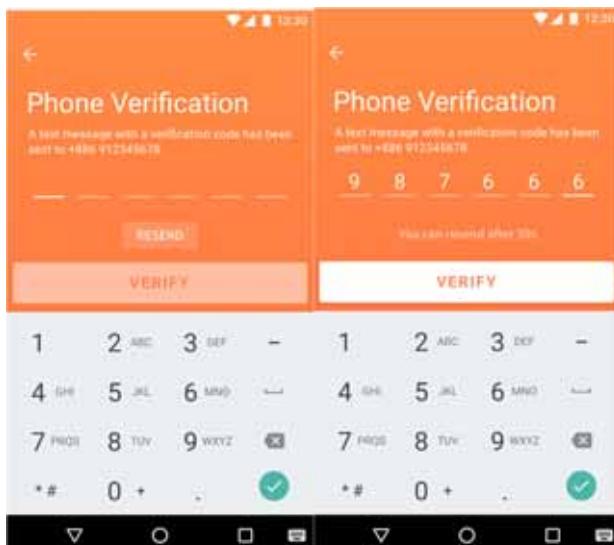
Figure 7a   **Figure 7b**

5. Fill in your personal details such as **Name, Sex and Date of Birth**. Once finished filling in all the information, tap on the **NEXT** button. (Notice: Please fill in the correct information as the information will no longer be editable after signing up.) *(Figure 8a* and *8b)*
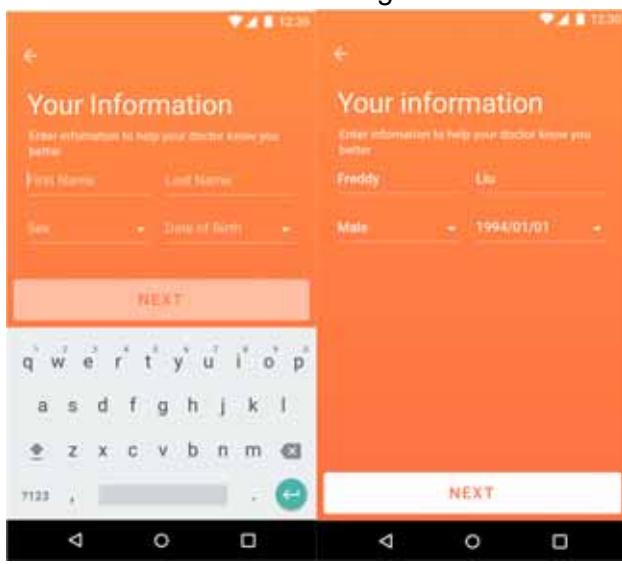
Figure 8a   **Figure 8b**

6. Enter your medical provider's name and tap on the **SEARCH** button. *(Figure 9a)*
   a. If your medical provider cannot be found, please contact **KNEESUP** Support for assistance.

7. Confirm your medical provider (MP), then tap on the **CONFIRM** button below. *(Figure 9b)*

Figure 9a   Figure 9b

8. Upload your selfie by tapping on the circle icon, you can either select Photo or Upload from your album. *(Figure 10a)*
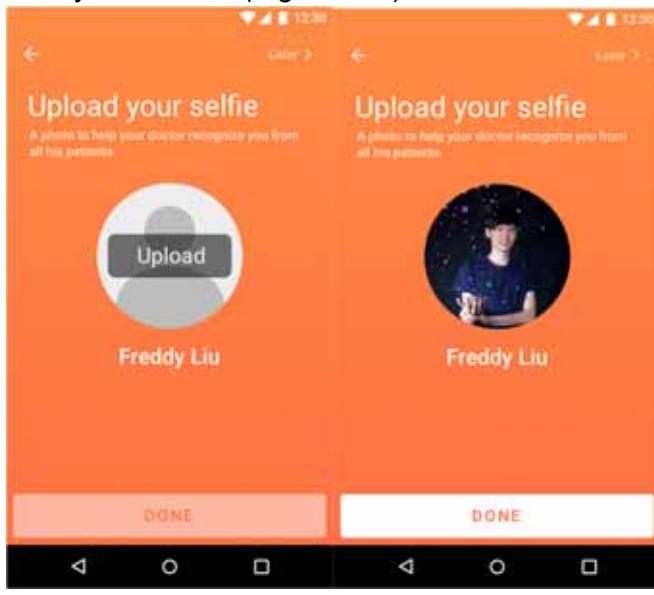
Figure 10a   Figure 10b

9. After uploading the photo tap on **DONE** to finish the sign up sequence. *(Figure 10b)*

ANGLE CALIBRATION

Notice:
- After signing up, there will be an initial angle calibration.
- Before calibrating, please be sure that the **Smart Core** is installed correctly onto the functional knee brace and connected to the App.

- Please calibrate your device once the angle of the knee brace does not match with the angle shown on the App.
- Please take off your functional knee brace before calibration in order to prevent angle inconsistency.
- Please follow the calibration sequence below to make our service fully functional.

1. Please set the **Flexion to 90º** and the **Extension to 0º**. (Restriction of the functional knee brace differs from brands, there are three types of adjustment below, if you have any problem please contact **KNEESUP** Support) *(Figure 11)*

Figure 11 (Source: https://www.breg.com)   Statement: Conzian, Ltd. do not own the functional knee brace above

2. Tap on the **Bluetooth icon** on the upper right to enter **Connect Smart Core**. *(Figure 12)*
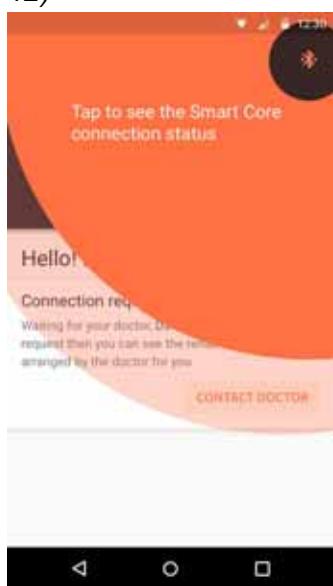
Figure 12

3. Tap on the **CALIBRATE** button below to start the calibration sequence. *(Figure 13)*

Figure 13

4. Rotate the functional knee brace to 0º, then tap on the **SYNC TO 0º** button, completes when the checking animation appears. *(Figure 14a, 14b* and *14c)*
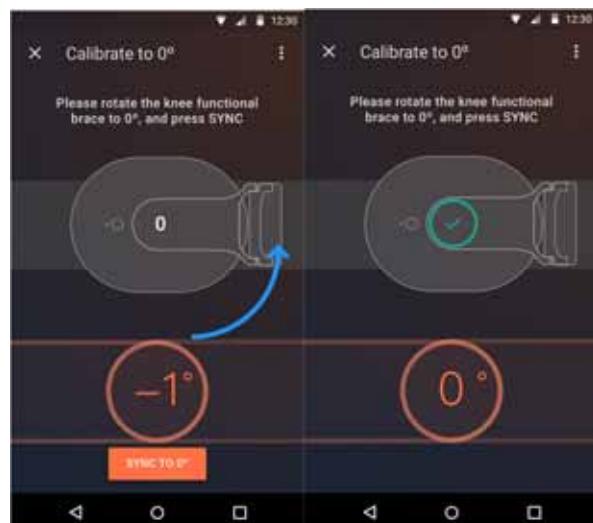
Figure 14a   Figure 14b   Figure 14c
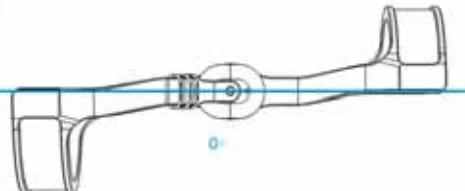
5. Rotate the functional knee brace to 90º, then tap on the **SYNC TO 90º** button, completes when the checking animation appears. *(Figure 15a, 15b* and *15c)*

Figure 15a   Figure 15b   Figure 15c
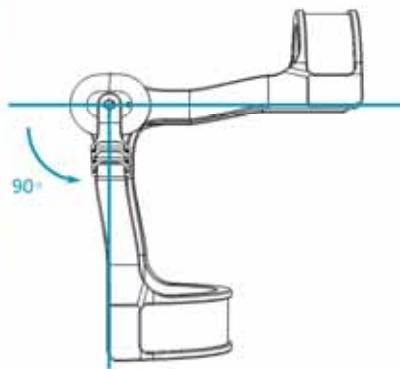
6. Returning to **Connect Device** page indicates the calibration sequence is finished, please examine if the knee angle is correct. If there is a deviation please repeat the **Calibration** sequence again.

START THE REHABILITATION (EXERCISE)

⚠ Notice：
  ● To ensure every patient will have their own responsible medical provider, there will be NO rehabilitation exercise before the medical provider's confirmation. *(Figure 16a and 16b)*
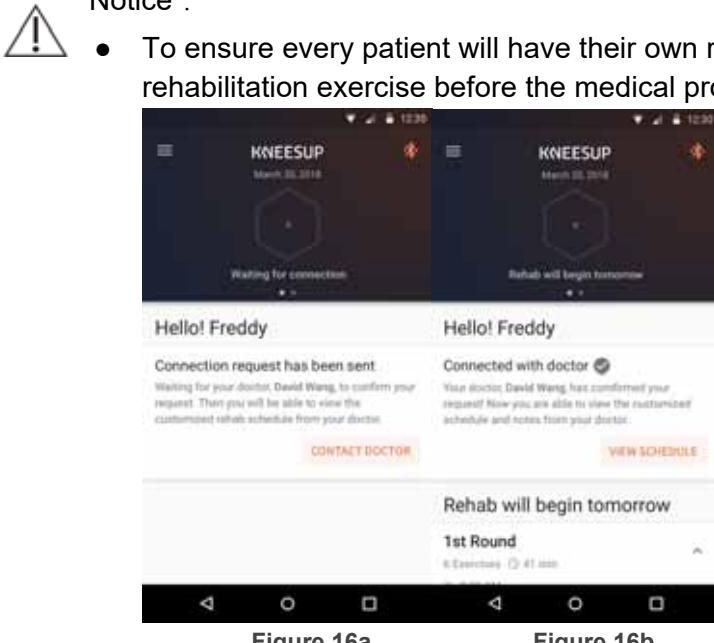
Figure 16a   Figure 16b

  ● After connecting with a medical provider, you will be arranged with rehab schedule and daily exercise. Then you can begin the rehabilitation on the next day.
  ● Before starting the rehabilitation, please put on the knee brace and confirm the **Smart Core** is ON and connected to the **KNEESUP** App
  ● Please watch the tutorial and the instructions first, before doing any rehabilitation. If the content is unable to understand, please refer to your medical provider for more information.

⚠ You can only start your rehabilitation after you fully understand the **given** exercise. Please do not proceed the rehabilitation if you cannot fully understand the exercise. Contact your medical provider for further information.

1. Tap the **START** button on the homepage. *(Figure 17a)*
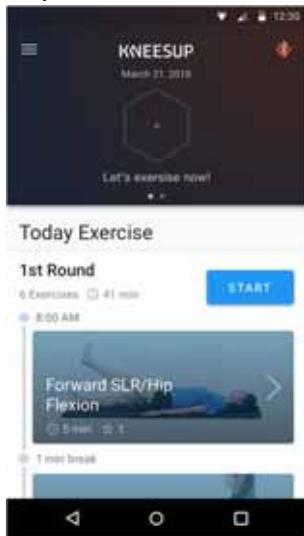
Figure 17a

a. If you haven't watched the tutorial, you will enter the exercise introduction, please tap ▶ **BUTTON** to watch the tutorial. After watching the tutorial, you can tap on START to start your rehabilitation. *(Figure 17b* and *17c)*
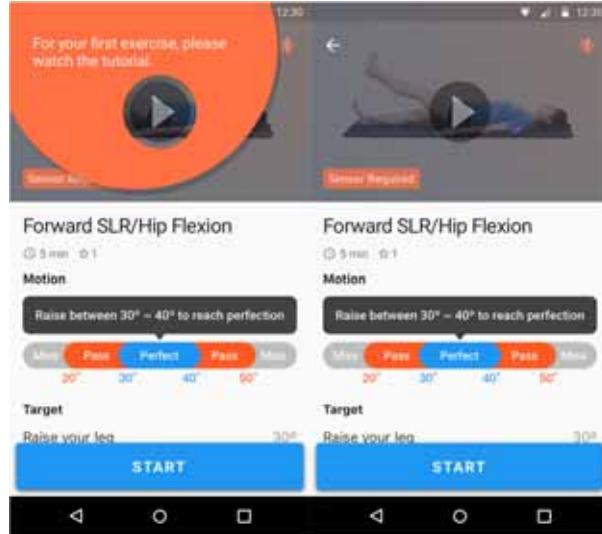
| Figure 17b | Figure 17c |

b. If you have already watched the tutorial, your rehabilitation will start from the first exercise. *(Figure 18a)*

2. Start the exercise *(Figure 18a, 18b* and *18c)*
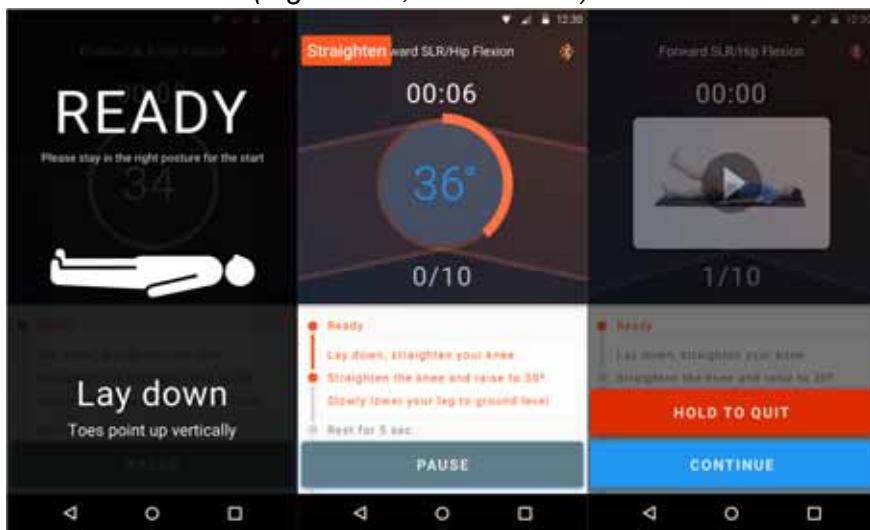
| Figure 18a | Figure 18b | Figure 18c |

a. During the exercise, there will be voice indications. Please follow the instructions.
b. After familiar with the exercise, you should focus on the exercise rather than the screen.
c. If pain or other emergency occurs, please tap on to the **PAUSE** button to stop the exercise. *(Figure 18b)*
d. When you are feeling incapable of achieving the exercise, please hold on the **HOLD TO QUIT** button for 1 second to quit the exercise. *(Figure 18c)*

3. After finishing an exercise, you will return to homepage for a break. After the break the next exercise will begin automatically or you can choose to skip the break to continue. *(Figure 19a)*
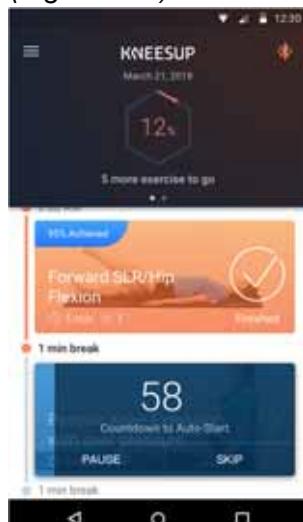
Figure 19a

4. After completing a round of exercise, there will be a summary page. Please fill in the questions with your actual condition. *(Figure 19b)*
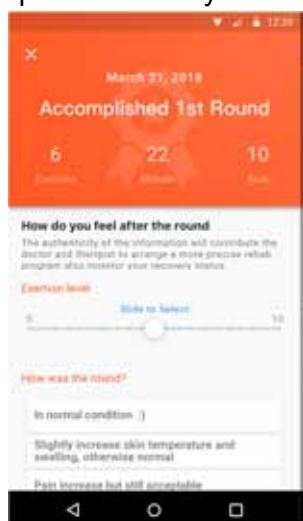
Figure 19b   Figure 19c   Figure 19d
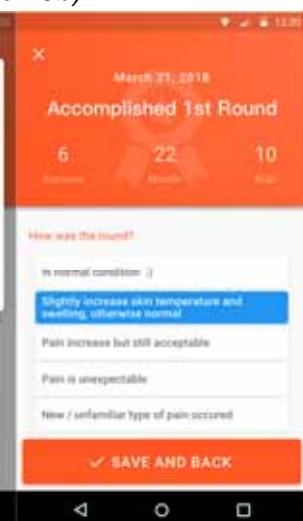
    a. To fill in **Exertion level**, please slide the **white circle**. *(Figure 19c)*
    b. To fill in **How was the round?** please tap on the option and the option will turn blue. *(Figure 19d)*
    c. After filling in all the questions, the **SAVE AND BACK** button will pop up, tap on the button to finish the feedback. *(Figure 19d)*

5. Congratulations! You have finished a round of rehabilitation.

PAIN FEEDBACK

Cautions & Notice：

⚠ During the rehabilitation, If you quit an exercise or report in certain pain conditions, **KNEESUP** App will pop up a dialog to know more about your condition. **Please fill in the questions with your actual condition, it helps your medical provider to know more about your condition.** *(Figure 20a* and *20b)*
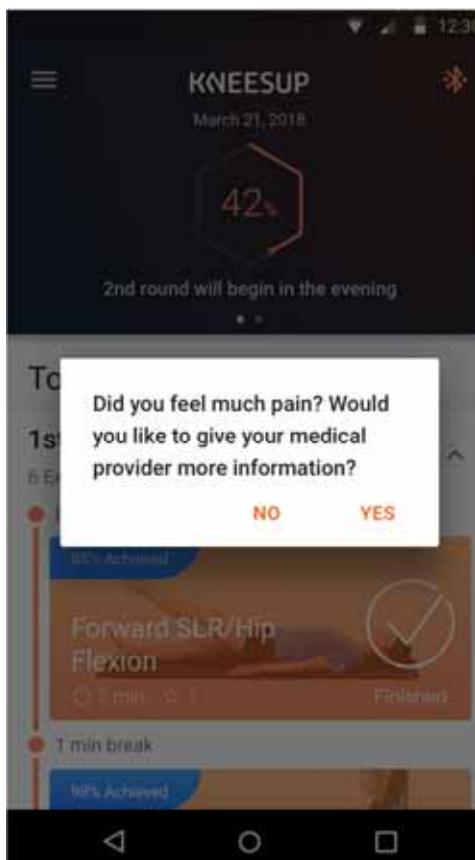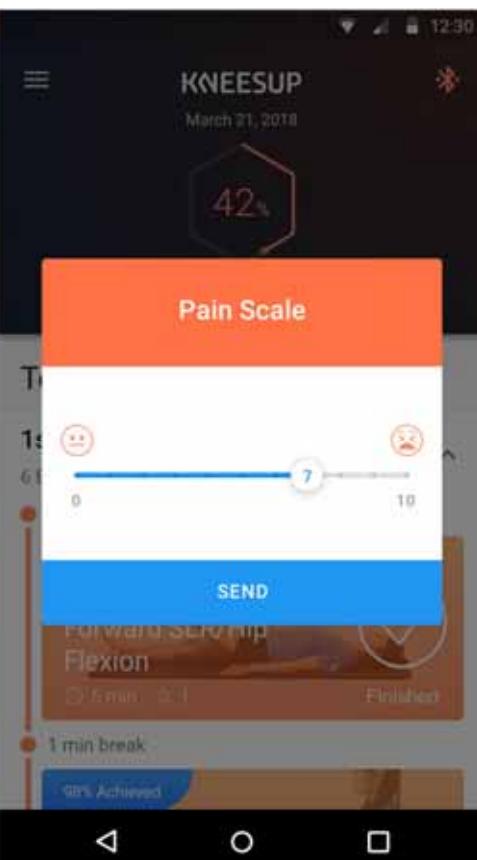
| Figure 20a | Figure 20b |

RE-LOG IN

Notice : Whenever you **log out** or **re-download KNEESUP** app, please follow the instruction below to RE-LOG IN

1. Tap on the **Already paired? Log In** below. *(Figure 21)*
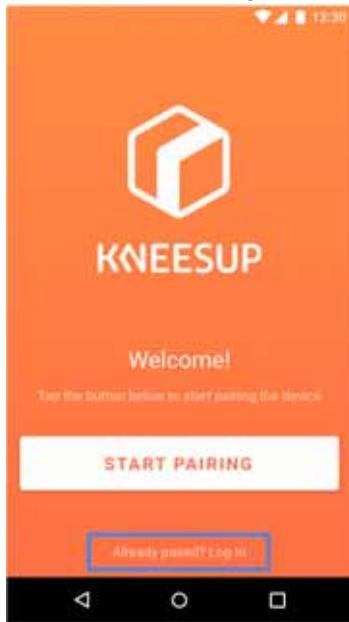
Figure 21

2. Enter your registered phone number, and tap on **LOG IN**. *(Figure 22a)*
3. You will receive a text message with six digits verification code, enter the code and tap on **LOG IN**. *(Figure 22b)*
    a. If you haven't receive the verification code in 60 seconds, please tap on **RESEND**. *(Figure 22b)*
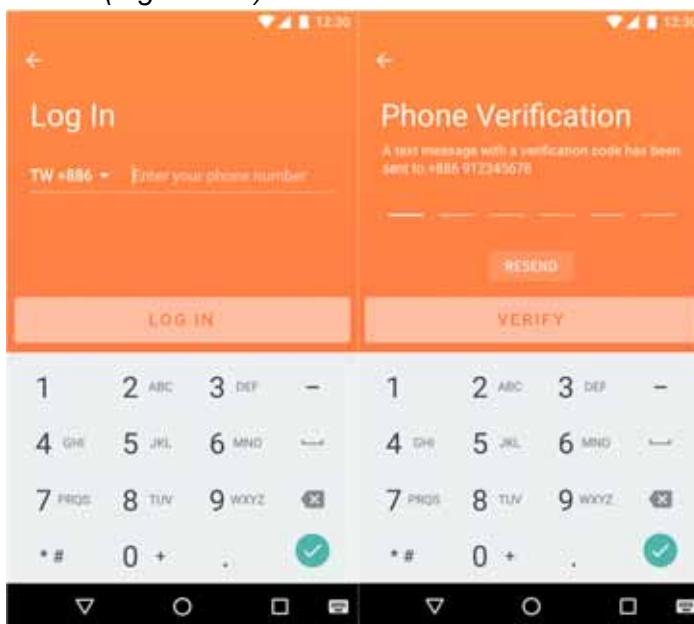
Figure 22a   **Figure 22b**

SMART CORE BATTERY REPLACEMENT
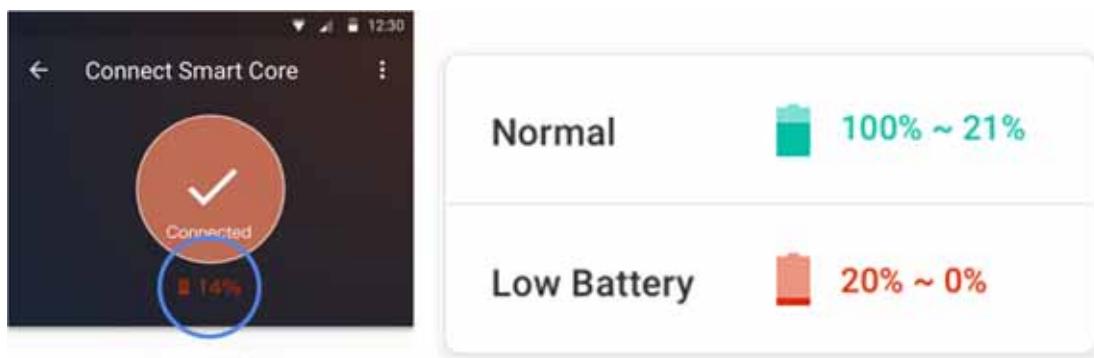
Please go to **Connect Smart Core** on App **(**Refer to ***Page.14*** *(Figure 12)***)** to check the remaining battery.

DO replace the battery in order to receive the precise measuring results, even if the device in on **Low Battery** (20%~0%) state and still functional.

The Smart Core could potentially disconnect during operation when battery is low which may result in measurement inaccuracy.
To increase battery life, please switch off the device after use

Cautions & Notice：

- Use **AAA Alkaline battery** only. The use of other types of battery is strictly prohibited. Any accidents or damages caused will not be cover by warranty and the users will be at their own risks.
- DO take out the battery if the device is not going to operate for a long period.
- DO follow the local regulation of battery disposal.
- Before replacing the battery, please confirm of Smart Core is turned off properly. (Hold on to the power for 3 seconds to turn off the device)

When low on battery

1. Hold on to Smart Core, fingers cling on to the front bottom rear and pull slightly. Notice: When pulling, please follow the instructions on the picture. DO NOT pull from the side rear or when one's finger is not clinging on the bottom rear, the action may cause the battery cover remain on the base or irreparable damage. *(Figure 23)*
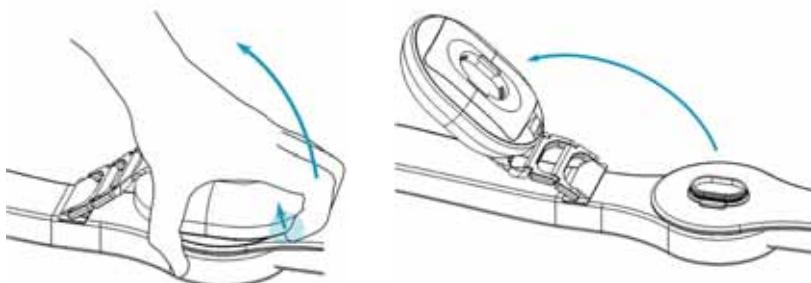
Figure 23

2. Push the Battery Cover Clip, and flip the battery cover over. *(Figure 24)*
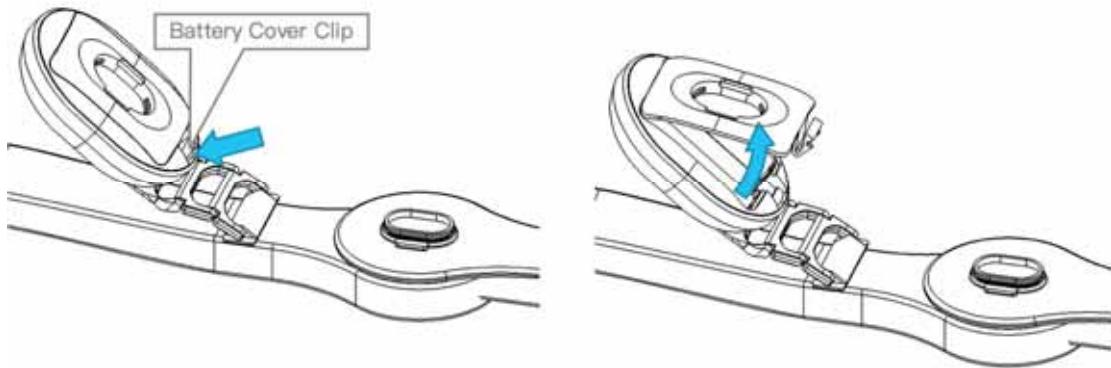
Figure 24

3. Remove the non-serviceable battery and replace with the serviceable **AAA battery**. (Do not reverse the polarity, positive and negative terminals of batteries.) *(Figure 25)*
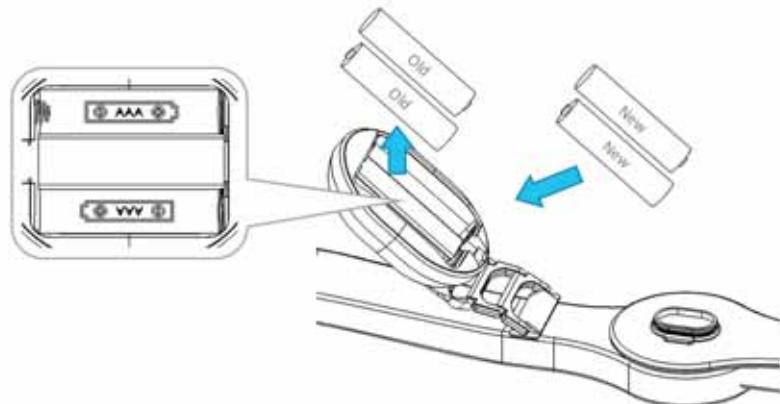
Figure 25

4. Plug the battery cover back to **Smart Core**, then push the battery cover clip back. *(Figure 26)*
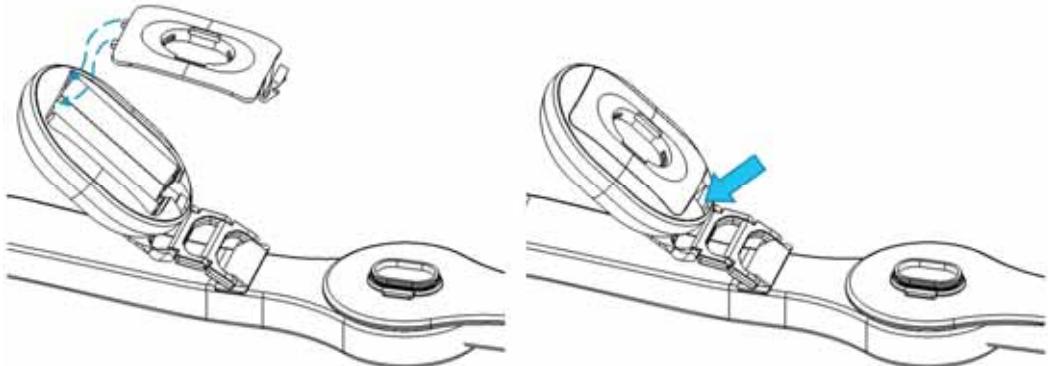
Figure 26

5. Re-Install **Smart Core** by putting it back on the functional knee brace, do place directly on the base, then push until you hear the "Kluck" sound. After installing please pull gently to make sure if it is installed on to the functional knee brace firmly. *(Figure 27a* and *27b)*
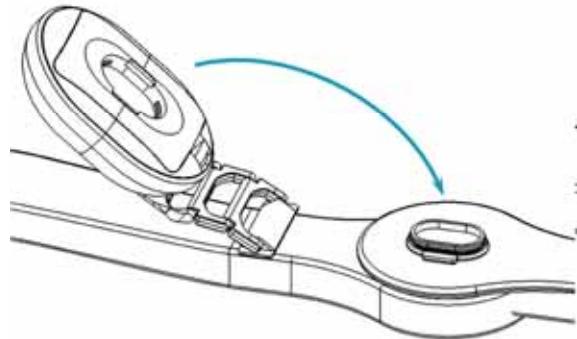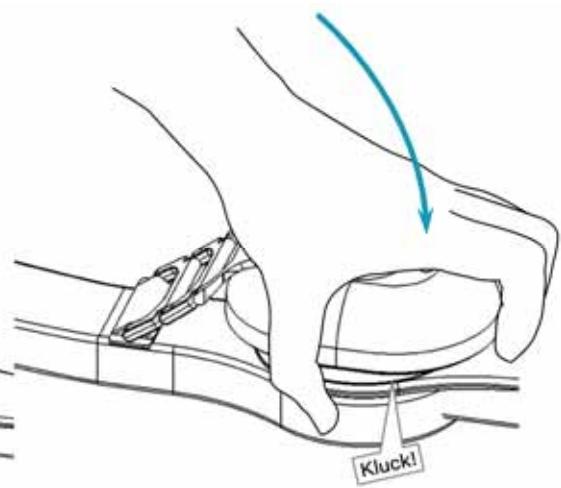
Figure 27a   Figure 27b

6. After replacing the battery, please open the KNEESUP app and tap on the upper right to ensure the angle remain synchronized. If the angle does not coordinate successfully, please perform calibration procedure. (Please refer to Page 14: Angle Calibration for more information)

CLEANING & MAINTENANCE INSTRUCTIONS

Clean the surface of **Smart Core** with an alcohol swab, clean cloth or tissue with 75% alcohol (75% or above).

Notice :

1. Please confirm the **Smart Core** is properly turned off before cleaning and maintenance.
2. Do not use corrosive detergent to clean the device.
3. Please avoid liquid infiltration while cleaning.

⚠ WARNINGS

- PLEASE KEEP A DISTANCE FROM THE OPERATING DEVICE WITH ((•)) TAG. THIS DEVICE SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT.
- WHEN ERROR OR UNMENTIONED EVENT OCCURS, FOR SAFETY REASONS, SMART CORE WILL AUTOMATICALLY SHUT DOWN. PLEASE DO FOLLOW THE INFORMATION OF EMC IN THE FOLLOWING MANUAL, INSTALL AND MAINTAIN THE SMART CORE CORRECTLY, THEN REBOOT THE DEVICE.
- PLEASE DO NOT ALTER ANY COMPONENT OF THE PRODUCT, TO AVOID UNEXPECTED DAMAGE OR HARM.
- PLEASE DO NOT USE ANY OTHER CABLES OR ACCESSORIES NOT APPROVED BY THE MANUFACTURER IN THIS MANUAL TO AVOID NEGATIVE INFLUENCE ON ELECTROMAGNETIC COMPATIBILITY.
- WHEN DISLOCATED FROM THE FUNCTIONAL KNEE BRACE, TO PREVENT DAMAGE, SMART CORE SHOULD BE CONTAINED IN ITS PACKAGE OR OTHER CONTAINERS.

TROUBLESHOOTING

If unable to fix the issue with the method below or the issue isn't listed below, please contact **KNEESUP** Support.

Possible Issue	How to Fix
Out of battery	Please replace the battery with serviceable battery
Unable to power **Smart Core** or other issue	Please replace with new batteries. Contact **KNEESUP** Support if issue remain unresolved. DO NOT ATTEMPT TO REPAIR.
Error with the angle measurement	Please re-calibrate, if there is still an error after calibration, contact **KNEESUP** Support
Smart Core LED Off	This is a common act under ECO mode, Please press and hold the button to reboot.

Smart Core disconnected from **KNEESUP** App during operation	Please ensure that the **Smart Core** is fully charged and within 3 meters of your mobile device without blockage. Please contact **KNEESUP** Support if connection issues occurred frequently.
Smart Core unable to switch off	Please remove the battery in order to force shut down the **Smart Core**.
Smart Core components or accessories damaged.	Please contact **KNEESUP** Support.
KNEESUP App crashes or not responding	Please update to the latest version of the application or delete the application and reinstall. If the problem still occurs, please contact **KNEESUP** Support.
KNEESUP App unable to connect Smart Core	Please reboot **Smart Core** and confirm if your mobile phone or tablet enabled Bluetooth, If still, please reboot your mobile phone or tablet or reset the Bluetooth system setting.
KNEESUP App crashes after a system update on mobile phone or tablet	If the system version is not compatible with the App, we will provide a new version of **KNEESUP** App and push a notification to remind users to update.

SMART CORE SPECIFICATIONS

Model	KSC01-EN
Measurements	64.3L / 49.3W / 25H (mm), 22.4±2g without battery
Power	1.5V AAA battery × 2
Functional Angle	0º ~ ±130º
Life cycle	Angle measurement：2 million cycles (Expected life: 6 months) Providing a 6 months warranty
Data Transmission	Bluetooth Low Energy
IP Rating	IP22

BLUETOOTH LOW ENERGY SPECIFICATIONS

Frequency Range	2402~2480MHz
Bluetooth Version	V4.2 Single mode
Channel number	40 channels
Modulation type	GFSK

GUIDANCE AND MANUFACTURER'S DECLARATION

According to FCC **15.19**

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 of the device.

Federal Communications Commission (FCC) Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. For body worn operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

As electronic device widespread, the chance of medical device getting interfered by other electronic devices' electromagnetic force also increased. Such interference may cause the medical device malfunction or even causing danger, also should **Smart Core** not interfere others. We are now following the regulation of IEC60601-1-2, the regulation of managing EMC (Electromagnetic compatibility), to prevent the product from causing danger. This regulation also defines the rate of electromagnetic interference immunity and the maximum rate of the medical devices' electromagnetic radiation.

The medical device manufactured by Conzian.Inc conform to IEC60601-1-2 : 2014, not only the rate of radiation but also immunity.

To maintain the precision and quality of the product, please use the accessories and environment provided or suggested by Conzian.

If accessories or cables NOT suggested by Conzian are used, may cause the device to increase the emission of electromagnetic radiation or decrease the electromagnetic immunity.

Smart Core is designed to be operated under a certain electromagnetic environment. Please do make sure if the environment complies.

Manufacturer's declaration-electromagnetic emissions		
The KNEESUP Smart Core is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the KNEESUP Smart Core should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for home healthcare environment)**
RF emissions CISPR 11	Group 1	The KNEESUP Smart Core uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The KNEESUP Smart Core is suitable for use in all establishments, including domestic

Harmonic emissions IEC 61000-3-2	Not applicable	establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration-electromagnetic immunity

The KNEESUP Smart Core is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the KNEESUP Smart Core should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment- guidance (for home healthcare environment)
Electrostatic discharge(ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	$\pm$ 2kV for power supply lines $\pm$ 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	$\pm$ 0.5kV, $\pm$1kV line(s) to line(s) $\pm$ 0.5kV, $\pm$1kV,$\pm$ 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Voltage interruptions: 0 % U_T; 250/300 cycle	Voltage dips: Not applicable Not applicable Not applicable Voltage interruptions: Not applicable	Mains power quality should be that of a typical home healthcare environment. If the user of the KNEESUP Smart Core requires continued operation during power mains interruptions, it is recommended that the KNEESUP Smart Core be powered from an uninterruptible power supply or a battery.

Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The KNEESUP Smart Core power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The KNEESUP Smart Core is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the KNEESUP Smart Core should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Not applicable Not applicable	**Portable and mobile RF communications equipment should be used no closer to any part of the** KNEESUP Smart Core including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** d = 1,2 d = 1,2 80MHz to 800 MHz d = 2,3 800MHz to 2,7 GHz 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). Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distance between portable and mobile RF communications equipment and the KNEESUP Smart Core			
The KNEESUP Smart Core is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the KNEESUP Smart Core can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KNEESUP Smart Core as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter(W)	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz d =1,2	**80 MHz to 800 MHz** d =1,2	**800 MHz to 2,7 GHz** d =2,3
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The KNEESUP Smart Core is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the KNEESUP Smart Core should assure that it is used in such an environment.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)

385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13,17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4, 25; MTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE   If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a)   For some services, only the uplink frequencies are included.
b)   The carrier shall be modulated using a 50 % duty cycle square wave signal.
c)   As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

DISPOSAL

Dispose of product according to local regulations.

WARRANTY

The warranty is only apply to eligible **KNEESUP Care** by **Conzian Ltd.** Any damage caused by accident, modification, alteration, abuse, misuse are excluded from the warranty. Please preserve the original package in order to send back the device in the case of damage.

Conzian Ltd. will replace all or part of the unit and its accessories for material or workmanship defects for a period of **6 months from the date of sale.** To the extent the terms of this warranty are inconsistent with local regulations. The provisions of such local regulations will apply.

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