Powered Fall Detection & Preventive Care Device

3501 N. US Hwy 67
San Angelo, Texas 76905
MyNotifi™ 800-541-1420
www.medhab.com

myNotifi
Stay fit. Stay safe. Stay notified.

MedHab ,LLC

Caution: Federal (U.S.A) law does not restrict this device to sale by or on the order of a physician. MyNotifi™ is not a prescription* device & can be purchased without prescription.

Overview of the MyNotifi™ device

The MyNotifi™ system consists of a cloud-based server with a configurable user interface, a mobile device, one wristband device and one belt clip housing. The band is designed to fit on the wrist with the device on the outside of the wrist in the same manner a watch is worn. MyNotifi™ can be transferred to the belt clip housing to be worn on a belt or waistband of a garment facing forward. The device measures movement, acceleration and rotational speed, using an embedded chip. The device is designed to detect and report falls and is embedded with multiple exercises to strengthen muscles and to maintain or enhance range of motion of upper and lower extremities. Exercises can only be performed if the device is worn on the wrist or ankle. When a fall occurs, a notification is automatically transmitted to the mobile device, which then transmits the data directly to personal caregivers (family, friends, call centers) and also stores the data on a HIPAA secured server. Users can also program exercises from a menu and can set personal protocols. Upon exercise completion, data is automatically transmitted to the mobile device, where it is tracked over time and can be viewed by the user. The exercise data is also transmitted to the cloud-based MedHab™ server. Access to the data is via a HIPAA secured user interface system. The MedHab™ server can be accessed by the user or other designated caregivers to monitor progress. See Figure 3 for a diagram of the MyNotifi™ system.

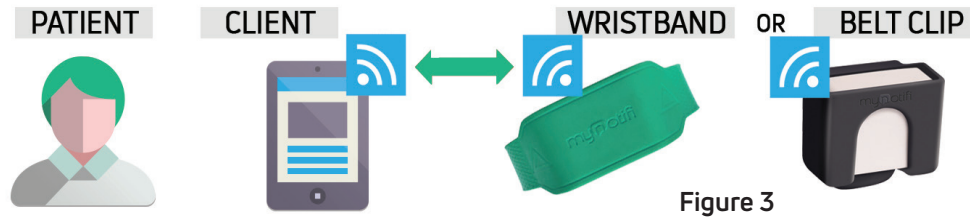

Figure 3

MyNotifi™ is a monitoring and biofeedback system indicated for use for the following:

- Monitoring range of motion of users with or without mobility impairment (when worn on the wrist or ankle for exercises only)
- Monitoring speed of motion of users with or without mobility impairment (when worn on the wrist or ankle for exercises only)
- To provide a means by which family, friends, and caregivers of the user are messaged when a fall is detected
- Monitoring falls in the aged population and other persons who may be prone to falling
- To provide a means by which the user has the ability to perform exercise protocols designed to maintain and/or increase range of motion and speed of motion (when worn on the wrist or ankle for exercises only)
- Intended to be used in any situation in which the user, family, or a physician determines the user would benefit from objectively measuring range of motion, speed of motion, and fall detection
- Personal help device intended to monitor residents in the home environment, out of doors, long-term care facilities, assisted living and rehabilitation settings, and independent living situations

The data provided by the MyNotifi™ device allows the user and family to continuously update/revise range of motion and strengthening protocols to meet the individual's physical needs. Additionally, MyNotifi™ constantly monitors for fall detection and automatically informs the family of when a fall occurs. Fall detection is not perfect in this sense, and therefore, MyNotifi™ is designed with features in an attempt to support the user when fall detection may be missed by the device.

Contents of a MyNotifi™ package
(See Figure 1)

- MyNotifi™ wrist device
- MyNotifi™ belt clip housing
- Package Insert
- User Guide
- Extender Magnetic Band
- Battery Charging Mat

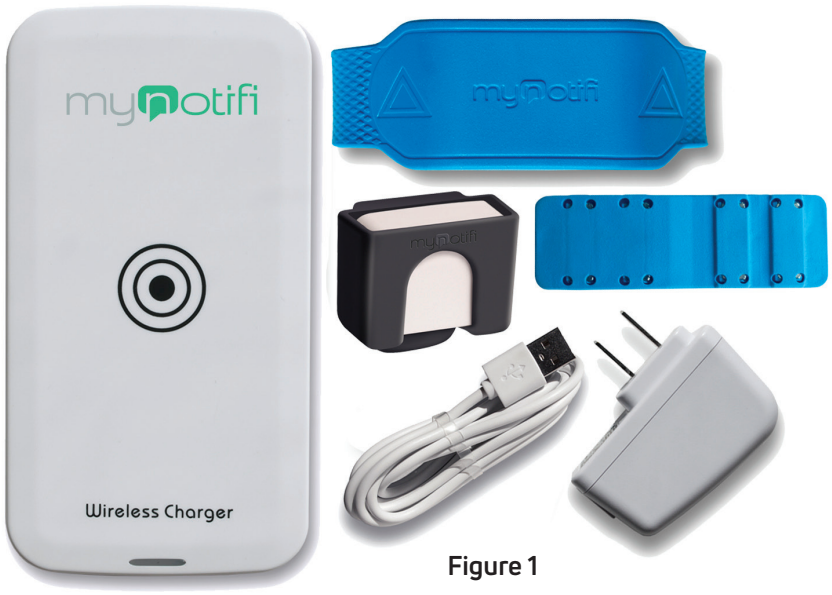

Figure 1

For purposes of security, MyNotifi™ transmits all data to the cloud based server from the user interface system (device) and mobile devices (smart device). All user data is encrypted using a combination of key pair authentication procedures including the Secure Socket Layer (SSL) cryptographic protocol and Amazon S3 Server Side Encryption (SSE) services.

1. Using the MyNotifi™ website, users or their family of caregivers will purchase a MyNotifi™ device
2. Medhab verifies the order, pulls a device from storage and ships the device to the orders destination
3. Upon receipt of the MyNotifi™ device, the user installs the application, logs into it and connects the device
4. User develops their own, personalized set of workouts that they would like to perform
5. User performs workouts at their leisure to maintain fitness and prevent future falls from occurring. Data is stored on the device and the cloud for review
6. The MyNotifi™ device automatically monitors for falls and alerts users and their family if one occurs. Fall detection is not perfect in this sense, and therefore, MyNotifi™ is designed with features in an attempt to support the user when fall detection may be missed by the device.
7. MyNotifi® uses the GPS (Global Positioning System) in your smartphone to discover your location. At times, the location provided by your smartphone will not be available or may be inaccurate, leading to inaccuracies reported by MyNotifi®.

   The MyNotifi® application employs a technique by which it attempts to discover a more accurate position in the time after an emergency event (fall detection or help request) occurs. If a new, more accurate location is discovered, MyNotifi® will report this new location to your group of caregivers.

Instructions for use (initial set up)

1. The user sets up a unique online account at MyNotifi™ which is a secured website. This allows the user to access MyNotifi™ where all information is generated and inventoried.
2. During account setup the user is prompted to complete risk management information. This data is only collected in the aggregate for statistical purposes.
3. The user has the ability by which to develop strength and conditioning protocols. The system allows flexibility for establishing multiple protocols for daily use.
4. The user extends invitations to friends, family, neighbors, and other potential care givers to participate in the chat room that sends fall detection messages and other notifications.

User notifications

1. Users will receive quarterly notifications asking to update risk management parameters, which can be updated via the smart device or within the users account using a computer.
2. Users will receive notifications via the app when the battery charge is less than 20%.
3. User will receive notifications when the device is idle or disconnected for 3 hours.

Family notifications

1. Family, friends, and caregivers will receive notifications when a fall is detected, as well as whether or not the timer has been deactivated by the user.
2. Family, friends, and caregivers will receive a notification when the device is idle or disconneced for 3 hours.
3. Family, friends, and caregivers will receive notifications when the battery is below 10%.
4. Family, friends, and caregivers will receive notifications when the device idles for any three hour and 24 hour time period.
5. Family, friends, and caregivers will receive notifications when the device is disconnected for any three hour and 24 hour period.
6. Family, friends and caregivers will receive notifications of fall events that help them identify the location of the event.

Adjust the protocol as needed

1. Using the app interface, the user can adjust the protocol at any time to include exercise removal and exercise addition. In this manner, the user can manage more efficiently their ability to maintain a healthy and mobile lifestyle. This feature only works when the device is worn on the wrist or ankle for exercise periods.

The user's process for receiving and using the MyNotifi™ device

- MedHab Ships The Device To The User
- User unpacks contents of box
- User places device on supplied charger (see Figure 2)

Figure 2

Charging the device while in the wristband: bands must be connected and the device must be face down.

Charging the device while in the belt-clip: clip must be face down with belt attachment facing up.

User Signs Into Web Based Account

- User registers online via computer or smart device
- User downloads app from app store

User Creates and Follows Exercise Program On Mobile App

The mobile device app systematically moves the user through each exercise through audible and written language. Once exercises are complete, users simply press "stop recording". Data is automatically uploaded to the secured cloud based website for automatic report generation. Dashboards of all exercises can also be seen on the app dashboards immediately. The mobile app contains instructions available at all times for users utilizing the device, including instructional videos for each exercise.

Training

The training video is optional; however, it is highly recommended to ensure proper use of the MyNotifi™ device, as well as, to fully understand how to read the user reports.

Maintenance and disposal

Cleaning instructions

MyNotifi™ can be wiped clean using germicidal wipes (Clorox Germicidal Wipes containing 0.55% bleach), or household bleach diluted in water using a slightly dampened rag. The device should not be laundered, should not be immersed in liquid of any kind and should not be cleaned with any chemicals representing extremes of pH, such as acids or bases. A moistened rag as described above is sufficient for cleaning purposes and should be followed by the use of a dry towel.

Reuse and Disposal

MyNotifi™ is designed to be used by only one person.

Storage™ requirements

For storage purposes, extremes in temperature should be avoided. Do not store the device near heat generating equipment.

Battery life

The battery is the only component with an "expiration" period. The battery has a lifetime charge loss depending on temperature and charging discipline. It is recommended that batteries be fully charged, at minimum, once every month when not in use to not experience possible capacity loss. For example, if a battery is left on a shelf for 2 years at 25° C, it will lose roughly 40% of its storage capacity. As such, there is no real "marked" expiration date for the battery. For additional information see energizer link.

Caution: Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions

Recharging the mobile device

Recharge the mobile device as needed using the charger provided.
A routine complete charge cycle is approximately 2.5 hours. Note: During charging, the "idle timer" feature is inactivated.

Recharging the MyNotifi™ device

It is recommended that the MyNotifi™ device be charged once the charge indicator falls between 10% and 20%. In order to complete charging, the user places the wristband on the charging mat, face down. The charging mat LED will light and the charger will tone when device makes full charging contact. The charging mat is plugged in until charge is complete. The charging system being utilized is a Qi compatible inductive charging system. This consists of a receiver coil embedded in the insole (Figure 4) as well as a dual coil transmitter charging base. The Charging circuit will automatically stop charging when the battery is fully charged and will trickle charge afterwards to maintain optimum charge.

Warning: Charge only with the charger provided with your Mynotifi™ device and in accordance with these instructions

Servicing instructions

As with all electronic devices, there may be instances in which an upgrade on existing software might be necessary, including either or both uploads or downloads. This process will occur automatically through secured user interface. In the event that such upgrading activities are necessary, MyNotifi™ will provide users an email notification of the event. Contact MedHab at **800-541-1420** if you have difficulty uploading upgrades. The MyNotifi™ device contains no repairable parts. If your MyNotifi™ device does not function properly, contact MedHab™ at **800-541-1420**.

Warnings

- Charge only with the charger provided with your MyNotifi™ device and in accordance with these instructions. Do not open the battery, dispose of in fire, or short circuit the battery—it may ignite, explode, leak, or become hot and therefore, cause personal injury
- Do not overcharge the battery. Overcharging a lithium polymer battery can cause an explosion or fire.
- Do not puncture the battery. Fire can occur if the battery cell is punctured.
- Risk of EMI interference of the wireless communication with other medical devices.

Precautions

- For proper data transmittal, the mobile device must not be further than 30 meters (98 feet) away from the MyNotifi™ device.
- Use only the charger provided with your MyNotifi™ device.
- MyNotifi™ is waterproof™, but has not been tested past 10 feet in depth.
- Cleaning chemicals could damage the MyNotifi™ device. Follow the instructions in the Cleaning section of this document.

Adverse reactions

- Users may experience skin irritation if allergic to urethane, the wristband material.
- If allergic to urethane, MyNotifi™ is not recommended for use.

The following symbols may appear on your MyNotifi™ device:

Symbol	Meaning
⎓	Direct Current
	Type BF
	Caution
	Consult Accompanying Documents
	Refer To Instruction Manual/Booklet

Specifications

Allowable user weight range:
Non Specified

Classifications

Type BF Applied Parts

Environmental conditions

Transport & Storage Temperature: 15°C - 25°C (59°F - 77°F)
Operating temperature range: 0°C - 50°C (32°F - 122°F)

Wireless communication

Blue Tooth Low Energy

Battery

3.7V 110mAh Lithium Polymer Rechargeable Battery
PCM and 10k NTC with Standard Molex Connector
Dimensions: 3.8 x 24 x 36mm
Cell carries UL1642, IEC 62133, UN/DOT38.3

Shipping weight

-1lbs

LC -004 Rev 2 [Date of issuance document control 8-01-2018]
For product information, questions pertaining to sales and service, please contact your local sales representative or MedHab customer service.