USER MANUAL

#EMB-SP069-B-20160001

rev 0.3, Mar 2016

1. INTRODUCTION

Thank you for purchasing the Embrace watch with Empatica Alert App.

2. INTENDED USE and USERS

Indication for use statement:

Embrace is a smartwatch that measures changes in your physical activity and in the surface of your skin. Embrace can detect changes that may be important, signal them to the Alert App, and summon a caregiver to come and check on you. Always follow your doctor's advice when using Embrace. Embrace is not intended to diagnose or treat disease, and is not a medical device.





3. USER TYPES

User

A User wears the Embrace and runs the Alert app on their smartphone.

Caregiver

A Caregiver is designated in the Alert App and receives voice and SMS notifications on their phone when Embrace detects changes in the User.

Customei

A Customer is the individual or institution that purchased the Embrace watch.

GENERAL AGREEMENTS

The purchase of an Empatica device is subject to a purchase agreement between Empatica and a legal entity that acquires the product, namely the Customer. The Customer is responsible for the maintenance of the Empatica products and their proper use. Empatica is not responsible for any damage caused by improper use of the device, which cannot be opened by the user to access the circuit board and internal components. Any alteration caused by the user might be prosecuted. Furthermore, changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment

This document is used for the sole purpose of supporting the Customer, User and Caregiver(s). It contains critical information for understanding correct device use and maintenance. The manual should be read carefully. The Customer, User, and Caregiver must strictly adhere to the rules it contains.

Additional agreements for use in research settings:

All research studies that make use of the Embrace watch must be reviewed by a qualified institutional review board (IRB) or ethics committee. The Customer is responsible for making sure that Users are fully informed and have consented before participating in any studies. The Customer is responsible for safeguarding any User personal information.

MANUFACTURER DETAILS

Produced by: Empatica S.r.l. Street: Via Stendhal 36 City: Milano (MI) 20144 Zip code: EIN: 07462810966 EROI: 07462810966 Website: www.empatica.com Support: support@empatica.com **Embrace Smartwatch** Commercial Name:

Model: Embrace watch with Empatica Alert App for iOS®

Commercialization year: 2016

Empatica S.r.l. may be referred to as Empatica or Manufacturer

4. PRODUCT LABELING INFORMATION

The Empatica Embrace labeling system is compliant with the requirement outlined in EN ISO13485:2012

Each device is identified by:

- Manufacturer logo etched on the top cover
- Product Name: "Embrace" and Manufacturer name "Empatica" etched on the bottom cover.
- Serial number composed of 10 alphanumeric characters, e.g. 1CWY5111A3, which uniquely distinguishes each device.
- IP code: 67 indicating that Embrace is dust tight and resistant to immersion in water up to 1 m depth.

Most of the labeling information is laser printed on the bottom cover of the device. We also included the following marks denoting compliance to their corresponding standards:

Regulatory compliance:

- CE
- FCC
- RoHS

Laboratory tests:

Electromagnetic compatibility

- IEC 60601-1-2:2007 (third edition)
- FCC CFR 47 Part 15c
- ETSI EN 301 489-17 V2.2.1

embrace ⁸

Embrace is a smartwatch that monitors daily activity, sleep and changes in the nervous system. It detects variations in physiological signals that may not be normal in someone's daily life. When an unusual event is detected, it sends an alert through a smartphone, so that a friend or a parent can check on the user.



Manufactured by:

Empatica S.r.l. Milan, Italy







FCC ID 2AGGH-EMB

DOC #EMB-SP069-A-20160001





Represents compliance of Embrace product with the European Community directive on medical devices 93/42/EEC.



Compliance of the Embrace product with the Waste Electrical and Electronic Equipment Directive.



Embrace watch has two metal contact points that are used by the EDA sensor. This is a type BF part that means that it may generate a current leakage when in contact with the skin. ISO60601-1 safety test demonstrated that this part is safe.

6. WARRANTY AND SUPPORT

The Embrace devices are covered by warranty as stated in the general sale terms, where the modalities are described by which a broken or defective device can be returned to Empatica. If a malfunction arises during the warranty coverage period and the malfunction belongs to one of the categories listed in the warranty statement, Empatica, after a proper test of the device, will replace or repair it. Any intervention on the device done without the explicit indication by Empatica will void the warranty and Empatica will not be responsible for any damage to the modified product.

For technical support, please refer to the contact information below:

Empatica Support Portal - https://support.empatica.com - View answers to frequently asked questions, initiate and manage support request tickets.

Support request tickets can also be initiated within the Empatica Alert app or by sending an email to support@empatica.com

Return merchandise authorization (RMA)

If Empatica support representatives are unable to resolve an issue remotely, an RMA will be issued. The Customer must fill in the RMA form and follow the instructions provided to return the product to Empatica for servicing. Empatica will not be responsible for returned merchandise without an executed RMA form.

7. PRECAUTIONS FOR USE

The Embrace is in the process of undergoing certification as a CE Medical class 2a device according to ISO 13485:2012. Risk analysis has demonstrated that the Embrace can be considered a low risk profile device.

The Embrace 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.



- a. WARNING For timely dissemination of notifications to Caregivers the following conditions must be met:
 - The User wearing the Embrace watch remain within close proximity of a paired smart-phone running the Empatica Alert app.
 - The paired smart-phone must have Internet connectivity.
 - The Caregiver's phone must be connected to a wired or wireless telephone network.
- b. WARNING Users who wear pacemakers, or have health conditions which might be sensitive to the tiny electrical signals used by the Embrace in measuring EDA should always consult their physicians before wearing any electronic device, including the Embrace watch.
- c. WARNING If the equipment is used in a manner not specified by the manufacturer the protection provided by the equipment may be impaired.
- d. WARNING Adult supervision required. Due to the presence of small parts used in the Embrace it is strongly advised that the device only be used on small children under adult supervision.
- e. CAUTION Do not place the Embrace watch over broken or damaged skin.
- f. CAUTION Do not use unapproved accessories with the Embrace watch.
- g. CAUTION The buckle and the face of the Embrace are made of aluminum and nickel-free chrome plated metal, and the band is made of stretchy material. The electrodes are in surgical stainless steel SUS316L, which should not cause any skin reactions. Nevertheless, if a person has a known metal allergy or is generally sensitive to skin contact with metals, please contact Empatica before wearing the device.
- h. CAUTION Check the Embrace watch for sharp edges and damage before each use. Do not use the watch if damaged.
- CAUTION Keep the device away from other devices that may cause electromagnetic interference of any nature.
- j. CAUTION Embrace is splash proof but protect the Embrace against immersion in water. Do not wear the device while showering, bathing or swimming. In the event that there is water ingress into the case the User will not be harmed, but the device may stop working. If Embrace exhibits any issues after water exposure contact the Empatica Support Team immediately.
- k. CAUTION Do not leave the Embrace Watch in environments in which the device may become heated beyond the recommended environmental limits (such as a hot car). If the Embrace is left exposed to high temperatures allow it to cool before handling it to avoid potential skin burns.
- I. CAUTION Users should never attempt to wear the watch while charging the battery.

Synthesis of cautions

m. Functional hazards -

including any error that might result from errant read and /or transfer of data that affects the output of one or more sensor (i.e., EDA, Temperature, Accelerometers, Gyroscope). *Very Low risk level – no harm –* safe transfer protocols and fault detection algorithms monitor the validity of data. Moreover the Embrace is not intended to diagnose a disease; only trained personnel may interpret the data.

- n. Current leakage through the EDA electrodes
 - The EDA circuit drives a small amount of ionic current through the skin to operate: Max 100 μ A as required by IEC 60601-1:2005 **Very Low risk level no harm** the Embrace has been validated to be compliant with ISO 60601-1:2005 after design validation and verification, which means that the amount of current produced is safe for the user.
- o. Battery

Very Low risk level – no harm – batteries have a low energy density and an explosion is a rare event. Batteries are qualified before use and are also certified by the Supplier.

p. Water resistance

Very Low risk level – no harm – the device is splash proof and will operate normally after contact with sweat, rain or splashes. The device is not fully waterproof so the user should not submerge it in liquid or wear it in the shower. In the event that there is water ingress into the case the User will not be harmed, but the device may stop working.

a. Biocompatibility

Very Low risk level – no harm - the Embrace is made of a well-known biocompatible material and the manufacturer is qualified, ensuring that no contamination occurs during the manufacturing process. Materials are outlined in Technical Specifications section.

r. Electromagnetic compatibility

Very Low risk level – no harm – design validation and verification has been conducted and has demonstrated that the Embrace is safe for use with other electronic devices. It is compliant with the following standards:

- IEC 60601-1-2:2007 (third edition)
- FCC CFR 47 Part 15C e IC RSS-210_RSS-247 (Industry Canada)
- ETSIEN301489-1e3V

There should be no precautions to be taken for any interference with the magnetic fields, or to the environmental conditions of use.

Conditions for Use

Ambient - Embrace can be used in home settings, indoors or outdoors; it is resistant to water but cannot be immersed in water, it can be lost by subject during use, it should be worn tight against the wrist.

Environmental condition - Temperature -20°C +70°C, Relative humidity 20% - 95%, Air pressure – 500hPa to 1200hPa, Acoustic level - not relevant

Proper storage after use - The Embrace should be properly stored. Do not expose Embrace to direct sunlight, moisture, humidity or rain.

Product disposal - Dispose Embrace, Charging Dock, and USB cable in accordance with local regulations. Do not dispose of the battery with regular household waste. Recycle you package in accordance with local regulations.

Use with other accessories (i.e. battery charger) - It's forbidden to use the Embrace with other accessories, unless approved by Empatica. It is expressly forbidden to plug the Embrace into any charger that is not compliant with IEC 60950-1. Check with your retailer to ensure compliance.

Use with children - The Embrace does not require any particular safety procedure when used with children.

Transport and Handling - The Embrace watch is shipped in a cardboard box, which can be recycled after the unpacking. Each cardboard box may contain one or more devices that are stored inside their original plastic box. Place the Embrace inside its original plastic box to prevent any accidental damage when it is not in use.

The Embrace can be stored in it's original box for a maximum of 1 month without charging. If the Embrace will not be used for a longer period make sure to charge the device at least once a month to maintain the battery.

Disinfection before use - The Embrace is designed to be suitable for repeated use by multiple Users. The Customer must ensure that the device is properly disinfected before being transferred between individual Users to prevent the transmission of skin diseases.

8. TECHNICAL SPECIFICATIONS

Expected product life

The expected life of the device depends mainly on the battery life that is 2 years.

Dimensions

Embrace watch:

Length: 37.6mm (1.480") Width: 29.7mm (1.169") Height: 10.3mm (4.055") Weight: 13g (0.459oz)

Watchband: Spring bar: 27 mm (fits 24 mm watch bands)

Fahric

Min Circumference: 100 mm (3.937")
Max Circumference: 200 mm (7.874 ")

Width: 24mm (0.945")

USB Charging Dock:

Length: 45.9mm (1.807") Width: 31.0mm (1.220") Height: 21.0mm (0.827") Leather: (optional accessory)

Min Circumference: 130 mm (5.118") Max Circumference: 210 mm (8.268")

Width: 24mm (0.945")

USB Cable:

Length 180mm (7.087")

Connection type 1 (Micro USB B, male) Connection type 2 (USB A, male)

Sensors

EDA Sensor:

Sampling frequency: 4 Hz (Non customizable).

• Resolution: 1 digit ~55 fSiemens.

• Range: 0 μSiemens – 80 μSiemens.

• Alternating current (8Hz frequency) with a max peak to peak value of 80 μAmps (at 80 μSiemens).

• Electrodes:

Placement on either the ventral (inner) wrist or dorsal (outer) wrist.

Temperature Sensor

Sampling frequency: 1 Hz
Range: -40°C - 125°C
Resolution: 0,026°C (at 35°C)

3-Axis accelerometer

- Sampling frequency: 32 Hz
- High sensitivity motion detection across 3 axes:

X,Y, and Z.

• Range ± 16g.

• Resolution: 16 bits

Gyroscope

- Sampling frequency: 32 Hz
- High sensitivity motion detection across 3 axes: X.Y. and Z.
- Range ± 500degrees/sec.
- Resolution: 16 bits

Power

Battery Characteristics3.7V LiPol battery pack
90 mAh minimum capacity

AC Adapter Specifications

Input Voltage: 5 V Output Current: 100 mA

Packaging: USB A (charge only, no data transfer)

9. BIOCOMPATIBILTY

The Embrace has the following set of components that can be in contact with the skin.

Case:

Top coverBottom cover:Band frameAnodized aluminumPolycarbonate (PC) baseAluminum + Nickel-free chromePolycarbonate (PC) light pipeSUS316L electrodes*plating

SUS410 screws

Watchbands:

Fabric watchband:

High Lycra content Polyester Band Aluminum + Nickel-free chrome plating buckle Leather watchband: (optional accessory)

Polyurethane core

SUS430 + Nickel-free chrome plated buckle

Magnetic clasp

Known allergic reactions

Among all Embrace users (thousands) we have been reported with two cases of allergic reactions of light intensity (few days of persistence). Those people were also allergic to other types of substances. Please contact immediately our support team for any issue related to this topic.

During summer, the mechanical interference between the Embrace watchband and the skin may cause the skin to become itchy. This is not related to any allergy but if this happen we suggest to pause the use of the device for few hours.

Cleaning and Disinfection

Before switching between users, carefully clean all parts of the device that come in contact with the skin. The disinfection processes should include one or more of the following methods:

- Exposure to UV lamp.
- Cleansing with cotton soaked with a small quantity of ethyl or isopropyl alcohol.
- Cleansing with a solution containing Alkyl C12-16 Dimethylbenzyl Ammonium Chloride.

Do not use cleaning agents other than those described above without explicit written instructions from Empatica support.

^{*316}L, a Surgical Stainless Steel contains Nickel (Ni) but the Ni release rate is well under 0.5 µg/cm2/week and within EN 1811:2011 tolerances for use in wrist-watch cases, watch straps, and tighteners.

10. Interacting with the Embrace watch

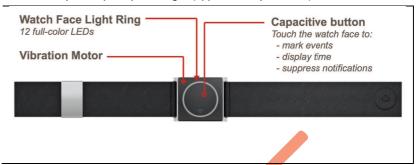
Button, LED indicator light-ring/watch face, and vibration motor

The Embrace runs continuously until its battery is completely discharged (approximately 36 hours).

The Embrace is controlled with a capacitive button interface.

Time and device status is indicated using a 12-light ring of multi-color Light Emitting Diodes (LEDs).

The Embrace can vibrate to draw attention to the LED indications



Basic Embrace watch Interactions

- To check if the Embrace is powered on tap the watch face. If the Embrace does not react to a tap on its face it means that the battery has completely discharged and lost the connection to the smartphone.
- Read the time: Tap once on the center of the watch face and you will be able to see two led-lights: the fixed Blue LED indicates the hour, while the flashing white one indicates the minute (with 5-minute resolution). If the hour and minute are in the same position on the watch face the blue LED will be illuminated with dim white LEDs on either side.
- Log an event: by tapping twice on the center of the watch face. The Embrace vibrates once and all 12 White lights blink for 1 second twice. This will log an event that can be annotated using a smart-phone app.

Indications using LED lights and vibration/haptic feedback during operation

- RED FULL LED RING PULSE 1 Hz + VIBE EVERY SECOND UNTIL CANCELLED Unusual activity has been detected and Empatica Alert initiates a notification
 - o To silence the embrace touch and hold the watch face for 3 seconds.
 - Note you must cancel the Empatica Alert notification to caregivers using the smartphone app
- Vibrate once + pulse RED LED at 12:00 every 3 seconds check the Empatica Alert App to identify one of the
 following warnings: poor skin contact, low battery approximately 1 hour runtime remaining) or low device
 memory
 - To silence the embrace touch and hold the watch face for 3 seconds.
- Vibrate once + pulse ORANGE LED at 12:00 every 3 seconds battery insufficient for bed-time less than 8 H remaining
- Vibrate once + pulse RED X at 10:00, 2:00, 4:00, and 8:00 every 3 seconds the Empatica Alert App cannot be reached. Move the Embrace closer to the smartphone if that does not correct the issue re-launch the app to attempt a reconnection. If all else fails re-start your smart-phone and launch Empatica Alert.
 - o To silence the embrace touch and hold the watch face for 3 seconds.
- White ⁽⁽⁾ with LEDs illuminated along the bottom of the watch face a Bluetooth Low Energy connection between the Embrace and the Smartphone has been established.

11. Software and Hardware Requirements

The Embrace watch must be paired with an Apple® iPhone 6s, 6s Plus, 6, 6 Plus, 5s, 5c, 5 and iPod touch 6th generation. Alert 2.0 will need at least iOS 8.2 (8.0.x or 8.1.x are not compatible with the Alert app).

12. Start using the Embrace watch with Empatica Alert

A. Unbox the Embrace watch and review the guides

The Embrace watch is shipped with the following accessories in the box:

- The Embrace watch with preinstalled fabric or leather watchband.
- A USB Charging Dock (for charging the battery in the Embrace watch).
- A USB MICRO-B cable (to connect the charging dock to a powered USB port)
- A Printed copy of the quick-start guide and User Manual.

B. Charging the Embrace and understanding the battery level:

To charge the Embrace you will need to connect the charging dock to a powered USB port on a computer or dedicated wall adaptor. Once connected, the charging dock will be powered and ready to use.



If you are using a wall adaptor make sure it bears a CE mark (in the European Union) or bear an appropriate OSHA designated Nationally Recognized Test Lab (NTRL) mark in the United States. Check the OSHA website at osha.gov for a current list of approved NTRLs and their safety marks.

safety marks.

Position the Empatica symbol on the Embrace watch face in line



le NRTL Logos:



If the Embrace is completely discharged, once connected to the charger the lights around the face of the Embrace will be come completely white. During charging:

with the $\stackrel{\triangleright}{\triangleright}$ on the powered Charging Dock.

- The light at the 3:00 position, next to the & symbol on the watch face, will blink Orange indicating that the Embrace is charging.
- Additional orange lights will activate around the watch face proportional to the % charge level i.e. six LEDs (from 3:00 to 8:00 on the watch face) will be illuminated at approximately 50% charge.
- Once the battery is completely full, all 12 LEDs will be illuminated in a steady green light.

Charge the Embrace for at least two hours every time for the best long-term battery performance.

C. Wearing your Embrace

Embrace is worn like a watch. Embrace should fit snugly above the wrist joint *as illustrated*. Review the instructions below to optimize the signal from the Embrace to the smartphone.

- a. Loosen the band by sliding the buckle towards the Embrace.
- b. Wear the Embrace on the dominant wrist or ankle (right side for right-handed people, left side for left-handed people). If the Embrace is worn in the wrist, please be sure that the E> logo is oriented in the 3 o'clock position.
- c. The Embrace should fit comfortably snug so that the sensors remain in constant contact with the skin surface. Adjust the tightness of the band to ensure that the Embrace is comfortable, does not constrict blood flow does and does not shift in position on the arm or the leg during movement. When worn correctly marks may be temporarily visible on the skin after removal.

D. Download the Embrace Alert App

0 Before you begin make sure you have your smartphone and an internet connection.



1 Launch the App Store and search for "Empatica Alert" and tap the "GET" and "INSTALL" buttons to install.



E. Create your Embrace Account

0 Before you begin make sure you have your smartphone with Empatica Alert app installed and an Internet Connection.



1 Tap the Empatica Alert icon to launch the app.



At this point you'll see a WARNING window of "Untrusted Enterprise Developer". Go in iPhone Settings, Impostazioni/General/Device Management/Empatica Srl/Trust Empatica Srl.

A new window will appear and Click OK in order to allow the app to send you notifications, like alerts, sounds and icon badges.



2 Click on the "Create Account"



3 Carefully review the End User License Agreement (EULA). If understand and agree with the terms of the EULA tap the "Accept" button to continue. The EULA is also available for review under the Preferences menu.

If you do not agree press "Decline" and please contact support to share your concerns.



4 An email address and a secure password will be used as Empatica account credentials. To get started enter a valid email address and a secure password 8 characters or longer. Tap next to continue.

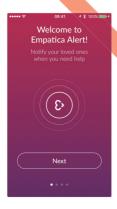


5 Enter a first name, last name, and contact phone number for the User. Tap "create account" to continue.



F. Review introduction screens

After the first login Alert will preset a basic introduction.









G. Pair your Embrace with the Empatica Alert app on your smartphone

O Before you begin make sure you have (1) your smartphone with Empatica Alert app, (2) your Embrace watch, (3) Your Embrace Charging Dock and USB Cable, (4) a USB power source, and (5) and Internet connection. Make sure to review section 12 B. "Charge your Embrace"



- 1 Tap the Empatica Alert icon to launch the app.
- 2 Tap "Login", enter your email and password credentials and tap "Login" again to proceed.



3 To wake up the Embrace connect it to the powered Charging Dock. Tap "Start Pairing" and then "OK" to proceed.



4 Make sure the Embrace is close to the smartphone and tap "Pair". The smartphone will begin to search for the Embrace.



5 Once the Embrace is found, the smartphone will ask if you want to "Pair" or "Cancel" – Tap "Pair to create a Bluetooth connection between your smartphone and the Embrace.

You can remove the connection under your smartphone's

Settings > Bluetooth menu (click the "info" symbol and select

"forget this device")



6 Embrace takes a moment to start sending information to the Alert app so you may see an "Embrace Not Found" warning for a few seconds.



7 After pairing the Embrace and your smartphone will remain connected as long as they are both charged and close to each other.



H. Add a Caregiver

Once the Embrace is paired with your smartphone it's time to add one or more Caregivers to the Alert app. When unusual activity is detected by Embrace, the Empatica Alert app will send a notification to a designated caregiver.

Before you begin make sure you have your smartphone with Empatica Alert app installed and an Internet Connection.



1 Launch Alert, login, and tap on the "caregivers" tab.

You can enter the Caregiver's name, phone number and email address information manually or tap "Search Contacts" to browse your phone book for a contact. The Caregiver phone number can be any mobile or landline phone number.

You can add multiple caregivers, they will all receive notifications simultaneously

- Once you have the Caregiver contact information entered, tap "Save Caregiver" to continue. The Caregiver will receive a text message confirmation if they entered a mobile phone number.
- 3 When Embrace detects unusual activity it will vibrate and illuminate a red pulsing light. As long as the User's smartphone is in Bluetooth range Alert app will activate a notification service and the Caregiver will be sent an SMS and voice message indicating that the User needs assistance.



Hi! You are now a caregiver for the Empatica Alert app. You may receive calls and messages reporting an alert.

This is an Embrace Alert: Dan needs your help!

[phone rining image]

I. Review Alerts

After configuring Alert app, when Embrace detects an unusual change in physical activity and skin conductance a notification is sent to the Caregiver and the event is logged in the app. Notifications may be triggered by everyday activities (false alarms) or by unusual events. Review notifications in the Alert app frequently and mark false alarms to improve the Embrace watch experience.

Defore you begin make sure you have your smartphone with Empatica Alert app installed and an Internet Connection.

1 Tap on the "Recent" icon to view a list of recent notifications.

RECENT ALERTS

here's the list of alerts you have sent

TODAY

10 Feb 2016 09:18

Caregiver

VESTERDAY

09 Feb 2016 10:29

Caregiver

OF Feb 2016 10:29

Caregiver

To mark a false alarm, tap on a notification and then tap "Mark as false alarm"

RECENT ALERTS

RECENT ALERTS

RECENT ALERTS



J. Configure your device and app settings

Tap on the "Settings" tab to access Alert app and Embrace configuration options.

To edit your name, phone number or email address tap on "My Profile".

To provide Empatica with information about your experience tap on "Send Feedback".

To review the terms of use, access Empatica's support center, report an issue, or check your existing requests tap on "Support".

To logout of the app Tap "Logout" and confirm.

To update your Embrace's on-board software, also known as firmware (FW), format the Embrace's memory or adjust your data usage settings tap on "My Embrace".



K. Managing mobile data usage

Alert will upload Embrace data to Empatica Servers continuously supporting analysis and advanced options. If you are on a limited mobile data plan you can set Alert to store data on your phone until you have a WiFi internet connection and avoid using your mobile data plan for uploads.

To prevent Alert from uploading data over a mobile internet connection tap on Settings and then tap the "Upload data only via WiFi" switch so that it is green (as pictured).

You can also see how many sessions are pending upload.

DEACTIVATING MOBILE DATA UPLOADS WILL NOT PREVENT ALERT FROM SENDING NOTIFICATIONS TO CAREGIVERS. It will just limit the upload of device data to Empatica servers until you have access to a WiFi network on your mobile device.



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