AutoTQ®

A Golden Hour Medical Innovation

theautotq.com

Instructions for Use

Manufactured by Golden Hour Medical®

Welcome!

We are here to guide you through the process of setting up, storing, and using AutoTQ. This guide provides a brief overview of AutoTQ. Users are encouraged to familiarize themselves with more details, training, and more by visiting our website:

theautotq.com

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Standard Use Guidelines

Read this entire booklet and undergo training before attempting to utilize AutoTQ. The intended use of AutoTQ is to control blood flow to the arms and/or legs below the hip or shoulder. Intended users of AutoTQ should only use as directed by user's military service component guidelines, EMS authority, or under the supervision of a physician, and in strict compliance with these Instructions for Use. Only trained users are qualified to operate AutoTQ. Read the entire manual prior to using AutoTQ. Use AutoTQ cuffs as specified by the manufacturer. Failure to use AutoTQ on limbs smaller than 33 inches (leg cuff only) or smaller than 13 inches (arm cuff only) may lead to inadequate pressure for the bleed to stop. The use of any tourniquet longer than 2 hours may lead to permanent neurological or muscular damage. AutoTQ should not be applied if direct pressure is adequate to control bleeding. AutoTQ must NOT be applied over solid objects within the clothing. As soon as possible, the injured limb should be evaluated and AutoTQ should be placed on a single bone above the injury directly to the skin. The minimum pressure required to stop arterial blood flow should be used and the tourniquet should be used for the minimum amount of time possible. AutoTQ should be stored in a cool, dry place away from direct sunlight. Re-use of AutoTQ Cuff may introduce risk of infection. The AutoTQ Cuff is a single use device and must be disposed of after each use. Dispose of used AutoTQ Cuff in accordance with local regulations for biomedical waste. The AutoTQ Inflator must be thoroughly cleaned in compliance with these instructions for use prior to re-use. Please report all serious incidents in relation to AutoTQ to the manufacturer and appropriate regulatory authority.

Contraindications: AutoTQ is contraindicated if hemorrhage can be prevented by other conventional emergency medicine techniques (e.g. pressure bandages). This decision rests solely with the user and should be made in accordance with the policies of the user's practice setting. The tourniquet should not be used on patients with known arterial insufficiency or severe peripheral vascular disease.

Standard Use Guidelines

Contraindications cont'd: Avoid using the tourniquet on patients with suspected or diagnosed blood clotting disorders. Pregnant women should consult a healthcare professional before using the tourniquet.
Precautions: When using a tourniquet on patients with sickle cell disease or trait, severe post-tourniquet pain may result in the affected limb which may be caused by sickling of cells. Do not allow fluids to flow and collect under the tourniquet where they may cause chemical burns. If recommended by the policies of the user's practice setting, the limb may be exsanguinated prior to tourniquet inflation. Inflation must be done as rapidly as possible to occlude arteries and veins simultaneously. Heat generated by outside sources is not dissipated in limbs under tourniquet control and tissue may be subject to drying or trauma. Frequent irrigation, and special draping are recommended to reduce the risk of thermal damage. Prolonged ischemia may lead to temporary or permanent damage to tissues, blood vessels, and nerves. Tourniquet paralysis with possible irreversible functional loss may result from either excessive or insufficient pressure. Prolonged tourniquet time can also produce changes in the coagulability of the blood with an increase in clotting time. In severe cases, pooling of blood in the edemic limb may cause cardiac arrest and death. Observe the tourniquet during inflation and check periodically while inflated to ensure the tourniquet does not move on the patient's limb to a position that may lead to nerve/bone impingement (for example at the ankle, knee, or elbow), or a position causing bleeding to resume. If the tourniquet does move on the limb to an unsafe position, apply a pressure dressing to the wound, then deflate and reapply the tourniquet in the proper position. Whenever the tourniquet pressure is released, the wound must be protected from blood surging back by applying pressure dressings and, if necessary, elevating the limb. If full color does not return within 3 to 4 minutes after release, the limb should be placed in a position slightly below body level and the circulation should be checked. Completely remove the deflated tourniquet and any underlying padding immediately following tourniquet deflation. Even the slightest impedance of venous return may lead to congestion and pooling of blood at the wound site.
Adverse effects: A dull, aching pain (tourniquet pain) may develop throughout the limb following tourniquet use. Stiffness, weakness, reactive hyperemia, and skin discoloration may also occur to some degree in all patients after tourniquet use. Pathophysioiogical changes due to pressure, hypoxia, hypercarbia, and acidosis of the tissue occur and become significant after about 1 1 /2 hours of tourniquet use. Symptoms of tourniquet paralysis are: motor paralysis and loss of the sense of touch, pressure, and proprioceptive responses.
Continued blood loss after tourniquet application may be caused by: 1. Inadequate tourniquet pressure allowing arterial flow to enter the limb. 2. Blood entering through the nutrient vessels of the long bones (such as the humerus)

Standard Use Guidelines

Limb Size: AutoTQ has been tested to accommodate limbs up to 32.5″ in circumference. The arm cuff may be used up to 13 inches, and the leg cuff may be used up to 33 inches. If in doubt about the size of the limb, exercise caution and select the larger cuff (i.e. if the limb appears to be larger than 13 inches in circumference, select the leg cuff). If the arm cuff is used on a limb smaller than 5 inches, or the leg cuff is used on a limb smaller than 13 inches, do not be alarmed: the cuff will not adhere to velcro and the air bladder will expand straight out, however occlusion will still be reached at the limb site when AutoTQ is fully inflated.
Warnings: AutoTQ is designed for use on adults and children with a limb circumference within its operational range. It may not be suitable for very small children or infants due to the risk of improper fit and potential injury. Pressure may fall or rise at any time while the tourniquet is inflated depending on the conditions of each individual case. Inflate the tourniquet to the minimum pressure required to stop arterial bleeding distal to the tourniquet and a distal pulse can no longer be felt. Required pressure is unique to every case and depends on tourniquet location, snugness of tourniquet application, limb size and properties, patient physiology, and other factors. Monitor the injured person continuously for signs of arterial or venous bleeding, or venous engorgement of the limb distal to the tourniquet. To minimize the chance of further injury to the limb, minimize the time that the tourniquet is continuously inflated on the limb. Deflate and remove the tourniquet as soon as bleeding can be controlled by alternate means. If bleeding resumes, increase tourniquet pressure the minimum amount required to stop bleeding and a distal pulse from being felt. In individuals with sensitive skin or known skin conditions, the AutoTQ may cause skin damage or reactions. Use with caution and monitor the skin condition frequently. The AutoTQ is a medical device. It should never be used as a restraint device or weapon, or outside of these indications for use.

Liability Limitations: The tourniquet must be applied at the proper location on the limb, for an appropriate period of time, and within the appropriate pressure range, all determined solely by the user. Failure to follow the guidelines, warnings, and instructions provided with AutoTQ limits the manufacturer's liability for any injuries or damages resulting from misuse. Any malfunction, failure, or incident resulting in a potential or actual injury must be reported to the manufacturer to facilitate corrective measures and prevent future occurrences.

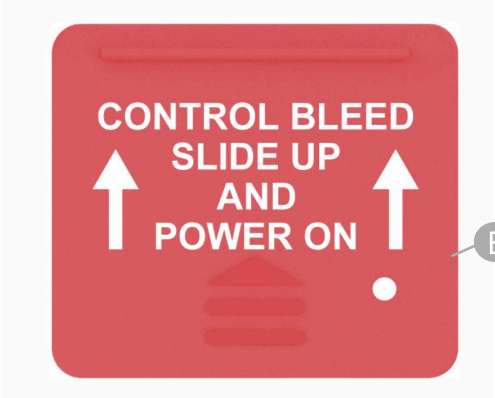
Maintenance: This product is subject to wear and deteriorates with use. It is essential to inspect this device after each use before repacking for reuse by replacing the AutoTQ cuff and undergoing training again by plugging AutoTQ into the computer. If the tourniquet fails to pass training, it is no longer usable and must be discarded. Use of a damaged tourniquet could result in one or more of the following events: loss of tourniquet pressure; release of the tourniquet from around the patient's limb; movement of the tourniquet on the patient's limb; or excessive leakage of tourniquet pressure. Do not puncture the tourniquet or store the tourniquet near sharp objects, any puncture will cause leakage to the tourniquet and render it unusable.

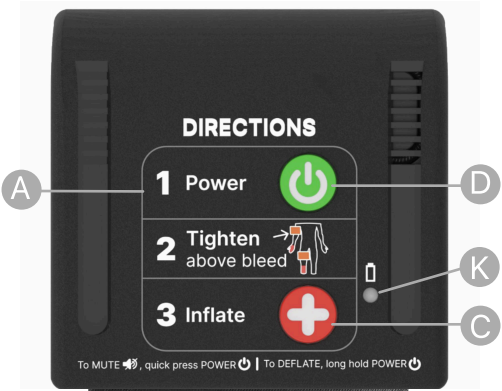
Standard Use Guidelines

Maintenance Cont'd: AutoTQ Inflator must be thoroughly cleaned with a diluted IPA Alcohol / water solution prior to re-use to avoid risk of infection. AutoTQ must be charged regularly to avoid a depleted battery. Allow a full charge cycle, wherein the LED will turn solid green, prior to use. Confirm the battery level by plugging AutoTQ in to the monitoring platform prior to storing. AutoTQ's battery must be checked monthly, and training should be completed at minimum quarterly. Only charge AutoTQ with the provided USB-C cable. Ensure AutoTQ is kept in idle mode when it is not being used. AutoTQ contains a lithium battery that must be disposed of in accordance with local regulations. The manufacturer reserves the right to update instructions, warnings, and contraindications based on new information or regulatory guidance. Always ensure you have the latest information regarding the use of the AutoTQ, which can be found on our website at theautotq.com/labeling. By adhering to these additional precautions and properly educating intended users, you can further mitigate risks associated with the use of the AutoTQ and protect both users and patients from potential harm. Failure to adhere to these proper storage and useage guidelines could cause catastrophic injury, including death, to the patient by releasing blood.

Proper Use Guidelines: AutoTQ is exclusively designed for application on limbs (arms and legs). It must never be used around any part of the body other than the limbs, as this can lead to serious injury or death. AutoTQ should not be placed over any joint, such as the shoulder, elbow, wrist, hip, knee, ankle, etc. Application of the tourniquet over the area of the peroneal nerve (the knee or ankle), or over the area of the ulnar nerve (the elbow) may produce nerve/bone impingement resulting in nerve damage or paralysis. Avoid using improvised padding under the AutoTQ. Use only approved accessories or configurations as recommended by the manufacturer to allow proper pressure distribution and effectiveness. Follow the manufacturer's instructions carefully to apply the appropriate amount of pressure. Over tightening can cause injury to the limb. Only use the AutoTQ that fits the patient's injured limb. Regularly assess the necessity of the tourniquet and remove it as soon as medically appropriate. Do not remove AutoTQ without supervision from a licensed physician medical professional in a healthcare setting. Ensure that users are properly trained in the use of the AutoTQ, including its application, monitoring, and removal. Untrained users are not permitted or qualified to use AutoTQ. By using AutoTQ, you agree to our terms of service (www.theautotq.com/termsofservice) and our privacy policy (www.theautotq.com/privacypolicy).

Get to Know AutoTQ





Get to Know AutoTQ

Components

A **Pictorial instructions.** These instructions are purposed to show where and how to apply and pressurize AutoTQ.

B **Cuff.** The cuffs come in two configurations: “ARM” nad “LEG”. They are inflatable and disposable after each use.

C **Inflate Button.** The inflate button is used to add pressure to the tourniquet.

D **Power Button.** The power button is used to wake up and mute the tourniquet.

E **Slide Up Cover**. The slide up cover is used to protect AutoTQ from impact and the elements.

F **Loop.** The loop is used to adjust AutoTQ to fit different limb sizes. The loop may look different than that pictured.

G **USB Port.** The USB port is used for charging the device.

H **Receiver.** The receiver is used for attachment to the cuff.

I **Limb size label.** Limb size label for ARMS or LEGS to identify cuff dimensions. TIME section to note time applied.

J **Slider.** The slider is coupled to the receiver during setup.

K **Status LED**. The status LED changes color depending on device status.

Initial Device Setup

Before using AutoTQ:

1. **Train and register** your AutoTQ unit by visiting theautotq.com/training. Follow the instructions on screen.
2. **Connect** AutoTQ to Wifi on the training platform, and you will receive an email when AutoTQ needs to be charged or updated. Alternatively, check this manually at least once per month.
3. **Store** your AutoTQ in a location that is easy to find. Log placement of your device in the online training platform.
4. **After using, report** a life saved on our website at theautotq.com/report. It is our honor to send you a new cuff free of charge.

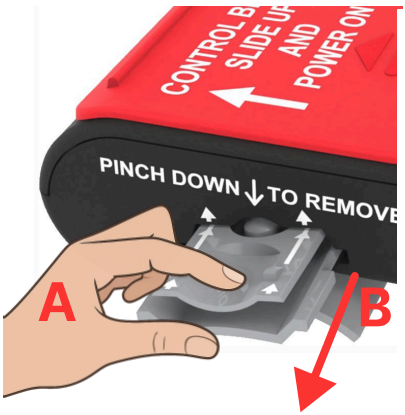
Specifications

Dimensions	L85*W81*H29 (mm)
Weight	165 grams
Input type	USB Type-C
Charging Time	3.5 hours
Maximum air pressure	600 mmHg
Operating temperature	10°C to 48°C
Storage temperature	-20°C to 60°C
Maximum drop	4 feet

How to Use

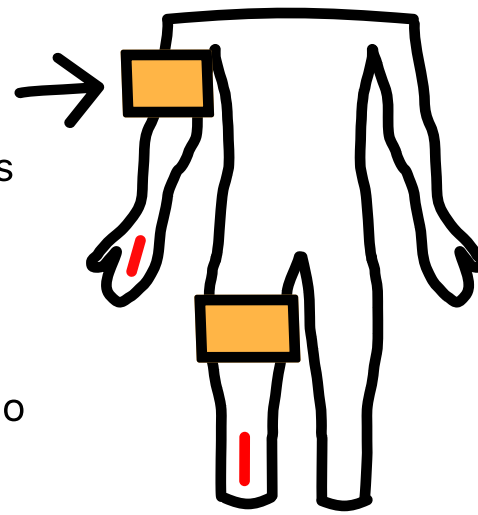
Apply direct pressure to bleed. If bleeding does not stop, proceed to use AutoTQ. Complete e-training for full tutorial at theautotq.com/training.
To use AutoTQ:

1. **Select** the necessary cuff, either “ARM” or “LEG”.
    a. Note: the ARM cuff maximum limb circumference is 14 inches. The LEG cuff maximum is 33 inches. For large arms, use the LEG Cuff. For small legs, use the ARM cuff.
2. **Switch** cuffs if necessary by pinching down the slider (A), removing the inflator (B), and reattaching it to the correct cuff (C) following the arrows (D).



How to Use

3. **Select "POWER".** The green indicator LED will turn on, the buttons will illuminate, and AutoTQ will deliver audio instructions.
4. **Position** the AutoTQ Cuff above the site of bleeding on a single-boned limb (i.e. upper arm or upper leg).
5. **Loop** the distal end of the cuff through the loop, and pull AS TIGHT AS POSSIBLE. Secure the velcro.
6. **Press the "INFLATE"** button. If bleeding does not stop, press "INFLATE" again.
7. Write the TIME applied on the red cuff label.
8. Call for medical help. Do not remove tourniquet unless you are a healthcare practitioner in a healthcare setting.



Troubleshooting

- **If limb continues bleeding after full inflation**, hold “POWER” to deflate AutoTQ, detach the velcro, and pull the cuff tighter. Select “INFLATE” again.
- If limb still continues bleeding when cuff is AS TIGHT AS POSSIBLE, place the unused cuff (i.e. arm or leg) below the site of the original cuff application.
- If limb still continues bleeding, hold direct pressure on the wound after the tourniquet is on.

LED Indications

Button Lights

- **Solid White**: Ready
- **Inflate button blinking blue**: Inflating
- **Either button briefly blue**: button press detected
- **Both buttons flash red**: Deflating, or detachment detected from cuff
- **Both buttons flash yellow, red**: Inflate detected off of cuff
- **3 light blue blinks**: strap not tight enough

Battery Light

- **Solid green:** ready and charged
- **Blinking green**: charging
- **Yellow**: medium battery life
- **Red**: very low battery, charge immediately
- **Flashing red**: charging, but very low battery

FCC Statement

FCCID: 2BOHWAUTOTQ

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.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

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.

RF Exposure Information
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Specific Absorption Rate (SAR) information:
This Communicator meets the government's requirements for exposure to radio waves. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies.

The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health. FCC RF Exposure Information and Statement the SAR limit of USA (FCC) is 1.6 W/kg averaged over one gram of tissue.

Device types: Communicator has also been tested against this SAR limit. This device was tested for typical body-worn operations with the back of the Communicator kept 0mm from the body. To maintain compliance with FCC RF exposure requirements, use accessories that maintain an 0mm separation distance between the user's body and the back of the Communicator. The use of belt clips, holsters and similar accessories should not contain metallic components in its assembly. The use of accessories that do not satisfy these requirements may not comply with FCC RF exposure requirements, and
should be avoided.

Warranty and Maintenance

Golden Hour Medical, Inc. (“GHM”) warrants that the AutoTQ automated pneumatic tourniquet system (inflator unit) will be free from defects in materials and workmanship under normal use and service for a period of one (1) year from the date of purchase, unless otherwise stated in writing.

This warranty applies only to devices that have been:

- Used and stored in accordance with the Labeling and Instructions for Use by a Trained User;
- Not subjected to misuse, neglect, modification, or physical damage (including dropping or crushing); and
- Operated within the recommended environmental conditions.

If the device fails to power on, inflate, or otherwise perform as intended during the warranty period, discontinue use immediately and contact GHM for evaluation. GHM will, at its discretion, repair, replace, or refurbish the unit after inspection. Units that have been returned, refurbished, or reprocessed will be clearly labeled as “Refurbished” per FDA requirements.

Maintenance and Service

The AutoTQ inflator is a reusable electromechanical device that requires inspection monthly, proper storage, and visual inspection prior to use.

To ensure continued reliability:

- **Inspection**: Before each use, inspect the inflator and cuff for visible damage, corrosion, or loose components. Do not use if any abnormalities are observed.
- **Battery Health**: The internal battery is critical to performance. If the device does not power on or show a battery light above 50%, discontinue use and return it for preventive maintenance.
- **Environmental Conditions**: Store and operate the device at room temperature and relative humidity (non-condensing). Temperature limits are -20C to 60C for storage, and 10C to 48C for operating. Avoid prolonged exposure to direct sunlight, high heat, or freezing temperatures.
- **Field Exposure**: If the unit has been exposed to extreme environmental conditions (e.g., used outdoors for several hours in high heat or cold), contact GHM to perform a preventive maintenance check before reuse.
- **Handling**: If dropped, crushed, or otherwise subjected to impact, the unit should be returned to GHM for inspection prior to further use.
- **Preventive Maintenance**: Users may request a remote or in-person maintenance evaluation if performance anomalies are observed (e.g., button intermittency or inconsistent inflation). GHM may provide a replacement unit during evaluation.

Training and Authorized Use

This product is intended for use by individuals who have completed GHM-approved training or received instruction on proper operation. Use by untrained individuals may void warranty coverage and should be limited to emergency situations only.

Non-Clinical and Demonstration Units

Certain units may be labeled “DEMO – Not for clinical use.” If devices were given by GHM for free or for a demo fee, devices are demos and not for clinical use. Such devices are not covered by this warranty and must not be used for patient care or live training involving clinical application.