



ONE-TOUCH WIRELESS HEALTH TRACKER

# BODY LIFE TRACKER

*B.O.L.T Chest ECG*

**User Manual**

**Model: VA 07**

Document No : AMI-PRD-UM-B-VA 07

Version : 1.1

Date : 14.05.2018

# Legal

## **Disclaimer**

This publication/content contains proprietary information which is protected by copyright. No part of this publication may be reproduced, transcribed, stored in a retrieval system, translated into any language or computer language, or transmitted in any form whatsoever without the prior written consent of the publisher. American Megatrends India Private Ltd. retains the right to update, change or modify this publication at any time, without notice.

For Additional Information

Call American Megatrends India Private Ltd at 1800-200-8001.

## **Limitations of Liability**

In no event shall American Megatrends India Private Ltd be held liable for any loss, expenses, or damage of any kind whatsoever, whether direct, indirect, incidental, or consequential, arising from the design or use of this product or the support materials provided with the product.

## **Limited Warranty**

No warranties are made, either expressed or implied, with regard to the contents of this work, its merchantability, or fitness for a particular use. American Megatrends India Private Ltd assumes no responsibility for errors and omissions or for the uses made of the material contained herein or reader decisions based on such use.

## **Trademark and Copyright Acknowledgments**

Copyright © 2018 American Megatrends India Private Ltd. All Rights Reserved.

AMERICAN MEGATRENDS INDIA PRIVATE LTD.,

KUMARAN NAGAR,

SEMMENCHERY, OFF RAJIV GANDHI SALAI (OMR),

CHENNAI (TN) 600119.

All product names used in this publication are for identification purposes only and are trademarks of their respective companies.

## Document History

Version	Date	Comment
1.0	31-12-2015	Initial Release
1.1	14-05-2018	Updated with new images and contents

## Table of Contents

1.0	Intended Use .....	5
2.0	Product Description .....	5
3.0	Package Contents .....	6
4.0	Product Quality Reliability and Safety .....	6
4.1	Warning .....	6
4.2	Caution.....	8
4.3	Care and Maintenance .....	8
4.4	Disposal .....	8
5.0	Contraindications.....	9
6.0	Product Features .....	9
7.0	Operating Environment.....	9
8.0	Prerequisites .....	9
9.0	Using Mobile Application .....	10
10.0	B.O.L.T Chest ECG Measurement procedure .....	10
11.0	Charging the B.O.L.T Chest ECG Devices .....	12
12.0	Troubleshooting .....	14
13.0	Technical Specifications.....	16
14.0	Explanation of Indicators/Symbols.....	17
15.0	Certifications .....	19
16.0	FCC compliance statements .....	20
17.0	Warranty Information.....	21
18.0	Customer Care Support.....	21
19.0	Contact us .....	22

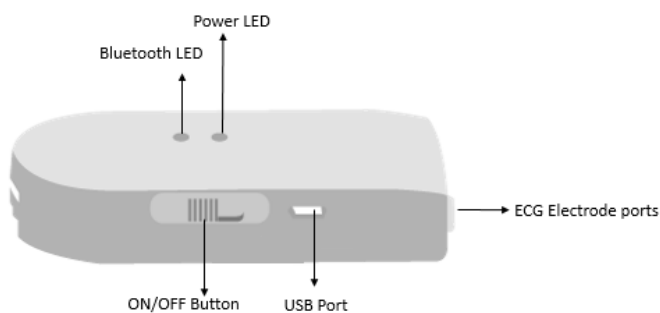
## Model VA 07 - B.O.L.T Chest ECG

### 1.0 Intended Use

B.O.L.T Chest ECG is intended to acquire the ECG parameters of adult users. The acquired ECG parameters can be used to obtain clinical consultation from cardiologists or healthcare practitioners.

### 2.0 Product Description

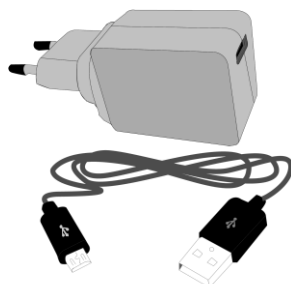
B.O.L.T Chest ECG device is a portable monitoring system which can measure/monitor the electrical activity of the heart over a period of time using the ECG electrodes placed on the user's body. The device monitors the ECG waveform from the Left & Right chest with a reference Electrode. The acquired and processed ECG data obtained from the device is transmitted to a mobile device wirelessly for further processing and analysis. The ECG data acquired by the device can be used to obtain clinical consultation from cardiologists or healthcare practitioners.



B.O.L.T Chest ECG Device



ECG Electrode Cables



## Charging Adapter &amp; USB Cable

## Disposable ECG Electrodes

### 3.0 Package Contents

S. No	Packing List	Quantity
1	B.O.L.T Chest ECG Device	1
2	ECG Electrode cables	3
3	Disposable ECG Electrodes	3 Pack
4	Power Adapter	1
5	USB Cable	1
6	Warranty Card	1
7	Quick Reference Guide	1
8	Dust Cap for USB Port	1

### 4.0 Product Quality Reliability and Safety

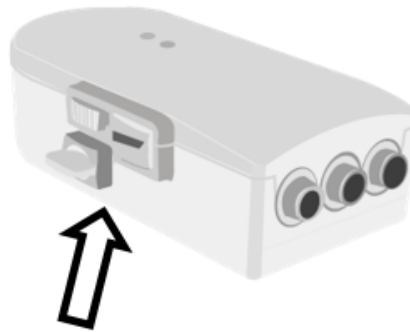
The device has been designed with an emphasis on quality, reliability and safety, but AMI can only accept responsibility for these aspects, provided the following conditions are met

- The device should be used as per the operating instructions mentioned in the user manual provided by AMI.
- All modifications and repairs to the device are carried out by authorized AMI personnel or their agents.
- Do not use the device when charging with a wall mount adapter as it may introduce noise in the waveform.
- The device must comply with regulation specified in warning and cautions.

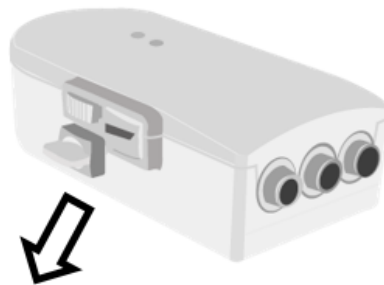
#### 4.1 Warning

- All users should read the user manual thoroughly. An electronic version of the current copy of this manual can be obtained from the official website.
- Read the Intended use, Warnings and Cautions carefully before the use of the product.
- Do not plug or unplug the AC adapter with wet hands.
- Do not clean the device while the power is ON.
- Use of the device is restricted to one patient at a time.
- Exposure of the device to water is prohibited.

- Do not expose the device to strong shocks or vibrations.
- The device is designed for adults and not recommended for the neonates, pediatrics and infants.
- Do not disassemble, repair, or modify the device by yourself, as this could affect the safety, and voids the warranty of the device if the seal is broken.
- The user is recommended to insert the given USB plug in the USB port of the ECG device during battery mode operation.



**Inserting USB Plug**



**Removing USB Plug**

- The user can remove the USB Plug while charging the device.
- Adhesives present in consumables like disposable ECG electrodes are free from any harmful substances. However, if any allergic reaction/irritation is observed, remove the part immediately from human contact. Clean the area with a mild soap and water to remove any residual particles of adhesive.
- Keep the device away from infants, small children or anyone who is incapable of using the device in an appropriate manner.
- Make sure that the ECG electrodes positioning place are clean shaved for accurate

ECG measurement.

- Do not attempt self-diagnosis or self-treatment based on the measurements provided by the device.
- Remove electrodes, patient lead wires, and recorder from patient before defibrillation.



## 4.2 Caution

- Do not use unauthorized parts and accessories.
- Do not store or use this device in locations which are maintained above/below the specified temperature and humidity ranges.
- Wrong positioning of the ECG electrodes may lead to inaccurate readings.
- Use only American Megatrends India Specified batteries and charging devices.

## 4.3 Care and Maintenance

- Store the device and the components in a clean and safe location.
- Charge the device for minimum two hours during first time usage.
- Do not disassemble, repair or modify the device and the components by yourself.
- Wipe the device using 70% Isopropyl alcohol and let air dry.
- Do not clean with ketones or other flammable agents.

## 4.4 Disposal

Dispose of the instrument, accessories and consumables according to local disposal and recycling laws



— This symbol is applicable for EU member countries only.

To avoid potential negative consequences for the environment and possibly human health, care should be taken while disposing (i) for EU member countries - in accordance with WEEE (Directive on Waste Electrical and Electronic Equipment), or (ii) for all other countries, in accordance with local disposal and recycling laws.

- Disposable ECG Electrodes used with the ECG device are considered as disposable products.
- The ECG Electrodes needs to be disposed after the single member usage to avoid cross-contamination.
- The ECG Electrodes disposal after use should adhere to the local authority guidelines/norms.



## 5.0 Contraindications

The analyzed results from the ECG device are not by itself sufficient to make a correct diagnosis of the patient's clinical condition. A detailed clinical history of the patient is also required together with the results of any other tests suggested by a doctor. The results depend on the person's ability to usage. If the fundamental procedure is not followed then the result obtained during the ECG monitoring will not be considered accurate, and therefore the test results are not acceptable.

## 6.0 Product Features

- Provides & Displays ECG waveform
- Measures Heart Rate Variability (HRV), Respiration rate (RR) and Heart Conditions Available for Android and Windows smartphones and tablets.
- Easy-to-use B.O.L.T app instantly displays results and health condition.
- Comfortable accessories to use.
- Ability to store data in B.O.L.T Personal Health Cloud.
- Maintain historical / trend data of all vital statistics measured.
- Multi-language support.
- Multi-user login support with built-in security to safeguard and protect personal health data.
- Rechargeable Battery.
- Extensible API to support integration with external health systems and web applications.

## 7.0 Operating Environment

B.O.L.T Chest ECG device has been designed for use in the hospitals, clinics or directly by the patient at home to monitor the heart conditions. The user or the physician is responsible for ensuring that the device is stored and used in appropriate environmental conditions.

## 8.0 Prerequisites

Some basic requirements must be adopted as mentioned below to ensure better operation of the product.

- B.O.L.T Chest ECG device is designed to be operated with applications like Android, or Windows.
- The Android OS version of the computer/mobile device should be 4.0 or higher.
- The Windows OS version of the computer/mobile device should be 8 or higher.

## 9.0 Using Mobile Application

### Downloading and Installing Mobile application on your computer/mobile device

1. Download and Install the “B.O.L.T “Application from Play store/Application store/Windows application market.
2. On successful installation, launch the application on the mobile device.
3. Create a User Name with your Email ID or use Facebook Credentials for login.



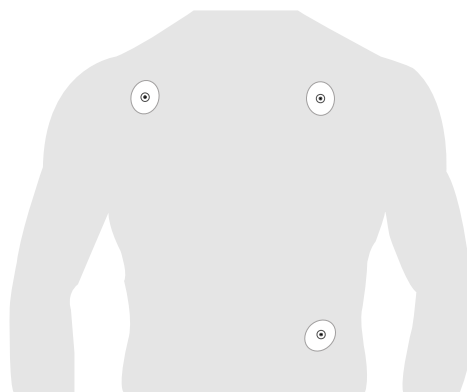
**NOTE** *You can also login as a guest user while internet unavailability which might not store the measured vital parameters in the cloud storage space on the measured parameters.*

## 10.0 B.O.L.T Chest ECG Measurement procedure

1. Position the disposable ECG electrodes on the user`s body as shown below.

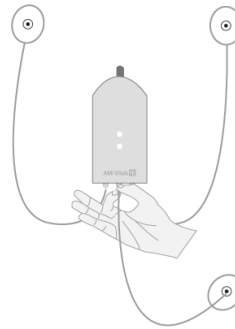
**Note:** *Kindly replace all the 3 ECG electrodes in case of 24 hours usage. While replacing, do not place the electrodes in the same position. Instead, place it slightly away / adjacent to the previous location.*

2. Ensure that the positioning spots of the human body are clean shaved.

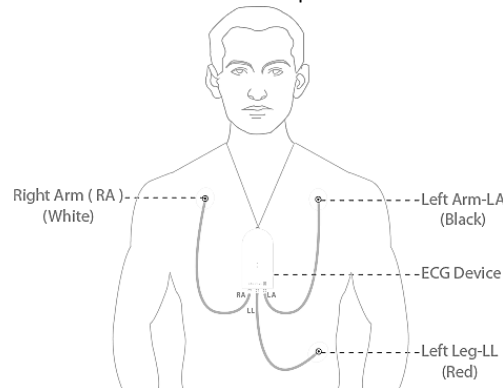



3. Connect the ECG electrode cables to the ECG device with appropriate matching color on connectors of the ECG device. RA is white color, LA is black color and LL is red color.

**RA – Right Arm, LA – Left Arm & LL – Left Leg**



4. Clip/button the ECG Electrode cable to the disposable ECG electrode as shown below.



5. Once the setup is connected ensure that the user is comfortable with the measurement.
6. Switch ON the mobile device, and Enable Bluetooth & Wi-Fi Internet Connectivity.
7. Switch ON the ECG device using the slide power button.
8. Blue LED on the ECG device will start blinking, which means that the ECG device is searching for Bluetooth device for pairing.
9. Launch the B.O.L.T application from the mobile device.
10. On successful login, Choose Check vitals menu.
11. Choose the ECG option from the mobile application test list.
12. Choose the ECG device from the available list of vitals devices.(e.g. AMI Chest ECG 01)
13. Confirm the device selection and provide default pairing password 1234 for pairing the ECG device (on request for the first time pairing).
14. Ensure that the Bluetooth LED stops blinking in the E.C.G device.
15. Select "Start" option to perform the ECG data monitoring/measurement.
16. Monitoring vitals data will be displayed within a couple of minutes on the application screen.
17. Once the test is completed, Click Stop and proceed back to home screen.
18. Click  to upload the result to the cloud on demand for further analysis.
19. Kindly ensure to remove the disposable ECG electrodes from the user body and dispose in the disposable container after completing the test.



**NOTE** *On Successful pairing of the mobile device, Blue LED stops blinking in the device. Ensure that the save option is enabled for storing the data in the cloud.*



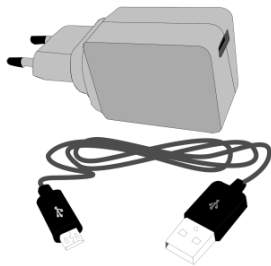
**NOTE** For sync to occur successfully between the device and the tablet there must be a valid Bluetooth connection.



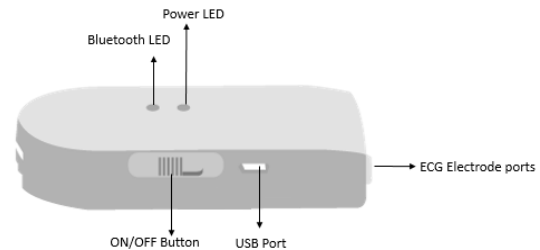
**NOTE** Bluetooth indicator starts blinking if the pairing connection between the device and tablet is lost.

## 11.0 Charging the B.O.L.T Chest ECG Devices

The Chest ECG is operated with an inbuilt rechargeable battery, which can be charged using the power adapter and USB cable as guided below. It is mandatory to charge the devices for a minimum period of 2 hours before the first time usage. Kindly connect the devices to the power source, if low battery status is indicated in the mobile application screen.



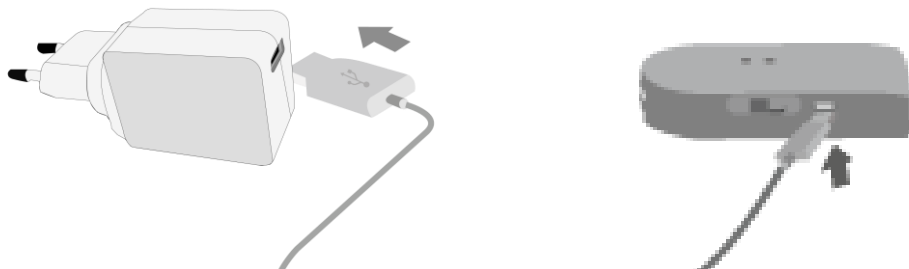
Power adapter & USB cable



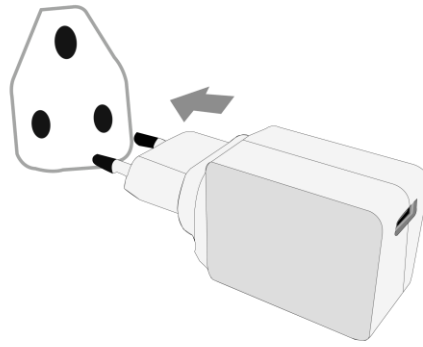
B.O.L.T Chest ECG device

### Charging Procedure:-

1. Connect the USB cable to the power adapter.
2. Connect the micro USB port to the ECG device's power port (USB port).



3. Plug the adapter into the AC mains (110V, 60Hz or 230V, 50Hz).



4. Switch ON the AC mains to charge the device.
5. Check whether the power indicator turns red while charging the device.

## 12.0 Troubleshooting

PROBLEM	POSSIBLE CAUSE	SOLUTION
Application not installing from the App store/Play store/Windows market	<ol style="list-style-type: none"> <li>Internet/Data disconnection</li> <li>Memory space unavailability</li> </ol>	<ol style="list-style-type: none"> <li>Check your Internet connectivity</li> <li>Move some of the application from Phone storage to SD card</li> <li>If the issue persists, delete some unwanted application and try to install the B.O.L.T application.</li> </ol>
Application Login problem	Internet/Data disconnection	Enable Internet connection through mobile data or Wi-Fi and try to login.
Change Password is not getting updated	Internet/Data disconnection	Enable internet connection through mobile data or Wi-Fi and try again.
Device requests for Bluetooth pairing password	Bluetooth pairing permission required	Give the password as 1234
Bluetooth communication disconnected while measuring vitals and Bluetooth indicator starts blinking	Bluetooth communication error	Close the application. Restart the ECG device and restart the entire process again
ECG device switched ON, but not showing in List of available Bluetooth device in the application	Bluetooth pairing problem	Restart the ECG device, Then try to connect again.
ECG device switched ON, but Bluetooth (Blue) LED not blinking.	ECG device not booted properly	Connect the respective power adaptor to the device and power ON, if still blue LED is not glowing kindly get it repaired in the











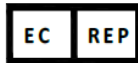


		authorized service center.
ECG device switched ON, but no LED is glowing	No charge for battery	Connect the respective power adaptor to the ECG device and charge. Then power ON, if still blue LED is not glowing kindly get it repaired in authorized service center






## 13.0 Technical Specifications

<b>Product Name</b>	<b>B.O.L.T Chest ECG</b>
Model	VA 07
<b>B.O.L.T Chest ECG Unit</b>	
Unit Dimensions	85 (L) X 40 (H) X 20 (D) mm
Unit Weight	45 grams (Including Battery)
Heart Rate	30 to 200 BPM
Heart Accuracy	+/- 1% or 1 BPM whichever is greater
Heart Resolution	1 BPM
Respiration	7-120 RPM
Respiration Resolution	1 RPM
Respiration Accuracy	+/- 2 RPM
ECG Channels	Single Channel
Input Dynamic Range	10mV Peak-to-Peak
Bluetooth	Bluetooth 4.0 EDR or Lower, Bluetooth Low Energy (BLE)
Radio Protocol Bluetooth	(BDR+EDR) / BLE
Operating Frequency Range	2400 MHz – 2483.5 MHz;
Verified RF Power	BT: -05.45 dBm / BLE: -5.46 dBm
<b>Circuitry</b>	
Frequency Response	0.5 Hz to 40Hz
CMRR	120 dB
Input impedance	> 5 MOhm
Differential Range	+/- 5 mV
A/D Sampling Rate	500 samples/second
Resolution	24 bit
<b>Power Requirements</b>	
Power Source	DC 5V 2A
Battery Type	3.7 -850mAh Li-Poly Battery
<b>Environmental Specification</b>	
Operational Temperature	+10 to +45 degree C
Operational Humidity	10% to 95% (non-condensing)
Storage Temperature	-20 to +60 degrees C
Storage Humidity	10% to 95% (non-condensing)



## 14.0 Explanation of Indicators/Symbols

Indicators/ Symbols	Function/Description
	The indicator displays full battery power of the gadget in the computer/mobile device.
	The indicator displays low battery power of the gadget in the computer/mobile device.
 (Blue)	<ul style="list-style-type: none"> <li>○ Flashing of the Bluetooth light indicates that the gadget is waiting for pairing with the mobile/tab.</li> <li>○ Steady Bluetooth light indicates that the gadget is paired and ready for the measurement.</li> </ul>
 (Green)	<ul style="list-style-type: none"> <li>○ Steady green light indicates that the gadget is operating in battery mode.</li> </ul>
 (Red)	Steady red light indicates that the gadget is in the charging mode.
	Symbol for “DISPOSAL”
	Symbol for “KEEP DRY”
	Symbol for “MANUFACTURER”
	Symbol for “MANUFACTURED DATE”
	Symbol for “SERIAL NUMBER”
	Symbol for “EUROPEAN REPRESENTATIVE”
	Symbol for “EUROPEAN CONFORMITY”
	Symbol for “Federal Communication Commission”

	Symbol for "Follow Instructions for use"
	Symbol for "Warning"
	Symbol for "Caution"
	Symbol for "Temperature limitation"
	Symbol for "Fragile"
	Symbol for protected against access to hazardous parts with a finger and against vertically falling water drops when tilted up to 15 degrees

## 15.0 Certifications

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.

This device complies with the following normative documents:

- EN 301489-1:V3.2.0:2017 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
- EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- EN 60601-1:2012 General requirements for basic safety and essential performance
- EN 60601-1-2-2007/AC: 2010 General requirements for safety -Collateral standard: Electromagnetic compatibility.
- EN 60601-1-6:2010 Collateral standard: Usability
- IEC 60601-1-4:1996 General requirements for safety- Collateral standard: Programmable electrical medical systems.
- IEC 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601- 2-27:2011 Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment



## 16.0 FCC compliance statements

### FCC ID: 2AFV6-AMI-ECG-02

This device complies with Part 15 of the FCC Rules. Its 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.

### FCC Caution

- Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

### Part 15B compliance statements for digital devices:

**NOTE:** *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 or 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 to 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.

For more information kindly visit our website: [www.amibolt.com](http://www.amibolt.com)

## 17.0 Warranty Information

The B.O.L.T is warranted to be free from defects in materials and workmanship within one year from the date of purchase when used in accordance with the provided instructions. The warranty is extended only to the end user. The company will repair free of charge any part or parts of the product if the defect is due to the faulty material or workmanship.

To obtain warranty service contact customer care support by calling 1800-200-8001.

Enclose the warranty card, Proof of Purchase. Include a letter, with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit.

The warranty shall not apply to defects resulting from:

- Unauthorized modification/misuse/mishandling of the device.
- Operation of the device outside the environmental specifications of the product (e.g.: temperature, electrical requirements etc.)
- Any other reason external to the equipment (e.g.: accidents, vibrations etc.)

## 18.0 Customer Care Support

AMI's flexible approach allows the customers to get Technical Support and Warranty services for B.O.L.T through our customer care support.

- Toll-free number (India): 1800-200-8001
- Customer Care Support timings: 10 am - 6 pm Monday – Friday (Except National Holidays)
- E-mail address: [support@amibolt.com](mailto:support@amibolt.com)

## 19.0 Contact us



AMERICAN MEGATRENDS INDIA PRIVATE LTD.,

KUMARAN NAGAR,

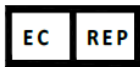
SEMENCHERY, OFF RAJIV GANDHI SALAI (OMR)

CHENNAI (TN) 600119

Tel – (91) 44 66540922, Fax – (91) 44 66540901

Website: [www.amibolt.com](http://www.amibolt.com); [www.amiindia.co.in](http://www.amiindia.co.in)

### European Representative



American Megatrends International GmbH

Truderingerstraße (Truderinger Strasse) 283

81825 München (Munich), Deutschland (Germany)

Tel: [49] 89 969995-10

Email: [europesales@ami.com](mailto:europesales@ami.com)