



Locating Efficiencies in Health Care

BLE Module BLE-M

User Manual

Centrak BLE Module family

**PART NUMBER FAMILY:
BLE**

USER MANUAL

**FCC ID: ST2-BLEM
IC: 6012A-BLEM**

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IMPORTANT NOTES:

- **This module is limited to OEM Installation only.**
- **The End User should not either install or remove the module. As such no instructions regarding Module Installation or Removal should be given to the End-User.**
- **No instructions for module use will be given to the customer. The module will only be used in conjunction with the integrated product**

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Locating Efficiencies in Health Care

BLE Module BLE-M

User Manual

ELIGIBILITY REQUIREMENTS FOR REGULATORY MODULE APPROVAL	4
User Guide Information	5
United States of America Requirements	5
General User Guide Requirements	5
Topics Not Covered	6
UNITED STATES REGULATORY APPROVAL FCC MODULAR APPROVAL	7
Design Criteria for Modular Approval	7
General Conditions	7
Antenna	7
Antenna Interconnect & Impedance	
Physical Implementation	
Emissions Compliance Testing	7
Co-location of Additional Transmitters	8
Product Labeling Requirements	8
INDUSTRY CANADIAN REGULATORY APPROVAL	9
Design Criteria for Modular Approval	9
General Conditions	9
Antennae	9
Antenna Interconnect & Impedance	
Physical Implementation	
Emissions Compliance Testing	9
Product Labeling Requirements	10



Locating Efficiencies in Health Care

BLE Module BLE-M

User Manual

UNITED STATES AND INTERNATIONAL TYPE APPROVAL (STANDARD REGULATORY EQUIPMENT CERTIFICATION)	14
CONTACT INFORMATION	14
APPENDIX A:	15
Agency Certifications:	15
Regulatory Certification Requirement:	15
MECHANICAL CHARACTERISTICS:	16
APPENDIX B:	17
FCC Grant# - FCC ID: ST2-BLEM	17

ELIGIBILITY REQUIREMENTS FOR REGULATORY MODULE APPROVAL

The Centrak BLE-M module (the BLE-M) is a device that transmits and receives radio signals in accordance with the spectrum regulations for the 2.4-GHz unlicensed frequency range. Regional regulatory agency approval may be required to operate BLE-M throughout the world.

For purposes of ease of integration, time to market, and product surety, Centrak submitted BLE-M to relevant agencies and obtained regulatory approvals for specific countries. BLE-M was approved under the "Modular Approval (MA) Grant". This certification represents a significant cost savings to the OEM.

The radio certification portion of this grant is transferable to Digital Electronic Device manufacturers given adherence to specific implementation criteria noted herein. Any modification of the BLE-M will void the manufacturer's warranty. Any alteration or deviation from the documented installation and/or use of the BLE-M will void the MA Grant as it applies to the end-product.

This module is to be installed only in mobile or fixed applications and please add a reference to part 2.1091(b) for a definition of mobile and fixed devices. Note, that separate approval is required for all other operating configurations, including portable configurations with respect to 2.1093 and different antenna configurations.

In the event the Digital Electronic Device manufacturer alters the herein described and approved installation of the BLE-M, the end-product may require a complete battery of regulatory agency certification test Digital Electronic Device manufacturer may be required to submit to a complete battery of tests, depending on the requirements noted in the region they wish to sell their product.

The MA Grant provides that Digital Electronic Device manufacturers who incorporate the BLE-M Module **as tested and approved**, and can be relieved from having to perform the Radio Regulatory certification portion of the respective agency certification.

The MA Grant is valid only in countries that recognize the MA Grant certification process. Countries currently accepting the MA Grant include; the USA, Canada, and many European countries as noted in the General User Guide Requirements Section of this document. Terms and conditions of regulatory approval for these countries are also described herein. However, this "grandfathered" radio certification does **not** relieve the Digital Electronic Device manufacturers from submitting their device for digital emissions certifications.

Electronic device manufacturers may disregard the requirements of this section provided they accept full responsibility for regulatory type-approval of the electronic device with an integrated BLE-M wireless module.

User Guide Information

Electronic device manufacturers using Centrak's Modular Approval are required to place the below text in their product user's guide in accompaniment with other regulatory information. The text may be disbursed according to language or geographic regions if desired, but the exact text shown below must be maintained.

United States of America Requirements

The following text must be copied exactly into the products user's guide:

"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.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment."

General User Guide Requirements

The following text must be copied exactly into the product's user's guide:

"This product contains a radio transmitter with BLE-M Module which has been tested and found to be compliant with the applicable regulations governing a radio transmitter in the 2.400 GHz to 2.4835 GHz frequency range."

The following countries associated regulatory agencies recognizing the noted certifications for this product as authorized for sale and use are:

USA	Canada	Belgium
Denmark	France	Finland
Germany	Italy	Netherlands
Spain	Sweden	UK

This list will be updated to reflect additional grants obtained or needed in future revisions.

Note: As of the date of publication, Japan does not recognize the "Modular Approval" certification. Regulatory certification for Japan (TELEC) must be acquired through typical approval procedures. These approvals are the sole responsibility of the OEM.



Locating Efficiencies in Health Care

BLE Module BLE-M User Manual

Topics Not Covered

Topics that not covered in this manual include:

- ¾ Standard type approval for any country
- ¾ Japan's (TELEC) regulatory approvals

UNITED STATES REGULATORY APPROVAL FCC MODULAR APPROVAL (MA)

The requirements for FCC Modular Approval were released in February 2013 in the FCC's Public Notice: FCC Public Notice DA 00-1407, Part 15 Unlicensed Modular Transmitter Approvals.

Design Criteria for Modular Approval**General Conditions**

The following conditions must be strictly adhered to for modular approval:

- 1. No modification to the module including the circuitry is permitted**
- 2. The design criteria including antenna, interconnects and transmission line**
- 3. Testing of the final device configuration for Digital Emissions Compliance**

The BLE-M may not be altered or modified in any way by the OEM or other integrator(s). Additionally, no component(s) may be added which change the radio frequency (RF) characteristics. These include unintentional or spurious emissions, immunity, ESD characteristics, or other items commonly associated with RF devices. This includes all components; passive and active (such as RF filters, RF amplifiers, RF switches, etc). Additionally, no RF components may be placed between the RF output of the BLE-M and the antenna. OEM/Integrator shall include instructions or statements in the host user's manual that are required by Part 15.19 and 15.21.

Antennae

The antenna is integrated in the module and has been qualified and approved for use under the Modular Approval certification. This antenna is designed to be compatible with the RF impedance and frequency range of the BLE-M. This antenna may not be modified or altered in any way from the original design as represented by the manufacturer.

The antenna selected have been specifically tested with the BLE-M, and it is certified through the regulatory agencies in the US, Canada, and European Union for authorized use. Use of an altered antenna in a platform other than the antenna selected by Centrak voids the MA grant for that platform.

Emissions Compliance Testing

Notwithstanding the Modular Approval for the Radio Device with associated antenna, the end product configuration must meet digital emissions compliance and must be tested in accordance with FCC Part 15 requirements confirming radiated emissions are within specified limits.

Applicable sections include:

- Part 15 Section 15.109 Sub-paragraph A, Class B Radiated Emission Limits

These emissions tests can be conducted by the manufacturer or by contacting an approved test facility equipped and certified accordingly. The results of these emissions tests are not required to be submitted to the FCC or Centrak, but should be kept on file by the OEM.

Co-location of Additional Transmitters

Digital Electronic Devices manufacturers using this MA grant should refer to Appendix B (FCC Grant #) for end-products using two or more co-located RF transmitters. This grant states:

“This modular transmitter is approved for use in Digital Electronic Devices and may operate in conjunction with other mobile and portable transmitters in the same device; provided, the other mobile and portable transmitters have satisfied the appropriate RF exposure requirements contained in the FCC rules. The grantee must also provide Digital Electronic Device integrators, or end users if marketed directly to end users, with installation and operating instructions for satisfying RF exposure requirements. The Grantee must inform second manufacturers/installers that in order for this module to be operated in any configuration other than that permitted in the preceding sentences, a separate FCC equipment authorization must be obtained for each device into which this module is installed.”

This modular approval is granted provided Digital Electronic Devices manufacturers assume responsibility for ensuring that other transmitters operating in conjunction with the BLE-M comply with RF exposure requirements associated with their use. The use of one or more additional RF transmitters will require review by the FCC and may require end-product re-certification, including the BLE-M to ensure emissions compliance and RF safety. It is the sole responsibility of the Digital Electronic Device manufacturer to obtain end-product regulatory compliance for configurations including two or more RF transmitters.

Power

This module is approved for battery or AC line operated devices. The module operation voltage can range from 1.8-3.6 volts.

Product Labeling Requirements

FCC product labeling requirements stipulate an FCC label, including specific text, be placed on the device containing the BLE-M module. The product label must include the following text and must be affixed to the exterior of the OEM's product. The text should be located beneath the FCC compliance logo.

“Module FCC ID:ST2-BLEM”

Locating Efficiencies in Health Care

To ensure compliance with all non-transmitter functions the host manufacturer is responsible for ensuring compliance with the module(s) installed and fully operational, such that the host manufacturer is responsible for ensuring that after the module is installed and operational the host continues to be compliant with the Part 15B unintentional radiator requirements, the

Part 2 Subpart J Equipment Authorization Procedures , KDB784748 D01 v07, and KDB 997198 about importation of radio frequency devices into the United States.

For a host using a certified modular with a standard fixed label, an additional permanent label referring to the enclosed module: "Contains Transmitter Module FCC ID: ST2-BLEM" or "Contains FCC ID: ST2-BLEM" must be used. The host OEM user manual must also contain clear instructions on how end users can find and/or access the module and the FCC/IC IDs.

RF Safety

To comply with FCC / IC regulations limiting both maximum RF output power and human exposure to RF radiation, the maximum antenna gain including cable loss in a mobile-only exposure condition must not exceed 0dBi peak gain.

If the final host / module combination is intended for use as a portable device (see classifications below) the host manufacturer is responsible for separate approvals for the SAR requirements from FCC Part 2.1093 and RSS-102.

Mobile Device RF Exposure Statement (If Applicable):

RF Exposure - This device is only authorized for use in a mobile application. At least 20 cm of separation distance between the (Product Name) device and the user's body must be maintained at all times.

Portable Device RF Exposure Statement:

RF Exposure - This device has been tested for compliance with FCC RF exposure limits in a portable configuration. At least (*Insert Required Separation Distance from RF Exposure Evaluation*) cm of separation distance between the (*Product Name*) device and the user's body must be maintained at all times. This device must not be used with any other antenna or transmitter that has not been approved to operate in conjunction with this device.

Centrak will offer assistance to OEM installer for compliance to Part 15B requirements. The separate approval is required for all other operating configuration, including portable configurations with respect to Part 2.1093 and different antenna configurations.

The module is limited to OEM installation ONLY. The OEM integrators are responsible for ensuring that the end-user has no manual instruction to remove or install the module.

INDUSTRY CANADIAN REGULATORY APPROVAL

Industry Canada regulatory approval typically conforms to the FCC in terms of emission levels and other regulatory requirements. It is the position of the Industry Canada agency that the OEM primarily responsibility for ensuring end product compliance. Centrak as grantee and supplier of the module maintains responsibility for the Modular Approved design.

Design Criteria for Modular Approval

General Conditions

The following conditions must be strictly adhered to for modular approval:

- 1. No modification to the module including the circuitry is permitted**
- 2. The design criteria including antenna, interconnects and transmission line**
- 3. Testing of the final device configuration for Digital Emissions Compliance**

The BLE-M may not be altered or modified in any way by the OEM or other integrator(s). Additionally, no component(s) may be added which change the radio frequency (RF) characteristics. These include unintentional or spurious emissions, immunity, ESD characteristics, or other items commonly associated with RF devices. This includes all components; passive and active (such as RF filters, RF amplifiers, RF switches, etc). Additionally, no RF components may be placed between the RF output of the BLE-M and the antenna(e) except the RF interconnect transmission line.

Antennae

The antenna is integrated in the module and has been qualified and approved for use under the Modular Approval certification. This antenna is designed to be compatible with the RF impedance and frequency range of the BLE-M. This antenna may not be modified or altered in any way from the original design as represented by the manufacturer.

The antenna selected have been specifically tested with the BLE-M, and they are certified through the regulatory agencies in the US, Canada, and European Union for authorized use. Use of an altered antenna in a platform other than the antenna selected by Centrak voids the MA grant for that platform.

Emissions Compliance Testing

Notwithstanding the Modular Approval for the Radio Device with associated interconnect and antennae, the end product configuration must meet digital emissions compliance and must be tested in accordance with Industry Canada RSS-210 (Low Power License-Exempt Radio communication Devices) requirements confirming radiated emissions are within specified limits.

Applicable sections include:

- Part 15 Section 15.109 Sub-paragraph A, Class B Radiated Emission Limits

These emissions tests can be conducted by the manufacturer or by contacting an approved test facility equipped and certified accordingly. The results of these emissions tests are not required to be submitted to the FCC or Centrak, but should be kept on file by the OEM.

Note:

Industry Canada generally follows the guidelines of the FCC for emissions level requirements. FCC end-product compliance certification results may be used to satisfy Industry Canada requirements. Please consult the Industry Canada, RSS 210 specifications to confirm inter-agency compliance. If comparable FCC testing has not been performed or if the specifications are not cross compliant, RSS 210 testing will be required.

Product Labeling Requirements

Industry Canada product labeling requirements stipulate specific text be placed on the device containing the BLE-M module. The product must include the following text and must be located on the exterior of the OEM's product. This same information must be included in the product user manual.

**“This product contains Centrak BLE-M module
Canadian Cert No IC: 6012A-BLEM”**

EUROPEAN UNION REGULATORY APPROVAL

The requirements for EU Regulatory Approval were released in April 2000 in the EU R&TTE Directive.

This directive supports self directed testing and certification for “harmonized” bands within OEM facilities or by third party.

Article 6 of the R&TTE directive states: “The manufacturer or the person responsible for placing the apparatus on the market provides information for the user on the intended use of the apparatus, together with the declaration of conformity to the essential requirements.”

Ensuring regulatory compliance of the end product is the sole responsibility of the OEM. Centrak maintains responsibility for conformance of the BLE-M MODule, the interconnect, and the antenna, as the manufacturer.

The R&TTE directive maintains that first level compliance be reviewed by a “Notified Body” prior to general product marketing. This is not mandatory, but reduces the risk of the product being challenged for non-compliance. Although not specifically stated in the R&TTE Directive, corrections of non-compliance issues are the responsibility of the end product manufacturer.

Design Criteria for Modular Approval

General Conditions

The following conditions must be strictly adhered to for modular approval:

- 1. No modification to the module including the circuitry is permitted**
- 2. The design criteria including antennas, interconnects and transmission line**
- 3. Testing of the final device configuration for Digital Emissions Compliance**

The BLE-M may not be altered or modified in any way by the OEM or other integrator(s). Additionally, no component(s) may be added which change the radio frequency (RF) characteristics. These include unintentional or spurious emissions, immunity, ESD characteristics, or other items commonly associated with RF devices. This includes all components; passive and active (such as RF filters, RF amplifiers, RF switches, etc). Additionally, no RF components may be placed between the RF output of the BLE-M and the antenna(e) except the RF interconnect transmission line.

Antennae

The antenna is integrated in the module and has been qualified and approved for use under the Modular Approval certification. This antenna is designed to be compatible with the RF

impedance and frequency range of the BLE-M. This antenna may not be modified or altered in any way from the original design as represented by the manufacturer.

The antenna selected have been specifically tested with the BLE-M, and they are certified through the regulatory agencies in the US, Canada, and European Union for authorized use. Use of an altered antenna in a platform other than the antenna selected by Centrak voids the MA grant for that platform.

Emissions Compliance Testing

The end-product configuration must meet digital emissions compliance and must be tested in accordance with the European Union standards ETSI 300 328 (European Telecommunications Standard for 2.4 GHz ISM band Emissions) and ETSI 300 826 (Electromagnetic Compatibility). Detailed European Union documents may be obtained from the web location:

<http://europa.eu.int/comm/enterprise/rtte/infor.htm>

These emissions tests can be conducted by the manufacturer or by contacting an approved test facility equipped and certified accordingly. The results of these emissions tests are not required to be submitted to the FCC or Centrak, but should be kept on file by the OEM.

Note:

The European Union generally follows the guidelines of the FCC for emissions level requirements. FCC end-product compliance certification results, if available, may be used to satisfy EU requirements (Substitution Method). Please consult the ETSI 300 328 specifications to confirm inter-agency compliance. If comparable FCC testing has not been performed or if the specifications are not cross compliant, ETSI 300 328 testing will be required. Additionally, testing to the ETSI 301 489-17 (immunity testing) is strongly recommended. Centrak assumes no responsibility for compliance of the end-product configuration.

Exterior Labeling Requirements

European Union product labeling requirements stipulate specific text is placed on the device containing the BLE-M module. The product must include the following text and must be located on the exterior of the OEM's product. This same information may be included in the product user manual, however is not mandatory. Packaging and user documentation must indicate the use restrictions of the end-product (i.e. countries disallowing the operating frequencies of the BLE-M).

CE 0122 !

Note:

The end-product must be labeled "CE" and an exclamation mark to the right of the CE mark should have; '!' with a circle around it. The exclamation mark designates a non-harmonized frequency band.

UNITED STATES AND INTERNATIONAL TYPE APPROVAL (STANDARD REGULATORY EQUIPMENT CERTIFICATION)

OEMs may need to obtain standard equipment regulatory agency certification as previously noted herein, and for end-product deployment in countries where Modular Approval is not recognized, or for implementations using non-certified antennae or interconnections.

The details of standard equipment regulatory compliance are beyond the scope of this document. OEMs needing standard equipment regulatory testing or who need council for determining regional requirement should contact approved certification and test service providers accordingly.

The following test house(s) have been identified by Centrak to assist in both US and International approval processes. This list is by no means complete or preferential:

1. Advanced Compliance Lab, Inc.

Filing with certification facilities typically requires the submission of technical information (ie block diagrams, schematics, etc.) pertinent to the radio portions of the BLE-M. Centrak will provide assistance in obtaining such documents when required by the OEM.

CONTACT INFORMATION

CORPORATE HEADQUARTERS:

**Centrak Corporation
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Newtown, PA 18940**

Israel Amir:

1.215-860-2928 X 213

Email:

iamir@Centrak.com

Web:

www.Centrak.com

APPENDIX A:**Agency Certifications:****Regulatory Certification Requirement:**

The Centrak BLE-M module has been tested against the relevant requirements of standards: FCC part 15 and Industry Canada RSS-210. The module is certified by the regulatory authorities in the USA and Canada and complies with the applicable essential requirements of the Radio & Telecommunication Terminal Equipment (R&TTE) directive in the EU. The module can thus be incorporated into products sold with little or no additional testing of the module itself. The end product must meet the appropriate technical requirements that apply to that product type but re-certification of the radio module is not required in the USA and Canada. In the EU, the integrator is responsible for evaluating their product type per the essential performance requirements of the R&TTE directive (except those associated with the module), declaring compliance and then notifying the member states prior to marketing the product (because the module uses a frequency band that is not harmonized in the EU). It is the responsibility of the module integrator to obtain the necessary approvals to sell products incorporating this module in other countries outside of North America and the EU. The report of measurements performed on the module in compliance with the FCC rules and EN standards can be used in these submittals (as the requirements in many other markets around the world are based in part or in whole on the standards prevalent in North America and the EU)

EUROPEAN UNION “DECLARATION OF CONFORMITY”

DECLARATION OF CONFORMITY

Centrak Corporation
5 Caufield Place
Newtown, PA 18940
USA

declare under our sole responsibility that the product(s)

Wireless BLE Module

to which this declaration relate(s) is in conformance with the following standards:

EN 300-328 v1.3.1
EN 301 489-17
EN 55022 limits B

following the provisions of the 73/23/EEC and 89/336/EEC Directives.

Centrak Corporation, Newtown, PA – Israel Amir, CTO



MECHANICAL CHARACTERISTICS:

Item	Description	Specification
1	PCB Material	FR-4
2	PCB Layers	2
3	Connector Type	None
4	PCB Number	BLE Module PCB V[A] 20160615
5	Flammability Rating	UL94 V-0
6	BLE-M Dimensions	16X33X2.5 mm
8	User Serviceable Parts	None

APPENDIX B:**FCC Grant# FCC ID: ST2-BLEM**

The modular transmitter is approved for use in Digital Electronic Devices and may operate in conjunction with other mobile and portable transmitters in the same device; provided, the other mobile and portable transmitters have satisfied the appropriate RF exposure requirements contained in the FCC rules. The grantee must also provide Digital Electronic Device integrators, or end users if marketed directly to end users, with installation and operating instructions for satisfying RF exposure requirements. The Grantee must inform second manufacturers/installers that in order for this module to be operated in any configuration other than that permitted in the preceding sentences; a separate FCC equipment authorization must be obtained for each device into which this module is installed.