

Occlusense
Regulatory Compliance Information

This document covers the Regulatory Compliance information which will be part of the Occlusense Module datasheet and related documents shared with customers.

2.1 United States

The Occlusense module has received Federal Communications Commission (FCC) CFR47 Telecommunications, Part 15 Subpart C “Intentional Radiators” single-modular approval in accordance with Part 15.212 Modular Transmitter approval. Single modular transmitter approval is defined as a complete RF transmission sub-assembly, designed to be incorporated into another device, that must demonstrate compliance with FCC rules and policies independent of any host. A transmitter with a modular grant can be installed in different end-use products (referred to as a host, host product, or host device) by the grantee or other equipment manufacturer, then the host product may not require additional testing or equipment authorization for the transmitter function provided by that specific module or limited module device.

The user must comply with all of the instructions provided by the Grantee, which indicate installation and/or operating conditions necessary for compliance.

A host product itself is required to comply with all other applicable FCC equipment authorization regulations, requirements, and equipment functions that are not associated with the transmitter module portion. For example, compliance must be demonstrated: to regulations for other transmitter components within a host product; to requirements for unintentional radiators (Part 15 Subpart B), such as digital devices, computer peripherals, radio receivers, etc.; and to additional authorization requirements for the non-transmitter functions on the transmitter module (i.e., Verification or Declaration of Conformity) as appropriate (e.g., Bluetooth and Wi-Fi transmitter modules may also contain digital logic functions).

2.1.1 Labeling and User Information Requirements

The Occlusense modules have been labeled with its FCC ID number. If the FCC ID is not visible when the module is installed inside another device, then the outside of the finished product into which the module is installed must display a label referring to the enclosed module. This exterior label can use wording as follows:

For the Occlusense:

Contains Transmitter Module FCC ID: 2BAUV-OCCLUSENSE

or

Contains FCC ID: 2BAUV-OCCLUSENSE

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.

A user's manual for the finished product should include the following statement:

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 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

Changes or modifications made to the device not expressly approved by Dr. Jean Bausch GmbH & Co. KG could void the user's authority to operate the equipment.

Additional information on labeling and user information requirements for Part 15 devices can be found in KDB Publication 784748, which is available at the FCC Office of Engineering and Technology (OET) Laboratory Division Knowledge Database (KDB) <https://apps.fcc.gov/oetcf/kdb/index.cfm>

2.1.2 RF Exposure

All transmitters regulated by FCC must comply with RF exposure requirements. KDB 447498 General RF Exposure Guidance provides guidance in determining whether proposed or existing transmitting facilities, operations or devices comply with limits for human exposure to Radio Frequency (RF) fields adopted by the Federal Communications Commission (FCC).

From the FCC Grant: Output power listed is conducted. This transmitter is restricted for use with the specific antenna tested in this application for Certification.

In the end product, the antenna used with this transmitter must be installed to provide a separation distance of at least 6.5 cm from all persons and must not be co-located or operation in conjunction with any other antenna or transmitter. User and installers must be provided with antenna installation instructions and transmitter operating conditions for satisfying the RF exposure compliance.

2.1.3 Approved Antenna Types

To maintain modular approval in the United States, only the antenna types that have been tested shall be used. It is permissible to use a different antenna, provided the same antenna type and antenna gain (equal to or less than) is used. An antenna type comprises antennas having similar in-band and out-of-band radiation patterns.

2.1.4 Helpful Websites

Federal Communications Commission (FCC): <http://www.fcc.gov>
FCC Office of Engineering and Technology (OET) Laboratory Division Knowledge Database (KDB): <https://apps.fcc.gov/oetcf/kdb/index.cfm>

3.1 Canada

The Occlusense module has been certified for use in Canada under Innovation, Science and Economic Development Canada (ISED, formerly Industry Canada) Radio Standards Procedure (RSP) RSP-100, Radio Standards Specification (RSS) RSS-Gen and RSS-247. Modular approval permits the installation of a module in a host device without the need to recertify the device.

3.1.1 Labeling and User Information Requirements

Label Requirements (from RSP-100 Issue 11, Section 3): The host device shall be properly labeled to identify the module within the host device.

The Innovation, Science and Economic Development Canada certification label of a module shall be clearly visible at all times when installed in the host device, otherwise the host device must be labeled to display the Innovation, Science and Economic Development Canada certification number of the module, preceded by the words “Contains”, or similar wording expressing the same meaning, as follows:

For the Occlusense module:

Contains IC: 30548-OCCLUSENSE

User Manual Notice for License-Exempt Radio Apparatus (from Section 8.4 RSS-Gen, Issue 4, November 2014): User manuals for license-exempt radio apparatus shall contain the following or equivalent notice in a conspicuous location in the user manual or alternatively on the device or both:

This device complies with Industry Canada license exempt RSS standard(s). Operation is subject to the following two conditions:

- (1) This device may not cause interference, and**
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.**

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

- (1) l'appareil ne doit pas produire de brouillage, et**
- (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.**

Transmitter Antenna (From Section 8.3 RSS-GEN, Issue 4, November 2014): User manuals, for transmitters shall display the following notice in a conspicuous location:

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut

fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Immediately following the above notice, the manufacturer shall provide a list of all antenna types approved for use with the transmitter, indicating the maximum permissible antenna gain (in dBi) and required impedance for each.

3.1.2 RF Exposure

All transmitters regulated by ISED must comply with RF exposure requirements listed in RSS-102 - Radio Frequency (RF) Exposure Compliance of Radio communication Apparatus (All Frequency Bands).

This transmitter is restricted for use with a specific antenna tested in this application for certification, and must not be co-located or operating in conjunction with any other antenna or transmitters within a host device, except in accordance with Canada multi-transmitter product procedures.

The installation of the transmitter must ensure compliance is demonstrated according to the ISED SAR procedures.

3.1.3 Helpful Web Sites

Industry Canada: <http://www.ic.gc.ca/>