

PIEX01 modular integration instruction in host device

The PIEX01 (RFID reader module) are manufactured by Intuitive Surgical, Inc. to be installed in host products manufactured by Intuitive Surgical, Inc.

The intended use of the PIEX01 module is to detect, identify and track number of uses of endoscopes that are plugged into the module. The PIEX01 module will wirelessly communicate at 13.56 MHz with a passive RFID tag inside the endoscope (client device). The PIEX01 module has permanently attached integral loop antenna (13.9 mm x 10.6 mm) that is not accessible or replaceable by the end user.

Per FCC KDB 996369, host product manufacturers shall follow modular integration instructions of this document when they integrate PIEX01 into a host product.

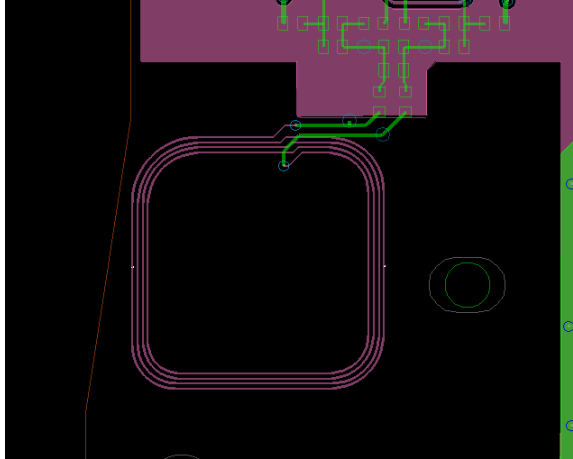
The reasons that PIEX01 has limited modular approval is because the module does not have its own shielding per FCC §15.212 (a) (1) (i) and it cannot be tested stand-alone.

1. List of applicable FCC rule parts that are applicable to the modular transmitters
47 CFR §15.207, §15.209 and §15.225
2. Summary of specific operational use conditions
PIEX01 has a built-in, integral loop/coil antenna. Host product manufacturer is not allowed to make changes to the built-in antenna.
3. Limited module procedures
Full testing and a Class II permissive change are required on the module grant of PIEX01 to certify the host device as a specific host approved with the PIEX01 module. Full testing includes fundamental, spurious, out of band and band edge radiated emissions, conducted emissions on AC power port per 47 CFR §15.207, §15.209 and §15.225.
4. Trace antenna designs
Not applicable. PIEX01 has a built-in, integral loop/coil antenna. Host product manufacturer is not allowed to make changes to trace antenna designs.

5. RF exposure considerations

PIEX01 may be installed such that it can be operated as close as 0 cm to users or nearby persons. The use condition applies for portable use. If integration is such that the user would be 20 cm or farther, then mobile use is applied. The module is not authorized to be used in any other host without a Class II permissive change. If full testing is required for each host, this would include a RF exposure assessment or SAR testing.

6. Antennas

PIEX01	Integral loop antenna Inductance: 450 nH Number of turns: 4-turn loop of 0.004-inch trace width with 0.004-inch spacing between the traces in square shape with truncated corners. Dimensions in mm: 13.9 mm x 10.6 mm. 
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7. Label and compliance information

FCC

The host product must be labeled with the following:

Contains FCC ID: 2AAZF-PIEX01

The host product user manual must include the following statements:

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.”

ISED

The host product must be labeled with the following:

Contains IC: 11508A-PIEX01

The host product user manual must include the following statements:

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 (eirp) is not more than necessary for successful communication.

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 harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Conformément à la réglementation d'Industrie Canada, cet émetteur radio peut fonctionner uniquement à l'aide d'une antenne de type et de gain maximum (ou moindre) approuvés pour l'émetteur par Industrie Canada. Pour réduire le risque d'interférence aux autres utilisateurs, le type d'antenne et son gain doivent être choisis afin que la puissance isotrope rayonnée équivalente (PIRE) n'excède pas celle nécessaire à une communication réussie.

Cet appareil est conforme au(x) standard(s) des CNR d'Industrie Canada pour appareils radio exempt(s) de licence. Son fonctionnement est soumis aux deux conditions suivantes: (1) ce dispositif ne doit pas causer d'interférences nuisibles, et (2) cet appareil doit accepter toute interférence reçue, y compris les interférences qui peuvent provoquer un fonctionnement indésirable.

8. Information of test modes and additional testing requirements

Host product with PIEX01 installed shall have endoscope plugged into the module. A host product requiring FCC approval shall be tested to FCC Part 15 Subpart B to check for emissions that may occur due to the intermixing of emissions with digital circuitry or due to enclosure of the host product. Full testing includes fundamental, spurious, out of band and band edge radiated emissions as well as conducted emissions on AC power port and an RF exposure assessment. The PIEX01 module requires additional temporary components of a switch and a potentiometer be installed in order to operate the RFID in a test mode. The switch should be installed between TP3 and Ground, and Vcc and GND pins of the potentiometer should be installed across C32 and Output pin of the potentiometer should be installed on test pad near R11.

9. Additional testing, part 15 Subpart B disclaimer

PIEX01 is only FCC authorized for specific rule parts listed on the grant, and the host product manufacturer is responsible for compliance to any other FCC rules that apply to the host not covered by the modular transmitter grant of certification. The final host product which requires FCC approval still requires Part 15 Subpart B compliance testing with PIEX01 installed. Such additional testing should include any co-located radios.

10. The alignment detection and interlocking mechanism inside the endoscope receptacle cannot be overridden by hardware or software.