

The RFID module (Model: ACCRX02) is used with the host devices (model PS4000 and PS4200) and as such, required testing and approval is completed. Use with any other host device may or may not require additional testing and approval. Consult Hardware Compliance Engineering for assistance.

The RFID module includes the main block (P/N 318215), the top plate (P/N 318216), the ACCR PCA (P/N 353240-08), ACCRA PCA (P/N 343460-05), the pod support (P/N 318273), and board support (P/N 318230).

For instruction on how to install RFID module to the host device (PS4000 and PS4200), refer to Manufacturer Process Instruction, Carriage, Housing Assembly, USM, IS4000 (P/N 1001924) and Manufacturer Process Instruction, Carriage Integration, USM, IS4000 (P/N 844505-01). USM = Universal Surgical Manipulator (aka. Robot Arm).

The label (P/N 510196-02) contains FCC ID (2AAZF-ACCRX02), IC ID (11508A-ACCRX02), and RFID Model name (ACCRX02) for identification. See Figure 1.

The label having white background with black text, is affixed to the module in a manner such that it will remain adhered to the module during the expected life of the product. The minimum size of the font is 4 pt. The label is applied on the main carriage block near the ACCR PCA location. See Figure 2.

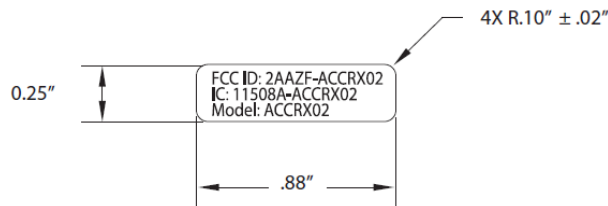


Figure 1: Label of RFID module (P/N 510196-01)

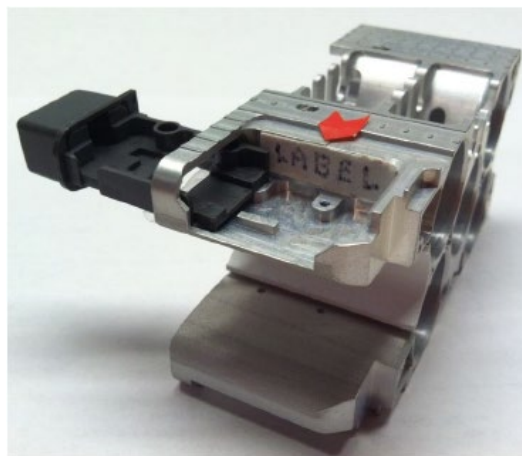


Figure 2: Location of Label of RFID module

The label of RFID module is not visible when RFID module is installed on host device. This is acceptable because FCC ID and IC ID information are also marked on the rear vent panel of the host device. See Figure 4 for example of label of the host device containing FCC ID and IC ID information of RFID module. See Figure 5 for the location.

In addition, the intentional radiator symbol (see Figure 3) is also affixed along with FCC ID and IC ID information (refer to Label P/N 880175-06 for PS4000 and P/N 880341-03 for PS4200) on the host device, per EN 60601-1-2 Ed.3. This marking is readily visible to the user of the host device without the use of tools.



Figure 3: Intentional radiator symbol

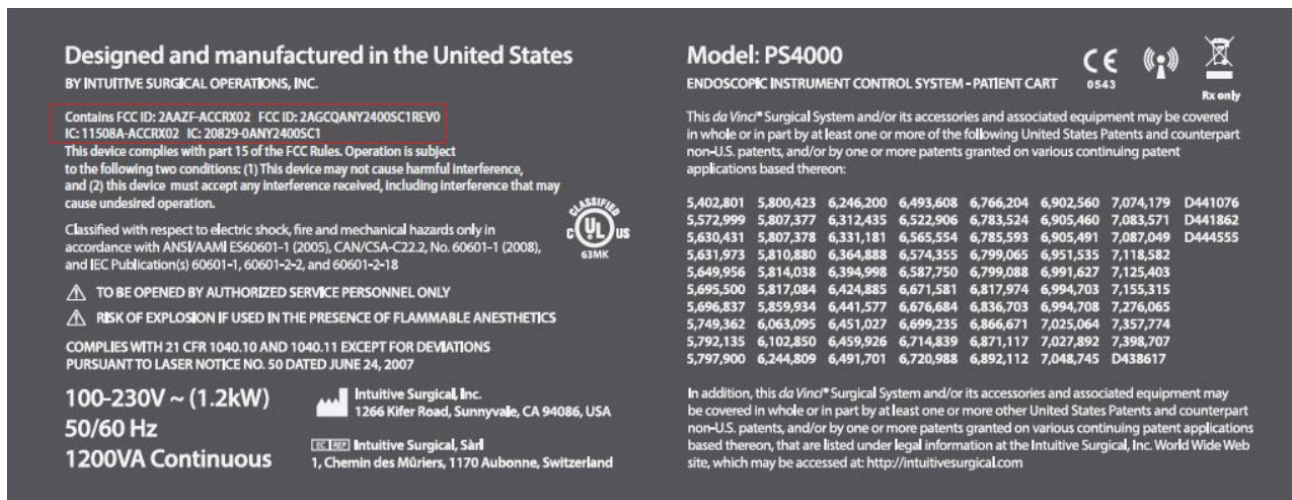


Figure 4: Example of label of host device containing FCC ID and IC ID of RF ID module

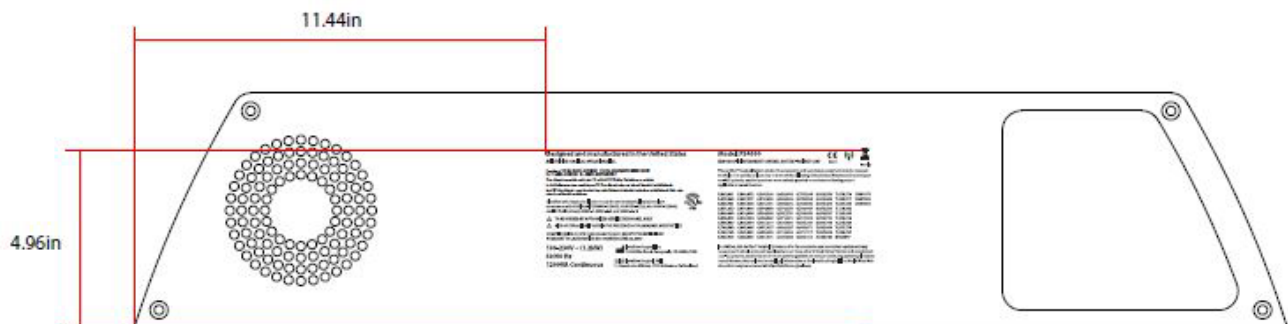


Figure 5: Location of label on rear vent panel of host device

Note: Statements below that are within quotation marks have fixed wording.

FCC

The host product must be labeled with the following:

“Contains FCC ID: 2AAZF-ACCRX02”

The host product manual must include 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.”

Changes or modifications, not expressly approved by Intuitive Surgical, may void the user’s authority to operate the equipment. (Note: the wording for this statement is not fixed)

Industry Canada

The host product must be labeled with the following (in English and French):

“Contains IC: 11508A-ACCRX02”

The host product manual must include following statements (in English and French):

“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 ".