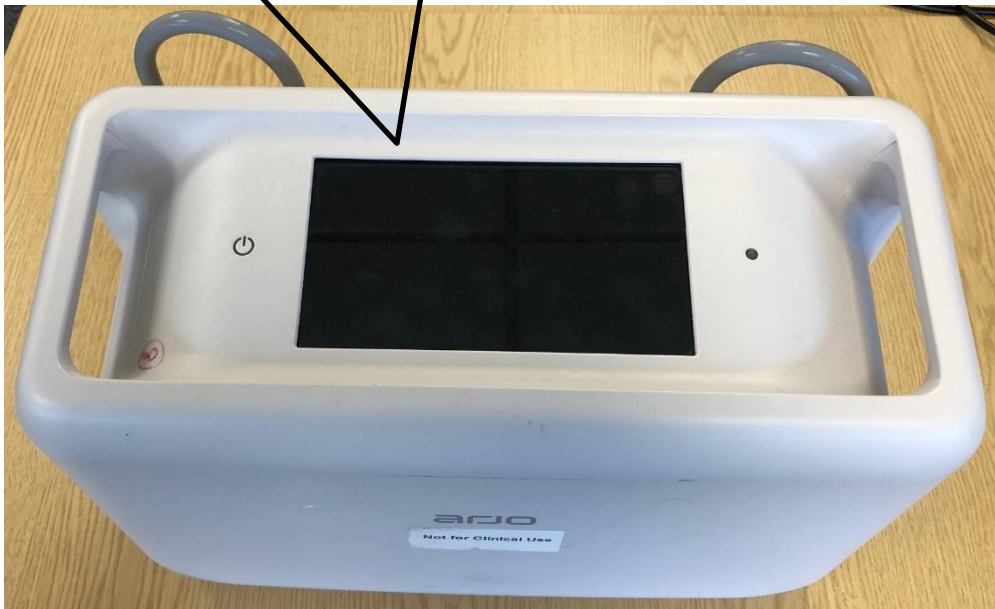
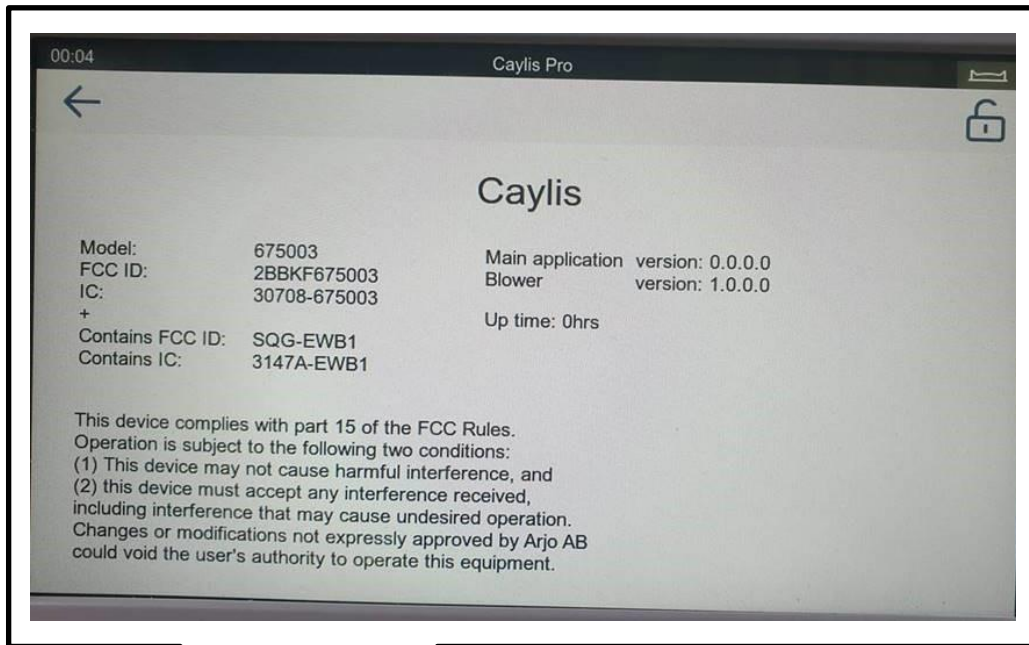


Labelling – Caylis

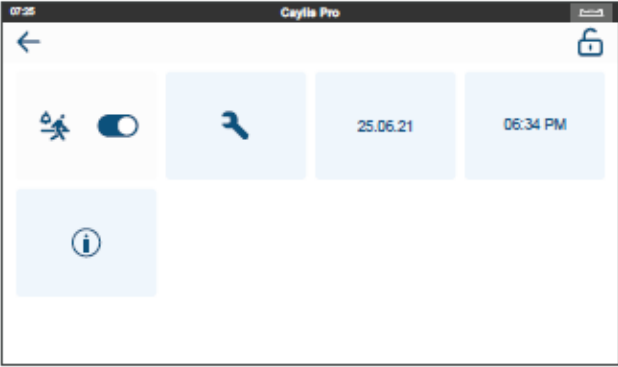




elabelling FCC and ISSED

Caylis Pump 675003

Pump Display show the following on Information screen:

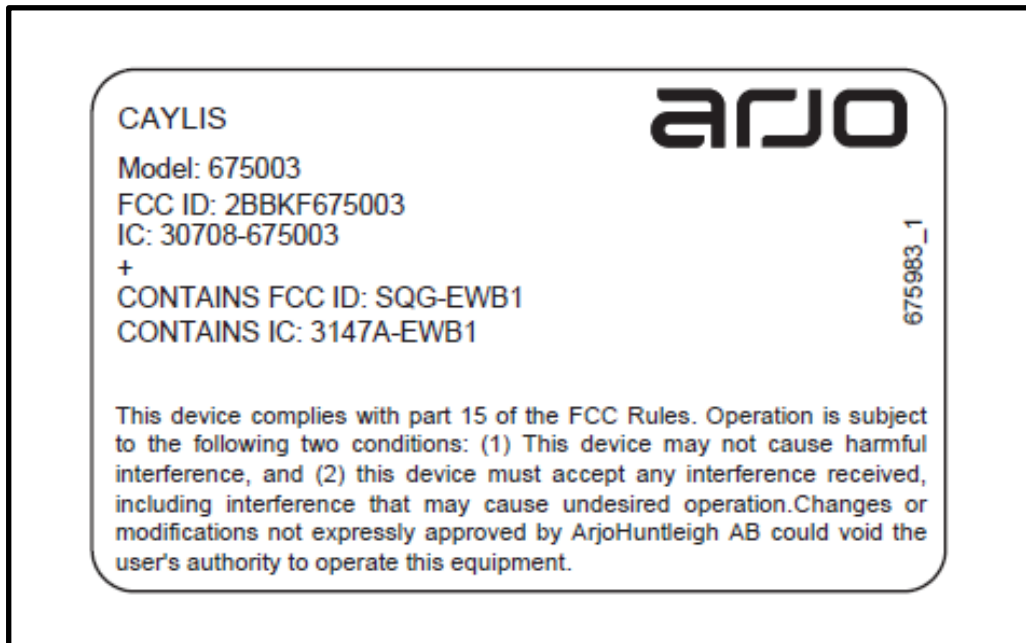


Access to Information Screen is described in Instructions for Use:

Extract from IFU	Comment
<p>Settings</p>  <p>Tap  to access the settings screen.</p>	<p>Page 21</p>
<p>Access Product information</p> <ol style="list-style-type: none"> 1. Tap . 2. The Regulatory Compliance information and Software information is displayed.  <ol style="list-style-type: none"> 3. Tap  to return to Settings. 	<p>Page 22</p>

Box containing Caylis Pump delivered to customer:

Has the following label applied next to other labelling.



Extract from IFU	Comment
<div data-bbox="220 331 686 380"> <h2>Regulatory compliances</h2> </div> <div data-bbox="220 436 1201 1682"> <div data-bbox="231 443 1201 483"> REGULATORY COMPLIANCES: </div> <div data-bbox="231 488 1201 1675"> <p>FCC Conformity section</p> <p>FCC ID: 2BBKF675003 IC: 30708-675003</p> <p>Also contains radio module with the following approvals:</p> <p>FCC ID: SQG-EWB1 IC: 3147A-EWB1</p> <p>US FCC compliance statement</p> <p>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.</p> <p>Any changes or modifications not expressly approved by ArjoHuntleigh AB could void the user's authority to operate this equipment.</p> <p>This device complies with FCC RF exposure limits for general population / uncontrolled environments. A separation distance of at least 20 cm must be maintained between the antenna and all persons. This device must not be co-located with any other antenna or transmitter.</p> <p>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 to correct the interference by one or more of the following measures:</p> <ul style="list-style-type: none"> • 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. <p>ISED Conformity.</p> <p>Canada ISED compliance statement</p> <p>This device complies with ISED Canada licence-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.</p> <p>This Class B digital apparatus complies with Canadian ICES-003.</p> <p>Le présent appareil est conforme aux CNR d'ISDE 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'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.</p> <p>Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada</p> </div> </div>	<div data-bbox="1305 302 1410 336"> Page 60 </div>

REGULATORY COMPLIANCES:

This device complies with ISED RF exposure limits for general population / uncontrolled environments. A separation distance of at least 20 cm must be maintained between the antenna and all persons. This device must not be co-located with any other antenna or transmitter.

Cet appareil se conforme aux normes ISED sur les limites d'exposition aux radiofréquences pour la population générale et environnements non contrôlés. Une distance minimale d'au moins 20cm doit être maintenue entre l'antenne et toute personne. Cet appareil ne doit pas être co-localisé avec toute autre antenne ou transmetteur.

EU and UK conformity section

Connectivity	Operating Frequency	Max Power Output
RFID	13.56 MHz	< 50 dBuV/m @ 3m
Wi-Fi	2.4 - 2.483.5 GHz	< 20.0 dBm EIRP
BT	2.4 - 2.483.5 GHz	< 10.0 dBm EIRP

This product complies with the following standards:

EN 301 489-1 v2.2.3, EN 301 489-17 v3.2.4, EN 300 328 v2.2.2, EN 300 330 v2.1.1

This product complies with the following safety standards:

EN 60601-1, EN 60601-1-2

ArjoHuntleigh AB as the manufacturer of this medical device, takes sole responsibility and declares conformity with the applicable provisions of EU Directive 2014/53/EU and the UK Radio Equipment Regulations 2017. Full Declarations can be found at: www.arjo.com

This device is intended for indoor use only.