

## 1. PillSense Capsule

Issue	Cause	Action
Capsule is damaged. (e.g., unexpected rusty color or fog inside the capsule, visible cracks on the capsule)	Capsule failure Mishandling	<ol style="list-style-type: none"> <li>1. Do not use.</li> <li>2. Select another capsule.</li> <li>3. If second capsule presents the same issue, contact Customer Service.</li> </ol>
Capsule not working. (LEDs are not blinking)	Capsule failure	<ol style="list-style-type: none"> <li>1. Use your hand to shield the light from the room entering the cavity for better visibility and make sure LEDs are not blinking.</li> <li>2. Do not use current capsule if problem persists.</li> <li>3. Select another capsule.</li> <li>4. If second capsule presents the same issue, contact Customer Service.</li> </ol>
Capsule address available to pair does not match the capsule address on the capsule packaging or does not appear in the list of available capsules.	System failure Interference	<ol style="list-style-type: none"> <li>1. Ensure that capsule is working; if the capsule is not working, see instruction above.</li> <li>2. Ensure the capsule is fully removed from its packaging/tray and within 8-9 feet from the receiver.</li> <li>3. Do not use current capsule if problem persists.</li> <li>4. Select another capsule.</li> <li>5. If second capsule presents the same issue, contact Customer Service.</li> </ol>
Capsule Battery Check fails.	Capsule failure	<ol style="list-style-type: none"> <li>1. Unpair and do not use current capsule.</li> <li>2. Select another capsule and restart procedure.</li> <li>3. If second capsule presents the same issue, contact Customer Service.</li> </ol>
Capsule packaging is damaged and/or items are missing from the package.	Capsule failure Mishandling	<ol style="list-style-type: none"> <li>1. PillSense Capsule contains a packaged capsule, the IFU, a patient leaflet and a patient card. Ensure that the missing item is not in the box.</li> <li>2. Do not use, if any part of the packaging seems damaged and/or compromised.</li> <li>3. Select another capsule.</li> <li>4. If second capsule presents the same issue, contact Customer Service.</li> </ol>

## 2. PillSense Receiver

Issue	Cause	Action
Receiver not turning on even after charging the unit for a minimum of 1 hour.	Receiver failure	<ol style="list-style-type: none"> <li>1. Do not use.</li> <li>2. Select another receiver.</li> <li>3. Contact Customer Service.</li> </ol>
Receiver does not charge when plugged in.	End of life Mishandling	<ol style="list-style-type: none"> <li>1. Ensure the provided charger is used and/or the charger is fully plugged into a functioning plug.</li> <li>2. Do not use the current receiver if problem persists.</li> <li>3. Select another receiver.</li> <li>4. Contact Customer Service.</li> </ol>
Screen is frozen, unresponsive, and/or black.	Receiver failure End of life Mishandling	<p><b>If data acquisition has not started yet:</b></p> <ol style="list-style-type: none"> <li>1. Restart the unit by turning the receiver off and on.</li> <li>2. Do not use the current receiver if problem persists.</li> <li>3. Select another receiver.</li> <li>4. Contact Customer Service.</li> <li>5. Send faulty receiver to Cook Medical.</li> </ol> <p><b>If the data acquisition is ongoing but cannot proceed due to this problem:</b></p> <ol style="list-style-type: none"> <li>1. Discard any result that might appear on the screen and terminate the procedure by turning off the receiver.</li> <li>2. Abort procedure and contact Customer Service.</li> </ol>
Receiver case or screen are damaged.	Mishandling	<ol style="list-style-type: none"> <li>1. Do not use a damaged receiver.</li> <li>2. Select another receiver.</li> <li>3. Contact Customer Service.</li> </ol>
Power cables are damaged.	Receiver failure Mishandling	<ol style="list-style-type: none"> <li>1. Do not use a damaged power cable.</li> <li>2. Select another power cable if available.</li> <li>3. Contact Customer Service.</li> </ol>
Receiver packaging is damaged and/or items are missing from the package.	Mishandling	<ol style="list-style-type: none"> <li>1. PillSense Receiver box contains a receiver, the IFU and a power cable, which is comprised of 2 parts. Ensure that the missing item is not still in the box.</li> <li>2. Do not use the receiver if any part of the packaging seems damaged and/or compromised.</li> <li>3. Select another receiver.</li> <li>4. Contact Customer Service.</li> </ol>

### 3. Data acquisition, review, and wireless communication issues

Issue	Cause	Action
<p>Communication warning symbol is displayed.</p> 	<p>System failure Interference</p>	<ol style="list-style-type: none"> <li>1. Ensure PillSense Receiver is not plugged into a wall outlet during monitoring session.</li> <li>2. Bring the receiver closer to the patient.</li> <li>3. Try to remove any obstacle in between the patient torso and the receiver.</li> <li>4. Hold the receiver as close as possible to the patient, until monitoring time reaches at least 5 minutes.</li> <li>5. If the problem persists, you may not be able to complete the monitoring session and an "inconclusive" message will appear.</li> <li>6. Abort the procedure.</li> <li>7. Contact Customer Service.</li> </ol>
<p>Communication warning page is displayed.</p> 	<p>System failure Interference</p>	<ol style="list-style-type: none"> <li>1. Ensure PillSense Receiver is not plugged into a wall outlet during monitoring session.</li> <li>2. Bring the receiver closer to the patient.</li> <li>3. Once a strong connection has been resumed, the monitoring will resume automatically or you can try to restart monitoring by selecting <b>Retry</b> in the warning page.</li> <li>4. If the problem persists, you may not be able to complete the monitoring session and an "inconclusive" message will appear.</li> <li>5. Abort the procedure.</li> <li>6. Contact Customer Service.</li> </ol>
<p>Sensor output does not progress.</p>	<p>System failure Interference</p>	<ol style="list-style-type: none"> <li>1. Ensure the communication is stable. If a communication warning symbol or page are displayed, see section above to solve the issue.</li> <li>2. Abort the procedure, if a stable communication cannot be re-established.</li> <li>3. Discard any result that might appear on the screen.</li> <li>4. Contact Customer Service.</li> </ol>
<p>Sensor output is 0.</p>	<p>Capsule failure</p>	<ol style="list-style-type: none"> <li>1. Sensor output in a dark environment (after ingestion) should be higher than zero. If the capsule has been ingested and there are no other sources of light within the GI tract, this is a sign of a faulty capsule.</li> <li>2. Abort the procedure.</li> <li>3. Discard any result that might appear on the screen.</li> <li>4. Contact Customer Service.</li> </ol>
<p>Monitoring time does not increment.</p>	<p>System failure Interference</p>	<ol style="list-style-type: none"> <li>1. A monitoring time that is not incrementing is a sign of a weak communication. Follow the instruction above for "Communication warning symbol is displayed."</li> </ol>
<p>Capsule address and/or patient ID cannot be found when reviewing previous record.</p>	<p>System failure</p>	<ol style="list-style-type: none"> <li>1. If the capsule address and/or patient ID do not appear in the list of previous records, select <b>More</b> and enter the capsule address and/or patient ID that you wish to review.</li> <li>2. If the capsule address and/or patient ID cannot be found, ensure you have entered the correct capsule address and/or patient ID.</li> <li>3. If the problem persists, contact Customer Service.</li> </ol>
<p>Incorrect chart (wrong capsule address and/or patient ID) is displayed when reviewing previous records.</p>	<p>System failure</p>	<ol style="list-style-type: none"> <li>1. Ensure you have selected the correct capsule address and/or patient ID.</li> <li>2. If the problem persists, contact Customer Service.</li> </ol>

Please refer to the product's Instructions for Use (IFU) for full prescribing information, warnings, precautions, contraindications, and potential adverse events.

## Customer Service

EU Website: [cookmedical.eu](http://cookmedical.eu)  
EDI: [cookmedical.eu/edi](http://cookmedical.eu/edi)  
Distributors: +353 61239240, [ssc.distributors@cookmedical.com](mailto:ssc.distributors@cookmedical.com)  
Austria: +43 179567121, [oe.orders@cookmedical.com](mailto:oe.orders@cookmedical.com)  
Belgium: +32 27001702, [be.orders@cookmedical.com](mailto:be.orders@cookmedical.com)  
Denmark: +45 38487607, [da.orders@cookmedical.com](mailto:da.orders@cookmedical.com)  
Finland: +358 972519996, [fi.orders@cookmedical.com](mailto:fi.orders@cookmedical.com)  
France: +33 171230269, [fr.orders@cookmedical.com](mailto:fr.orders@cookmedical.com)  
Germany: +49 6950072804, [de.orders@cookmedical.com](mailto:de.orders@cookmedical.com)  
Hungary: +36 17779199, [hu.orders@cookmedical.com](mailto:hu.orders@cookmedical.com)  
Iceland: +354 800 7615, [is.orders@cookmedical.com](mailto:is.orders@cookmedical.com)  
Ireland: +353 61239252, [ie.orders@cookmedical.com](mailto:ie.orders@cookmedical.com)  
Italy: +39 0269682853, [it.orders@cookmedical.com](mailto:it.orders@cookmedical.com)  
Netherlands: +31 202013367, [nl.orders@cookmedical.com](mailto:nl.orders@cookmedical.com)  
Norway: +47 23162968, [no.orders@cookmedical.com](mailto:no.orders@cookmedical.com)  
Spain: +34 912702691, [es.orders@cookmedical.com](mailto:es.orders@cookmedical.com)  
Sweden: +46 858769468, [se.orders@cookmedical.com](mailto:se.orders@cookmedical.com)  
Switzerland - French: +41 448009609, [fr.orders@cookmedical.com](mailto:fr.orders@cookmedical.com)  
Switzerland - Italian: +41 448009609, [it.orders@cookmedical.com](mailto:it.orders@cookmedical.com)  
Switzerland - German: +41 448009609, [de.orders@cookmedical.com](mailto:de.orders@cookmedical.com)  
United Kingdom: +44 2073654183, [uk.orders@cookmedical.com](mailto:uk.orders@cookmedical.com)

USA Website: [cookmedical.com](http://cookmedical.com)  
EDI: [cookmedical.com/edi.do](http://cookmedical.com/edi.do)  
**Americas:**  
Phone: +1 812.339.2235, 800.457.4500, Fax: 800.554.8335  
E-mail: [customersupport@cookmedical.com](mailto:customersupport@cookmedical.com)  
**Australia:**  
Phone: +61 734346000, 1800777222, Fax: +61 734346001, 1800077283  
E-mail: [cau.custserv@cookmedical.com](mailto:cau.custserv@cookmedical.com)



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