

FSN Ref: SOOIL QA-200102-01(2)

## **Urgent Field Safety Notice**

**Device: DANA Diabecare RS insulin pump (All Less than version 3.0)**  
**FSCA Ref: SOOIL QA-200102-01(2)**  
**Filed Safety Notice:**  
**Enhanced cyber security for DANA RS insulin pumps**

**Date:** 2020-Mar-xx

**Attention:** Dear User of DANA Diabecare RS Insulin Pump

**Details on affected devices:**

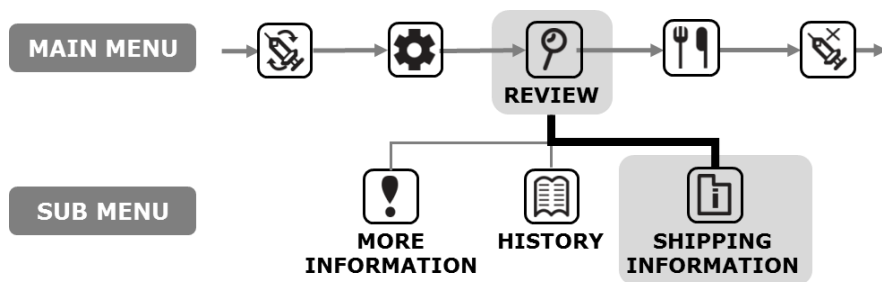
DANA Diabecare RS Insulin Pump (All Less than Version 3.0)  
 AnyDANA-A & AnyDANA-i mobile application (All Less than Version 3.0)



**Description of the problem:**

We, SOOIL has been guided by the German Federal Bureau of Cyber Security (BSI BUND DE) to a possible vulnerability in cybersecurity to the DANA RS system. If the vulnerability is exploited, there is a risk of hackers remotely controlling the insulin pump. But, this risk is from testing in an isolate environment of professional institutions and has not been reported in real-world usage.

**Advise on action to be taken by the user:**

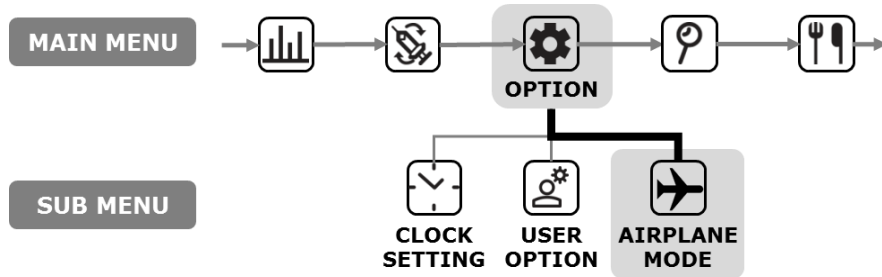
**Step.1 Check the version of your DANA RS insulin pump**

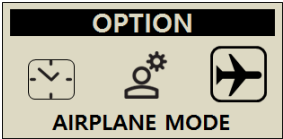
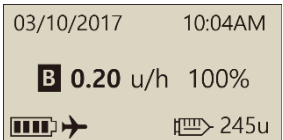


<p style="text-align: center;"><b>REVIEW</b></p>  <p style="text-align: center;"><b>SHIPPING INFORMATION</b></p>	<p>From <b>MAIN MENU</b> select <b>REVIEW</b> screen then open <b>SHIPPING INFORMATION</b> from the sub menu.</p>
<p>1.S/N : AAA00000AA                  2.COUNTRY : KOR                  3.DATE : 01/MAR 2017                  4.VERSION : BPN X.X </p>	<p>Display includes:</p> <ul style="list-style-type: none"> <li>• Pump serial number</li> <li>• Country pump was originally distributed from</li> <li>• Date of manufacture</li> <li>• <b>Pump software version number</b></li> </ul>

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**If the version is lower than 3.0, Immediately set the insulin pump to "airplane mode"**



	<ol style="list-style-type: none"> <li>1. Select <b>OPTION</b> from the <b>MAIN MENU</b> then select <b>AIRPLANE MODE</b> from the OPTION's sub menu.</li> </ol>
	<ol style="list-style-type: none"> <li>2. The airplane symbol is displayed on the initial screen.</li> </ol>

**Step.2 Insulin pump firmware upgrade**

You can upgrade your insulin pump firmware through the distributor below.

[Information of Distributer](#)

**Caution** After upgrading, the version of the insulin pump is 3.0. DANA RS version 3.0 is not connected to the exiting mobile application (version 1.0 or 2.0).

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### **Step.3 Mobile application upgrade and connection**

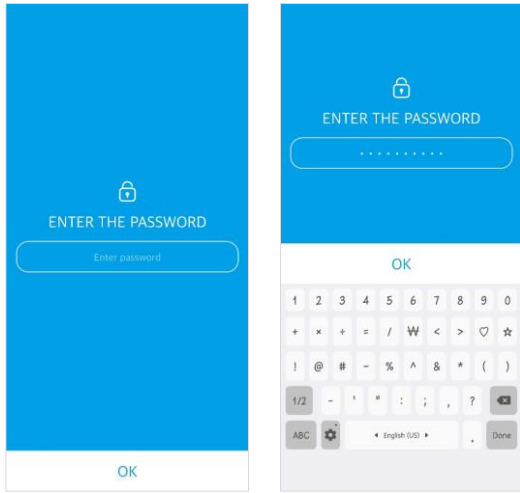
Upgrade your mobile application to version 3.0 through Google Play or Apple App Store. The new connection method is as follows.

#### **➤ Pairing to Insulin Pump**

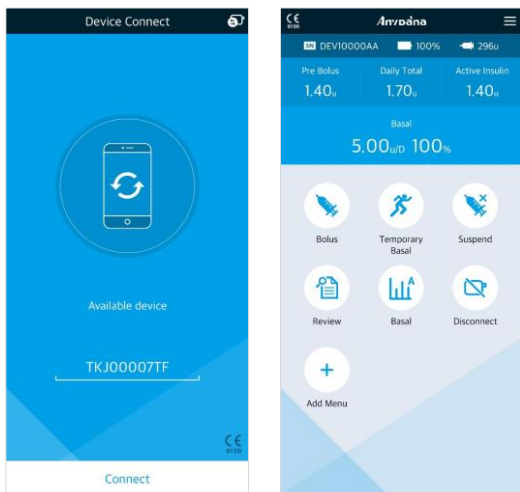
		<ol style="list-style-type: none"> <li>1. Open AnyDANA on the smart-phone. Set the password to run the application.</li> <li>2. Press "Search Device" on the Initial screen.</li> </ol> <p><b>Notice</b> The 9~12-digit application password can include alpha, numerals and special characters.</p> <p><b>Notice</b> If you forget your password, you can reset your password by deleting and reinstalling the app.</p>
		<ol style="list-style-type: none"> <li>3. From 'Device List', select the pump serial number you want to connect.</li> <li>4. Select "Yes" to request the passcode. Press "Ok" on the pump screen to confirm pairing.</li> </ol> <div data-bbox="983 1305 1264 1440" style="border: 1px solid black; padding: 5px; text-align: center;"> <p><b>CONFIRM PAIRING ?</b></p> <p><input type="checkbox"/> :NO <input checked="" type="checkbox"/> :YES</p> </div>
		<ol style="list-style-type: none"> <li>5. Enter the pairing key 1 and 2 shown on the pump screen.</li> </ol> <div data-bbox="965 1753 1241 1888" style="border: 1px solid black; padding: 5px; text-align: center;"> <p><b>PAIRING KEY</b></p> <p>1 : 33857531F193 2 : E7739B9F</p> </div>

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➤ **Connection Procedure**



1. The serial number of the pump paired appears. When 'Searching...' phrase becomes 'Available device', it is ready to connect. Then, press "Connect".
2. Input the correct password.



3. Press the connect button.
4. Main menu is displayed.

**If you are unable to this action, contact your distributor or pump trainer immediately.**

\*The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

SOOIL Development Co., Ltd  
Quality Management Representative

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