

Field safety notice

FSN-Ref: CAPA_01 2025 Hb	FSCA-REF: 03398/25	Date: 06/02/2025
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To whom it may concern

ESCHWEILER was informed about the lack of internal function control and the absence of possibility to carry out external quality controls in connection with the Hb sensor.

Due to the lack of guarantee of functionality, there is a possible risk for the patient.

In this context, we have decided to deactivate the Hb sensors until the necessary testing procedures have been carried out.

This letter is addressed to dealers and users who commission and use ESCHWEILER combiline devices with Hb sensor. Distributor are obliged to inform all users of the devices in question with this letter.

The necessary data for implementing this measure are described below.

1. Information about the affected product	
1.1	product types
	Hb sensor type III
1.2	trade names
	Hb-sensor type III complete
1.3	Unique device identification
	--
1.4	Intended purpose
	The Hb sensor is used to determine the total hemoglobin concentration in human whole blood.
1.5	Model/Catalog/Part Number
	50 2 10 06
1.6	Affected serial/lot number range
	all devices with Hb sensor
1.7	Related Products
	Not applicable

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2. Reason for the field corrective action (FSCA)	
2.1	Description of the product problem*
Despite the long-term stability of the factory calibration of the optical Hb sensor, there is no way to detect systematic errors.	
2.2	Threat that triggers FSCA
Larger measurement deviations are detected and the measurement is then discarded, but smaller deviations can lead to an incorrect treatment decision. This means that patients may receive treatment that was not necessary, or may receive incorrect treatment, or no treatment at all.	
2.3	probability of the problem occurring
Very rare	
2.4	Anticipated risk to patients/users
The consequences can range from minor to potentially life-threatening.	
2.5	Further information on the characterization of the problem
Not applicable	
2.6	Background information on the topic
Not applicable	
2.7	Other information relevant to the FSCA
Not applicable	

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3. Type of risk mitigation measures			
3.1	Actions to be taken by the user*		
Disabling the Hb sensor ESCHWEILER combiline devices by users To disable the Hb sensor in ESCHWEILER combiline devices, please follow these steps: 1. Access the Menu . 2. Navigate to Standard Data . 3. Select Sensor Selection . 4. Set all configured sensors to ON and switch OFF the Hb sensor. 5. Exit the program to apply the changes.			
When should the measure be completed?			
Immediately after receiving this FSN			
3.2	Action to be taken by the distributor		
Deactivation of the Hb sensor by distributor In order to deactivate the Hb sensor in the ESCHWEILER combiline please follow the following steps: 1. Turn OFF analyser. 2. Turn ON analyser. 3. Press function key RESET within the first 3 seconds after switching on. Analyser must be in warm up then. 4. Enter calibration data according to dialogue. 5. Press PROGRAM key 3 times for menu STANDARD DATA . 6. Press key "0" for Parameter Configuration . 7. Deactivate the Hb sensor by pressing the OFF button. 8. Turn OFF analyser. 9. Turn ON analyser. 10. Press function key RESET within the first 3 seconds after switching on.			
When should the measure be completed?			
At the next scheduled maintenance – by 05/2025 at the latest.			
3.3	Special Considerations		
Not applicable			
3.4	Is a response from the customer required? * (If yes, attach form stating the return deadline)		
ESCHWEILER asks you to confirm the implementation of the measure by completing and signing the enclosed response form and sending a scanned copy by email to info@eschweiler-kiel.de immediately after the measure has been implemented.			
3.5	Measure taken by the manufacturer		
All distributors will be informed and provided with this FSCA implementation action plan with a form to confirm this implementation. The action plan provides for the following:			

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<div>1. Immediate shutdown of the Hb sensor. This can be done by the customer (user) via the device menu.</div> <div>2. Medium-term deinstallation of the Hb sensor at application level during regular maintenance by the distributor.</div> <div>3. Development of an internal functional control on our part.</div> <div>4. Development of an external quality control on our part.</div>			
By when should the measure be completed?			
<div>Point 1: immediately after receiving this instruction</div> <div>Point 2: 05/2025</div> <div>Point 3: 2025</div> <div>Point 4: 2025</div>			
3.6	Does the FSN need to be communicated to the patient/non-professional user?		
Not applicable			
3.7	If so, has the manufacturer provided additional information for the patient/non-professional user in an information letter/sheet for the patient/non-professional user?		
Not applicable			

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4. General information	
4.1	FSN type*
new	
4.2	For updated FSN, Reference number and date of the previous FSN
Not applicable	
4.3	For updated FSN, new key information as follows
not applicable	
4.4	Further information that is already expected in the following FSN*
Not applicable	
If another FSN is expected, what should the further notice refer to?	
Not applicable	
4.5	--
4.6	Expected timeframe for subsequent FSN
see point 3	
4.7	manufacturer's specifications (The contact details of the local representative can be found on page 1 of this FSN)
Name:	
ESCHWEILER GmbH & Co. KG	
Address:	
Holzkoppelweg 35 24118 Kiel	
Website:	
https://www.eschweiler-kiel.de	
4.8	The competent (regulatory) authority has been informed of this communication to customers*
4.9	list of attachments
Appendix 1 – User Response Form – 1 page Appendix 2 – Dealer Response Form – 1 page	

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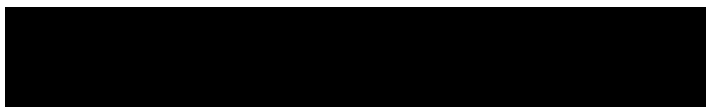
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<p>Transmission of this safety instruction in the field</p> <p>This instruction must be passed on to all persons who need to be aware within your organization or to any organization to which the potentially affected equipment has been transferred, as appropriate.</p> <p>Please forward these instructions to other organisations affected by this measure (as appropriate)</p> <p>Please observe these instructions and the resulting actions for a reasonable period of time to ensure the effectiveness of the remedial action.</p> <p>Please report any incidents related to the device to the manufacturer, distributor or local representative and, where appropriate, to the competent national authority, as this will provide important feedback.</p> <p>IN PARTICULAR, this letter is addressed to dealers and users who commission and use ESCHWEILER combiline devices with Hb sensor.</p> <p>The distributors are obliged to inform all users of the devices in question with this letter.</p>

*Note: Fields marked with * are required for all FSNs. Others are optional.*

Kiel, 06.02.2025

Place, Date



Signature of Management

ESCHWEILER GmbH & Co. KG
Holzkoppelweg 35
24118 Kiel

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APPENDIX 1 – USER RESPONSE FORM – Page 1/1

It is hereby confirmed that the measures (according to point 3.1) of this FSN have been taken.
ESCHWEILER greatly appreciates your immediate cooperation in this matter.

If you need further information, please contact info@eschweiler-kiel.de.

The measures to be implemented are described again below:

Disabling the Hb sensor ESCHWEILER combiline devices by users

To disable the Hb sensor in ESCHWEILER combiline devices, please follow these steps:

1. Access the **Menu**.
2. Navigate to **Standard Data**.
3. Select **Sensor Selection**.
4. Set all configured sensors to **ON** and switch **OFF** the Hb sensor.
5. Exit the program to apply the changes.

name of the institution	
address of the facility	
name of the contact person	
serial number of the affected device	

Immediately after carrying out the measure, please send the enclosed response form, completed and signed, as a scanned copy by email to info@eschweiler-kiel.de !

Place, Date

Signature

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APPENDIX 2 – DISTRIBUTOR RESPONSE FORM

This confirms that the measures (according to point 3.2) of this FSN have been taken.

This measure must be carried out during the next scheduled maintenance – by 05/2025 at the latest.

ESCHWEILER greatly appreciates your immediate cooperation in this matter.

If you need further information, please contact info@eschweiler-kiel.de.

The measures to be implemented are described again below:

Deactivation of the Hb sensor by distributor

In order to deactivate the Hb sensor in the **ESCHWEILER combiline** please follow the following steps:

1. Turn OFF analyser.
2. Turn ON analyser.
3. Press function key **RESET** within the first 3 seconds after switching on. Analyser must be in warm up then.
4. Enter calibration data according to dialogue.
5. Press **PROGRAM** key 3 times for menu **STANDARD DATA**.
6. Press key **"0"** for **Parameter Configuration**.
7. Deactivate the Hb sensor by pressing the **OFF** button.
8. Turn OFF analyser.
9. Turn ON analyser.
10. Press function key **RESET** within the first 3 seconds after switching on.

Name distributor	
address	
name of the contact person	
Name and address of the facility where the device is located	
serial number of the affected device	

Immediately after carrying out the measure, please send the enclosed response form, completed and signed, as a scanned copy by email to info@eschweiler-kiel.de !

Place, Date _____

Signature _____

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To whom it may concern

ESCHWEILER was informed about the lack of internal function control and the absence of possibility to carry out external quality controls in connection with the Hb sensor.

Due to the lack of guarantee of functionality, there is a possible risk for the patient.

In this context, we have decided to deactivate the Hb sensors until the necessary testing procedures have been carried out.

This letter is addressed to dealers and users who commission and use ESCHWEILER modularPro devices with Hb sensor. Distributor are obliged to inform all users of the devices in question with this letter.

The necessary data for implementing this measure are described below.

1. Information about the affected product	
1.1	product types
	Hb sensor type III
1.2	trade names
	Hb-Sensor type MP complete with Hb-analog CL3 2.0
1.3	Unique device identification
	--
1.4	Intended purpose
	The Hb sensor is used to determine the total hemoglobin concentration in human whole blood.
1.5	Model/Catalog/Part Number
	70 2 10 06
1.6	Affected serial/lot number range
	all devices with Hb sensor
1.7	Related Products
	Not applicable

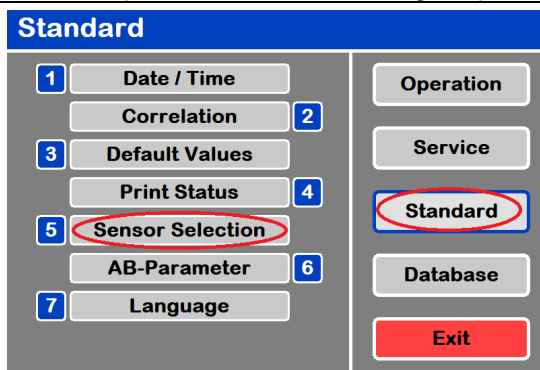
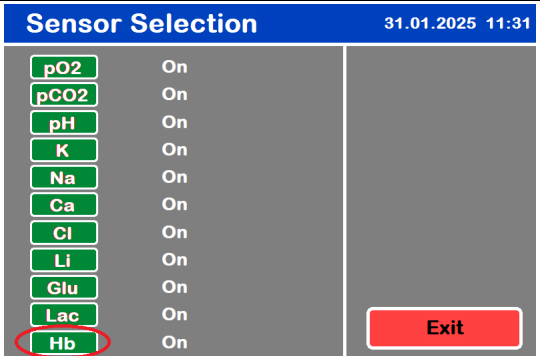
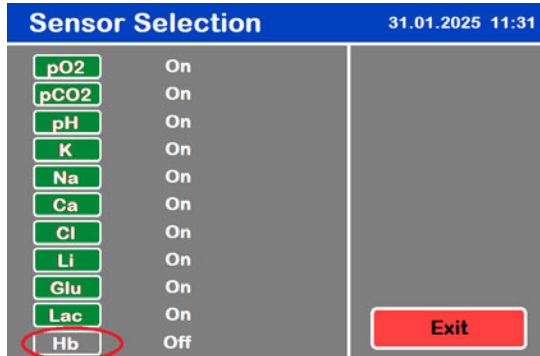
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2. Reason for the field corrective action (FSCA)	
2.1	Description of the product problem*
Despite the long-term stability of the factory calibration of the optical Hb sensor, there is no way to detect systematic errors.	
2.2	Threat that triggers FSCA
Larger measurement deviations are detected and the measurement is then discarded, but smaller deviations can lead to an incorrect treatment decision. This means that patients may receive treatment that was not necessary, or may receive incorrect treatment, or no treatment at all.	
2.3	probability of the problem occurring
Very rare	
2.4	Anticipated risk to patients/users
The consequences can range from minor to potentially life-threatening.	
2.5	Further information on the characterization of the problem
Not applicable	
2.6	Background information on the topic
Not applicable	
2.7	Other information relevant to the FSCA
Not applicable	

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3. Type of risk mitigation measures	
3.1	Actions to be taken by the user*
Deactivation of the Hb-sensor in modularPro by Users	
In order to switch of the Hb-sensor in the modularPro instruments please follow the following steps:	
1. Select: Menu => Standard => Sensor selection	
2. Click on the Hb sensor	
3. Now the Hb-sensor has been switched off.	
When should the measure be completed?	
Immediately after receiving this FSN	

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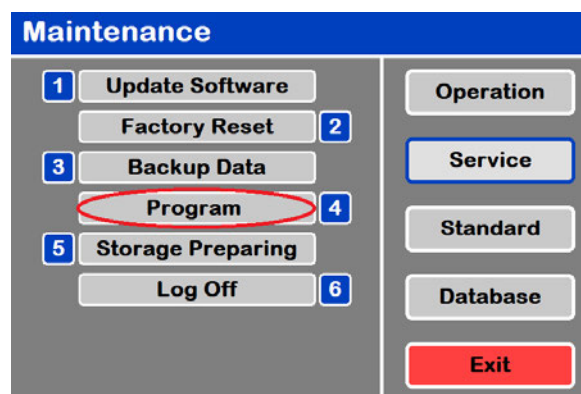
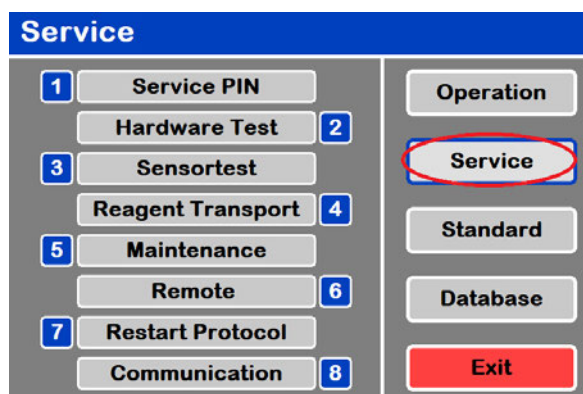
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3.2 Action to be taken by the distributor

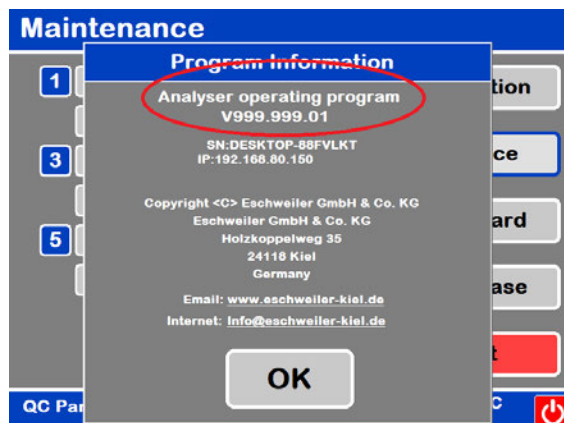
Deactivation of the Hb-sensor in modularPro by distributor

In order to deactivate the Hb-sensor in the modularPro instruments please follow the following steps:

1. Select: **MENU => SERVICE => MAINTENANCE => PROGRAM INFO**

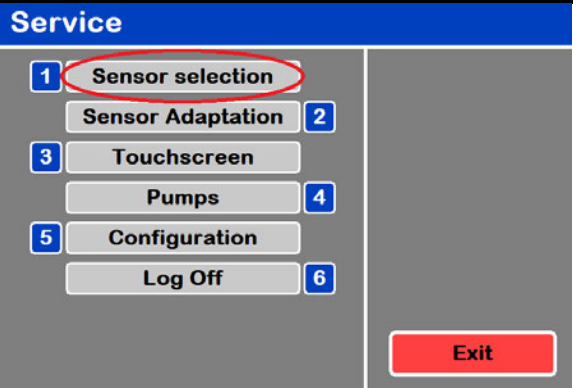
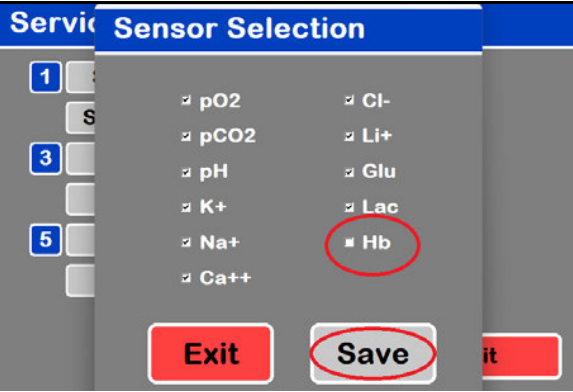


2. Make a double-touch on "Analyser operating program".



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3. Selection: Selection sensors	
4. Deactivate the Hb sensor by deselecting the Hb. 5. Finally, click Save to save the changes.	
When should the measure be completed?	
At the next scheduled maintenance – by 05/2025 at the latest.	
3.3	Special Considerations
Not applicable	
3.4	Is a response from the customer required? * (If yes, attach form stating the return deadline)
ESCHWEILER asks you to confirm the implementation of the measure by filling out the enclosed response form, signing it and sending it as a scanned copy by email to info@eschweiler-kiel.de immediately after the measure has been implemented!	

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3.5	Measure taken by the manufacturer
<p>All distributors will be informed and provided with this FSCA implementation action plan with a form to confirm this implementation.</p> <p>The action plan provides for the following:</p> <ol style="list-style-type: none"> 1. Immediate shutdown of the Hb sensor. This can be done by the customer (user) via the device menu. 2. Medium-term deinstallation of the Hb sensor at application level during regular maintenance by the distributor. 3. Development of an internal functional control on our part. 4. Development of an external quality control on our part. 	
By when should the measure be completed?	
<p>Point 1: immediately after receiving this instruction</p> <p>Point 2: 05/2025</p> <p>Point 3: 2025</p> <p>Point 4: 2025</p>	
3.6	Does the FSN need to be communicated to the patient/non-professional user?
Not applicable	
3.7	If so, has the manufacturer provided additional information for the patient/non-professional user in an information letter/sheet for the patient/non-professional user?
Not applicable	

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FSN-Ref: CAPA_01 2025 Hb	FSCA-REF: 03398/25	Date: 06/02/2025
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4. General information	
4.1	FSN type*
new	
4.2	For updated FSN, Reference number and date of the previous FSN
Not applicable	
4.3	For updated FSN, new key information as follows
Not applicable	
4.4	Further information that is already expected in the following FSN*
Not applicable	
If another FSN is expected, what should the further notice refer to?	
Not applicable	
4.5	--
4.6	Expected timeframe for subsequent FSN
see point 3	
4.7	manufacturer's specifications (The contact details of the local representative can be found on page 1 of this FSN)
Name:	
ESCHWEILER GmbH & Co. KG	
Address:	
Holzkoppelweg 35 24118 Kiel	
Website:	
https://www.eschweiler-kiel.de	
4.8	The competent (regulatory) authority has been informed of this communication to customers*
4.9	list of attachments
Appendix 1 – User response form – 2 pages Appendix 2 – Response form for distributors – 2 pages	

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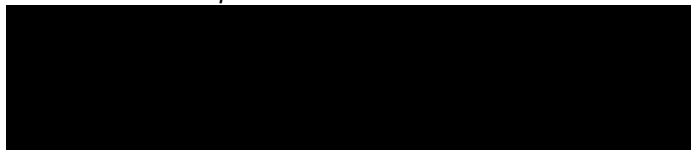
FSN-Ref: CAPA_01 2025 Hb	FSCA-REF: 03398/25	Date: 06/02/2025
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<p>Transmission of this safety instruction in the field</p> <p>This instruction must be passed on to all persons who need to be aware within your organization or to any organization to which the potentially affected equipment has been transferred, as appropriate.</p> <p>Please forward these instructions to other organisations affected by this measure (as appropriate)!</p> <p>Please observe these instructions and the resulting actions for a reasonable period of time to ensure the effectiveness of the remedial action.</p> <p>Please report any incidents related to the device to the manufacturer, distributor or local representative and, where appropriate, to the competent national authority, as this will provide important feedback.</p> <p>IN PARTICULAR, this letter is addressed to distributors and users who commission and use ESCHWEILER modularPro devices with Hb sensor.</p> <p>The distributors are obliged to inform all users of the devices in question with this letter.</p>
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*Note: Fields marked with * are required for all FSNs. Others are optional.*

Kiel, 06.02.2025

Place, Date



Signature of Management

ESCHWEILER GmbH & Co. KG
Holzkoppelweg 35
24118 Kiel

Field Safety Notice

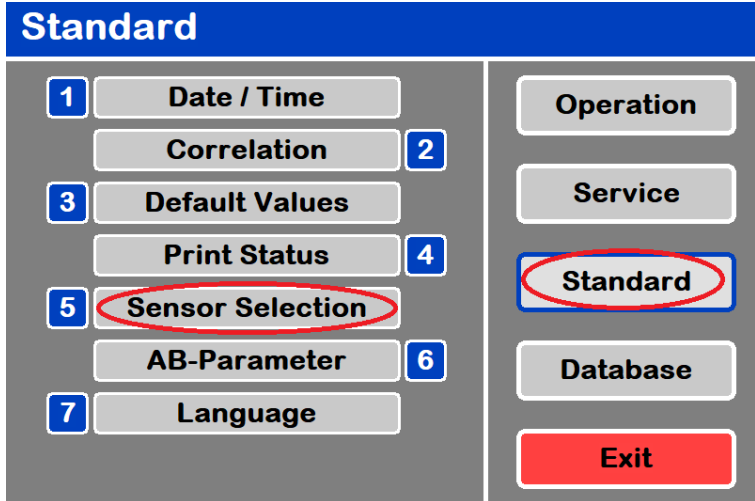
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APPENDIX 1 – USER RESPONSE FORM – Page 1/2

It is hereby confirmed that the measures (according to point 3.1) of this FSN have been taken.
 ESCHWEILER greatly appreciates your immediate cooperation in this matter.
 If you need further information, please contact info@eschweiler-kiel.de.

Name and address of the institution	
name of the contact person	
serial number of the affected device	

The measures to be implemented are described again below:

1. Select: Menu=> Standard => Sensor Selection	
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APPENDIX 1 – USER RESPONSE FORM – Page 2/2

2. Click on the Hb-sensor	<div style="background-color: #0056b3; color: white; padding: 5px;"> Sensor Selection 31.01.2025 11:31 </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="background-color: #008000; color: white; text-align: center;">pO2</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">pCO2</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">pH</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">K</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Na</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Ca</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Cl</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Li</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Glu</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Lac</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Hb</td><td style="text-align: center;">On</td></tr> </table> <div style="text-align: right; margin-top: 10px;"> <div style="background-color: #ff0000; color: white; padding: 10px 20px; border-radius: 5px;">Exit</div> </div>	pO2	On	pCO2	On	pH	On	K	On	Na	On	Ca	On	Cl	On	Li	On	Glu	On	Lac	On	Hb	On
pO2	On																						
pCO2	On																						
pH	On																						
K	On																						
Na	On																						
Ca	On																						
Cl	On																						
Li	On																						
Glu	On																						
Lac	On																						
Hb	On																						
3. Now the Hb-sensor has been switched off .	<div style="background-color: #0056b3; color: white; padding: 5px;"> Sensor Selection 31.01.2025 11:31 </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="background-color: #008000; color: white; text-align: center;">pO2</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">pCO2</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">pH</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">K</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Na</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Ca</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Cl</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Li</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Glu</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Lac</td><td style="text-align: center;">On</td></tr> <tr><td style="background-color: #008000; color: white; text-align: center;">Hb</td><td style="text-align: center;">On</td></tr> </table> <div style="text-align: right; margin-top: 10px;"> <div style="background-color: #ff0000; color: white; padding: 10px 20px; border-radius: 5px;">Exit</div> </div>	pO2	On	pCO2	On	pH	On	K	On	Na	On	Ca	On	Cl	On	Li	On	Glu	On	Lac	On	Hb	On
pO2	On																						
pCO2	On																						
pH	On																						
K	On																						
Na	On																						
Ca	On																						
Cl	On																						
Li	On																						
Glu	On																						
Lac	On																						
Hb	On																						

Immediately after carrying out the measure for each device, please send the enclosed response form, completed and signed, as a scanned copy by email to info@eschweiler-kiel.de !

Place, Date

Signature

Field Safety Notice

FSN-Ref: CAPA_01 2025 Hb	FSCA-REF: 03398/25	Date: 06/02/2025
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APPENDIX 2 – DISTRIBUTOR RESPONSE FORM – Page 1/2

This confirms that the measures (according to point 3.2) of this FSN have been taken.

This measure must be carried out during the next scheduled maintenance – by 05/2025 at the latest.

ESCHWEILER greatly appreciates your immediate cooperation in this matter.

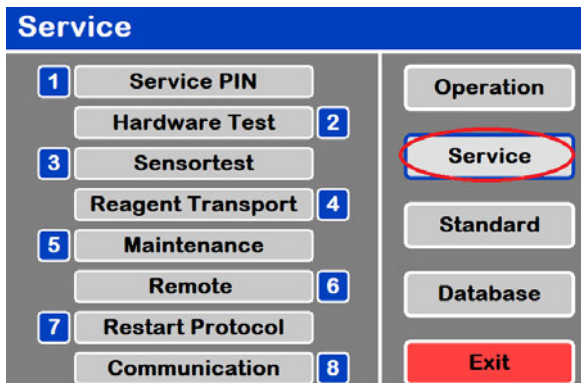
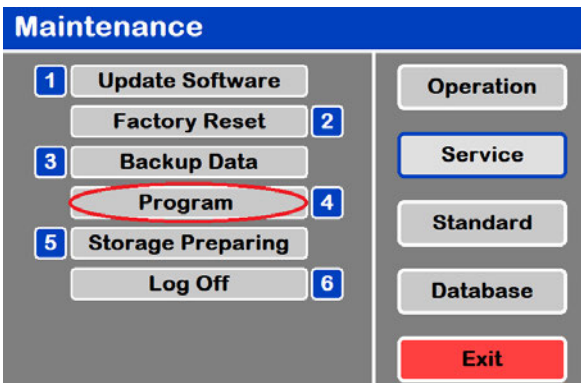
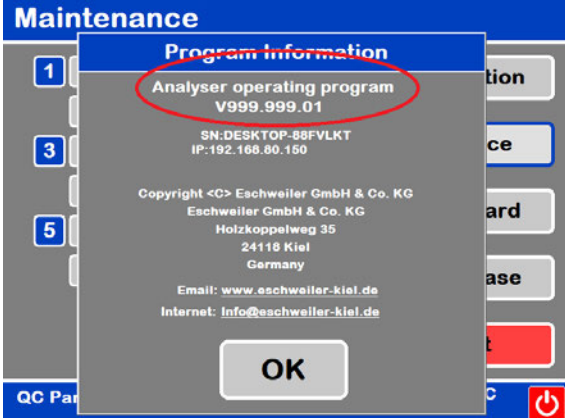
If you need further information, please contact info@eschweiler-kiel.de.

The measures to be implemented are described again below:

Deactivation of the Hb sensor in the modularPro by the distributor.

In order to deactivate the Hb-sensor in the modularPro instruments please follow the following steps:

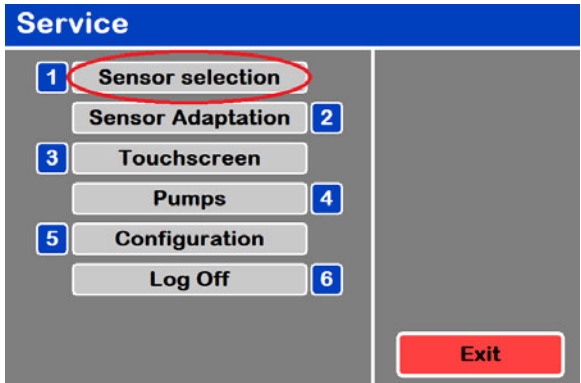
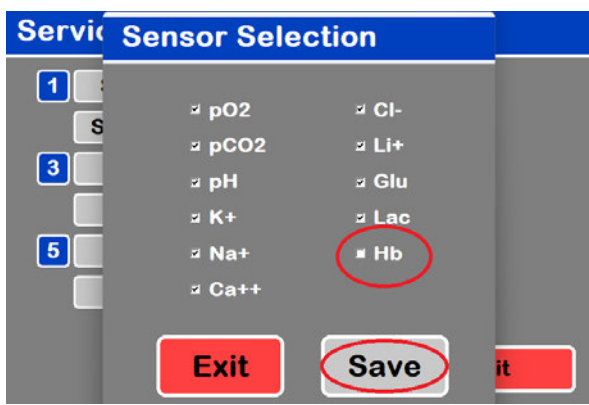
1. Select: **MENU => SERVICE => MAINTENANCE => PROGRAM**

 <p>Service</p> <p>1 Service PIN Operation</p> <p>Hardware Test 2</p> <p>3 Sensortest Service</p> <p>Reagent Transport 4</p> <p>5 Maintenance Standard</p> <p>Remote 6</p> <p>7 Restart Protocol Database</p> <p>Communication 8 Exit</p>	 <p>Maintenance</p> <p>1 Update Software Operation</p> <p>Factory Reset 2</p> <p>3 Backup Data Service</p> <p>Program 4</p> <p>5 Storage Preparing Standard</p> <p>Log Off 6 Database</p> <p>Exit</p>
<p>2. Make a double-touch on “Analyser operating program”.</p>	 <p>Maintenance</p> <p>Program Information</p> <p>1 Analyser operating program V999.999.01</p> <p>3 SN:DESKTOP-88FVLKT IP:192.168.80.150</p> <p>5 Copyright <C> Eschweiler GmbH & Co. KG Eschweiler GmbH & Co. KG Holzkoppelweg 35 24118 Kiel Germany Email: www.eschweiler-kiel.de Internet: info@eschweiler-kiel.de</p> <p>OK</p>

Field Safety Notice

FSN-Ref: CAPA_01 2025 Hb	FSCA-REF: 03398/25	Date: 06/02/2025
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APPENDIX 2 – DISTRIBUTOR RESPONSE FORM – Page 2/2

3. Select: Sensor selection	
4. Deactivate the Hb sensor by deselecting the Hb . 5. Finally, click Save to save the changes.	

Name distributor	
address	
name of the contact person	
Name and address of the facility where the device is located	
serial number of the affected device	

Immediately after carrying out the measure for each device, please send the enclosed response form, completed and signed, as a scanned copy by email to info@eschweiler-kiel.de !

Place, Date _____

Signature _____