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## ICG Sensor - Labels and Symbols

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# 1 Meta-Information

## 1.1 Approval

Version	Date *)	Last modified by	Document	Status
2	2023-Nov-03	Manuela Hagedorn	ICG Sensor - Labels and Symbols	 Released

\*) The date represents the date the document was given for review. See version history below for further approval information.

## 1.2 Product / Software

<b>Product name</b>	ICG Sensor	<b>Hardware Version</b>	1
		<b>Software Version</b>	--

## 1.3 Version History

Version	Date	Created/Changed by	Description
1	2023-JUN-26	Manuela Hagedorn	Initial creation as extraction of "Technical Data" labeling information from <a href="#">Ueb - ICG Sensor</a> (v14) <ul style="list-style-type: none"> <li>N1201-5 and N1209-5 pouch labels updated</li> <li>N1201-5 box label updated</li> </ul>
2	2023-NOV-03	Manuela Hagedorn	Box labels updated: <ul style="list-style-type: none"> <li>languages added: pt/pt-br, cn, ko</li> <li>Order of UDI data identifiers updated</li> </ul> Pouch labels updated: <ul style="list-style-type: none"> <li>Order of UDI data identifiers updated</li> </ul>

### Release Table

Version	Date*)	Author or Approver	Status **)
1	2023-Jun-26	Manuela Hagedorn	
1	2023-Jun-26	Susann Balling	
2	2023-Nov-03	Manuela Hagedorn	
2	2023-Nov-03	Susann Balling	

Version numbers can increase during the approval process

\*\*) Status: Draft, Reviewed, Released

## 1.4 Addressees and Intention of this Document

This document is for the manufacturing teams and defines the labeling requirements for the ICG sensors.

## 1.5 Relevant Documents

No	Document	Description
1	<a href="#">LIS - Glossar / LIS - Glossary</a>	Company-specific definition of terms and definitions
2	<a href="#">ICG Sensor - Content of Technical File</a>	Links between the versions of documents in the technical file (e.g. this one) and the product versions.
3	<a href="#">ICG Sensor - Instructions for Use</a>	Instructions for use of the ICG Sensors

## 2 Scope

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This document outlines the necessary labeling for the ICG sensors.

### 3 Labeling ICG Sensor

#### 3.1 ICG Sensor

ICG Sensor (N1209-5)

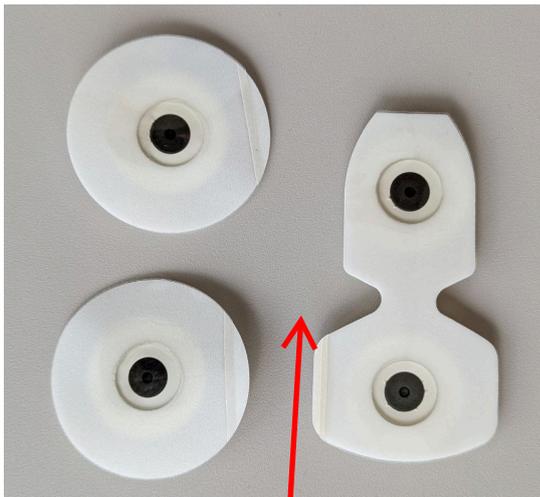
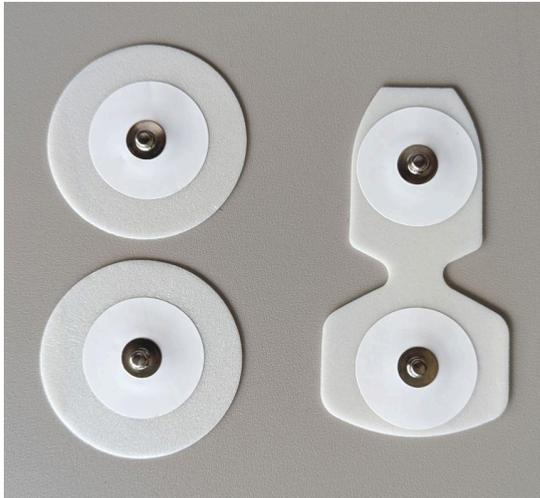


Illustration of the sensors: all sensors in front view (top) and back view (bottom)

ICG Sensor (1201-5)



Illustration of the sensors: two sensors in front view (left) and two in back view (right)

1.1.6 nr.

### 3.2 Pouch Label

ICG sensor pouch label indicating the model, manufacturer and manufacturing information, as well as the CE mark and safety symbols:

	ICG Sensor (N1209-5)	ICG Sensor (1201-5)
Pouch Label	<p>170 x 70 mm</p> <p>4TECT ICG Sensors Adult 2⊕+1⊗ / Ag/AgCl</p> <p>REF N1209-5 LOT 230601 2023-06 2025-05</p> <p>medis. Medizinische Messtechnik GmbH Phone: +49-3677-46 29 0 Fax: +49-3677-46 29 29 Email: sales@medis.company Werner-von-Siemens-Str. 6 98693 Ilmenau, Germany www.medis.company</p> <p>1.1.3 nr. (points to Xiphoid p.) 1.1.5 nr. (points to Ag/AgCl) 1.1.4 nr. (points to REF)</p>	<p>120 x 170 mm</p> <p>ICG Sensors Adult professional 4⊕ / Ag/AgCl</p> <p>REF N1201-5 LOT 231116 2023-11 2025-10</p> <p>medis. Medizinische Messtechnik GmbH Phone: +49-3677-46 29 0 Fax: +49-3677-46 29 29 Email: sales@medis.company Werner-von-Siemens-Str. 6 98693 Ilmenau, Germany www.medis.company</p>
Version	v6/2023	v5/2023
Source file	N1209-5_Package_v6-2023.svg	N1201-5_Package_v5-2023.svg

**Information to be  
changed for each LOT**

- LOT number
- Date of manufacture
- Use-by date
- UDI (data matrix and human-readable)

### 3.3 Box Label

Box label of ICG Sensors:

	ICG Sensor (N1209-5)	ICG Sensor (1201-5)
<b>Box Label</b>	<p>147 x 104 mm</p> <div style="border: 1px solid black; padding: 10px;"> <p><b>4TECT ICG Sensors Adult</b></p> <p>Einmal-ICG-Sensoren für Erwachsene                      Disposable ICG Sensors for adults                      Sensori ICG monouso per adulti                      Capteurs ICG à usage unique pour adultes                      Sensores ICG desechables para adultos                      Sensores de ICG descartáveis para adultos                      用于成人的一次性ICG传感器                      성인용 일회용 ICG 센서</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><b>Inhalt Contents</b> 50 x </p> <p>Ag/AgCl</p> <p style="text-align: center;"><b>MD</b></p> <p>Medizinprodukt Klasse I                      Medical device class I                      Dispositivo medico di classe I                      Dispositif médical de classe I                      Dispositivo médico de classe I                      Dispositivo médico classe I                      Ⅰ级医疗设备                      의료 기기 클래스 I</p> <p style="text-align: center;"><b>CE</b></p> <p><b>medis.</b>                      Medizinische Messtechnik GmbH                      Phone: +49-3677-46 29 0                      Fax: +49-3677-46 29 29                      Email: sales@medis.company                      Werner-von-Siemens-Str.8                      98693 Ilmenau, Germany                      www.medis.company</p> </div> <div style="width: 45%; text-align: right;"> <p><b>REF</b> N1209-5</p> <p><b>LOT</b> 230601</p> <p> 2023-06</p> <p> 2025-05</p> <p></p> <p>(01)04260667445248                      (11)230601                      (17)250531                      (10)230601</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 20%; font-size: 8px;">Rev. 3/2023</div> <div style="width: 60%; text-align: center;"> </div> <div style="width: 20%; font-size: 8px;">Rev. 4/2023</div> </div> </div>	<p>147 x 104 mm</p> <div style="border: 1px solid black; padding: 10px;"> <p><b>ICG Sensors Adult professional</b></p> <p>Einmal-ICG-Sensoren für Erwachsene                      Disposable ICG Sensors for adults                      Sensori ICG monouso per adulti                      Capteurs ICG à usage unique pour adultes                      Sensores ICG desechables para adultos                      Sensores de ICG descartáveis para adultos                      用于成人的一次性ICG传感器                      성인용 일회용 ICG 센서</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><b>Inhalt Contents</b> 50 x </p> <p>Ag/AgCl</p> <p style="text-align: center;"><b>MD</b></p> <p>Medizinprodukt Klasse I                      Medical device class I                      Dispositivo medico di classe I                      Dispositif médical de classe I                      Dispositivo médico de classe I                      Dispositivo médico classe I                      Ⅰ级医疗设备                      의료 기기 클래스 I</p> <p style="text-align: center;"><b>CE</b></p> <p><b>medis.</b>                      Medizinische Messtechnik GmbH                      Phone: +49-3677-46 29 0                      Fax: +49-3677-46 29 29                      Email: sales@medis.company                      Werner-von-Siemens-Str.8                      98693 Ilmenau, Germany                      www.medis.company</p> </div> <div style="width: 45%; text-align: right;"> <p><b>REF</b> N1201-5</p> <p><b>LOT</b> 231116</p> <p> 2023-11</p> <p> 2025-10</p> <p></p> <p>(01)04260667445200                      (11)231101                      (17)251031                      (10)231116</p> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 20%; font-size: 8px;">Rev. 3/2023</div> <div style="width: 60%; text-align: center;"> </div> <div style="width: 20%; font-size: 8px;">Rev. 4/2023</div> </div> </div>
<b>Version</b>	v3/2023	v4/2023
<b>Source files</b>	<a href="#">boxlabel_N1209-5_v3-2023.svg</a>	<a href="#">boxlabel_N1201-5_v4-2023.svg</a>
<b>Information to be changed for each LOT</b>	<ul style="list-style-type: none"> <li>• LOT number</li> <li>• Date of manufacture</li> <li>• Use-by date</li> <li>• UDI (data matrix and human-readable)</li> </ul>	

<p><b>Product description languages</b></p>	<p>de, en, it, fr, es, pt/pt-br, cn, ko</p>	<p>de, en, it, fr, es, pt/pt-br, cn, ko</p>
<p><b>Labeled box (example)</b></p>	 <p>Example of labeled box containing 50 pouches</p> <p><b>Note:</b> The image may show an older version of the box label and is for illustration purposes only. Always use the latest version of the box label!</p>	 <p>Example of labeled box containing 50 pouches</p> <p><b>Note:</b> The image may show an older version of the box label and is for illustration purposes only. Always use the latest version of the box label!</p>

## 4 Explanation of Used Symbols

Symbol	Comment
	Manufacturer
	Date of manufacture
	Use-by date
	Reference number
	Batch number
	Keep away from sunlight
	Keep dry
	Temperature limit
	Do not re-use
	Consult instruction for use
	Not contains or presence of natural rubber latex

Symbol	Comment
	<p>Medical device</p>
	<p>CE mark</p>