



**International  
Standard**

**ISO 5834-4**

**Implants for surgery — Ultra-high-  
molecular-weight polyethylene —**

**Part 4:  
Oxidation index measurement  
method**

*Implants chirurgicaux — Polyéthylène à très haute masse  
moléculaire —*

*Partie 4: Méthode de mesurage de l'indice d'oxydation*

**Third edition  
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ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This third edition cancels and replaces the second edition (ISO 5834-4:2019), which has been technically revised.

The main changes are as follows:

- the normative references have been updated;
- updates have been made to harmonize this document with ASTM F2102-17.

A list of all parts in the ISO 5834 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

This document describes a method for the measurement of the relative extent of oxidation present in ultra-high molecular weight polyethylene (UHMWPE) intended for use in surgical implants. The material is analysed by infrared spectroscopy. The intensity of the carbonyl absorptions ( $>C=O$ ) centred near  $1\,720\text{ cm}^{-1}$  is related to the amount of chemically bound oxygen present in the material. Other forms of chemically bound oxygen ( $R_1OR_2$ ,  $R_1OOR_2$ ,  $ROH$ , etc.) are not detected by this method.

Although this method provides the investigator with a means to compare the relative extent of carbonyl oxidation present in various UHMWPE specimens, it is recognized that other forms of chemically bound oxygen can be important contributors to characteristics of these materials.

The applicability of the infrared method has been demonstrated by many literature reports. This particular method, using the intensity (area) of the C-H absorption centred near  $1\,370\text{ cm}^{-1}$  to normalize for the specimen's thickness, has been validated by an interlaboratory study (ILS).



# Implants for surgery — Ultra-high-molecular-weight polyethylene —

## Part 4: Oxidation index measurement method

### 1 Scope

This document specifies a method for the measurement of the relative extent of oxidation present in ultra-high-molecular-weight polyethylene (UHMWPE) moulded forms or forms fabricated for use in the manufacture of surgical implants.

### 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5834-2, *Implants for surgery — Ultra-high molecular weight polyethylene — Part 2: Moulded forms*

ISO 21304-1, *Plastics — Ultra-high-molecular-weight polyethylene (PE-UHMW) moulding and extrusion materials — Part 1: Designation system and basis for specifications*

ISO 21304-2, *Plastics — Ultra-high-molecular-weight polyethylene (PE-UHMW) moulding and extrusion materials — Part 2: Preparation of test specimens and determination of properties*

ASTM F2102, *Standard Guide for Evaluating the Extent of Oxidation in Polyethylene Fabricated Forms Intended for Surgical Implants*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 21304-1, ISO 21304-2 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

#### 3.1 aperture size

$L_a$   
length and width of a rectangular aperture, or the diameter of a circular aperture used by an infrared spectrometer to make spectral measurements