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Standard Guide for Assessment of Surface Texture of Non-Porous Biomaterials in Two Dimensions¹

This standard is issued under the fixed designation F2791; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reappraisal. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reappraisal.

1. Scope

1.1 This guide describes some of the more common methods that are available for measuring the topographical features of a surface and provides an overview of the parameters that are used to quantify them. Being able to reliably derive a set of parameters that describe the texture of biomaterial surfaces is a key aspect in the manufacture of safe and effective implantable medical devices that have the potential to trigger an adverse biological reaction *in situ*.

1.2 This guide is not intended to apply to porous structures with average pore dimensions in excess of approximately ~~50 nm~~ 50 nm (0.05 μm).

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

~~C813~~ [C813 Test Method for Hydrophobic Contamination on Glass by Contact Angle Measurement](#)

~~F2312~~ [F2312 Terminology Relating to Tissue Engineered Medical Products](#)

~~F2450~~ [F2450 Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products](#)

~~F2664~~ [F2664 Guide for Assessing the Attachment of Cells to Biomaterial Surfaces by Physical Methods](#)

2.2 Other Standards:³

~~ISO 3274~~ [ISO 3274 Geometrical Product Specifications \(GPS\)—Surface Texture: Profile Method—Nominal Characteristics of Contact \(Stylus\) Instruments](#)

~~ISO 4287~~ [ISO 4287 Geometrical Product Specifications \(GPS\)—Surface Texture: Profile Method—Terms, Definitions and Surface Texture Parameters](#)

¹ This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.42 on Biomaterials and Biomolecules for TEMPs.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

- [ISO 4288 Geometrical Product Specifications \(GPS\)—Surface Texture: Profile Method—Rules and Procedures for the Assessment of Surface Texture](#)
- [ISO 5436-2 Geometrical Product Specifications \(GPS\)—Surface Texture: Profile Method; Measurement Standards—Part 2: Software Measurement Standards](#)
- [ISO 10993-19 Biological Evaluation of Medical Devices—Part 19: Physico-chemical, Morphological and Topographical Characterization of Materials](#)
- [ISO 12179 Geometrical Product Specifications \(GPS\)—Surface Texture: Profile Method—Calibration of Contact \(Stylus\) Instruments](#)
- [ISO 13565—ISO 13565-1 Geometrical Product Specifications \(GPS\)—Surface Texture: Profile Method—Surfaces Having Stratified Functional Properties; Filtering and General Measurement Conditions](#)
- [ISO 19606 Fine Ceramics \(Advanced Ceramics, Advanced Technical Ceramics\)—Test Method for Surface Roughness of Fine Ceramic Films by Atomic Force Microscopy](#)
- [ISO 21920-1 Geometrical Product Specifications \(GPS\)—Surface Texture: Profile—Part 1: Indication of Surface Texture](#)
- [ISO 21920-2 Geometrical Product Specifications \(GPS\)—Surface Texture: Profile—Part 2: Terms, Definitions and Surface Texture Parameters](#)
- [ISO 21920-3 Geometrical Product Specifications \(GPS\)—Surface Texture: Profile—Part 3: Specification Operators](#)
- [ISO 25178-1 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 1: Indication of Surface Texture](#)
- [ISO 25178-2 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 2: Terms, Definitions and Surface Texture Parameters](#)
- [ISO 25178-3 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 3: Specification Operators](#)
- [ISO 25178-6 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 6: Classification of Methods for Measuring Surface Texture](#)
- [ISO 25178-70 Geometrical Product Specification \(GPS\)—Surface Texture: Areal—Part 70: Material Measures](#)
- [ISO 25178-71 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 71: Software Measurement Standards](#)
- [ISO 25178-72 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 72: XML File Format x3p](#)
- [ISO 25178-73 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 73: Terms and Definitions for Surface Defects on Material Measures](#)
- [ISO 25178-600 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 600: Metrological Characteristics for Areal Topography Measuring Methods](#)
- [ISO 25178-601 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 601: Nominal Characteristics of Contact \(Stylus\) Instruments](#)
- [ISO 25178-602 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 602: Nominal Characteristics of Non-Contact \(Confocal Chromatic Probe\) Instruments](#)
- [ISO 25178-603 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 603: Nominal Characteristics of Non-Contact \(Phase-Shifting Interferometric Microscopy\) Instruments](#)
- [ISO 25178-604 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 604: Nominal Characteristics of Non-Contact \(Coherence Scanning Interferometry\) Instruments](#)
- [ISO 25178-605 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 605: Nominal Characteristics of Non-Contact \(Point Autofocus Probe\) Instruments](#)
- [ISO 25178-606 Geometrical Product Specification \(GPS\)—Surface Texture: Areal—Part 606: Nominal Characteristics of Non-Contact \(Focus Variation\) Instruments](#)
- [ISO 25178-607 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 607: Nominal Characteristics of Non-Contact \(Confocal Microscopy\) Instruments](#)
- [ISO 25178-700 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 700: Calibration, Adjustment and Verification of Areal Topography Measuring Instruments](#)
- [ISO 25178-701 Geometrical Product Specifications \(GPS\)—Surface Texture: Areal—Part 701: Calibration and Measurement Standards for Contact \(Stylus\) Instruments](#)

3. Terminology

3.1 *Definitions of Terms Specific to This Standard: Definitions:*

3.1.1 *biomaterial, n*—any substance (other than a drug), synthetic or natural, that can be used as a system or part of a system that treats, augments, or replaces any tissue, organ, or function of the body. **F2664F2312**

3.1.2 *evaluation length, l_n , n*—length in the direction of the x -axis used to assess for assessing the profile under evaluation.

3.1.2.1 *Discussion—*

The evaluation length may contain one or more sampling lengths.

ISO 4287

3.1.3 *hydrophilic, adj*—having a strong affinity for water; wettable.

3.1.3.1 *Discussion*—

Hydrophilic surfaces exhibit zero contact angles.

C813

3.1.4 *hydrophobic, adj*—having little affinity for water; nonwetable.

3.1.4.1 *Discussion*—

Hydrophobic surfaces exhibit contact angles appreciably greater than zero: generally greater than 45° for the advancing angle.

C813

3.1.5 *implant, n*—~~a substance in medicine, or object that is put in the body as a prosthesis, or for treatment or diagnosis~~ an object, structure, or device intended to reside within the body for diagnostic, prosthetic, or other therapeutic purposes.

F2664

3.1.6 *lay, n*—~~the direction of the predominant surface pattern.~~ ISO 13565-1

3.1.6 *primary profile, n*—~~the total~~ profile after application of the short wavelength filters. ISO 3274

3.1.7 *profile peak, n*—an outwardly directed (from the material to the surrounding medium) portion of the assessed profile connecting two adjacent points of the intersection of the profile with the *x*-axis. ISO 4287

3.1.8 *profile valley, n*—an inwardly directed (from surrounding medium to material) portion of the assessed profile connecting two adjacent points of the intersection of the assessed profile with the *x*-axis. ISO 4287

3.1.9 *real surface, n*—~~surface limiting the of a workpiece, body and separating it~~ a set of features which physically exist and separate the entire workpiece from the surrounding medium. ISO 4287 ISO 25178-600

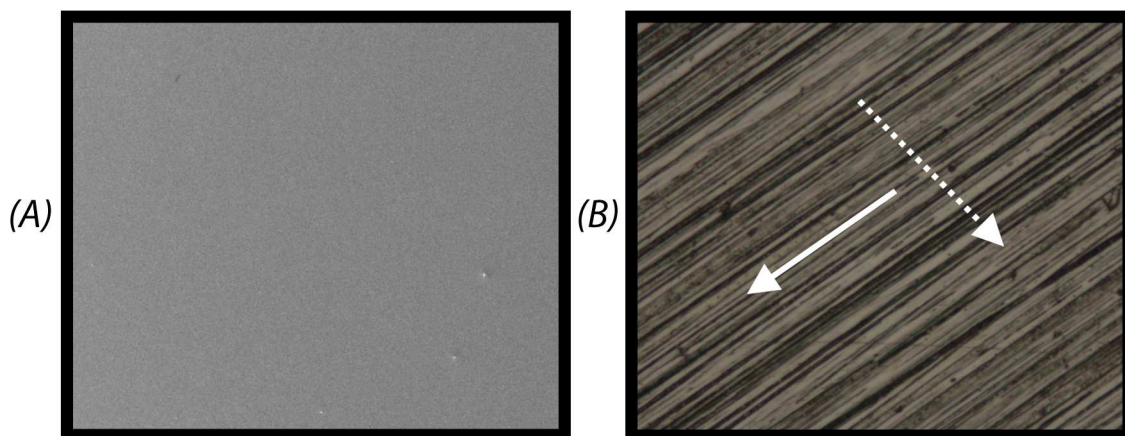
3.1.10 *sampling length, *l_r*, n*—length in the direction of the *x*-axis used for identifying the irregularities characterizing the profile under evaluation. ISO 4287

3.1.11 *scaffold, n*—~~a support, delivery vehicle or matrix~~ vehicle, or matrix for facilitating the migration, binding, or transport of cells or bioactive molecules used to replace, repair, or regenerate tissues. F2450 F2312

3.1.12 *surface profile, n*—profile that results from the intersection of the real surface by a specified plane. ISO 4287

3.1.12.1 *Discussion*—

In practice, it is usual to choose a plane with a normal that nominally lies parallel to the real surface and in a suitable direction. ISO 4287



NOTE 1—The surface shown in (A) has no directionality or lay, therefore, profiles can be oriented at any angle. Profiles (dashed line arrow) are drawn perpendicular to the lay (solid line arrow) in surfaces that have directionality (B).

FIG. 1 Profile Orientation and Surface Features

3.1.13 *surface texture, n*—irregularities on a surface (peaks and valleys) produced by the forming process.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *lay, n*—the direction of the predominant surface pattern.

4. Significance and Use

4.1 The term “surface texture” is used to describe the local deviations of a surface from an ideal shape. Surface texture usually consists of long wavelength repetitive features that occur as results of chatter, vibration, or heat treatments during the manufacture of implants. Short wavelength features superimposed on the long wavelength features of the surface, which may arise from polishing or etching of the implant, are referred to as roughness.

4.2 This guide provides an overview of techniques that are available for measuring the surface in terms of Cartesian coordinates and the parameters used to describe surface texture. It is important to appreciate that it is not possible to measure surface texture per se, but to derive values for parameters that can be used to describe it. ISO has published a series of standards on surface texture measurements that may be consulted for more information (ISO 3274, ISO 4287, ISO 4288, ISO 5436-2, ISO 10993-19, ISO 12179, ISO 13565-1, ISO 19606, ISO 21920-1, ISO 21920-2, ISO 21920-3, ISO 25178-1, ISO 25178-2, ISO 25178-3, ISO 25178-6, ISO 25178-70, ISO 25178-71, ISO 25178-72, ISO 25178-73, ISO 25178-600, ISO 25178-601, ISO 25178-602, ISO 25178-603, ISO 25178-604, ISO 25178-605, ISO 25178-606, ISO 25178-607, ISO 25178-700, ISO 25178-701).

5. The Relationship Between Surface Texture, Surface Chemistry, Surface Energy, and Biocompatibility

5.1 The biocompatibility of materials is influenced by many factors such as size, shape, material bulk, and surface chemical composition, surface energy, and surface ~~topography~~ topography (ISO 10993-19). Changing any one of these related characteristics of a biocompatible material can have a significant effect on cell behavior. The response of a cell to a biomaterial can be assessed by measuring the adhesive strength between it and the underlying surface, monitoring changes in its shape or in the expression of biomarkers.

5.2 The chemical species present on a surface can be mapped in detail using surface sensitive analysis techniques (for example, X-ray photoelectron spectroscopy where the penetration depth is 10 nm or below **(1)**).⁴ The chemical species present on the surface together with the surface topography determine how hydrophilic the surface is. Measuring the contact angle between the surface and a fluid, usually water, can assess the degree of hydrophilicity of a surface. Care should be taken when comparing contact angle measurements made on different surfaces, as the relative contributions from the surface chemistry and texture are unlikely to be the same.

6. Surfaces and Surface Profiles

6.1 Conventionally, surfaces are described in Cartesian coordinates where the *x*-axis is defined as being perpendicular to the lay direction. The *y*-axis is in-plane and is perpendicular to the *x*-axis direction. The *z*-axis is out of plane. The profile of a surface that has a uniform, non-directional texture can be measured at any in-plane orientation (see Fig. 1(A)); however, several profiles at different orientations should be measured to find the maximum amplitude (see Fig. 1(A)). For patterned surfaces that have periodic features, a lay, the orientation of the profile is at right angles to it (see Fig. 1(B)).

6.2 The measured surface is composed of three components: form, waviness, and roughness. The form corresponds to the underlying shape and tilt of the surface with respect to the measuring platform. The software packages used for surface texture analysis all have a methodology for removing the form from the surface. The “corrected” surface can then be used to obtain a ~~2-D~~ **2D** profile that describes the surface texture. This profile after removal of form is defined according to ISO 3274 as the primary profile. The stages involved in the analysis of the measured profile through primary profile to the roughness profile are shown in Fig. 2.

7. Filtering and the Cut-Off Wavelength

7.1 Surface data can be filtered to remove unwanted noise or to remove texture information at unwanted wavelengths. Filters are

⁴ The boldface numbers in parentheses refer to a list of references at the end of this standard.

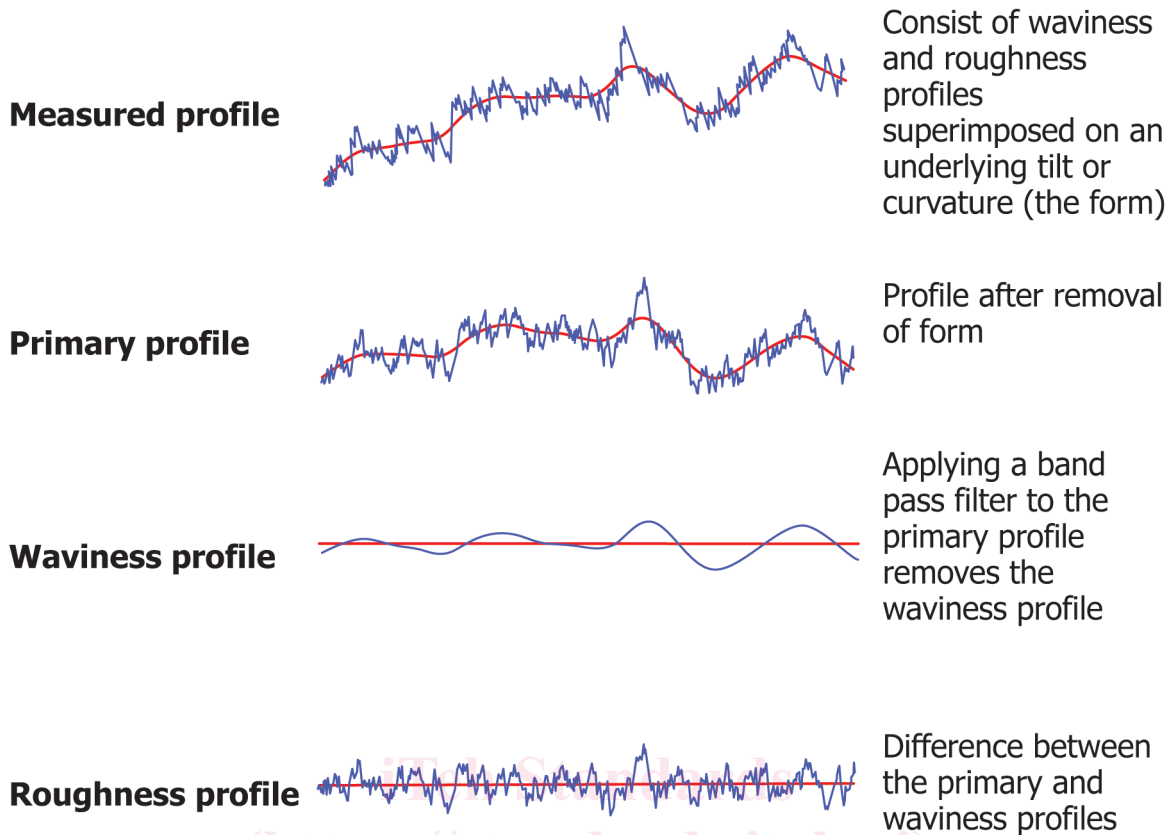


FIG. 2 Summary of Stages Involved in Analysis of Measured Profile to Obtain a Roughness Profile

classified according to the spatial periodicity that they allow to pass through; low-pass filters admit long wavelengths and reject short ones; high-pass filters do the opposite. Band-pass filters, as the name implies, allow a limited range of wavelengths to pass. In practice, using filters can create problems in deciding how much of the noise in the measurements is “real” and how much can be attributed to the surface. It should be noted that some aspects of the surface are not faithfully reproduced due to limitations of the measurement method, for example, an inability to track the sides of steep valleys that is in essence a form of filtering. This topic is further discussed in Section 11.

7.2 Filters used in surface texture measurements do not have a sharp cut-off in spatial frequency above or below which information is rejected. This gradual attenuation of high or low spatial frequency data helps avoid distortion of the measurements that can occur when strong features are close to the filtration limits. The point on the transmission curve at which the transmitted signal is reduced to 50 % is referred to as the cut-off wavelength, λ_c , of the filter (Fig. 3). For measurements made using a stylus instrument (Section 11), the choice of λ_c depends on the sampling frequency and the speed at which the stylus moves over the surface. For example, measurements made at intervals of 0.01 mm from a device moving at 1 mms^{-1} will generate data at a frequency of 100 Hz. Increasing the sampling interval to 0.1 mm will reduce the frequency at which data are obtained to 10 Hz. A high-pass filter that suppresses all frequencies below 10 Hz effectively removes any surface irregularities larger than 0.1 mm spacing from the data. Hence, filters can be used to bias the experimental data towards detecting profile (surface texture after applying a low-pass to filter the data), waviness (after applying a band-pass filter), and roughness (after applying a high-pass filter). Measurement conditions are set for filters according to the respective values of the sampling interval, measurement speed, and filtration limits, according to ISO 3274.

7.3 ISO 4287 specifies that 2D roughness parameters need to be determined over five sequential sampling lengths, l_r , unless otherwise specified. This grouping of five serial sampling lengths is referred to as the evaluation length, l_n . The sampling length varies according to the length scale of the texture being assessed; larger features require a long sampling length. Guidance as to which sampling length to use for a given range of feature sizes is shown in Table 1.

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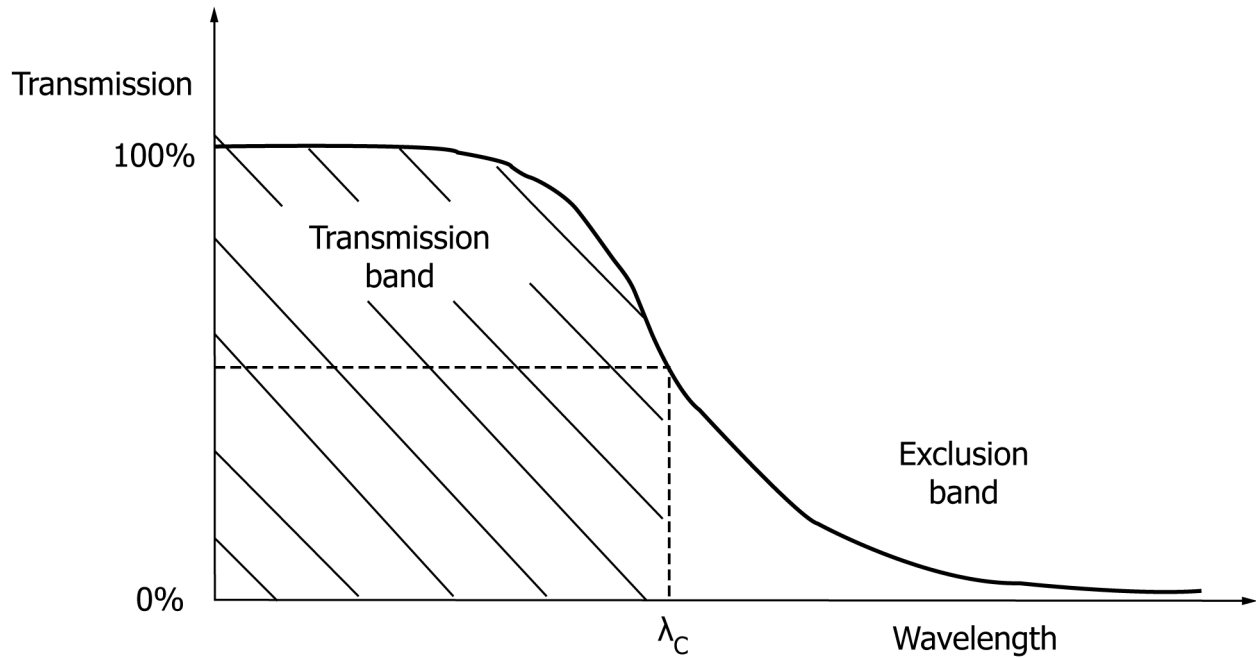


FIG. 3 50 % Reduction in Transmission Curve

TABLE 1 Guide to Choosing Sampling Lengths for the Measurement of Periodic Profiles^A

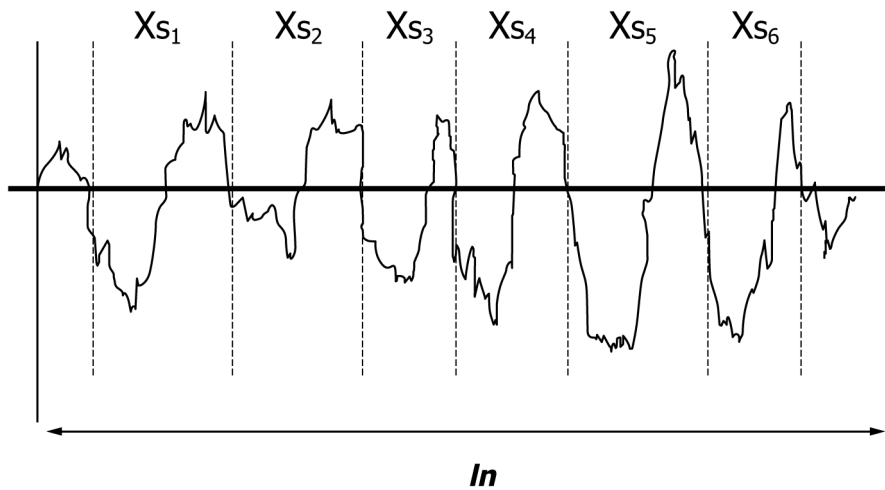
Mean profile element width, RSm (μm)	Sampling length, lr (μm)
$13 < RSm \leq 40$	80
$40 < RSm \leq 130$	250
$130 < RSm \leq 400$	800
$400 < RSm \leq 1300$	2500
$1300 < RSm \leq 4000$	8000

^ABased on ISO 4288. The evaluation length is usually taken to be five times the sampling length.

ASTM F2791-24

<https://standards.iteh.ai/catalog/standards/astm/ce3457c4-8b59-41ad-a5e9-9317e1f76481/astm-f2791-24>

iterations to identify the best value for lr . This can be achieved by calculating the mean width of a profile element, RSm (see Fig. 4), from a measured profile where the value for lr is based on a best guess. This initial iteration will enable a new value for RSm to be determined and that leads to a potential revision of lr according to Table 1.



NOTE 1—The sum of each peak and adjacent valley, Xs_i is RSm .

FIG. 4 Mean Width of Profile Elements Over the Evaluation Length