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Standard Guide for Assessment of Surface Texture of Non-Porous Biomaterials in Two Dimensions[1]

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 reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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 (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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

C813 Test Method for Hydrophobic Contamination on Glass by Contact Angle Measurement

F2312 Terminology Relating to Tissue Engineered Medical Products

F2450 Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue-Engineered Medical Products

F2664 Guide for Assessing the Attachment of Cells to Biomaterial Surfaces by Physical Methods

2.2 *Other Standards:*[3]

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

ISO 4287 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Terms, Definitions and Surface Texture Parameters

ISO 4288 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Rules and Procedures for the Assessment of Surface Texture

ISO 13565–1 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Surfaces Having Stratified Functional Properties; Filtering and General Measurement Conditions

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

~~3.1.1 *biocompatible, adj*—a material may be considered biocompatible if the materials perform with an appropriate host response in a specific application. F2312~~

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. **F2664**

[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.

3.1.2 *evaluation length, ln, n*—length in the direction of the *x*-axis used to assess 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; nonwettable.

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 or object that is put in the body as a prosthesis, or for treatment or diagnosis. **F2664**

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

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

3.1.8 *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**

3.1.9 *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**

3.1.10 *real surface, n*—surface limiting the body and separating it from the surrounding medium. **ISO 4287**

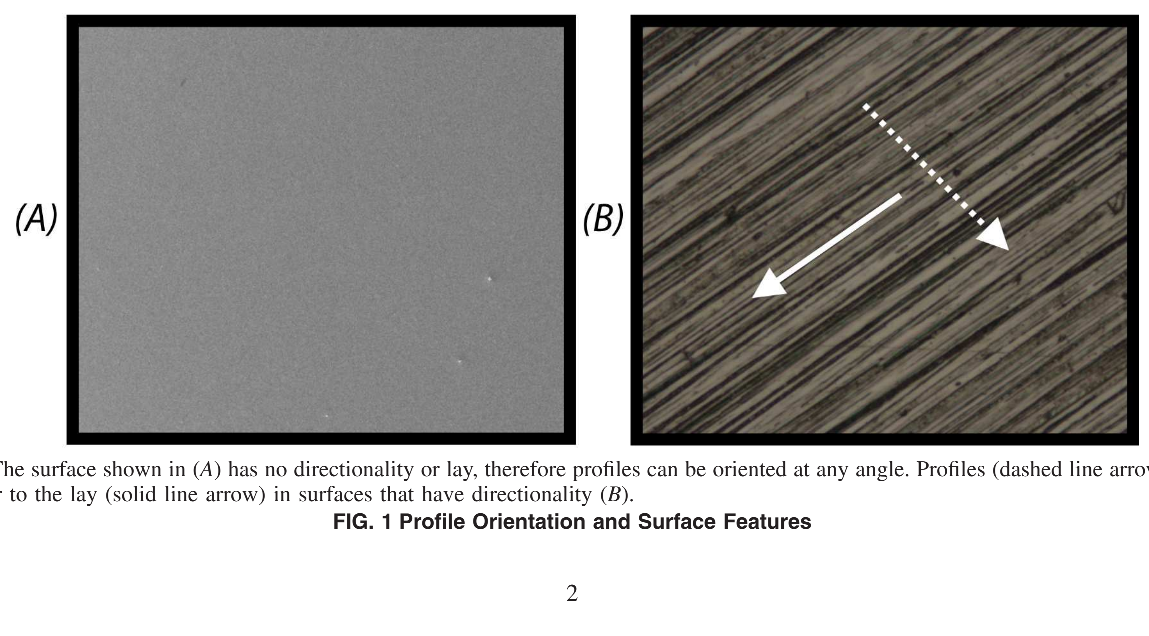
3.1.11 *sampling length, lr, n*—length in the direction of the *x*-axis used for identifying the irregularities characterizing the profile under evaluation. **ISO 4287**

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

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

3.1.13.1 *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

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 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.

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. 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~~ 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~~ 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 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 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, λc, of the ~~filter,~~ filter (Fig. 3~~.~~). For measurements made using a stylus instrument (Section 11), the choice of λc 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.

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

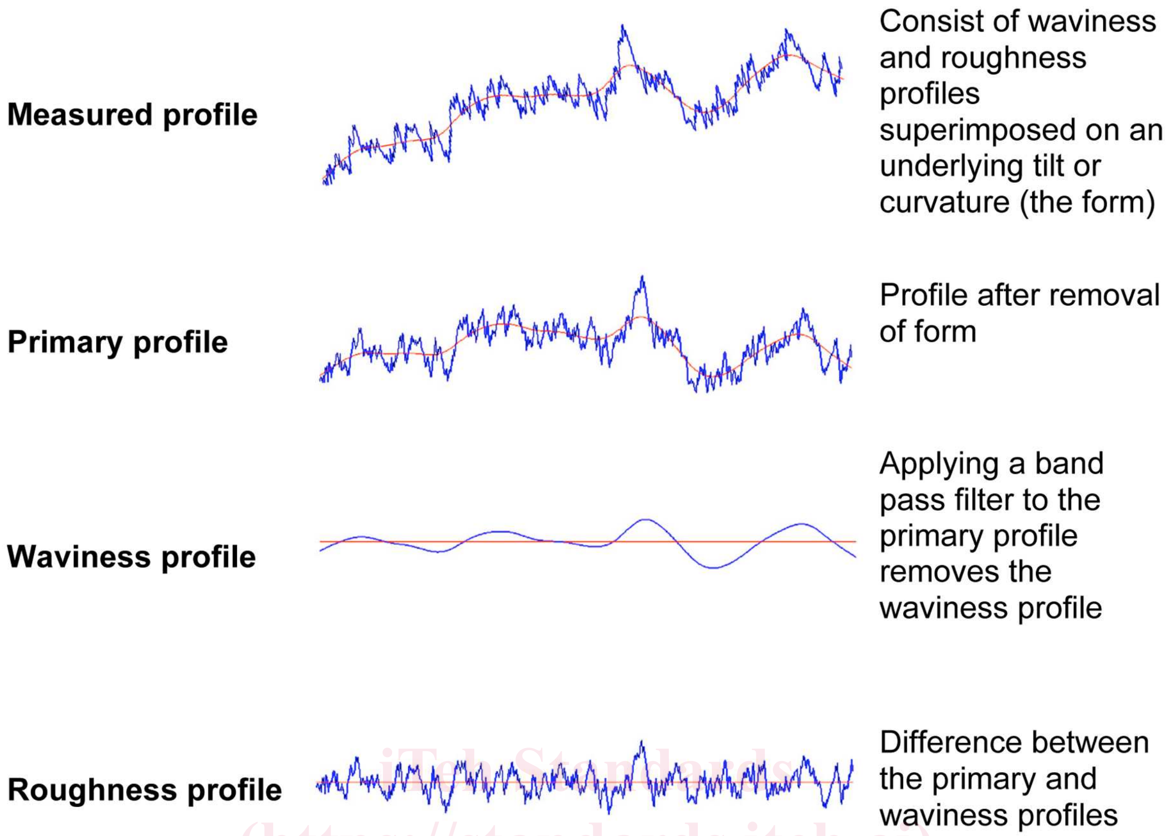


FIG. 2 Summary of Stages Involved in Analysis of Measured Profile to Obtain a Roughness Profile

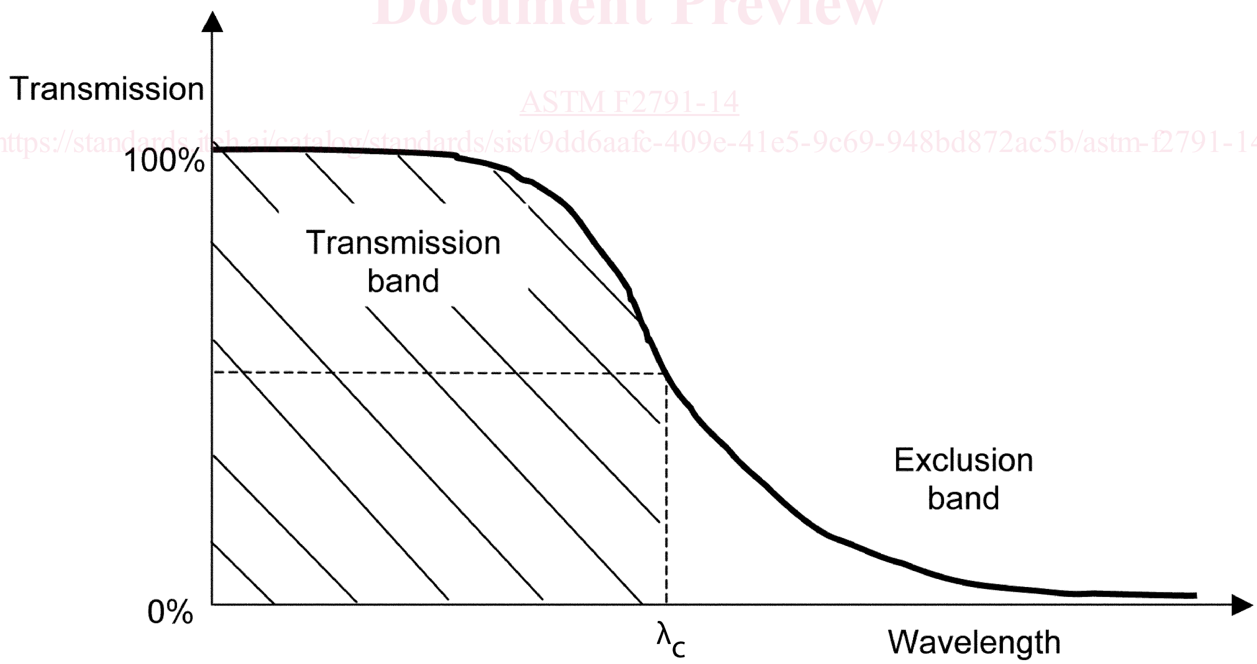


FIG. 3 50 % Reduction in Transmission Curve

7.3 ISO 4287 specifies that 2-D roughness parameters need to be determined over five sequential sampling lengths, *lr*, unless otherwise specified. This grouping of five serial sampling lengths is referred to as the evaluation length, *ln*. 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. It may be necessary to perform one or more

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

~~NOTE 1—Based on ISO 4288. The evaluation length is usually taken to be five times the sampling length.~~

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

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* ≤ 40	80
40 < *RSm* ≤ 130	250
130 < *RSm* ≤ 400	800
400 < *RSm* ≤ 1300	2500
1300 < *RSm* ≤ 4000	8000

[A]Based on ISO 4288. The evaluation length is usually taken to be five times the sampling length.

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.

8. Quantification of Surface Profiles

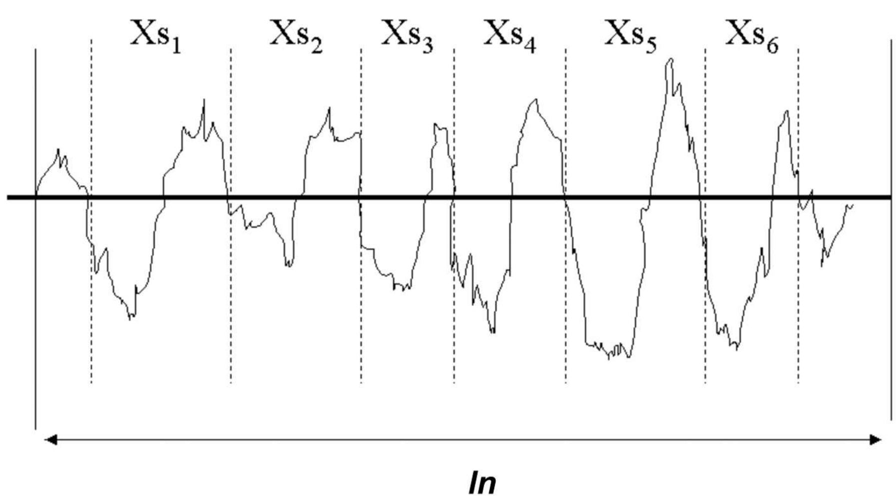
8.1 Parameters that are used to characterize 2-D surface profiles are grouped as:

8.1.1 Amplitude parameters, which are measures of variations in profile height. These parameters are split into two subclasses: averaging parameters, and peak and valley parameters;

8.1.2 Spatial parameters, which describe in-plane variations of surface texture; and

8.1.3 Hybrid parameters, which combine both amplitude and spatial ~~information, for~~information (for example, mean ~~slope.~~slope).

8.2 *Ra*—The most widely used parameter to quantify surface texture is the arithmetical mean deviation of the absolute ordinate values, *Z(x)*, of the profile from a center line (see Table 2 and Fig. 5). Despite its common usage, *Ra* does not provide a truly accurate representation of a surface profile since any information regarding peak heights or valley depths can be lost in its derivation. This insensitivity to surface texture is apparent in Fig. 6, which shows that quite different profiles can have the same *Ra* value. The statistical significance of *Ra* is improved by averaging the values obtained for each of the five sampling lengths.

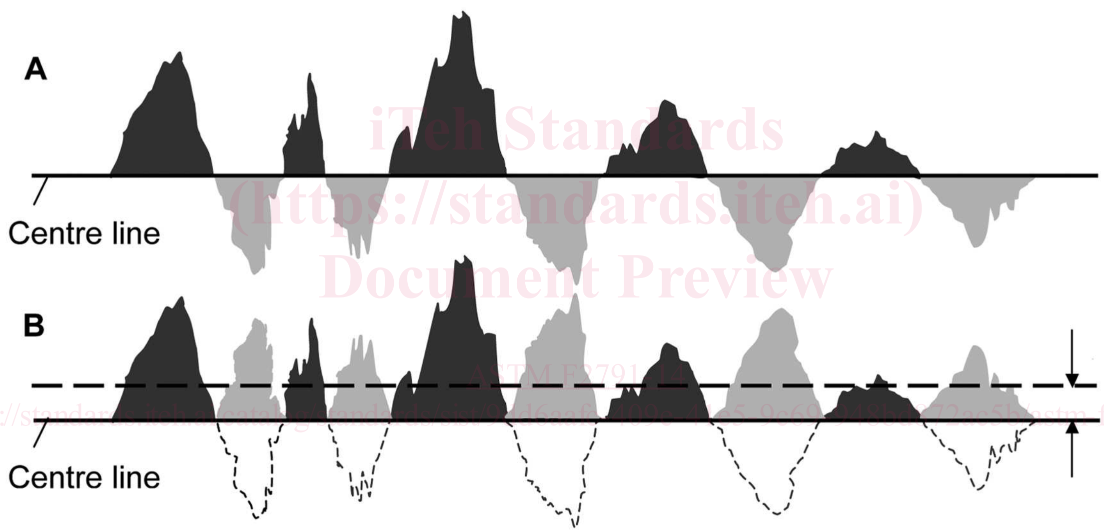


NOTE 1—The sum of each peak and adjacent valley, Xs_i is *RSm*.

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

TABLE 2 A Summary of Commonly Used Parameters for Quantifying 2-D Roughness Profiles

~~Type of Parameter~~	~~Parameter~~	~~Definition~~	
<u>Type of Parameter</u>	<u>Parameter</u>	<u>Definition</u>	
~~Amplitude (Average of ordinates)~~	~~*Ra*~~	~~Arithmetic mean deviation of the absolute ordinate value from a mean line.~~	
	<u>Amplitude (Average of cordinates)</u>	<u>*Ra*</u>	<u>Arithmetic m</u> <u>a mean line</u>
		Rq	Root-mean a midline.
		Rsk	A measure across a su
Rku		A measure of the similarity of the distribution of measured peaks and valleys to a Gaussian distribution (kurtosis).	
Amplitude (Peak and valley)	*Rp*	Maximum profile height above a mean line.	
	Rv	Maximum profile depth below a mean line.	
	Rz	Difference between *Rp* and *Rv*.	
	Rc	The mean value of the profile element widths within a sampling length.	
	Rt	The total height of profile.	
Spatial	*RSm*	The mean value of the profile element widths within a sampling length.	
Hybrid	*R*Δ*q*	The root mean square slope, *dz/dx*, over the length of the profile at a location *y* on the surface.	



NOTE 1—(*A*) Averaging the peaks and valleys in measured profile data over each sampling length is used to identify a midline. (*B*) The "valleys" are inverted to form "peaks" and averaged with existing peaks to obtain *Ra*, the arithmetic mean deviation from the midline.

FIG. 5 Derivation of *Ra*

8.3 *Rq*—The root-mean-square value of all distances of the measured profile away from the center line, *Rq*, although similar in terms of its derivation to *Ra*, has a subtle but significant difference. The deviations of the peak heights and valley depths from the midline appear as a squared term in *Rq*. That increases its sensitivity to high peaks or deep valleys. This sensitivity can be useful, but it should be noted that the presence of a foreign body, for example, hair or a scratch in the surface can have a significant influence on the value of *Rq*.

8.4 *Rsk*—Skewness, the distribution of peak heights and valley depths provides valuable information about surface texture. A surface that has a range of peak heights and valley depths will have a bell-shaped probability distribution centered on the mean. The dimensionless skewness parameter, *Rsk*, is used to quantify bias in the shape of this distribution. The skewness of a perfectly random surface with a wide range of peak heights and valley depths is zero. If the surface has more valleys than peaks then the distribution will skew away from the ideal distribution producing negative values of skewness. The converse will be true for a surface that has more peaks than valleys.

8.5 *Rku*—Kurtosis is a statistical measure of the sharpness of a distribution of peak heights and valley depths. Specifically, kurtosis is a means of quantifying the similarity of the measured profile with a Gaussian distribution characteristic of a perfectly random distribution of peak heights and valley depths.

8.6 *Rp*—The largest profile peak height above the mean line within the sampling length. This is not an averaging parameter.