Designation: F 2129 – 01

Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices[1]

This standard is issued under the fixed designation F 2129; 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 test method assesses the corrosion susceptibility of small, metallic, implant medical devices, or components thereof, using cyclic (forward and reverse) potentiodynamic polarization. Examples of device types, which may be evaluated by this test method include, but are not limited to, vascular stents, filters, support segments of endovascular grafts, cardiac occluders, aneurysm or ligation clips, staples, and so forth.

1.2 This test method is used to assess a device in its final form and finish, as it would be implanted. These small devices should be tested in their entirety. The upper limit on device size is dictated by the electrical current delivery capability of the test apparatus (see Section 6). It is assumed that test methods, such as Test Methods G 5 and G 61 have been used for material screening.

1.3 Because of the variety of configurations and sizes of implants, this test method provides a variety of specimen holder configurations.

1.4 This test method is intended for use on implantable devices made from metals with a relatively high resistance to corrosion.

1.5 *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:*

D 1193 Specification for Reagent Water[2]

G 3 Practice for Conventions Applicable to Electrochemical Measurements in Corrosion Testing[3]

G 5 Reference Test Method for Making Potentiostatic and Potentiodynamic Anodic Polarization Measurements[3]

G 15 Terminology Relating to Corrosion and Corrosion Testing[3]

G 61 Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements for Localized Corrosion Susceptibility of Iron-, Nickel-, or Cobalt-Based Alloys[3]

G 102 Practice for Calculation of Corrosion Rates and Related Information from Electrochemical Measurements[3]

3. Terminology

3.1 *Definitions:*

3.1.1 *potentiostat, n*—an instrument for automatically maintaining an electrode in an electrolyte at a constant potential or controlled potentials with respect to a suitable reference electrode (see Terminology G 15).

3.1.2 *potentiodynamic cyclic polarization (forward and reverse polarization), n*—a technique in which the potential of the test specimen is controlled and the corrosion current measured by a potentiostat. The potential is scanned in the positive or noble (forward) direction as defined in Practice G 3. The potential scan is continued until a predetermined potential or current density is reached. Typically, the scan is run until the transpassive region is reached, and the specimen no longer demonstrates passivity, as defined in Practice G 3. The potential scan direction then is reversed until the specimen repassivates or the potential reaches a preset value.

3.1.3 *scan rate, n*—the rate at which the controlling voltage is changed.

3.2 *Symbols:*

3.2.1 E_b = *Breakdown or Critical Pitting Potential*—the least noble potential at which pitting or crevice corrosion or both will initiate and propagate as defined in Terminology G 15. An increase in the resistance to pitting corrosion is associated with an increase in E_b.

3.2.2 E_{corr} or *OCP*—the potential of a corroding surface in an electrolyte relative to a reference electrode measured under open-circuit conditions, as defined in Terminology G 15.

3.2.3 E_f = *Final Potential*—a preset potential at which the scan is stopped.

3.2.4 E_i = *Initial Potential*—the potential at which the potentiostat begins the controlled potentiodynamic scan.

3.2.5 E_p = *Protection Potential*—the potential at which the reverse scan intersects the forward scan at a value that is less noble than E_b. E_p cannot be determined if there is no breakdown. Whereas, pitting will occur on a pit-free surface

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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[2] *Annual Book of ASTM Standards*, Vol 11.01.

[3] *Annual Book of ASTM Standards*, Vol 03.02.

above E_b, it will occur only in the range of potentials between E_p and E_b if the surface is already pitted. The severity of crevice corrosion susceptibility increases with increasing hysteresis of the polarization curve, the difference between E_b and E_p.

3.2.6 E_v = *Vertex Potential*—a preset potential, at which the scan direction is reversed.

3.2.7 i_{corr} = *Corrosion Current Density (mA/cm^2)*—the corrosion current density is extrapolated from the anodic and cathodic Tafel regions to the OCP (in accordance with Practice G 102).

3.2.8 i_t = *Threshold Current Density (mA/cm^2)*—a preset current density, at which the scan direction is reversed. Typically, the scan is reversed when a current density two decades higher than the current density at the breakdown potential (E_b) is reached.

4. Summary of Test Method

4.1 The device is placed in an appropriate deaerated simulated physiological solution and the corrosion potential (E_{corr}) is monitored for 1 h. The potentiodynamic scan is then started at an initial potential (E_i) 100 mV more negative than E_{corr}, and scanned in the positive or noble (forward) direction. The scan is reversed after the current density has reached a value approximately two decades greater than the current density measured at the breakdown potential. The reverse scan is stopped after the current has become less than that in the forward direction or the potential is 100 mV negative to E_{corr}. The data is plotted with the current density in mA/cm^2 on the *x* axis (logarithmic axis) versus the potential in mV on the *y* axis (linear axis). Appropriate reference medical devices in their final form and finish, as they would be implanted, are used as controls.

5. Significance and Use

5.1 Corrosion of implantable medical devices can have deleterious effects on the device performance or may result in the release of corrosion products with harmful biological consequences; therefore, it is important to determine the general corrosion behavior as well as the susceptibility of the devices to localized corrosion.

5.2 The forming and finishing steps used to create an implantable device may have significant effects on the corrosion resistance of the material out of which the device is fabricated. While testing the corrosion resistance of the materials is essential in the process of selecting materials to be used, it does not necessarily provide critical data regarding device performance.

5.3 To accommodate the wide variety of device shapes and sizes encountered, a variety of holding devices can be used.

5.4 Note that the method is intentionally designed to reach conditions that are sufficiently severe to cause breakdown and deterioration of the medical devices and that these conditions may not be necessarily encountered in vivo. The results of this corrosion test conducted in artificial physiological electrolytes can provide useful data for comparison of different device materials, designs, or manufacturing processes. However, note that this test method does not take into account the effects of cells, proteins, and so forth on the corrosion behavior in vivo.

6. Apparatus

6.1 *Potentiostat*, capable of maintaining an electrode potential within 1 mV of a preset value over a wide range of potentials, as described in Test Methods G 5 and G 61. The potential measuring circuit should have a high input impedance, that is, on the order of 10^{11} to 10^{14} Ω. The current measuring circuit should be capable of measuring current in the range of 1.0 to 10^5 µA.

6.2 *Working Electrode*, to be used as the test specimen. Its configuration and holder will depend on the type of specimen being tested, as described in Section 7. In all cases, the metallurgical and surface condition of a specimen simulating a device must be in the same condition as the device.

6.2.1 An appropriate reference medical device in its final form and finish, as it would be implanted, should be used as a reference or control. Appropriate reference device shall consist of a device, which is similar to the investigated device and has a history of good corrosion resistance in vivo, is used in a similar environment or location and is used to treat a similar disease. Again, as for the working electrode, the configuration and holder will depend on the type of reference specimen tested.

6.3 *Reference Electrode*—A saturated calomel electrode (SCE), as defined in Practice G 3, shall be used as a reference electrode.

6.4 *Salt Bridge*, such as a Luggin probe, shall be used between the working and reference electrode, such as the type shown in Test Method G 5.

6.5 *Auxiliary Electrodes*:

6.5.1 Two platinum auxiliary electrodes may be prepared from high-purity rod stock. The surfaces may be platinized, as per Test Method G 5.

6.5.2 Alternatively, high-purity graphite auxiliary electrodes may be used in accordance with Test Method G 5. Care should be taken to insure that they do not get contaminated during a test.

6.5.3 The auxiliary electrode surface area should be at least four times greater than the sample surface area. Use of wire-mesh platinum might be more cost-effective than platinum cylinders when testing larger specimens or whole devices.

6.6 *Suitable Polarization Cell*, with a volume of about 1000 cm^3, equivalent to or similar to that recommended in Test Method G 5.

6.7 *Water Bath*, or other heating appliance capable of maintaining the test solution temperature at 37 ± 1°C.

6.8 *Purge Gas Delivery System*, capable of delivering nitrogen gas at 150 cm^3/min.

7. Specimen Holders

7.1 There are a variety of holders that may be used in this practice. Each is designed for a specific type or class of device.

7.2 Short wire or coil specimens.

7.2.1 Specimens can be held suspended from a clamping device. For example, the threaded end of a Test Method G 5 holder can be used to hold two stainless steel nuts. The wire test specimen is clamped between these nuts and bent so as to enter the test solution.

7.2.2 The surface area of the test specimen shall be calculated based on the length of wire or coil immersed in the test solution.

7.2.3 This type of holder exposes the specimen to the air-liquid interface, which is subject to localized crevice corrosion. Test specimens should be examined carefully after testing to ensure that there is no localized corrosion at or just below the interface.

7.2.4 If specimens show evidence of localized corrosion at the air-liquid interface, then the portion of the specimen passing across this interface shall be sealed with an impervious coating.

7.3 Stents or cylindrical devices.

7.3.1 Fixture for holding stents **(1)**[4] or alternative methods can be used to create an electrical connection.

7.3.2 The fixture consists of a cylindrical mandrel of the shape shown in Fig. 1.

7.3.3 The larger diameter end of the mandrel has a recessed thread that will accommodate a standard electrode holder described in Test Method G 5. The smaller diameter end of the mandrel is machined to the maximum internal diameter of the stent to be mounted on it.

7.3.4 The stent is stress fit over the smaller end of the cylindrical mandrel.

7.3.5 A conductive epoxy then is used to bind the stress fit stent to the mandrel to obtain good electrical contact. This interface is sealed by applying a nonconductive masking agent over the interface. The whole fixture then is threaded on to an electrode holder in accordance with Test Method G 5.

7.3.6 The surface area of the specimen shall be calculated based on the surface area of the stent in contact with the test solution.

8. Reagents

8.1 Reagent grade chemicals shall be used for this test method. Such reagents shall conform to the specifications of the Committee on Analytical Reagents of the American Chemical Society.[5]

8.1.1 The water shall be distilled or deionized conforming to the purity requirements of Specification D 1193, Type IV reagent water.

8.1.2 The standard test solution should be prepared according to the specifications. As a reference, a list of common physiological solutions and their composition is provided in Appendix X2.

8.1.3 The pH of the electrolyte should be adjusted based on the nature of the solution by the addition of NaOH or HCl.

8.1.4 High-purity nitrogen gas for purge should be used when possible depending on the nature of the solution used. Gas purge may not be appropriate for simulated solutions that tend to foam excessively when agitated.

9. Test Specimen

9.1 Unless otherwise justified, all samples selected for testing should be taken from finished, clinical-quality product. Cosmetic rejects or other nonclinical samples may be used if the cause for rejection does not affect the corrosion behavior of the device. Sterilization may be omitted if it can be demonstrated that prior sterilization has no effect on the corrosion behavior of the device.

9.2 Surrogate devices used for design parameter studies should be prepared with the same processes and should have the same mechanical and electrochemical surface characteristics as the intended finished device.

10. Procedure

10.1 Prepare the specimen such that the portion exposed to the test solution is in the same metallurgical and surface condition as the implantable form of the medical device being studied.

10.1.1 Calculate the total surface area of the specimen exposed to the solution in order to determine the current

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

[5] *Reagent Chemicals, American Chemical Society Specifications*, American Chemical Society, Washington, DC. For suggestions on the testing of reagents not listed by the American Chemical Society, see *Analar Standards for Laboratory Chemicals*, BDH Ltd., Poole, Dorset, U.K., and the *United States Pharmacopeia and National Formulary*, U.S. Pharmacopeial Convention, Inc. (USPC), Rockville, MD.

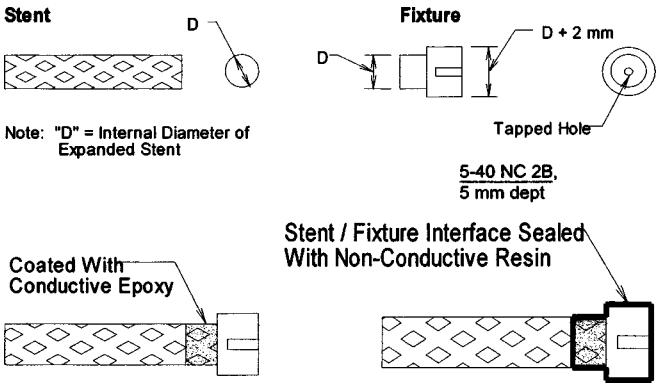

FIG. 1 Diagram for Assembly of Stent-Holding Fixture

density (current per surface area) generated by the specimen during the test.

10.2 Prepare enough test solution to immerse the device and auxiliary electrodes and so to avoid any appreciable change in the solution corrosivity during the test through exhaustion of the corrosive constituents or by accumulation of corrosion products that may affect further corrosion. At a minimum, transfer 500 mL of electrolyte to a clean polarization cell. Measure and record the pH of the solution before and after each test.

10.3 Place the auxiliary electrodes, salt bridge probe, thermometer, and gas purge diffuser in the test chamber and bring the temperature of the test solution to 37 ± 1°C.

10.4 Purge the solution for a minimum of 30 min with nitrogen gas at a flow rate of 150 cm^3/min.

10.5 Gently immerse the test specimen in the test solution and connect it to a potentiostat. Continue the nitrogen purge throughout the test.

10.6 Monitor E_{corr} for 1 h.

10.7 At the end of 1 h of monitoring E_{corr}, start the potentiodynamic scan in the positive or noble (forward) direction, as defined in Practice G 3. The scanning program should be set with the following parameters.

10.7.1 Starting or initial potential (E_i) at 100 mV negative or active to E_{corr}.

10.7.2 A scan rate of 0.167 mV/s is recommended and should be used, when possible. In cases in which this slow scan rate causes severe damage to the specimen, a higher scan rate (up to 1 mV/s) can be used to minimize the damage. Note, however, that using higher scan rates may affect the breakdown potential of the device and the shape of the passive region of the polarization curve. Comparisons should not be made between test results using different scan rates even if all other experimental parameters are held constant; thus, similar scan rates should be used to test the implant device and the control device.

10.7.3 A reverse voltage scan should be undertaken to determine the device's repassivation capacity; however, if severe damage occurs to the sample during the reverse scan, a surrogate standard specimen with similar surface characteristics as the device may be used. Comparable corrosion behaviors up to the pitting potential must be established between the medical device and the surrogate sample before its use.

10.7.3.1 A current density threshold two decades greater than the current density recorded at breakdown can be used to reverse the voltage scan.

10.7.3.2 Alternatively, a reversing or vertex potential (E_v) may be used to control the potentiostat. This should be set such that reversal occurs when the current density is two decades greater than the current density at breakdown.

10.7.4 The final potential (E_f) is 100 mV negative or active to E_{corr}.

10.7.4.1 Alternatively, the scan may be manually stopped at potentials above E_{corr} in cases in which a protection potential (E_p) is observed as a drop in current density below that of the passive current density or when no hysterisis loop is formed once the scan is reversed (E_v), indicating repassivation or oxygen evolution as shown in Fig. 2.

10.8 If control specimens are used, they shall be tested using the same method as the investigated devices.

10.9 The corrosion current density (i_{corr}) may be obtained using Tafel extrapolation of the anodic and cathodic portion of the corrosion curve to the OCP. Corrosion rates may be calculated in accordance with Practice G 102.

11. Report

11.1 The report should contain a detailed description of the test specimen, including metallurgical and surface conditioning.

11.1.1 When specimens are not finished devices, for example, surrogates, the sample preparation should be described in detail.

11.2 A description of the test conditions should also be reported.

11.3 The following results should be presented in the report (see Fig. 2):

11.3.1 The corrosion potential (E_{corr});

11.3.2 The corrosion current density (i_{corr});

11.3.3 The breakdown potential (E_b);

11.3.4 The protection potential (E_p). In the absence of repassivation, the final potential (E_f) shall be reported instead of E_p. If no hysterisis loop is formed, the vertex potential (E_v) shall be reported instead of E_b and E_p.

11.4 The pH of the solution should be reported before and after each test.

11.5 A copy of the cyclic polarization curve should be provided in the report.

11.6 A generic description of the appearance of any corrosion observed on the specimen should be described. Photographic documentation may be appropriate.

12. Precision and Bias

12.1 The precision and bias of this method have yet to be established.

13. Keywords

13.1 corrosion; corrosion current density; cyclic polarization; medical device testing; pitting potential; protection potential; rest potential

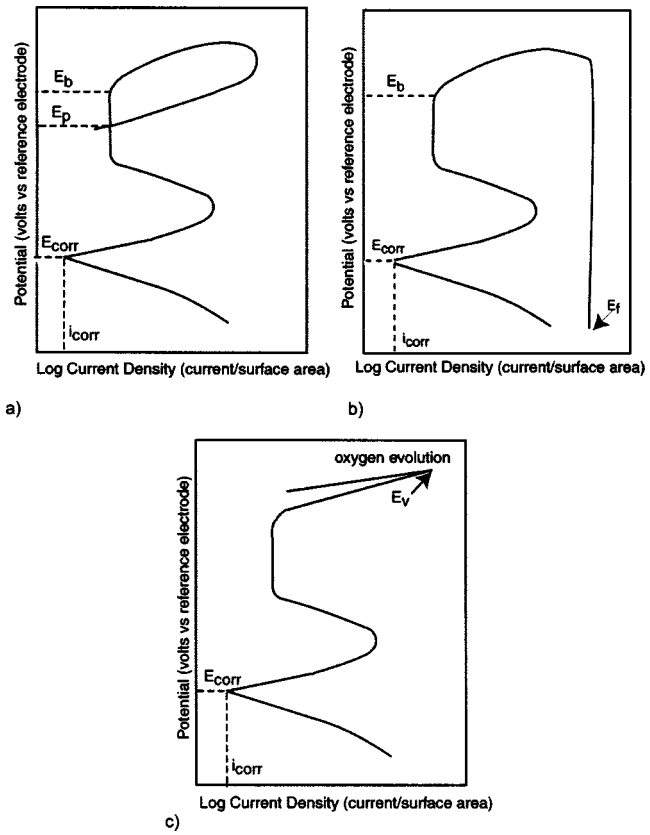

FIG. 2 Schematic Cyclic Potentiodynamic Curves Illustrating Corrosion Parameters: (*a*) Material That Exhibits a Protection Potential (E_{corr}, i_{corr}, E_b, and E), (*b*) Material That Does Not Exhibit a Protection Potential (E_{corr}, i_{corr}, E_b, and E_f), and (*c*) Material That Exhibits Oxygen Evolution at Its Surface (E_{corr}, i_{corr}, E_v).

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 This test method is a modification to Test Methods G 5 and G 61, to provide information regarding the corrosion susceptibility of small, finished medical devices in physiologic solutions. It is based on the original work of Cahoon et al **(2)** where susceptibility to pitting was indicated by the breakdown potential (E_b) and susceptibility to crevice corrosion by the protection potential (E_p). The critical data point is the potential above which pits nucleate and grow, that is, E_b. The higher the E_b, the more resistant the metal is to pitting corrosion. Once the direction of potential scan is reversed, and the potential begins to drop, we get a measure of how quickly the pits will heal. If E_p is high, that is, minimal hysteresis, then the metal is said to be very resistant to crevice corrosion. If there is some hysteresis, as in Fig. 2, then the metal may be susceptible to crevice corrosion; however, for materials or devices exhibiting a value of E_b above about 1 V, the presence of hysteresis during the reverse scan does not necessarily indicate susceptibility to crevice corrosion under normal physiological conditions. If the metal does not repassivate until a potential below E_{corr} is reached, then it is very susceptible to crevice corrosion.

X1.2 While all currently used metallic biomaterials have well characterized corrosion properties, many device manufacturing processes may alter the cyclic polarization characteristics of finished implant devices. Furthermore, complex-shaped devices with corners, recesses, and other design irregularities may have a significant effect on localized current densities. It is of concern that finished device testing may create fluctuating current densities that cannot be normalized over the complex-shaped surface areas. In such cases, careful examination of test specimens after testing is necessary. For some devices, cyclic polarization may not provide useful information.

X1.3 Deaerating the solution with nitrogen gas before and during the test will lower the concentration of oxygen in the solution and maintain it constant. This condition is similar to in vivo conditions and is a safer approach to assess the corrosion resistance of medical devices for several reasons. The amount of dissolved oxygen in a solution will greatly affect the

corrosion resistance of a material in terms of the corrosion potential and the general and repassivation corrosion behavior. Repassivation of the metal surface is more difficult in low dissolved oxygen conditions since most biomaterials rely on oxygen to repassivate. While it is true that blood contains oxygen, most of it is combined with hemoglobin (main component of red blood cells) and is not available for the alloy to repassivate. The amount of dissolved oxygen in blood is lower than the amount of dissolved oxygen under atmospheric conditions in artificial physiological solution. The partial pressure of oxygen in blood (PO_2) varies between 100 to 40 mmHg (arterial versus venous blood) while the PO_2 in air is 160 mm Hg. Furthermore, a study conducted by Morita et al **(3)**. demonstrated that corrosion-fatigue properties of stainless steel were overestimated when the in vitro study was conducted with a solution in contact with air or oxygen compared to in vivo performance of the same material. Deaeration of the solution with nitrogen gas to maintain low O_2 concentration was found to be more appropriate to predict in vivo performance of the material. Although this article reports the results of an implant in contact with bone and soft tissue, the same rationale is still valid for implants in the arterial system, (such as stents), since a cell layer will create a diffusion barrier to the transport of oxygen to the implant and thus decrease the amount of oxygen available for the material to repassivate. Finally, Kuhn et al **(4)** reported on synthetic environments for corrosion-testing biomaterials that the most common error is to use oxygen or air purges for those electrochemical techniques in which an external source of power is applied, for example, potentiostatic or potentiodynamic scans. To avoid introducing error in the rest potential and corrosion current density (and thus corrosion rate), purging with an inert gas such as nitrogen is necessary to remove oxygen in the solution. In terms of the observed current, an error can be introduced because of oxygen reduction. This can be very significant if the test electrode is a metal or alloy on which this reaction is fast and the corrosion rate slow. In accordance with Test Method G 61, it is important that all oxygen be removed by purging before polarization, otherwise more noble initial corrosion potential values will be observed.

X1.4 Since the absolute potential range that an implant should be able to withstand in vivo has not been established, absolute potential values such as the breakdown potential (E_b) and the protection potential (E_p) cannot assure that a device has sufficient resistance to corrosion; thus, reference specimens tested under the same conditions should be used to compare the results. The reference shall consist of a device, which is similar to the investigated device and has a history of good corrosion resistance in vivo, is used in a similar environment or location and is used to treat a similar disease.

X1.5 It is recommended to start the polarization 100 mV below OCP to extrapolate accurately i_{corr} and E_{corr} values based on Tafel extrapolations. As defined in Terminology G 15, the Tafel slope usually occurs at more than 50 mV from the OCP. Note that hydrogen might be introduced in the material during cathodic polarization; however, it has been shown in seawater conditions that cathodic potentials more noble than −1.0 V (SCE) at ambient temperature should not be detrimental for titanium and titanium alloys from a corrosion standpoint **(5)**.

X1.6 Corrosion cell setup and the methods of heating should be carefully chosen to avoid creating electromagnetic noise. Higher noise environments are suspected of reducing breakdowns.

X1.7 Test cell configuration has been found to affect breakdown potential significantly. It is conjectured that the effect may be due to difference in the atmospheric opening and the resulting difference in oxygen partial pressure in the solution. Though a nitrogen purge reduces the oxygen level in the solution, there is a driving force for a nonzero oxygen partial pressure that can affect the results of the test.

X2. COMPOSITION OF DIFFERENT PHYSIOLOGICAL ENVIRONMENTS

X2.1 *Composition of Different Body Fluids*:

X2.1.1 Table X2.1 presents the composition of three different body fluids **(4)**.

X2.1.2 Table X2.2 presents the comparison of blood plasma composition with saliva and bile **(6)**.

X2.1.3 For reference purposes, the composition of different artificial physiological solutions used as electrolytes for corrosion testing is reported in Table X2.3 **(4)**.

TABLE X2.1 Composition of Selected Components of Three Body Fluids[A]

Component	Interstitial Fluid, mg/L	Synovial Fluid, mg/L	Serum, mg/L
Sodium	3280	3 127	3 265
Potassium	156	156	156
Calcium	100	60	100
Magnesium	24	-	24
Chloride	4042	3 811	3 581
Bicarbonate	1892	1 880	1 648
Phosphate	96	96	96
Sulfate	48	48	48
Organic acids	245	-	210
Protein	4144	15 000	66 300

[A]Based on data from *Documenta Geigy Scientific Tables*, L. Diem and C. Lentner, Eds., 7th ed., Ciba-Geigy.

TABLE X2.2 Composition of Blood Plasma, Saliva, and Bile

Component	Blood Plasma, mg/L	Saliva, mg/L	Bile, mg/L
pH	7.35–7.45	5.8–7.1	7.8
Sodium	3128–3335	240–920	3082–3588
Potassium	140–220	560–1640	156–252
Chloride	3430–3710	525–1085	2905–3850
Bicarbonate	1403–1708	122–793	2318

TABLE X2.3 Composition of Simulated Physiological Solutions

	Tyrodes, g/L	Ringers, g/L	Hanks, g/L	Saliva, g/L **(7)**
pH	7.4	7.4	7.4	6.7
NaCl	8.0	9.0	8.0	
$CaCl_2$	0.20	0.24	0.14	
KCl	0.2	0.42	0.4	1.47
$MgCl_2$ $6H_2O$	0.10		0.10	
$MgSO_4$ $7H_2O$			0.06	
$NaHCO_3$	1.00	0.20	0.35	1.25
$Na_2H_2PO_4$	0.05		0.10	
$Na_2HPO_4.2H_2O$			0.06	
$Na_2HPO_4.12H_2O$				
KH_2PO_4				0.19
KSCN				0.52
$Ca(NO_3)_2.4H_2O$				
Glucose	1.00		1.00	

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