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# **Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program**

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## **Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff**

***DRAFT GUIDANCE***

**This draft guidance document is being distributed for comment purposes only.**

**Document issued on September 23, 2024.**

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, For questions about this document regarding CDRH-regulated devices, contact the ASCA Program at [ASCA@fda.hhs.gov](mailto:ASCA@fda.hhs.gov). For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and

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Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov).

**When final, this guidance will supersede Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program, issued September 25, 2020.**



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Center for Biologics Evaluation and Research

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See additional PRA statement in [Section VII](#) of this guidance

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## **Preface**

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1                   **Basic Safety and Essential**  
2                   **Performance of Medical Electrical**  
3                   **Equipment, Medical Electrical**  
4                   **Systems, and Laboratory Medical**  
5                   **Equipment – Standards Specific**  
6                   **Information for the Accreditation**  
7                   **Scheme for Conformity Assessment**  
8                   **(ASCA) Program**

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10                   **Draft Guidance for Industry,**  
11                   **Accreditation Bodies, Testing**  
12                   **Laboratories, and**  
13                   **Food and Drug Administration Staff**

15                   *This draft guidance, when finalized, will represent the current thinking of the Food and*  
16                   *Drug Administration (FDA or Agency) on this topic. It does not establish any rights for*  
17                   *any person and is not binding on FDA or the public. You can use an alternative approach*  
18                   *if it satisfies the requirements of the applicable statutes and regulations. To discuss an*  
19                   *alternative approach, contact the FDA staff or Office responsible for this guidance as*  
20                   *listed on the title page.*

21                   **I. Introduction**

22                   This guidance provides information regarding how basic safety and essential performance  
23                   standards are incorporated into the Accreditation Scheme for Conformity Assessment  
24                   Program (hereafter referred to as the ASCA Program). The ASCA Program is described in  
25                   FDA’s guidance on [The Accreditation Scheme for Conformity Assessment \(ASCA\)](#)  
26                   [Program](#).  
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28 For the edition of FDA-recognized consensus standard(s) included in the ASCA Program,  
29 see the [FDA Recognized Consensus Standards Database](#). For more information regarding use  
30 of FDA-recognized consensus standards in regulatory submissions, please refer to FDA’s  
31 guidances entitled [Appropriate Use of Voluntary Consensus Standards in Premarket](#)  
32 [Submissions for Medical Devices, Safety and Performance Based Pathway](#), and [Standards](#)  
33 [Development and the Use of Standards in Regulatory Submissions Reviewed in the Center](#)  
34 [for Biologics Evaluation and Research](#).

35  
36 FDA’s guidance documents, including this guidance, do not establish legally enforceable  
37 responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and  
38 should be viewed only as recommendations, unless specific regulatory or statutory  
39 requirements are cited. The use of the word *should* in Agency guidance means that  
40 something is suggested or recommended, but not required.

## 41 **II. Scope**

42 This guidance includes the following:

- 43
- 44 • the ASCA Program specifications for the FDA-recognized consensus standards and  
45 test methods for basic safety and essential performance;
  - 46 • assessment and accreditation of Testing Laboratories by ASCA-recognized  
47 Accreditation Bodies; and
  - 48 • the recommended premarket submission contents specific to FDA-recognized  
49 consensus standards and test methods for basic safety and essential performance  
50 when testing is conducted by an ASCA-accredited testing laboratory.

51  
52 FDA guidance [The Accreditation Scheme for Conformity Assessment \(ASCA\) Program](#)  
53 describes how accreditation bodies, testing laboratories, device manufacturers, and FDA staff  
54 participate in the ASCA Program as well as how FDA-recognized consensus standards and  
55 test methods are selected and how Program specifications are developed.

56

57 **III. FDA-Recognized Consensus Standards in the ASCA**  
58 **Program for Basic Safety and Essential Performance of**  
59 **Medical Electrical Equipment, Medical Electrical**  
60 **Systems, and Laboratory Medical Equipment**

61 Evaluation of safety is critical for electrically powered medical devices. The IEC  
62 60601/80601<sup>1</sup> series of standards applies to devices used in patient care settings, while the  
63 IEC 61010 series applies to devices used in laboratory settings. FDA encourages the use of  
64 these standards to support device safety in the majority of premarket submissions for  
65 electrically powered medical devices. These standards take an “all-hazards approach” to  
66 device safety, encompassing electrical, mechanical, and radiation hazards, among others, in  
67 addition to hazards posed by the environment of use. Besides addressing the wide range of  
68 generic safety requirements, the IEC 60601/80601 and IEC 61010 series include close to 100  
69 “particular standards” with safety requirements for specific types of devices, such as clinical  
70 thermometers, infusion pumps, infant incubators, and laboratory centrifuges.

71  
72 The [FDA Recognized Consensus Standards Database](#) lists all FDA-recognized consensus  
73 standards, including those included in the ASCA Program for basic safety and essential  
74 performance of medical devices and laboratory equipment (note that individual test methods  
75 are contained within standards). Any activities carried out by the testing laboratory under its  
76 scope of *ASCA Accreditation* to assess the conformity of a product to one or more of these  
77 standards is within the scope of the ASCA Program. The extent of FDA recognition  
78 (complete or partial) is provided in the Supplemental Information Sheet (SIS) for each  
79 standard included in the ASCA Program listed in the [FDA Recognized Consensus Standards](#)  
80 [Database](#). The SIS provides additional information to consider when using FDA-recognized  
81 consensus standards, such as relevant guidance documents that provide clarity on FDA  
82 recommendations for testing to support premarket submissions.  
83

84 **IV. Accreditation and Assessment of Testing Laboratories**

85 **A. Scope of Assessments**

86 Clause 7 of ISO/IEC 17011: *Conformity assessment – Requirements for accreditation bodies*  
87 *accrediting conformity assessment bodies* (hereafter referred to as “ISO/IEC 17011”)  
88 describes processes by which accreditation bodies assess testing laboratories. In order to  
89 maintain conformance to ISO/IEC 17011, an accreditation body assesses a sample of the  
90 scope of accreditation of its accredited testing laboratories at least every two years.<sup>2</sup> An  
91 accreditation body also performs a reassessment of its accredited testing laboratories before

---

<sup>1</sup> In this document, the reference to the IEC 60601/80601 series of standards includes the ANSI/AAMI ES 60601-1, the IEC and US adopted collaterals [6060-1-xx], the IEC 60601-2-xx particulars, and the IEC or ISO 80601-2-xx particulars.

<sup>2</sup> See 7.9.3 of ISO/IEC 17011: 2017: *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*.

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92 the end of the accreditation cycle that confirms the competence of each testing laboratory for  
93 all the requirements of the consensus standards within the laboratory’s scope of  
94 accreditation.<sup>3</sup> There are no additional expectations for assessments under the ASCA  
95 Program for basic safety and essential performance standards. That is, in the ASCA Program,  
96 ASCA-recognized accreditation bodies may assess a sample of the basic safety and essential  
97 performance standards to ensure competence across the testing laboratory’s entire scope of  
98 *ASCA Accreditation*.

99 **B. ASCA Program Specifications for Basic Safety and**  
100 **Essential Performance of Medical Electrical Equipment,**  
101 **Medical Electrical Systems, and Laboratory Medical**  
102 **Equipment**

103 The ASCA Program specifications in this section provide expectations for the accreditation  
104 of testing laboratories for basic safety and essential performance of medical electrical  
105 equipment, medical electrical systems, and laboratory medical equipment under the ASCA  
106 Program. ASCA-recognized accreditation bodies, following the processes of ISO/IEC  
107 17011, accredit testing laboratories to ISO/IEC 17025:2017: *General requirements for the*  
108 *competence of testing and calibration laboratories* (hereafter referred to as “ISO/IEC  
109 17025”) as well as to the ASCA Program specifications identified in this section. Throughout  
110 the ASCA Program specifications below, the term “will” before each action for testing  
111 laboratories is used to convey that they they are able to provide supportive documentation or  
112 information demonstrating competence to each of the ASCA Program specifications below  
113 when undergoing assessments by ASCA -recognized accrediting bodies. ASCA-recognized  
114 accreditation bodies will assess the laboratories to the specifications to ensure ASCA  
115 Program specifications are met.

116  
117 In addition, all testing should be conducted considering the recommendations of relevant  
118 FDA guidance documents (*refer to [Section III](#) of this guidance*). For readability and ease of  
119 reference, the numbering and nomenclature (including the term “requirements”)<sup>4</sup> below  
120 correspond to the numbering and nomenclature of clauses/subclauses in ISO/IEC 17025.

121 **ISO/IEC 17025 Clause 4 “General requirements”**

122 For the purposes of the ASCA Program, testing laboratories inspect the device  
123 manufacturer’s risk management file to the extent necessary to assess compliance with the  
124 expectations of IEC 60601/80601 or IEC 61010. The testing laboratories do not make  
125 judgments concerning the adequacy of the device manufacturer’s risk management process.  
126 Nor do they make judgments concerning the acceptability of risk or the adequacy of the  
127 device manufacturer’s decisions concerning risk. Each time a clause or subclause of IEC  
128 60601/80601 or IEC 61010 calls for inspection of the risk management policy, plan, or

---

<sup>3</sup> See 7.9.4 of ISO/IEC 17011: 2017: *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*.

<sup>4</sup> Some definitions within FDA-recognized consensus standards refer to ‘requirements.’ FDA’s references to them for the ASCA Program do not make them legal or regulatory requirements unless specifically identified as such.



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129 records (i.e., the risk management file), the testing laboratory is to check to see if a related  
130 IEC 60601/80601 or IEC 61010 expectation has been complied with.

131 4.1 Impartiality

132 If any services, such as consulting, design, or research, are offered by the testing laboratory,  
133 it will have a policy and procedure for maintaining impartiality through separation of those  
134 services from its testing activities.

135  
136 A device manufacturer’s internal testing laboratory will have policies and procedures that  
137 specifically ensure and protect the impartiality of the laboratory to test or otherwise evaluate  
138 devices manufactured by the laboratory’s parent organization and, if applicable, other device  
139 manufacturers without regard to the impact of the test results on the parent organization’s  
140 business interests.

141 4.2 Confidentiality

142  
143 There are no additional specifications above those set forth in ISO/IEC 17025.

144 **ISO/IEC 17025 Clause 5 “Structural requirements”**

145  
146 There are no additional specifications above those set forth in ISO/IEC 17025.

147 **ISO/IEC 17025 Clause 6 “Resource requirements”**

148 6.1 General

149  
150 There are no additional specifications above those set forth in ISO/IEC 17025.

151 6.2 Personnel

152 a) The testing laboratory will maintain technical personnel who are qualified and  
153 competent to:

- 154 • Establish and perform the appropriate test methods required for the standard.  
155 • Understand and apply the specifications and underlying rationale (including such  
156 concepts as basic safety and essential performance).  
157 • Understand other normative references in the relevant standards forming part of  
158 the requested scope of accreditation.  
159 • Assure the suitability of means used to confirm the basic safety and essential  
160 performance of the medical device under test.

161 b) The testing laboratory will:

- 162 • Document and maintain a program for the initial and ongoing training of technical  
163 personnel, including procedures for applying new/updated test methods and  
164 performing required tests.

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- 165           • Provide ongoing training of technical personnel at specified intervals or when test  
166           standards or methods are updated or developed, as well as when responsibilities  
167           have changed.  
168           • Conduct training through appropriate training mechanisms, such as on-the-job  
169           training or formal classroom training.  
170           • Document and maintain records of training for technical personnel.

- 171           c) The testing laboratory will maintain job descriptions that specify and document the  
172           responsibilities and required competencies of managerial, technical, and key support  
173           personnel involved in requested scope of accreditation.

174   6.3 Facilities and environmental conditions

175

176   There are no additional specifications to those set forth in ISO/IEC 17025.

177   6.4 Equipment

- 178           a) The testing laboratory will ensure that all equipment used for testing and evaluating  
179           devices is available and in proper working order for the requested scope of  
180           accreditation.

- 181           b) The testing laboratory will ensure that its procedures specify the steps for establishing  
182           calibration intervals for each type or item of equipment, and specify criteria, steps,  
183           and approvals for extending the calibration interval of an instrument.

- 184           c) The testing laboratory will ensure that its procedures address adding, deleting,  
185           modifying, or maintaining information in equipment records in an accurate and timely  
186           manner, and specify the personnel responsible for these tasks.

- 187           d) The testing laboratory will have procedures to examine the effects of defective or out-  
188           of-tolerance equipment on calibrations and tests. The testing laboratory further agrees  
189           that procedures will identify the personnel responsible for such examinations, specify  
190           their responsibilities, and provide the steps for the examination, including:

- 191           • Determining whether the effects are unacceptable (including the accept/reject  
192           criteria);  
193           • Identifying the devices affected;  
194           • Analyzing the particular tests impacted for these devices; and determining  
195           whether retesting is required;  
196           • Preparing a report of the examination;  
197           • Notifying customers when retesting is required; and  
198           • Specifying the steps to follow to perform the retesting.

199   6.5 Metrological traceability

200

201   There are no additional specifications to those set forth in ISO/IEC 17025.

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202 6.6 Externally provided products and services

203

204 There are no additional specifications to those set forth in ISO/IEC 17025.

205 **ISO/IEC 17025 Clause 7 “Process requirements”**

206 7.1 Review of requests, tenders, and contracts

207 a) The testing laboratory will have contracts with customers that require the customer to:

- 208 • Identify those tests and test results that are intended to be used to support
- 209 premarket submissions to the FDA;
- 210 • Identify special test conditions and additions or modifications to test methods
- 211 and/or acceptance criteria as permitted by IEC 60601-1 subclauses 4.2.3.2 and 4.5
- 212 and ISO/IEC 17025 subclause 7.2.1.4; and
- 213 • Indicate that per the risk management requirements of IEC 60601/80601 and IEC
- 214 61010 the customer maintains responsibility for specifying and documenting
- 215 acceptance criteria.

216 7.2 Selection, verification and validation of methods

217 a) The testing laboratory agrees that its management system will include procedures

218 governing the development, maintenance, and use of test procedures (including

219 associated records in paper or electronic format such as test data forms and

220 checklists). The testing laboratory further agrees that these management system

221 procedures will include steps for:

- 222 • Ensuring that test procedures are documented and reviewed prior to use;
- 223 • Identifying the personnel responsible for developing, reviewing, and maintaining
- 224 test procedures;
- 225 • Ensuring that new and revised test procedures are reviewed by personnel who are
- 226 competent and trained in the applicable standard(s); and
- 227 • Specifying the criteria for review.

228 b) The testing laboratory agrees that test procedures and project-specific test plans will

229 include or specify, as appropriate, the following information:

- 230 • Unique identification of the test procedure or plan, including title, document
- 231 number, revision, and effective date;
- 232 • Specific test equipment to use or the salient performance characteristics required
- 233 of the equipment to be used;
- 234 • Warnings/caution statements to alert the operators of potential hazards;
- 235 • Normal and any unusual ambient conditions (including tolerances) for tests;
- 236 • Test data to be obtained and recorded;
- 237 • Objective acceptance criteria for results including the essential performance
- 238 required to be maintained;
- 239 • Testing techniques required to ensure consistent results;
- 240 • Instructions on equipment operation and on handling and preparation of test
- 241 samples (including instructions on multiple sample marking, if applicable); and

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- 242           • The methods to be used to assess or monitor the performance of the test sample.
- 243           c) The testing laboratory will ensure that relevant contextual information from the  
244           intended use of the device’s essential performance specifications, including any  
245           metrological stability, are reflected in the relevant test procedure or project-specific  
246           test plan.
- 247           d) The testing laboratory will ensure that each test procedure adequately addresses all  
248           the applicable requirements of the standard for the equipment under test.
- 249           e) The testing laboratory will give preference to using test methods in the requested  
250           scope of accreditation. Modified test methods as permitted by IEC 60601-1  
251           subclauses 4.2.3.2 and 4.5 and ISO/IEC 17025 subclause 7.2.1.4 may be used within  
252           the ASCA Program as long as details of the rationale for the modification, test  
253           method, and results are provided.
- 254           Note: Recommendations for how to report the modified test method can be found in  
255           FDA’s guidance [Recommended Content and Format of Non-Clinical Bench](#)  
256           [Performance Testing Information in Premarket Submissions](#).
- 257           f) The testing laboratory will include relevant sections of the test report in the ASCA  
258           Summary Test Report as necessary to explain any testing to address risks that are  
259           different or in addition to those found in the FDA-recognized consensus standard.
- 260           g) Where a clause or subclause of the FDA-recognized consensus standard requires  
261           inspection of the risk management file to obtain objective evidence, the testing  
262           laboratory agrees, at a minimum, to include pass/fail criteria in the inspection  
263           procedure and record the list of documents examined during the inspection in the  
264           testing laboratory’s records.

265   7.3 Sampling

266  
267   There are no additional specifications to those set forth in ISO/IEC 17025.

268   7.4 Handling of test or calibration items

269  
270   There are no additional specifications to those set forth in ISO/IEC 17025.

271   7.5 Technical records

272  
273   There are no additional specifications to those set forth in ISO/IEC 17025.

274   7.6 Evaluation of measurement uncertainty

275  
276   There are no additional specifications to those set forth in ISO/IEC 17025.

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277 7.7 Ensuring the validity of results

278

279 There are no additional specifications to those set forth in ISO/IEC 17025.

280 7.8 Reporting of results

281 a) The testing laboratory will have procedures to record and report all required  
282 information in ISO/IEC 17025 for each test conducted, including the following:

- 283 • A statement of the extent to which the articles that were tested complied or did  
284 not comply with the specifications of each clause or subclause that were part of  
285 the standard tested;
- 286 • A detailed description of the medical device tested including accessories, options,  
287 software versions, and configurations tested;
- 288 • A test plan including reference to the device manufacturer’s stated intended use  
289 and essential performance claims monitored during testing, any additional device-  
290 specific acceptance criteria (beyond those detailed in specific consensus  
291 standards) monitored during testing, reporting of the operational state(s) of the  
292 equipment during each test, as well as, if needed, any modified test methods as  
293 permitted by IEC 60601-1 subclauses 4.2.3.2 and 4.5 and ISO/IEC 17025  
294 subclause 7.2.1.4.

295

296 Note: Recommendations for how to report the modified test methods can be found  
297 in the guidance document [Recommended Content and Format of Non-Clinical  
298 Bench Performance Testing Information in Premarket Submissions](#).

299

- 300 • The date and location of the test(s) performed;
- 301 • The test report’s unique identifier;
- 302 • The signatures and printed names of the personnel responsible for the test results;
- 303 • The test conditions, e.g., supply voltage, ambient temperature or humidity, when  
304 relevant to the test;
- 305 • All of the applicable data required for equipment under test according to the  
306 standard;
- 307 • A statement of the estimated uncertainty of measurement, when it is relevant to  
308 the validity or application of the test results, when a customer’s instructions so  
309 requires or when the uncertainty affects compliance to a specification limit; and
- 310 • A statement that test report meets ASCA Program specifications.

311

312 b) The testing laboratory agrees not to report test results in a “simplified way” as  
313 mentioned in subclause 7.8.1.3. Instead, the testing laboratory will report to the  
314 customer all information listed in subclauses 7.8.2 through 7.8.7 to the extent  
315 applicable (Subclause 7.8.4 is for calibration certificates and is not applicable when  
316 testing to the requirements of IEC 60601).

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- 318 c) The testing laboratory will convey to the customer, in writing, all opinions and  
319 interpretations, including concerns about basic safety and essential performance such  
320 as:
- 321 • Anomalous test results noted during any part of the testing that were not resolved
  - 322 to the testing laboratory’s satisfaction; and
  - 323 • Concerns regarding any other aspect of conformity to the standard.
- 324 d) The testing laboratory will require that testing conducted by subcontractors will also  
325 comply with the above test report specifications, as applicable.
- 326 e) The testing laboratory agrees that an ASCA Summary Test Report including the  
327 content specified in this guidance will be submitted to the customer at the end of  
328 testing activities.
- 329 f) The testing laboratory will convey to the customer, in writing, all observations  
330 recorded during execution of a project test plan.

331  
332 Note. An observation is a device behavior that is not directly related to the pass/fail  
333 assessment being made at that time. An observation is recorded to make the customer  
334 aware of a device behavior that, while it might be out-of-scope for the test plan being  
335 executed, could indicate a potential quality issue. It is the customer’s responsibility to  
336 assess this further.

337 7.9 Complaints

338  
339 There are no additional specifications to those set forth in ISO/IEC 17025.

340 7.10 Nonconforming work

341  
342 There are no additional specifications to those set forth in ISO/IEC 17025.

343 7.11 Control of data and information management

344  
345 There are no additional specifications to those set forth in ISO/IEC 17025.

346 **ISO/IEC 17025 Clause 8 “Management system requirements”**

347 8.1 Options

348 Regardless of the option selected (i.e., ISO/IEC 17025 Option A or Option B), the testing  
349 laboratory will maintain an index of standard operating procedures (SOPs) and any relevant  
350 ASCA test-related documents (i.e., SOPs, test methods, work instructions, master protocols,  
351 test-specific protocols, data collection worksheets, training information, completed ASCA  
352 Summary Test Reports, and associated complete test reports) applicable to any of the  
353 relevant FDA-recognized consensus standards included in the ASCA Program for basic  
354 safety and essential performance of medical devices and laboratory equipment and the  
355 associated specifications detailed in this document.

356 **C. Scope of Accreditation Issued by Accreditation Bodies**  
357 **Including ASCA Basic Safety and Essential Performance of**  
358 **Medical Electrical Equipment, Medical Electrical Systems,**  
359 **and Laboratory Medical Equipment Standards**

360 Once testing laboratories have been assessed by an ASCA-recognized accreditation body to  
361 ISO/IEC 17025 and the ASCA Program specifications identified in [Section IV.B](#) of this  
362 guidance, the accreditation body will issue a proposed scope of accreditation under the  
363 ASCA Program to the testing laboratory (see sample in Appendix D of [ASCA Program](#)  
364 [guidance document](#)). The testing laboratory should work with their accreditation body to  
365 ensure the applicable exclusions are accurately and clearly listed in the ASCA section of the  
366 scope of accreditation.

367  
368 Appendix D of the [ASCA Program guidance document](#) highlights that the scope of *ASCA*  
369 *Accreditation* should accurately capture when excluded clauses and/or subclauses of one  
370 standard may also apply to others within the scope of accreditation. For example, excluded  
371 subclauses of ANSI AAMI ES60601-1 (referred to as the “general standard” throughout the  
372 collaterals and particulars of the 60601/80601 series of standards) will also apply to the  
373 applicable collateral and particular standards in the scope of accreditation that reference the  
374 excluded clauses/subclauses (e.g., particulars can state “Clause 11 of the general standard  
375 applies,” or “Clause 8 of the general standard applies except as follows...” adding an  
376 additional subclause or requirement that could be excluded if Clause 8 or subclause 8.x.x.x is  
377 excluded in ANSI AAMI ES60601-1). The testing laboratory should work with their  
378 accreditation body to ensure these types of exclusions are accurately and clearly captured in  
379 the conditional and any subsequently updated accreditation.

380  
381 Testing laboratories should also consider the recommendations in [Appendix B](#) of this  
382 guidance, regarding representing exclusions to the scope of accreditation under the ASCA  
383 Program in the Clauses/Subclauses Tested section of the ASCA Summary Test Report.  
384

385 **V. Recommendations for Participation in the ASCA**  
386 **Program**

387 **A. Test plan development as a collaboration between**  
388 **device manufacturers and testing laboratories**

389 As described in the draft ASCA Program guidance document, FDA recommends device  
390 manufacturers consult with ASCA-accredited testing laboratories when developing a  
391 comprehensive test plan for their device. FDA encourages a collaborative relationship  
392 between the device manufacturer and testing laboratory wherever possible. Such  
393 collaboration may help to ensure the appropriate selection and use of FDA-recognized  
394 consensus standards and test methods.  
395

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396 If the testing laboratory has questions or concerns associated with the device manufacturer’s  
397 proposed test plan (e.g., essential performance(s), unclear acceptance criteria), they should  
398 discuss such concerns/questions with the device manufacturer, preferentially in advance of  
399 finalization of the test plan. If those concerns or questions remain unresolved, the testing  
400 laboratory should consider detailing the potential issues in the ASCA Summary Test Report  
401 (e.g., in the Concerns Identified section in the example provided in [Appendix B](#) of this  
402 guidance).

403 **(1) Essential Performance**

404 FDA recommends the device manufacturer specifies the essential performance(s) of their  
405 device. Additionally, testing laboratories should have expertise in the terminology,  
406 evaluation, and performance of the FDA-recognized consensus standards to assist a device  
407 manufacturer in understanding the concept of essential performance and how it might relate  
408 to their device, as appropriate.

409 We recommend that testing laboratories and device manufacturers consider the content of the  
410 AAMI consensus report CR500:2019, Basic Introduction to the IEC 60601 Series, which  
411 includes clarifications to help device manufacturers understand “essential performance.”<sup>5</sup>  
412

413 If a device manufacturer is unsure what constitutes the essential performance(s) of their  
414 device, FDA recommends submitting a Q-submission<sup>6</sup> prior to initiating testing to request  
415 formal feedback from the appropriate CDRH Office of Health Technology (OHT) or CBER  
416 Review Office for their future premarket submission. For information on presubmissions,  
417 please see the FDA guidance entitled “[Requests for Feedback and Meetings for Medical  
418 Device Submissions: The Q-Submission Program.](#)”  
419

420 **(2) Electromagnetic Compatibility (EMC)**

421 For test plans that intend to use the current, FDA-recognized version of the IEC 60601-1-2  
422 collateral standard, we recommend that device manufacturers and testing laboratories  
423 consider the FDA guidance entitled “[Electromagnetic Compatibility \(EMC\) of Medical  
424 Devices.](#)” This guidance provides recommendations that might impact test plans including  
425 current, FDA-recognized versions of IEC 60601-1-2.  
426  
427

---

<sup>5</sup> For additional information about a regulatory perspective on “essential performance,” we recommend the AAMI consensus report entitled CR500:2019 Basic Introduction to the IEC 60601 Series.

<sup>6</sup> For more information, please see the FDA guidance entitled “[Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.](#)”



428 **B. Testing laboratory subcontracting within the Basic**  
429 **Safety and Essential Performance standards of the ASCA**  
430 **Program**

431 ASCA-accredited testing laboratories may subcontract testing, as allowed in ISO/IEC 17025  
432 and the ASCA specifications listed above, as long as that the outsourced testing is included  
433 in the ASCA-accredited testing laboratory’s scope of *ASCA Accreditation* (i.e., the testing  
434 laboratory issuing the ASCA Summary Test Report). Ultimately, the ASCA-accredited  
435 testing laboratory is responsible for the data, testing methodology, and results presented in  
436 the test reports provided to the device manufacturer.

437 **C. ASCA Summary Test Reports**

438 [Appendix B](#) of this guidance contains an example ASCA Summary Test Report that includes  
439 the information needed to support premarket review.

440  
441 Testing laboratories participating in the ASCA Program may devise their own ASCA  
442 Summary Test Report formats; however, the requested information outlined in each section  
443 of Appendix B should be addressed.

444  
445 FDA recommends device manufacturers review the example in Appendix B to familiarize  
446 themselves with the content of an ASCA Summary Test Report.

447 **(1) Concerns Identified by the Testing Laboratory**

448 If the testing laboratory identifies any concerns with the evaluation of the device, they should  
449 communicate these concerns to the device manufacturer and work to resolve them prior to  
450 the issuance of the ASCA Summary Test Report. In situations where concerns remain  
451 unresolved, the testing laboratory should detail the concerns in the ASCA Summary Test  
452 Report. For example, by using the “Concerns Identified” section included in the example  
453 ASCA Summary Test Report (*Refer to [Appendix B](#) of this guidance*).

454  
455 Examples of potential concerns that the testing laboratory may identify include, but are not  
456 limited to, concerns with the:

- 457
- 458 • test plan (e.g., unclear pass/fail criteria or essential performance(s),
  - 459 • risk analysis (e.g., underestimation of risk level, unidentified risks related to the  
460 device) based on the test lab’s experience with specific device types, or
  - 461 • presence of unique device features or characteristics that may raise safety concerns  
462 which may not be sufficiently assessed via the device manufacturer’s test plan.
- 463

464 FDA recommends device manufacturers address any concerns identified in the ASCA  
465 Summary Test Report in their declaration of conformity for the ASCA Program (ASCA  
466 DOC) and reference relevant sections of their premarket submission containing supporting  
467 documentation which may further mitigate any concerns identified by the testing laboratory.

468 **D. Devices intended to record, display, and/or analyze**  
469 **physiological data**

470 Devices that are intended to record, display, and/or analyze physiological data (e.g.,  
471 electrocardiographs) have inherent clinical components/performances/uses that cannot be  
472 directly evaluated by a testing laboratory. In testing these types of devices to FDA-  
473 recognized consensus standards, the performance of the device is typically monitored and  
474 evaluated for any observations or degradations which impact the intended performance (e.g.,  
475 assessment of the performance of devices exposed to electromagnetic disturbances).<sup>7</sup>

476  
477 If observations or degradations related to the recording, display and/or analysis of data are  
478 noted for these device types, the test report should include a description of the observations  
479 or degradations alongside representative data demonstrating the observed behavior in the  
480 Observations and Degradations During Testing section of the ASCA Summary Test Report  
481 or as an attachment to the report.

482 **VI. Premarket Submission Contents for FDA-Recognized**  
483 **Consensus Standards in the ASCA Program for Basic**  
484 **Safety and Essential Performance**

485 FDA recommends that the following be included in any regulatory submission that reports  
486 basic safety and essential performance testing conducted by an ASCA-accredited testing  
487 laboratory.

488 **A. Cover Letter**

489 FDA recommendations for a cover letter for a premarket submission containing testing  
490 results from an ASCA-accredited testing laboratory are provided in FDA’s draft guidance  
491 [The Accreditation Scheme for Conformity Assessment \(ASCA\) Program](#).

492 **B. ASCA Declaration of Conformity**

493 Section IV.A. of FDA’s guidance [Appropriate Use of Voluntary Consensus Standards in](#)  
494 [Premarket Submissions for Medical Devices](#) recommends contents for a DOC to an FDA-  
495 recognized consensus standard. For basic safety and essential performance testing from an  
496 ASCA-accredited testing laboratory, the device manufacturers should include the following  
497 additional items in an ASCA DOC:

- 498
- Date(s) the testing was conducted.
  - 499 • Location(s) where the testing was conducted.
  - 500 • Confirmation that the FDA-recognized consensus standards used during testing were
  - 501 within the laboratory’s scope of *ASCA Accreditation* and that such standards were not

---

<sup>7</sup> For more information, please see the FDA guidance entitled “[Electromagnetic Compatibility \(EMC\) of Medical Devices](#)” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices>) and IEC TR 60601-4-2.

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502 suspended from the scope of *ASCA Accreditation* at the time testing was conducted. If  
503 the relevant standard was impacted by a suspension of *ASCA Accreditation*, the  
504 ASCA DOC should include an explanation of how this suspension may or may not  
505 affect the testing results.

- 506 • Limitations on the validity of the ASCA DOC:
- 507 • How the test article compares with the device provided in the premarket  
508 submission, including any modifications made during testing. If modifications  
509 were made during testing, it is helpful if the ASCA DOC states whether or not  
510 these modifications are included in the final finished device. FDA also  
511 recommends that the ASCA DOC include a rationale for why it was deemed  
512 appropriate to leverage any testing conducted before the modifications were  
513 made.
  - 514 • Details about how any concerns communicated by the test laboratory have been  
515 mitigated (see [Section V.C.1.](#) above).
  - 516 • Details about how any observations and/or degradations during testing were  
517 resolved.
  - 518 • If there is additional data or documentation that support any of the limitations on  
519 the validity of the ASCA DOC, FDA recommends that a reference identifying  
520 where to find this information be provided in the ASCA DOC.

521 An example ASCA DOC is provided in [Appendix A](#) of this guidance.

### 522 **C. Supplemental Documentation**

523 In lieu of submitting the full test report, FDA recommends that testing performed under the  
524 ASCA program be submitted using the recommended ASCA Summary Test Report format.<sup>8</sup>  
525 An example ASCA Summary Test Report is provided in [Appendix B](#) of this guidance. Note  
526 that the ASCA-accredited testing laboratory provides the ASCA Summary Test Report to the  
527 device manufacturer who then includes it with its own ASCA DOC in a premarket  
528 submission to FDA.

529  
530 Under the ASCA Program, FDA generally will accept test results from ASCA-accredited  
531 testing laboratories when the standard and test methods are within the testing laboratory's  
532 scope of *ASCA Accreditation* at the time of testing. Examples of circumstances where FDA  
533 might request and review additional information relating to testing from an ASCA-accredited  
534 testing laboratory are described in the bulleted points of Section XIII.A of the [ASCA](#)  
535 [Program guidance](#).

536  
537 The ASCA Program processes and policies enhance confidence in testing results only when  
538 specific test methods and acceptance criteria are used. In cases where the standard permits

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<sup>8</sup> An ASCA Summary Test Report is different from the test report summary described in FDA's guidance [Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions](#).

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539 modifications or additions to individual clauses or subclauses to ensure basic safety and  
540 essential performance, FDA recommends the submitter include the test plan and procedure,  
541 acceptance criteria, and results justifying the safety claim in its premarket submission. In  
542 such cases, FDA recommends that the ASCA Summary Test Report include relevant  
543 information about the testing that was performed. The following examples illustrate a few  
544 situations where this additional documentation is appropriate:  
545

- 546 • Where a test method specified in a clause or subclause of the standard was modified  
547 based on specific characteristics and/or intended use of the device or its operating  
548 conditions.
- 549 • Where the acceptance criteria specified in a clause or subclause was modified based  
550 on the device manufacturer’s risk management.
- 551 • Where clauses or subclauses in the IEC 60601/80601 and IEC 61010 series do not  
552 provide specific test methods and acceptance criteria. For example, a clause or  
553 subclause might indicate “compliance is checked by inspection of the risk  
554 management file and functional tests, if necessary.” In other cases, a clause or  
555 subclause might provide for revision of the specific test methods and acceptance  
556 criteria based on risk management.

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557 **VII. Paperwork Reduction Act of 1995**

558

559 This guidance contains information collection provisions that are subject to review by the Office  
560 of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C.  
561 3501-3521).

562

563 The time required to complete this information collection is estimated<sup>9</sup> to average 95 hours per  
564 response for accreditation bodies and 47 hours for testing laboratories. Send comments regarding  
565 this burden estimate or suggestions for reducing this burden to:

566

567 FDA PRA Staff,  
568 Office of Operations,  
569 Food and Drug Administration,  
570 [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

571

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0889 (To find the current expiration date, search for this OMB control number available at <https://www.reginfo.gov>).

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<sup>9</sup> Rounded to the nearest whole number.

575 **Appendix A: Example ASCA Declaration of Conformity**  
576 **(ASCA DOC) for Basic Safety and Essential Performance**  
577 **Standards in the ASCA Program**

578 *Note: This example is intended to illustrate elements expected in an ASCA DOC. The content*  
579 *of an ASCA DOC expands on the content of a DOC described in FDA’s guidance*  
580 *[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical](#)*  
581 *[Devices](#).<sup>10</sup> Submitters should include an ASCA DOC as part of their premarket submission*  
582 *when including ASCA testing (i.e., an ASCA Summary Test Report).*

583  
584 **Responsible Party**

585 Name of entity responsible for DOC: \_\_\_\_\_

586 Address of entity responsible for DOC: \_\_\_\_\_

587

588 **Product/Device Identification**

*All identifying information for the product/device (e.g., product code(s), device marketing name(s), model number(s), etc.).*

589

590 **Statement of Conformity**

591  The test results demonstrate that the device is in conformity with the standard(s) listed  
592 below<sup>11</sup>:

- 593 • Title of Standard(s):<sup>12</sup> *(e.g., [ANSI/AAMI ES60601-1 Medical electrical equipment](#)*  
594 *- [Part 1: General requirements for basic safety and essential](#)*  
595 *[performance](#).)*
- 596 • FDA Recognition #(s): *(e.g., 19-46)*
- 597 • Options Selected
- 598  Standard(s) included no options
- 599  Standard(s) included options

*List of options selected in related standard(s) (e.g., subclause 5.3 permits modified test conditions if ambient temperature cannot be maintained). This section may reference the ASCA Summary Test Report provided as supplementary documentation.*

- 600 • Testing Laboratory Name: *(e.g., [Testing Laboratory ABC](#))*
- 601 • ASCA Testing Laboratory Identification Number(s): *(e.g., [TL-01](#))*

<sup>10</sup> Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>

<sup>11</sup> See section 514(c)(3)(A)(i) of the FD&C Act, cited in Section IV.A.(3)(f) of FDA’s guidance [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Device](#).

<sup>12</sup> A device manufacturer may declare conformity to multiple standards evaluated by a test lab within the ASCA Program.

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- 602
- 603
- 604
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- 606
- 607
- 608
- Testing Location(s): *(e.g., 1234 Example Road, Silver Spring, MD 20993)*
  - Testing Date(s): *(e.g., Sep 1, 2023 – Sep 15, 2023)*
  - ASCA Accreditation Status on the Date(s) of Testing:
    - Standard was not in testing laboratory’s scope of ASCA Accreditation
    - Standard was in testing laboratory’s scope of ASCA Accreditation;
      - ASCA Accreditation was not suspended
      - ASCA Accreditation was suspended

*If ASCA Accreditation was suspended during the testing date(s), a description of reasons for suspension and their impact on testing results should be provided. FDA may need to review additional information and/or ask questions to determine whether the test results can be used to support a decision on a premarket submission.*

***Note:** if the testing laboratory’s ASCA Accreditation was suspended or withdrawn at the time of testing, an ASCA DOC may not be submitted for the suspended or withdrawn FDA-recognized consensus standards and test methods. However, the submitter may submit a DOC as outlined in FDA’s guidance [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#).*

- 609
- 610
- 611
- 612
- 613
- 614
- 615
- 616
- 617
- 618
- Supplemental Documentation (Refer to [Section VI.C.](#) of this guidance for specific recommendations):
    - Supplemental documentation is not included
    - Supplemental documentation is included at the following location within the submission, and I have checked that there are no differences regarding protocol and data between the testing conducted and the supplemental documentation: *(e.g., IEC 60601-1-2 ASCA Summary Test Report located in Appendix A of this premarket submission)* \_\_\_\_\_

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619 **Limitations on Validity of DOC**

620

*Description of any limitation on the validity of the ASCA DOC (e.g., how long the declaration is valid, what was tested, or concessions made about the testing outcomes) including a reference to the relevant locations of such information in the premarket submission. For testing from an ASCA-accredited test lab, this should include:*

- Information on how the test article compares with the device provided in this premarket submission including, any modifications made during testing for basic safety and essential performance and whether the modifications are included in the final, finished device.*
- Information on how any concerns communicated by the test laboratory were resolved.*
- Information on how any observations and/or degradations during testing were resolved.*
- Information about how conformity was assessed for clauses or subclauses of the relevant standard(s) that were not evaluated by an ASCA-accredited testing laboratory, including detailed information about who performed such testing, the test methods used, and the test results*
- Information on how the labeling requirements of the standard are met (e.g., reference to relevant section/pages of the user manual).*

621

622

623 **Signature**

624 Printed name: \_\_\_\_\_

625 Function within entity responsible for DOC: \_\_\_\_\_

626

627

628 Signature \_\_\_\_\_ Date \_\_\_\_\_

629

630



631 **Appendix B: Example ASCA Summary Test Report for**  
632 **Basic Safety and Essential Performance Standards in the**  
633 **ASCA Program**

634 *Note: This example is intended to illustrate the supplemental documentation that should*  
635 *accompany the ASCA DOC as described in [Appendix A](#). The ASCA Summary Test Report is*  
636 *provided by the testing laboratory to the device manufacturer.*

637 **Administrative Information**

638  
639  
640  
641  
642  
643  
644

1. Testing Laboratory Name:
2. ASCA Testing Laboratory Identification Number:
3. Testing Location(s):
4. Testing Date(s):
5. Standard(s) evaluated:

FDA Recognition Number	Standard Designation Number	Tested conducted under the ASCA Program (Y/N)
<i>e.g., 19-4</i>	<i>e.g., ANSI AAMI ES60601-1</i>	<i>Y</i>
...	...	...

645  
646  
647  
648  
649  
650  
651

6. *ASCA Accreditation* Status on the Date(s) of Testing:
  - Standard was \*NOT\* in testing laboratory’s scope of *ASCA Accreditation*<sup>13</sup>
  - Standard was in testing laboratory’s scope of *ASCA Accreditation*
    - ASCA Accreditation* was not suspended
    - ASCA Accreditation* was suspended

*If ASCA Accreditation was suspended during the Date(s) of testing, a description of reasons for suspension and their impact on testing results should be provided.*

**Note:** *if the testing laboratory’s ASCA Accreditation was suspended or withdrawn at the time of testing, an ASCA DOC may not be submitted for the suspended or withdrawn FDA-recognized consensus standards and test methods. However, the submitter may submit a DOC as outlined in FDA’s guidance [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)*

652  
653

<sup>13</sup> See FDA’s guidance [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#) for information regarding supplemental documentation necessary to support FDA-recognized consensus standards that are not in a testing laboratory’s scope of *ASCA Accreditation*.

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654 **Device Essential Performance Characteristics**

*Description of the device essential performance characteristics supplied by the device manufacturer to the testing laboratory (including reference to any relevant particular standards with essential performance specified) and that were included in the testing. List any differences (if any identified) between the essential performance identified by the standard and the essential performance considered during the test. For multiple standards and/or multiple tests, include the essential performance characteristics used for each.*

655

656

657 **Device Pass/Fail Criteria**

*Description of any Pass/Fail criteria specific to the device beyond the requirements specified in the standard(s) being evaluated. This should include a brief description for how these criteria were identified and monitored during the testing.*

*Pass/Fail criteria specific to the device should be clear and verifiable. Pass/Fail criteria might include device-specific criteria for clinical functions unrelated to identified essential performance.*

658

659 **Use Environment**

- 660  Home Healthcare Environment [IEC 60601-1-11]
- 661  Professional Healthcare Facility Environment
- 662  Magnetic Resonance (MR) Environment
- 663  Commercial Aircraft Environment
- 664  Emergency Medical Services Environment [IEC 60601-1-12]
- 665  Special / Other Environment

666

*Include any relevant details regarding the specified use environment here.*

667 **Clauses/Subclauses Tested**

668 1. Clauses/Subclauses Deemed Applicable

- 669  All clauses/subclauses were deemed applicable.
- 670  The following clauses/subclauses were deemed not applicable.

671

*List of all clauses and subclauses identified as not applicable (N/A) with a rationale for every clause/subclause identified as N/A. This may be provided as an attachment to the Summary Test Report.*

*If specific clauses/subclauses are excluded on the testing laboratory's scope of accreditation, they should be listed either as N/A in this section, if appropriate, or in the next section as a clause or subclause that was not tested.*

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673 2. Clauses/Subclauses Tested

674  All applicable clauses/subclauses were tested

*For clauses or subclauses allowing multiple test methods, list the specific clause or subclause and test method used with a brief rationale for the choice.*

675

676  The following applicable clauses/subclauses were not tested.

*List of any applicable clauses or subclauses not tested. Rationales should also be provided to clarify why applicable clauses/subclauses were not tested.*

*If specific clauses or subclauses are determined to be applicable but are not within the testing laboratory's scope of accreditation (i.e., excluded in the scope of accreditation), then those clauses/subclauses should be listed here with a corresponding explanation.*

677

678 3. Clauses/Subclauses with Failing Results

679  No clauses or subclauses had failing results

680  The following clauses/subclauses had failing results

*List of any clauses and subclauses with failing results and a description of the failures.*

681 **Modification(s)<sup>14</sup> to Test Methods and/or Acceptance Criteria**

682  No test methods specified in the standard were modified

683  No acceptance criteria specified in the standard were modified

684  One or more test methods or acceptance criteria were modified

*List of test methods and/or acceptance criteria that were modified. Appropriate supporting documents should be attached to this ASCA Summary Test Report including the rationale for the modification, test plan and procedure, acceptance criteria that were applied, scientific rationale for the acceptance criteria, and the test results.*

685 **Additional Testing Performed to Demonstrate Conformity with the Standard<sup>15</sup>**

686  No additional testing was performed other than that specified in the standard

687  Additional testing was performed as specified by the device manufacturer to address a  
688 hazardous situation not specifically addressed by the standard  
689

<sup>14</sup> Modification(s) include special test conditions and additions or modifications to test methods and/or acceptance criteria as permitted by IEC 60601-1 subclauses 4.2.3.2 and 4.5 and ISO/IEC 17025 subclause 7.2.1.4.

<sup>15</sup> For example, subclause 4.2 of ANSI/AAMI ES60601 indicates that hazards not specifically addressed in the ANSI/AAMI ES60601-1 are to be addressed in the risk management process.

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*Description of additional testing performed to address a hazardous situation not specifically addressed by the standard. Appropriate supporting documents are attached to this ASCA Summary Test Report including the test plan and procedure, acceptance criteria that were applied, and the test results.*

690 **Device Configuration(s) and Mode(s) of Operation**

*Description of how device was configured including modes of operation used during testing.*

691 **Observations and Degradations During Testing**

- 692  Observations and degradations were NOT found during testing  
693  Observations and degradations were found, but deemed acceptable based on the pass/fail  
694 criteria identified by the device manufacturer  
695

*Description of observations and degradations of concern to the testing laboratory but deemed acceptable. Examples include:*

- *Instances of device showing unexpected behaviors (e.g., display of incorrect values, display of error messages, device or components needing to be restarted, if the device or components restart unexpectedly).*
  - *Representative bench data should be provided to visualize the unexpected behaviors observed affecting devices intended to record, display, and/or analyze physiological data*
- *Instances of device or components being unexpectedly damaged and needing replacement or other intervention to return to normal operation.*

*This list should capture any unexpected events. As an example, an error message would be unexpected (and therefore would be listed) during EMC testing when a valid input is present; conversely, the same error message would be expected (and therefore would not be listed) during a test that feeds an out-of-range input to verify the function of input errors. Any unexpected behavior is reported even if acceptable per the pass/fail criteria. If the unexpected behavior is listed as possible in the labeling (e.g., “the device may restart unexpectedly”), it should still be reported here.*

696 **Modifications to Test Article(s) During Testing**

- 697  No modifications were made to the test articles during testing  
698  Modifications were made to the test articles during testing. Description of modification  
699 including their impact on prior test outcome(s) are provided below.  
700

*Description of modifications made to test articles during testing. Description of prior tests that were repeated based on modifications made or justification for not repeating prior tests.*

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701 **Concerns Identified**

702  No concerns were identified.

703  Concerns were communicated to the device manufacturer; see list below.

*List and description of concerns communicated to the device manufacturer.*

*Concerns may include aspects that do not constitute a failure for the specific test conducted, but might have an impact on the safety and potential effectiveness of the device subject to the testing. Examples include, but are not limited to, concerns regarding the test plan (e.g., unclear pass/fail criteria or essential performance(s), disagreements regarding the evaluation of certain clauses or subclauses), inconsistencies in risk analysis (e.g., underestimation of risk level, unidentified risks related to the device) based on the test laboratory’s experience with specific device types, presence of unique features/characteristics which may raise safety questions not addressed via the test plan.*

704

705 I confirm that:

706  The above summary information includes all original and any retest data

707  The above summary information is an accurate representation of the testing conducted

708

709

710

711

712 Name: [TYPED NAME POSITION]

Date

713