

DECLARATION OF WAYNE C. McDANIEL, Ph.D.

I. BACKGROUND AND QUALIFICATIONS

(1) My name is Wayne Charles McDaniel. I am currently Associate Director of the Technology Management and Industry Relations office at the University of Missouri-Columbia. I am also an Adjunct Professor of Electrical and Computer Engineering at the University of Missouri. During my career, I have worked extensively in biomedical engineering research involving cardiac therapy and defibrillation. I am expert in the areas of internal atrial and ventricular defibrillation, external ventricular defibrillation, experimental methods for defibrillation research, and cardiac safety of stun guns.

(2) I hold a Bachelor of Arts in Biology, a Master of Science in Electrical Engineering with a biomedical engineering emphasis, and a Doctorate of Philosophy in Electrical Engineering with a biomedical engineering emphasis from the University of Missouri-Columbia.

(3) From 2001 to 2011, I held the position of Senior Licensing and Business Development Associate of the Technology Management and Industry Relations office at the University of Missouri-Columbia. From 1987 to 2001, I was a Research Assistant Professor of Cardiothoracic Surgery at the University of Missouri-Columbia. From 1993 to 2001, I was

Acting Director of Cardiothoracic Surgery Laboratory Investigation at the University of Missouri.

(4) I have over 35 years of experience in the biomedical engineering field and have published extensively in electrical ventricular defibrillation. For over twenty-five years, I have conducted and received numerous grants for research relating to cardiac therapy and defibrillation.

(5) I was one of the pioneers of the biphasic waveform that is now used in virtually all automatic implantable cardioverter defibrillators and virtually all transthoracic defibrillators, including automatic external defibrillators.

(6) I have authored or co-authored 34 published articles relating to cardiac therapy and defibrillation, including articles titled "Transthoracic Defibrillation of Dogs with Edmark, Biphasic, and Quadriphasic waveforms," "Double-pulse transthoracic defibrillation in the calf using percent fibrillatory cycle length as spacing determinate," and "Relationship between efficacy and frequency domain characteristics of defibrillatory shocks."

(7) I have given 46 presentations at national or international meetings, including a presentation entitled "Multiphasic truncated exponential waveforms require less peak current for atrial defibrillation than optimal biphasic waveforms" to the 22nd Annual Scientific Sessions of the North American Society for Pacing and Electrophysiology, in Boston, Massachusetts in May of 2001 and a presentation entitled "Comparison of the Efficacy of Two Transthoracic Biphasic Waveform Defibrillators" to the Europace 2003 Congress in

Dec. 2003 in Paris, France. I have presented at 33 colloquiums and symposiums, including presentations on ventricular and atrial defibrillation.

(8) I am the sole inventor on U.S. Patent No. 6,738,664 entitled “Method of and apparatus for atrial and ventricular defibrillation or cardioversion with an electrical waveform optimized in the frequency domain,” which issued on May 18, 2004.

(9) A copy of my C.V. is attached as **Appendix A**.

II. STATUS AS AN INDEPENDENT EXPERT WITNESS

(10) I have been retained in this matter by Fish & Richardson P.C. to provide various opinions regarding U.S. Patent No. 5,735,879 (“the ‘879 patent”); U.S. Patent No. 5,749,905 (“the ‘905 patent”); U.S. Patent No. 6,047,212 (“the ‘212 patent”); U.S. Patent No. 5,607,454 (“the ‘454 patent”); U.S. Patent No. 5,836,978 (“the ‘978 patent”); U.S. Patent No. 5,749,904 (“the ‘904 patent”); U.S. Patent No. 5,593,427 (“the ‘427 patent”); and U.S. Patent No. 5,803,927 (“the ‘927 patent”) (collectively, “the Philips Waveform Patents”). I am being compensated at the rate of \$300 per hour for my work. My fee is not contingent on the outcome of this matter or on any of the opinions I provide below.

(11) I have been advised that Fish & Richardson represents ZOLL Lifecor Corp. in this matter. I have no financial interest in ZOLL Lifecor Corp.

(12) I have been advised that Philips Electronics North America Corp. (“Philips” or “Patent Owner”) owns the Philips Waveform Patents. I have no financial interest in Philips Electronics North America Corp. or in the Philips Waveform Patents.

III. MATERIALS CONSIDERED

(13) In arriving at the opinions set forth herein, I have reviewed the Philips Waveform Patents and relevant portions of their respective file histories.

(14) Additional materials that I have reviewed and relied upon in arriving at the opinions set forth herein are: (1) Bell (Appendix B); (2) Pless (Appendix C); (3) Kroll (Appendix D); (4) Schuder (Appendix E); (5) Swanson (Appendix F); (6) De Coriolis (Appendix G); (7) Ideker (Appendix H); (8) Fain (Appendix I); (9) Baker (Appendix J); (10) Packer (Appendix K); (11) Hahn (Appendix L); (12) Bach (Appendix M); (13) Adams (Appendix N); (14) Herleikson (Appendix O); and (15) Cameron (Appendix P).

IV. DESCRIPTION OF THE RELEVANT FIELD AND RELEVANT TIMEFRAME

(15) Based on my review of the Philips Waveform Patents and the materials listed in Appendices B-P, I conclude that the relevant field of the Philips Waveform Patents for purposes of my testimony is waveforms used for defibrillation, and apparatus and techniques for generating and delivering such waveforms. I have been advised that the relevant timeframe is August 1993, which is the date that the applications that lead to the Philips Waveform Patents were filed.

(16) As described in Section I above, I have extensive experience in the field of defibrillation waveforms, and apparatus and techniques for generating and delivering such waveforms.

V. PERSON OF ORDINARY SKILL IN THE ART

(17) I have been advised that “a person of ordinary skill in the relevant field” is a mythical person to whom an expert in the relevant field could assign a routine task with reasonable confidence that the task would be successfully carried out. Here, the relevant field is waveforms used for defibrillation, and apparatus and techniques for generating and delivering such waveforms. Because these devices are used to deliver a shock to a patient’s heart, people engaged in developing these devices and related methods need to have a high level of skill. Based upon my experience in this area, one of ordinary skill in the art in this field at the relevant time frame would have had an advanced (post-Bachelor’s) degree in electrical engineering, biomedical engineering, or some closely related field, with at least 5 years of work experience in one or more of these fields, and at least 5 years of experience in developing (e.g., designing or implementing) medical devices for defibrillation, pacing, and/or cardiac medical devices (which experience could have overlapped in whole or part with the at least 5 years of experience in the fields of electrical engineering or biomedical engineering), or the equivalent of such experience. The person of ordinary skill in the art also must have been intimately familiar with the design of, theory behind, principles of operation of, and intended use of defibrillators, as well as the principles of human physiology that underlie the indications of use for defibrillators (cardiac arrest and ventricular fibrillation), and the theories as to why the delivery of certain shocks may be useful to correct these conditions.

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