

CAE Fidelis™ Maternal Fetal Simulator development partners and validation studies

Diogo Ayres de Campos, M.D., Ph.D., Perinatal Obstetrician and Professor of Medicine at the University of Porto

Willem Van Meurs, Ph.D., University of Porto, biomedical engineer and co-developer of the Human Patient Simulator (HPS) for anesthesiology

Carla Sá Couto, Ph.D., Coordinator of the Biomedical Simulation Center of Faculty of Medicine of University of Porto and researcher at the Center for Research in Health Technologies and Information Systems

Pedro Sá Couto, Ph.D., University of Aveiro, Portugal and member in Probability and Statistics Group of the Center of Research and Development in Mathematics and Applications (CIDMA), University of Aveiro, Portugal

Luísa Ferreira Bastos, Ph.D., Assistant Investigator at the Institute of Biomedical Engineering in Porto, Portugal.



Developed in collaboration with Instituto de Engenharia Biomédica (INEB) at the University of Porto in Portugal.

DIOGO AYRES-DE-CAMPOS, MD, PhD Biography and Publications

DIOGO AYRES-DE-CAMPOS, MD, PhD is currently Associate Professor at the University of Porto and Consultant in Obstetrics at the S. Joao Hospital in Porto, Portugal. He was the labour ward lead between 2004 and 2008.

His main areas of interest are intrapartum fetal monitoring and obstetric simulation. He has published 65 papers in international indexed peer-reviewed journals, edited 3 books and authored 35 book chapters. He is an Editor or member of the scientific council in 3 peer-reviewed journals, and was the editor-in-chief of the *Acta Obstetrica e Ginecologica Portuguesa* between 2006 and 2010.

He is currently the treasurer of the Federation of Portuguese Societies of Obstetrics and Gynecology and the co-ordinator for obstetric simulation in Portugal at the Portuguese College of Obstetrics and Gynecology. He presides over the Portuguese Health Authority nominated "Comission for Reduction of Cesarean Section rates".

He is a Council Member of the European Board and College of Obstetrics and Gynecology, and a member of its Working Group on Simulation Consortium. He is also a member of the Study Group on Intrapartum Monitoring of the European Association of Perinatal Medicine, and of the Safe Motherhood and Newborn Health committee at FIGO, where he is co-ordinating the revision of the FIGO guidelines on intrapartum fetal monitoring.

Physiological Modeling Validation Studies Related to the CAE Fidelis Maternal Fetal Simulator

1. Ayres-de-Campos D, Silva-Carvalho JL, Oliveira C, Martins-da-Silva I, Silva-Carvalho J, Pereira-Leite L. Interobserver agreement in analysis of basal body temperature graphs from infertile women. *Hum Reprod* 1995;10(8):2010-6.
2. Montenegro N, Bernardes J, Ayres-de-Campos D, Matias A, Areias JC. Monitoring of cardiac-extracardiac haemodynamics and automated fetal heart rate preceding intrauterine death. *Eur J Obstet Gynecol Reprod Biol* 1996;64:3-6.
3. Matos A, Bernardes J, Ayres-de-Campos D, Patrício B. Antepartum fetal cerebral hemorrhage not predicted by current surveillance methods in cholestasis of pregnancy. *Obstet Gynecol* 1997;89(part 2):803-4.
4. Bernardes J, Costa-Pereira A, Ayres-de-Campos D, van Geijn HP, Pereira-Leite L. Evaluation of interobserver agreement of cardiotocograms. *Int J Gynecol Obstet* 1997;57:33-7.
5. Bernardes J, Ayres-de-Campos D, Costa-Pereira A, Pereira-Leite L, Garrido A. Objective computerized fetal heart rate analysis. *Int J Gynecol Obstet* 1998;62:141-7.
6. Ayres-de-Campos D, Bernardes J. Early, variable and late decelerations: can a consensus be reached in their identification? *Int J Gynecol Obstet* 1999;65:305-6.
7. Ayres-de-Campos D, Bernardes J, Costa-Pereira A, Pereira-Leite L. Inconsistencies in classification by experts of cardiotocograms and subsequent clinical decision. *Br J Obstet Gynaecol* 1999;106:1307-10.
8. Costa-Santos C, Ayres-de-Campos D, Costa-Pereira A, Bernardes J. An interactive web site for research on fetal heart rate monitoring, with real data simulations. *Obstet Gynecol* 2000;95 (2): 309-11.
9. Bernardes J, Costa-Pereira A, Calejo L, Ayres-de-Campos D, Patrício B, Pereira-Leite L. Fetal heart rate baselines in twins: interobserver agreement in antepartum estimation. *J Reprod Med* 2000;45(2):105-8.

10. Ayres-de-Campos D, Bernardes J, Garrido A, Marques-de-Sá J, Pereira-Leite L. SisPorto 2.0: a program for automated analysis of cardiotocograms. *J Matern Fetal Med* 2000; 9(5):311-318.
11. Ayres-de-Campos D, Teixeira-da-Silva JM, Campos I, Patrício B. Intravaginal misoprostol in the management of first trimester missed abortions. *Int J Gynecol Obstet* 2000; 71(1):53-7.
12. van Meurs WL, Sá-Couto PM, Sá-Couto CD, Bernardes J, Ayres-de-Campos D. Development of fetal and neonatal simulators at the University of Porto. *Med Educ* 2003; 37, Suppl.1:29-33.
13. Ayres-de-Campos D, Bernardes J, Marsal K, Nickelsen C, Makarainen L, Banfield P, Xavier P, Campos I. Can the reproducibility of fetal heart rate baseline estimation be improved? *Eur J Obstet Gynecol Reprod Biol* 2004;112(1):49-54.
14. Ayres-de-Campos D, Bernardes J. Comparison of fetal heart rate baseline estimation by SisPorto® 2.01 and a consensus of clinicians. *Eur J Obstet Gynecol Reprod Biol* 2004;117:174-8.
15. Ayres-de-Campos D, Costa-Santos C, Bernardes J, for the SisPorto multicentre validation study group. Prediction of neonatal state by computer analysis of fetal heart rate tracings: the antepartum arm of the SisPorto® multicentre validation study. *Eur J Obstet Gynecol Reprod Biol* 2005; 118:52-60.
16. Reynolds A, Ayres-de-Campos D, Costa MA, Montenegro N. How should success be defined when attempting medical resolution of first-trimester missed abortion? *Eur J Obstet Gynecol Reprod Biol* 2005; 118:71-76.
17. Xavier P, Ayres-de-Campos D, Reynolds A, Guimaraes M, Costa-Santos C, Patricio B. The modified Misgav-Ladach versus the Pfannenstiel-Kerr technique for cesarean section: a randomized trial. *Acta Obstet Gynecol Scand* 2005; 84 (9):878-82.
18. Gonçalves H, Rocha AP, Ayres-de-Campos D, Bernardes J. Internal versus external intrapartum fetal heart rate monitoring: effect on linear and nonlinear parameters. *Physiol Meas* 2006; 27:307-19.
19. Calado E, Ayres-de-Campos D. Premature rupture of the membranes at 20 weeks; report of a successful outcome after transcervical application of fibrin glue. *Fetal Diagn Ther* 2006; 22(1):14-17.
20. Gonçalves H, Rocha AP, Ayres-de-Campos D, Bernardes J. Linear and nonlinear fetal heart rate analysis of normal and acidemic fetuses in the minutes preceding delivery. *Med Biol Eng Comput* 2006; 44(10):847-55.
21. Winter C, Macfarlane A, Deneux-Tharoux C, Zhang WH, Alexander S, Brocklehurst P, Bouvier-Colle MH, Prendiville W, Cararach V, van Roosmalen J, Berik I, Klein M, Ayres-de-Campos D, Erkkola R, Chiechi LM, Langhoff-Roos J, Stray-Pedersen B, Troeger C. Variations in policies for management of the third stage of labour and the immediate management of postpartum haemorrhage in Europe. *BJOG* 2007;114: 845-54.
22. Gonçalves H, Rocha AP, Ayres-de-Campos D, Bernardes J. Linear and nonlinear analysis of heart rate patterns associated with fetal behavioural states in the antepartum period. *Early Hum Dev* 2007; 83:585-91.
23. Ayres-de-Campos D, Sousa P, Costa A, Bernardes J. Omniview-SisPorto 3.5 – a central fetal monitoring station with online alerts based on computerized cardiotocogram + ST event analysis. *J Perinat Med* 2008; 36:260-4.
24. Gonçalves H, Rocha AP, Ayres-de-Campos D, Bernardes J. Frequency domain and entropy analysis of fetal heart rate: appealing tools for fetal surveillance and pharmacodynamic assessment of drugs. *Cardiovasc Hematol Disord Drug Targets* 2008; 8(2):91-8.
25. Bernardes J, Gonçalves H, Ayres-de-Campos D, Rocha AP. Linear and complex heart rate dynamics vary with sex in relation to fetal behavioural states. *Early Hum Dev* 2008; 84(7):433-9.

26. Reynolds A, Ayres-de-Campos D, Bastos LF, van Meurs WL, Bernardes J. Impact of labour & delivery simulation classes in undergraduate medical learning. *Med Educ Online* 2008;13:14.
27. Bernardes J, Gonçalves H, Ayres-de-Campos D, Rocha AP. Sex differences in linear and complex fetal heart rate dynamics of normal and acidemic fetuses in the minutes preceding delivery. *J Perinat Med* 2009; 37:168-76.
28. Deneux-Tharoux C, Macfarlane A, Winter C, Zhang WH, Alexander S, Bouvier-Colle MH, Ayres-de-Campos D, Berbik I, Bréart G, Brocklehurst P, Cararach V, Chiechi M, Erkkola R, Klein M, Langhoff-Roos J, Prendiville W, van Roosmalen J, Stray-Pedersen B, Troeger C. Policies for manual removal of placenta at vaginal delivery: variations in timing within Europe. *BJOG* 2009; 116(1):119-24.
29. Mota R, Costa F, Amaral A, Oliveira F, Santos C, Ayres-de-Campos D. Skin adhesive versus subcuticular suture for perineal skin repair after episiotomy - a randomized controlled trial. *Acta Obstet Gynecol Scand* 2009; 88:660-6.
30. Costa A, Ayres-de-Campos D, Costa F, Santos C, Bernardes J. Prediction of fetal acidemia by computer analysis of fetal heart rate and ST event signals. *Am J Obstet Gynecol* 2009; 201(5):464.e1-6.
31. Sá-Couto CD, Andriessen P, van Meurs WL, Ayres-de-Campos D, Sá-Couto PM. A model for educational simulation of hemodynamic transitions at birth. *Pediatr Res* 2010; 67(2):158-65.
32. Zhang W-H, Deneux-Tharoux C, Brocklehurst P, Juszczak E, Joslin M, Alexander S, Ayres-de-Campos D, Berbik I, Bouvier-Colle MH, Bréart G, Cararach V, Marconi AM, Erkkola R, Klein M, Langhoff-Roos J, Macfarlane A, Prendiville W, van Roosmalen J, Stray-Pedersen B, Troeger C, Winter C. Effect of a collector bag for measurement of postpartum blood loss after vaginal delivery: a cluster randomised trial in thirteen European countries. *BMJ* 2010; 340:c293.
33. Costa A, Ayres-de-Campos D, Machado AP, Santos C, Bernardes J. Comparison of a computer system evaluation of intrapartum cardiotocographic events and a consensus of clinicians. *J Perinat Med* 2010; 38:191-5.
34. Bernardes J, Ayres-de-Campos D. The persistent challenge of foetal heart rate monitoring. *Curr Opin Obstet Gynecol* 2010;22:104-9.
35. Ayres-de-Campos D, Bernardes J. Twenty-five years after the FIGO guidelines for electronic fetal monitoring. Time for a more simplified approach? *Int J Gynecol Obstet* 2010;110:1-6.
36. Bastos L, Lobo M, van Meurs W, Ayres-de-Campos D. An intrauterine pressure generator for educational simulation of labor and delivery. *Med Eng Phys* 2010;32(7):740-5.
37. Costa A, Costa-Santos C, Ayres-de-Campos D, Costa C, Bernardes J. Access to computerised analysis of intrapartum cardiotocographs improves clinicians' prediction of newborn umbilical pH. *BJOG* 2010;117(10):1288-93.
38. Reynolds A, Ayres-de-Campos D, Pereira-Cavaleiro A, Ferreira-Bastos L. Simulation for Teaching Normal Delivery and Shoulder Dystocia to Midwives in Training. *Educ Health (Abingdon)* 2010;23(3):405.
39. Ayres-de-Campos D, Ugwumadu A, Banfield P, Lynch P, Amin P, Horwell D, Costa A, Costa-Santos C, Bernardes J, Rosen K. A randomised clinical trial of intrapartum fetal monitoring with computer analysis and alerts versus previously available monitoring. *BMC Pregnancy and Childbirth* 2010;10:71.
40. Costa-Santos C, Bernardes J, Ayres-de-Campos D, Costa A, Costa C. The limits of agreement and the intraclass correlation coefficient may be inconsistent in the interpretation of agreement. *J Clin Epidemiol* 2011;64(3):264-9.
41. Ayres-de-Campos D, Arteiro D, Costa-Santos C, Bernardes J. Knowledge of adverse neonatal outcome alters clinicians' interpretation of the intrapartum cardiotocograph. *BJOG* 2011 Jul; 118(8):978-84.

42. Costa-Santos C, Bernardes J, Antunes L, Ayres-de-Campos D. Complexity and categorical analysis may improve the interpretation of agreement studies using continuous variables. *J Eval Clin Pract* 2011;17(3):511-4.
43. Costa C, Ayres-de-Campos D, Sousa P, Bernardes J. Audit of a fetal central monitoring station in a clinical setting. *J Matern Fetal Neonat Med* 2011;24(10):1249-53.
44. Reynolds A, Lobo M, Ayres-de-Campos D. Self-perceived impact of simulation-based training on the management of real-life obstetrical emergencies. *Eur J Obstet Gynecol Reprod Biol* 2011;159(1):72-6.
45. Ayres-de-Campos D, Siassakos D. Sustaining simulation training programs – experience from maternity care. *BJOG* 2011;118 (Suppl. 3):22–6.
46. Bastos L, van Meurs W, Ayres-de-Campos D. A model for educational simulation of the evolution of uterine contractions during labor. *Comput Meth Prog Bio* 2012 Aug;107(2):242-7.
47. Santo S, Ayres-de-Campos D. Human factors affecting the interpretation of fetal heart rate tracings: an update. *Curr Opin Obstet Gynecol* 2012;24(2):84-8.
48. Ayres-de-Campos D. Simulation-based training in Obstetrics and Gynaecology. *Facts, View & Vision Obstet Gynecol* 2012:28-32.
49. Nunes I, Ayres-de-Campos D, Figueiredo C, Bernardes J. An overview of central fetal monitoring systems in labour. *J Perinat Med* 2013; 41:93-99.
50. Lobo MF, Bastos LF, van Meurs WL, Ayres-de-Campos D. A model for educational simulation of the effect of oxytocin on uterine contractions. *Med Eng Phys* 2013; 35:524-31.
51. Almeida LM, Caldas J, Ayres-de-Campos D, Salcedo-Barrientos D, Dias S. Maternal healthcare in migrants: a systematic review. *Matern Child Health J* 2013 DOI 10.1007/s10995-012-1149-x.
52. Gonçalves H, Bernardes J, Ayres-de-Campos D, Salcedo-Barrientos D, Dias S. Gender-specific heart rate dynamics in severe intrauterine growth-restricted fetuses. *Early Hum Develop* 2013; 89:431-7.
53. Gonçalves H, Costa A, Ayres-de-Campos D, Costa-Santos C, Rocha AP, Bernardes J. Comparison of real beat-to-beat signals with commercially available 4 Hz sampling on the evaluation of fetal heart rate variability. *Med Biol Eng Comput* 2013;51:665–676.
54. Almeida LM, Casanova C, Caldas J, Ayres-de-Campos D, Dias S. Migrant Women’s Perceptions of Healthcare During Pregnancy and Early Motherhood: Addressing the Social Determinants of Health. *J Immigrant Minority Health* 2013: DOI 10.1007/s10903-013-9834-4.

Willem L. VAN MEURS, Ph.D. Biography and Publications

Willem L. van Meurs was born in Rotterdam, The Netherlands, in 1962. He obtained the MSc degree in electrical engineering at the Eindhoven University of Technology in 1987, and the Doctoral degree in control engineering from Paul Sabatier University, Toulouse, France, in 1991. At the University of Florida, from 1992-1998, he was co-inventor of the Human Patient Simulator, commercialized by CAE Healthcare, Sarasota, Florida. At the University of Porto from 1998-present, he was the lead inventor of a training simulator for obstetric emergencies. As a consultant to CAE Healthcare, from 1998-present, he was co-developer of the simulators: PediaSIM, BabySIM, iStan, and METIman, as well as of the Müse software. He presided the Society in Europe for Simulation Applied to Medicine (SESAM) from 2005-2007. He is the author of "Modeling and simulation in biomedical engineering: Application to cardiorespiratory physiology", New York, McGraw-Hill Professional, July 2011. He lives with his wife and two children in Lahitte-Toupière, France.

MONOGRAPH

Van Meurs WL: Automatisation de la circulation extracorporelle chirurgicale. Estimation des paramètres d'un modèle hémodynamique. Thèse de doctorat de l'Université Paul Sabatier, Toulouse. Spécialité automatique, Soutenue le 9 Sept. 1991, 113 pp (Surgical extracorporeal circulation automation: estimation of the parameters of a hemodynamic model. Ph.D. Thesis, Paul Sabatier University, Toulouse, France. Specialty: Control Engineering, Defended September 9, 1991, 113 p).

BOOK

Van Meurs W: Modeling and simulation in biomedical engineering: Application to cardiorespiratory physiology, New York, McGraw-Hill Professional, July 2011.

INVITED ARTICLES

Van Meurs W: Ein Patient aus Kunststoff und Elektronik. Spectrum der Wissenschaft, Sept. 1997:97 (in German).

Van Meurs WL, Sá Couto PM, Sá Couto CD, Bernardes JF, Ayres-de-Campos D. Development of foetal and neonatal simulators at the University of Porto. Med Educ 2003;37 Suppl 1:29-33.

PUBLICATIONS IN PEER REVIEWED INTERNATIONAL JOURNALS

Barthelemy R, Chauveau N, Van Meurs WL, Morucci JP. Automatisation évolutive en circulation extracorporelle. Revue Europeenne en Technologie Biomedicale 1988 10:151-3 (in French).

Van Meurs WL, Chauveau N, Barthelemy R, Morucci JP: L'automatisation de la circulation extracorporelle: analyse et reconception d'un régulateur de niveau. Innovation et Technologie en Biologie et Medecine 1989 10:87-98 (in French).

Chauveau N, Van Meurs WL, Barthelemy R, Morucci JP. Automatic modules for extracorporeal circulation control. Int J Artif Organs 1990 Oct;13(10):692-6.

Van Meurs WL, Chauveau N, Helies C, Barthelemy R, Morucci JP: Simulation de l'estimation des paramètres d'un modèle hémodynamique pour la circulation extracorporelle. Innovation et Technologie en Biologie et Medecine 1991, 12:179-90 (in French).

Lampotang S, Öhrn M, van Meurs WL. A simulator-based respiratory physiology workshop. *Acad Med* 1996 May;71(5):526-7.

Öhrn MAK, van Oostrom JH, van Meurs WL. A comparison of traditional textbook and interactive computer learning of neuromuscular block. *Anesth Analg* 1997 Mar;84(3):657-61.

Euliano TY, Caton D, van Meurs WL, Good ML. Modeling obstetric cardiovascular physiology on a full-scale patient simulator. *J Clin Monit* 1997 Sep; 13(5):293-7.

Van Meurs WL, Good ML, Lampotang S. Functional anatomy of full-scale patient simulators. *J Clin Monit* 1997 Sep;13(5):317-24.

Van Meurs WL, Nikkelen E, Good ML. Pharmacokinetic-pharmacodynamic model for educational simulations. *IEEE Trans Biomed Eng* 1998 May; 45(5):582-90.

Lampotang S, Gravenstein JS, Euliano TY, van Meurs WL, Good ML, Kubilis P, Westhorpe R. Influence of pulse oximetry on time to diagnosis of critical incidents in anesthesia: A pilot study using a full-scale patient simulator. *J Clin Monit Comput* 1998 Jul;14(5):313-21.

Nikkelen E, van Meurs WL, Öhrn MAK. Hydraulic analog for simultaneous representation of pharmacokinetics and pharmacodynamics: Application to vecuronium, *J Clin Monit Comput* 1998 Jul;14 (5):329-37.

Emilien G, van Meurs WL, Maloteaux JM. The dose-response relationship in Phase I clinical trials and beyond: use, meaning, and assessment. *Pharmacol Ther* 2000 Oct; 88(1):33-58.

De Beer NAM, van Meurs WL, Grit MBM, Good ML, Gravenstein D. Educational simulation of the electroencephalogram (EEG). *Technol Health Care* 2001; 9(3):237-56.

Sá Couto PM, van Meurs WL, Bernardes JF, Marques de Sá JP, Goodwin JA. Mathematical model for educational simulation of the oxygen delivery to the fetus. *Control Eng Practice* 2002;10:59-66.

Van Meurs WL, Nikkelen E, Good ML. Comments on using the time of maximum effect site concentration to combine pharmacokinetics and pharmacodynamics [letter]. *Anesthesiology* 2004 May; 100(5):1320.

Goodwin JA, van Meurs WL, Sá Couto CD, Beneken JEW, Graves SA. A model for educational simulation of infant cardiovascular physiology. *Anesth Analg* 2004 Dec; 99(6):1655-64.

Sá Couto CD, van Meurs WL, Goodwin JA, Andriessen P. A model for educational simulation of neonatal cardiovascular pathophysiology. *Simul Healthc*. 2006 Jan; 1 Spec no.:4-12.

Reynolds A, Bastos LF, Ayres-de-Campos D, van Meurs WL, Bernardes J: Impact of labor & delivery simulation classes in undergraduate medical learning. *Med Educ Online* 2008; 13:14:1-8.

Zijlmans M, Sá-Couto CD, van Meurs WL, Goodwin JA, Andriessen P: Corrected and improved model for educational simulation of neonatal cardiovascular pathophysiology [technical report]. *Simul Healthc*. 2009 Spring; 4(1):49-53.

Sá Couto CD, Andriessen P, van Meurs WL, Sá Couto PM, Ayres-de-Campos D: A model for educational simulation of hemodynamic transitions at birth, *Pediatr Res* 2010; 67(2): 158-165.

Bastos LF, Lobo MF, van Meurs WL, Ayres-de-Campos D: An intrauterine pressure generator for

educational simulation of labour and delivery, *Med Eng Phys.* 2010 Sep;32(7):740-5.

Bastos LF, van Meurs W, Ayres-de-Campos D: A model for educational simulation of the evolution of uterine contractions during labor, *Comput Methods Programs Biomed.* 2012 Aug; 107(2):242-7.

Lobo MF, Bastos LF, van Meurs WL, Ayres-de-Campos D: A model for educational simulation of the effect of oxytocin on uterine contractions, *Med Eng Phys.* 2013; 35: 524-531 [Epub ahead of print: Jul 24 2012].

BOOK CHAPTERS

Van Meurs WL, Chauveau N, Morucci JP, Barthelemy R: Extracorporeal circulation automation : application of control theory concepts, in Husson R (ed): *International Federation of Automatic Control Symposia Series*, N°5, 487-490, 1990.

Van Meurs WL, Euliano TY: Model driven simulators from the clinical instructor's perspective: Current status and evolving concepts, *Simulators in Anesthesiology Education*, editors: L. Henson, A. Lee, New-York: Plenum, Chapter 9, 65-73, 1998.

Öhrn MAK, van Oostrom JH, van Meurs WL: A comparison of traditional textbook and interactive computer learning of neuromuscular block. *International Medical Informatics Association Yearbook of Medical Informatics*, 478-482, 1998.

Van Meurs W, Østergaard D, Mönk S: Medical educational simulation: A European perspective. In Riley R, editor. *Manual of simulation in healthcare*. Oxford University Press, 2008. p. 525-8. Book received the 'Basis of Medicine' category award of the British Medical Association. Translated into Korean.