Court File No 01-GD-51928

***ONTARIO***
**SUPERIOR COURT OF JUSTICE**

BETWEEN

AHMAD SERHAN, deceased, By his Trustee without a will
ZEIN AHMAD SERHAN and BEVERLEY GAGNON

Plaintiffs

- and -

JOHNSON & JOHNSON
LIFESCAN CANADA LTD and LIFESCAN, INC

Defendants

## STATEMENT OF DEFENCE

1 The defendants, Johnson & Johnson, LifeScan Canada Ltd and LifeScan, Inc (together "the defendants") admit the allegations contained in paragraph 15 of the Amended Statement of Claim (the "Statement of Claim")

2 The defendants have no knowledge in respect of the allegations contained in paragraph 10 of the Statement of Claim

3 The defendants deny the allegations contained in the balance of the Statement of Claim and put the plaintiffs to the strict proof thereof

4 Johnson & Johnson is a U S Corporation based in New Jersey which develops, manufactures and markets healthcare products and provides related services

5 LifeScan, Inc ("LifeScan"), a U.S corporation based in California is a wholly owned subsidiary of Johnson & Johnson Johnson & Johnson acquired LifeScan in November 1986

LifeScan develops, manufactures and markets blood glucose monitoring products for use by individuals with diabetes

6 LifeScan Canada Ltd ("LifeScan Canada"), a Canadian corporation based in British Columbia, is a wholly owned subsidiary of LifeScan LifeScan Canada markets LifeScan's products in Canada

7 Each of the defendants is a separate operating company The defendants specifically deny the allegations in paragraphs 17, 26, 27, 62 and 65 of the Statement of Claim that the defendants are agents of each other or are vicariously responsible or otherwise liable for the acts or omissions of each other

**THE SURESTEP SYSTEM**

8 In the early 1990s LifeScan developed the SureStep system The SureStep system was introduced in Canada in February 1996

9 The SureStep system consists of a self–monitoring device which allows individuals with diabetes to measure their own blood glucose levels In order to obtain a blood glucose level reading, the individual pierces his or her finger using a lancet and applies a drop of blood to the membrane on a reagent test strip (the "Strip") The Strip must then be inserted into the glucose meter (the "Meter") and information concerning his or her blood glucose level is displayed on an LCD screen

10 In addition to the electronic information displayed on the LCD screen, each SureStep system includes a colour chart that allows users to visually match the colour of the Strip to a corresponding blood glucose range appearing on the chart to allow for visual confirmation of the user's blood glucose level

11 Johnson & Johnson has never designed, developed, tested, manufactured, licensed, assembled, distributed, marketed or sold the SureStep system

12 LifeScan manufactures the SureStep system LifeScan has never distributed or marketed the SureStep system in Canada

13 LifeScan Canada distributes the SureStep system in Canada It has no involvement in the design or manufacture of the SureStep system At all material times, LifeScan Canada distributed the SureStep system in Canada through a third party distributor The SureStep system was distributed to LifeScan Canada's customers which include pharmacies, wholesale drug distributors, diabetes care centres and clinics, physicians and hospitals

14 At no time did any of the defendants, or any one for whom they are at law responsible, sell the SureStep system to the plaintiffs or any end user The SureStep products were available for sale to end users only from pharmacies, clinics or similar locations but not from any of the defendants

**THE PLAINTIFFS' COMPLAINTS**

15 The defendants admit that the SureStep system contained imperfections No commercially available home blood glucose monitoring systems is perfect Despite its imperfections, the SureStep system was at all times reasonably fit for its intended purpose

16 Persons who purchase and use home blood glucose monitoring devices are reasonably expected to be aware that such devices are not perfect Users are expected to be aware of the limitations to home glucose monitoring It is reasonable to expect that users will rely upon a number of factors including awareness of clinical signs and symptoms and regular attendance at health professionals to monitor the state of their diabetes

**(a)** ***The ER1 Problem***

17 The original SureStep System included a glucose meter which was designed to provide a numerical indication of blood glucose levels at a range between 0 and 27 8 mmol/L (or 500 mg/dL) Above 27 8 mmol/L, the meter would not give a numeric reading In those circumstances a "HI" reading would be expected However, the software in the original version of the system (the "Affected Meters") permitted the meters to potentially give an "ER1" reading rather than a "HI" reading when the user had a blood glucose level above 27 8 mmol/L (the "ER1 Problem") Other causes of an "ER1" reading are outlined in the SureStep Owner's Booklet and include blood being applied to the wrong side of the test strip, not enough blood on the test strip, or that the test strip was inserted more than 2 minutes after applying the blood

18 As a result of identifying the ER1 Problem, enhanced instructions regarding this problem were given to LifeScan Canada's customer service personnel and hospital specialists (who are sales representatives who deal exclusively with hospitals) in June 1997 These enhanced instructions included troubleshooting steps that should be taken if the ER1 Problem was brought to their attention

19 The software in the SureStep meters was modified and the ER1 Problem was corrected in July 1997 (the "Corrected Meters") Thereafter, new meters were manufactured by LifeScan and distributed in Canada by LifeScan Canada

20 As of October 7 1997, LifeScan Canada distributed only Corrected Meters in Canada

21 In addition to the steps taken to correct the ER1 Problem noted above, on June 8, 1998, LifeScan Canada initiated a voluntary recall program for all Affected Meters

22 Pursuant to the voluntary recall program, upon being notified by a consumer, retailer or healthcare professional that they possessed an Affected Meter, LifeScan Canada immediately shipped out a replacement Corrected Meter

23 LifeScan Canada notified Health Canada of the voluntary recall program by way of letter in June 1998

24 In addition, healthcare professionals were made aware of the recall program via both the media (Canadian and U S TV and radio) and notification from LifeScan Canada beginning on June 16, 1998

25 Pharmacists were asked to send back any Affected Meter SureStep inventory Diabetes educators were asked to inform patients of the recall program, and SureStep users were asked to call LifeScan Canada directly to get a free meter exchange via a newly established toll-free SureStep Customer Care Hot Line LifeScan Canada sales staff was given instructions to assist in the recall.

26 LifeScan Canada also conducted a direct mailing to all of its known SureStep system users, retailers, and various healthcare professionals The mailing went out to approximately

- 16,725 users,
- 6,729 retailers, and
- 1,994 healthcare professions

27 In addition, between July 1998 and August 1999, bright green stickers which advised SureStep users to call the Customer Care Hotline for information about a free meter replacement were prominently placed on the top of all SureStep test strip cartons distributed to consumers in Canada

28 As of September 30, 2002, more than 21,000 replacement Corrected Meters had been shipped out by LifeScan Canada

29 Prior to the voluntary recall program, LifeScan, Inc and LifeScan Canada developed an Addendum to the SureStep system Owner's Booklet The Addendum was inserted into test strip packaging in Canada in May 1998 so that users of Affected Meters would receive the Addendum upon purchase of new test strips

30 The Addendum specifically advised users of the ER1 Problem – that is to say an ER1 message could possibly be caused by "a very high blood glucose level, possibly exceeding 27 8 mmol/L (500 mg/dL)" It advised the user to perform a visual check of the colour of the confirmation dot on the Strip versus the colour chart and to follow the advice of his or her health care professional

**(b)** ***The "Low Flier" Problem***

31 A second issue with the original SureStep System related to Strip insertion In particular, it was found that when a SureStep user failed to completely insert a Strip (short of full insertion by approximately 15 thousandths of an inch or more) into the blood glucose meter, the meter could, potentially give a lower-than-accurate blood glucose reading (the "Low Flier Problem")

32 SureStep system labelling always emphasized the need to insert the test strip fully in order to obtain an accurate blood glucose reading However, as a result of the concern over "low fliers" the following steps were taken

- October 1997 Enhanced instructions were given to Customer Service Representatives

- November 1997 — A decision was made to change the strip geometry by cutting a slight scallop in the strip tip which had the effect of requiring the strip to be fully inserted in order to reach the electrical contacts in the meter which triggered the testing process. The testing of this new design was completed in February, 1998 at which time LifeScan approved the launch of the new strips.

33 By mid-1998, LifeScan Canada began to distribute the new strips for sale in the Canadian marketplace.

**DENIAL OF CONSPIRACY**

34 The defendants specifically deny that any of them conspired in the manner alleged in paragraphs 58 to 62 of the Statement of Claim or in any manner whatsoever.

35 The defendants at all material times acted lawfully, and for legitimate business purposes. At no time did the defendants or any of them, conspire or intend to injure the plaintiffs or any other user of the SureStep system.

**DENIAL OF NEGLIGENCE**

36 The defendants specifically deny that they were negligent in any manner and deny that they breached any duty of care alleged to be owed to the plaintiffs.

37 With respect to paragraph 64, the defendants deny the allegations of negligence stated therein. The defendants further plead that all reasonable care was taken by them in connection with the SureStep system and that they acted at all times in accordance with any applicable standard of care.

38 The defendants deny that any alleged act or omission by the defendants or any of them gives rise to any claim on behalf of the plaintiffs

**REPRESENTATIONS**

39 The defendants deny that they or any of them made any false or misleading statement or representation with respect to the SureStep system

40 Further, or alternatively, if any statements were made by the defendants, all reasonable care was taken by the defendants in connection with the making of such statements If any such statement was incorrect or misleading, which is not admitted but specifically denied, such was not the result of any intentional or negligent conduct on the part of the defendants or any of them

41 The defendants deny that the plaintiffs were entitled to or did in fact rely upon any statements made by the defendants, or that the defendants knew or ought to have known of such reliance, and further deny that any loss allegedly suffered by the plaintiffs was caused by or arose from any such statements or reliance thereon

**COMPETITION ACT**

42 In response to paragraphs 71, 72 and 73 of the Statement of Claim, the defendants deny that any of them breached section 52 of the *Competition Act* The defendants specifically deny that this section has any application to any statements made by the defendants, and deny that the plaintiffs have any cause of action with respect to such alleged breach in any event

43 The Defendants plead and rely upon subsection 36(4) of the *Competition Act* The Plaintiffs' claim pursuant to section 52 of the *Competition Act* is statute barred as it was not commenced within the time period prescribed by law

**CONSTRUCTIVE TRUST**

44 The defendants deny that the plaintiffs have any claim or right to any revenue received by the defendants as a result of the sale of SureStep system In particular, the defendants deny they have been unjustly enriched or that a constructive trust exists with respect to such revenues

45 The defendants specifically deny that any relationship exists between the defendants and the plaintiffs which would constitute the defendants as constructive trustees in favour of the proposed class members The defendants further specifically deny that any conduct on the part of any of the defendants would justify the imposition of a constructive trust

46 Any amounts paid by the plaintiffs in connection with the purchase of the SureStep system were not paid to any of the defendants, but to other persons known to the plaintiffs

**STATUTORY DUTIES**

47 In December 2000, in the United States, LifeScan entered into a guilty plea to three no-intent strict liability Food and Drug Administration regulatory misdemeanours The plea arose from admissions that LifeScan had failed to adequately label the product and to report certain matters to the United States Food and Drug Administration

48 In any event, proceedings under a statute in the United States do not give rise to any cause of action on behalf of the plaintiffs

49 The defendants have complied with all statutory obligations under Canadian law The defendants specifically deny that they have breached any obligation to report to Health Canada None of the defendants have been investigated by or charged with any offence by Health Canada or any other Canadian regulatory body in relation to the SureStep system Any alleged breach of any such statutory obligation, which is not admitted but denied, does not give rise to any cause of action on behalf of the plaintiffs

50 The defendants specifically deny that any facts or circumstances give rise to any estoppel against the defendants with respect to the allegations contained in the Statement of Claim

**DAMAGES**

51 The plaintiffs suffered from diabetes and related health problems prior to their purchase of the SureStep system Their condition was not affected by any conduct of the defendants

52 If either of the plaintiffs experienced either the ER1 or Low Flier problems, and the plaintiffs were experiencing blood glucose levels which were significantly abnormal, then they would also have other clinical manifestations of this abnormality

53 Imperfections in home glucose testing equipment are unavoidable While it is denied that the imperfections referred to above were experienced by either of the plaintiffs, if they did occur, the plaintiffs did not suffer damages as a result

54 In the alternative, the defendants plead that any damages, loss or injury suffered by the plaintiffs was *de minimis* and/or frivolous in nature and, as such, not compensable

55 In the unlikely event that any of the plaintiffs have been required to repuncture a finger to draw an additional sample of blood as a result of one of the imperfections set out above, which is not admitted, such is too minimal to warrant legal compensation

56 If the plaintiffs have suffered any loss or damage, the plaintiffs had a duty to mitigate their losses, *inter alia* by participating in the voluntary recall, and by taking other reasonable steps in mitigation

57 If either of the plaintiffs has suffered loss or damages, such as are alleged, any such damages or loss were neither caused or contributed to buy any fault or negligence or breach of duty of the defendants or any of them or any person for whom the defendants are in law responsible

58 The defendants specifically deny the allegations contained in paragraph 81 of the Statement of Claim and deny that they are liable for punitive damages

59 The defendants plead and rely on the *Negligence Act*, R S O 1990, c N-1, as amended

February 12 , 2004

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Proceeding commenced at Windsor

**STATEMENT OF DEFENCE**

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Service of a copy hereof accepted this
12th day of February, ~~19~~2004

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Plaintiffs