APPENDIX A

Safety and Effectiveness

Continuous recordings provide information in the form of amplitude versus time, but it is difficult to understand because of the visual complexity of the record due to channel separation and duration of the recorded traces and sporadic nature of the activity. The software reports arranges the information in concise, reproducible, consistent reports that are more consistent than visual analysis.

The Small Bowel software adds no new information, but takes existing information and rearranges it to make it more accessible to interpretation. Source information has dimensions of amplitude and time while the software presents the same information including numerous calculated results, such as duration, mean, maximum and median, motility index, frequency and cycle values for contractions and clusters (groups of contractions).

Safety is assured in that the catheter and the sensors used to transduce the pressures are connected to fully electrically isolated amplifiers as per UL544.

The software only provides visual guidance for data interpretation. It is not considered in and of itself to be diagnostic without skilled interpretation.