

Lòók INSTRUMENTS	Requirement for Multi-sensor Infant Monitoring System	2nd Version
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DATE UPDATE	Design Requirements	SOURCES
10/16/07	<p>Overall Function: <i>Monitors certain Infant vital signs to reduce the onset of Sudden Infant Death Syndrome (SIDS)</i></p> <p>Device</p> <ul style="list-style-type: none"> • Must be portable and function as a home equipment • Must monitor respiratory pattern, and temperature of infant • Must monitor laying position of infant (on back or on stomach) during sleeping • Must show visual image of infant at all times • Baby suit with detachable sensing elements 	Dr. Anderson Lòók INSTRUMENTS
10/23/07	<p>Specification</p> <ul style="list-style-type: none"> • Mountable in typical bedroom • Work in light or dark room • Not excessively heavy, providing ease of travel 	Dr. Anderson Lòók INSTRUMENTS
10/16/07	<p>Environment</p> <ul style="list-style-type: none"> • Must be made with recycled components and recyclable itself • Minimal lead content (<0.5µg/ml) to reduce the risk of lead poisoning 	Lòók INSTRUMENTS
10/23/07	<p>Cost</p> <ul style="list-style-type: none"> • Mass production cost should be < \$250 	Lòók INSTRUMENTS
11/02/07	<p>Government Constraints</p> <ul style="list-style-type: none"> • Must meet the definition of a medical device in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act • Must adhere to the Food and Drug Administration (FDA) regulation of a maximum level of 0.5 µg/mL for lead content products intended for use by infants and children 	Lòók INSTRUMENTS