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Introducing a G185 incubator into the IVF lab: a practical perspective

Simon Phillips M.Sc
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K-Systems
ASRM
Atlanta
October 19, 2009

INTRODUCTION- WHO WE ARE?

CLINIQUE OVO

- OVO Fertility
- OVO Labo
- OVO Biosurance
- OVO Prenatal
- OVO R&D
- OVO Consulting
- OVO Foundation



INTRODUCTION - WHO WE ARE?

- OVO Fertility
 - Opened in 2003
 - 800 cycles IVF / ICSI per year
 - Fresh and Frozen IVF
 - Natural cycle IVF
 - Egg donation cycles
 - Surgical sperm retrieval
 - PGD



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INTRODUCTION – Fertility Laboratory

- 5 Embryologists, 1 Andrologist
- 6 Hereaus Heracell 240 incubators
- Laboratory restructure in August 2008
 - Improve layout
 - Increase cycle capacity
 - Improve results



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INTRODUCTION – Fertility Laboratory



PRODUCT REQUIREMENT

- Need additional incubators
- Considerations
 - Space
 - Usable internal area
 - Efficiency for IVF
 - Cost



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PRODUCT REQUIREMENT

- Available space for 2 Hereaus Heracell 240
- Is this the best option?



PRODUCT REQUIREMENT

- Heracell 240



- Large capacity but don't use this volume
- Large capacity incubators associated with increased loss of gas and temperature



PRODUCT REQUIREMENT

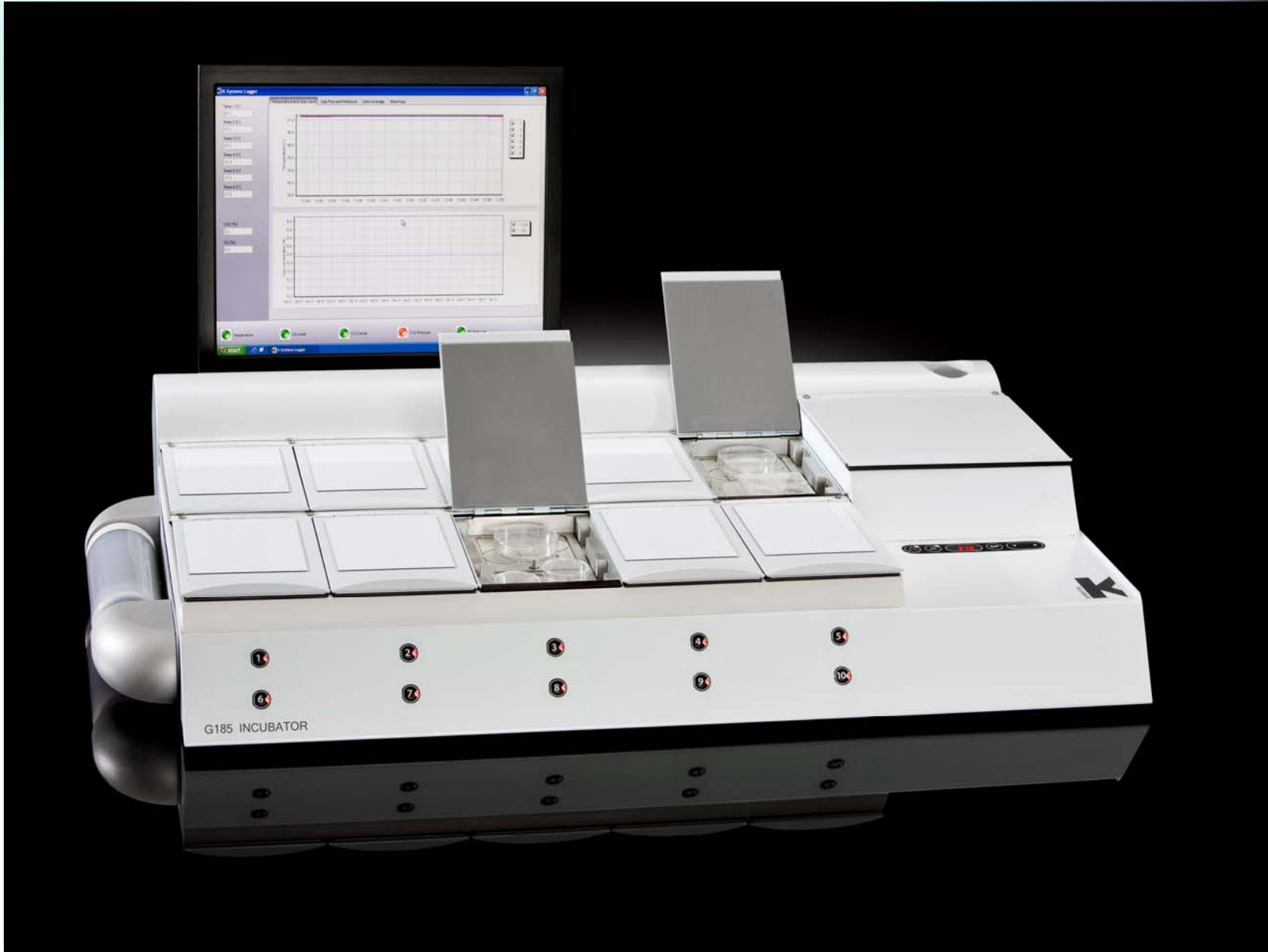
- Space efficient tri-gas incubator
- Equivalent or improved embryo culture conditions
- Use of 100% gas
 - CO₂
 - N₂
 - Use of current gas lines



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PRODUCT REQUIREMENT



PRODUCT SELECTION

- Temperature recovery time

- Chamber opened for specific time

- Chamber closed and recovery monitored every minute

- Minimum

- measurement 1 minute

- Ronny Janssen – unpublished data

<u>Time chamber opened</u>	<u>Recovery Time</u>
10 seconds	No effect seen
20 seconds	No effect seen
40 seconds	No effect seen
60 seconds	2 minutes
120 seconds	3 minutes



PRODUCT SELECTION

- Gas recovery

- Chamber opened

- Repeated every 10 minutes

- Chamber closed and recovery monitored every minute

- Minimum measurement 1 minute

<u>Gas</u>	<u>Recovery Time</u>
Carbon Dioxide	3 minutes
Oxygen	3 minutes

- Ronny Janssen – unpublished data



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PRODUCT SELECTION

	<u>G185</u>			<u>Reference Incubator</u>		
<u>Particle Size</u>	0.3µm	0.5µm	5.0µm	0.3µm	0.5µm	5.0µm
<u>Particle Count</u>	17380	472	0	205700	24510	192

•Ronny Janssen – unpublished data

Maximum permitted particles per m ³ equal or greater than tabulated size				
	At rest		In operation	
Grade	0.5µm	5.0µm	0.5µm	5.0µm
A	3520	20	3520	20
B	3520	29	352000	2900
C	352000	2900	3520000	29000
D	3520000	29000	Not defined	Not defined

Volume 4 EU Guidelines for GMP Medicinal Products for Human and Veterinary use- annex 1(feb 2008)



PRODUCT SELECTION

- Janssen's data demonstrated
 - Faster recovery of chamber gas and temperature
 - No significant impact on other chambers when opening
 - No significant difference in % fertilization rate in sibling oocyte study (vs. Heracell 240)
 - Increase in % 'good quality' embryos



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INITIAL SETUP



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INITIAL SETUP

- Used existing gas line (100% CO₂ and N₂)
- No increase in gas usage
 - One x 6.24m³ N₂/1.5 days
 - Addition of Heracell incubators had seen gradual increase in gas use from 1 x N₂/ 5 days up to 1 x N₂/ 1.5 days
- No need for pre-mixed gas
 - Cost and order issues
 - Additional gas line requirement



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INITIAL SETUP

- Considerations and Concerns
 - External validation of temperature, gas levels
 - Lack of humidification
 - ‘User Comfort’



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VALIDATION

- External temperature and gas validation



VALIDATION

- Lack of Humidification
 - Evaporation of media?
 - Changes in media osmolarity?
 - Use of water dish in each chamber?
 - Use of oil overlay sufficient?



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VALIDATION

- Mouse embryo assay
 - 1 cell mouse embryos
 - Compare results with Heracell
 - Average %blasts in G185 = 91%
 - Average %blasts in Heracell = 84%
 - Subjective blast scoring



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VALIDATION

- Sibling Oocyte Study (n=20)
 - IVF / ICSI
 - G185 vs. Heracell (2 units)
 - %2PN 63.9% vs. 65.6% (NS)



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CLINICAL USE

- G185 included in rotation of incubators
- Recent media study necessitated different %CO₂
 - G185 used for specific CO₂ requirement



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CLINICAL USE

- Future considerations
 - Additional 2x G185 planned
 - Cabinet for three units
 - Gradual replacement of Heracell units



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CLINICAL USE



CONCLUSION

- Easy integration of benchtop incubator into established IVF lab
- Minimal learning curve for use of benchtop incubator



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ACKNOWLEDGEMENTS

Staff at OVO FERTILITY

- Embryologists
 - Annick Courchesne
 - Karima Haddak
 - Bélen Herrero
 - Diane Noël
 - Mélanie Gendreau
- Andrologist
 - Josée Lefèbvre
- Meditech 1st, Montréal
 - Vivian Chebli
 - Patrick Chebli
- K-Systems
 - Rue de Silva
 - Vincent Attallah

