

The implementation of PTD at Biotrial has enabled its researchers to meet their main objectives of collecting high-quality data within an environment that maximizes animal welfare and ethical considerations.

Meeting guidelines and enhancing capabilities

Biotrial recently added new non-human primate research units to its facility that met its stringent requirements for good science and animal care, while positioning Biotrial as an industry leader for large animal monitoring capabilities among CROs. As part of this expansion, Biotrial implemented DSI’s PhysioTel Digital large animal telemetry platform to better comply with European Regulations for animal housing.

Figure 1: Primate housing at Biotrial designed to comply with European Directive 2010/63/EU



The Challenge

With legacy telemetry systems it was a challenge to meet the animal welfare guidelines as the technology did not accommodate social housing while monitoring. Additionally, the limited transmission range required the use of multiple receivers to fully cover large cages.

While designing its new animal facility, Biotrial complied with Directive 2010/63/EU on the protection of animals used for scientific purposes. The facility was designed to accommodate group housing, which promotes social interaction and natural hierarchy, ensuring animal welfare and implementing the 3Rs (Replace, Reduce, Refine) rule.

Table 1: Excerpt from European directive 2010/63/EU regarding animal housing for primates (Macaques and vervets)

	Minimum enclosure size (m ²)	Minimum enclosure volume (m ³)	Minimum volume per animal (m ³)	Minimum enclosure height (m)
Animals less than 3 yrs of age	2.0	3.6	1.0	1.8
Animals from 3 yrs of age	2.0	3.6	1.8	1.8

Note: All primate enclosures at Biotrial exceed the minimum requirements. The enclosure height is 2 m with a total volume of 4.2 m³.

Regarding housing and enrichment requirements for research animals, the European Directive (Annex III, section 3.3) states the following:

- **Housing** – Animals, except those which are naturally solitary, shall be socially housed in stable groups of compatible individuals. In cases where single housing is allowed in accordance with article 33(3) the duration shall be limited to the minimum period necessary and visual, auditory, olfactory and/or tactile contact shall be maintained.
- **Enrichment** – All animals shall be provided with space of sufficient complexity to allow expression of a wide range of normal behavior. They shall be given a degree of control and choice over their environment to reduce stress-induced behavior. Establishments shall have appropriate enrichment techniques in place, to extend the range of activities available to the animals and increase their coping activities including physical exercise, foraging, manipulative and cognitive activities, as appropriate to the species.

The Solution

Biotrial invested in DSI’s large animal PhysioTel™ Digital (PTD) system and was able to seamlessly incorporate this technology into its new facilities while meeting the standards defined in the European Directive.

- PTD allowed paired animals in large cages during data collection, eliminating the need to separate animals for data collection.
- PTD required only a single transceiver per cage, limiting the amount of hardware needed for data collection.



Figure 2: Pair-housed primates in home cage

The Outcome

Biotrial experienced the following advantages with PhysioTel Digital:

- Animals monitored in their home environment had reduced stress as evidenced among others by heart rate comparison (see Table 2 below).
- System allowed data collection while animals were group housed in large modules.

Table 2: Heart Rate from variety of monitoring scenarios

Mean heart rate (bpm; n=4)	Pair-housed animals in large modules	Single-housed in large modules	Single-housed in individual cages
Daylight period	111 ± 2	123 ± 4 (+10%)	138 ± 5 (+24%)
Night Period	82 ± 5	93 ± 6 (+13%)	99 ± 2 (+20%)

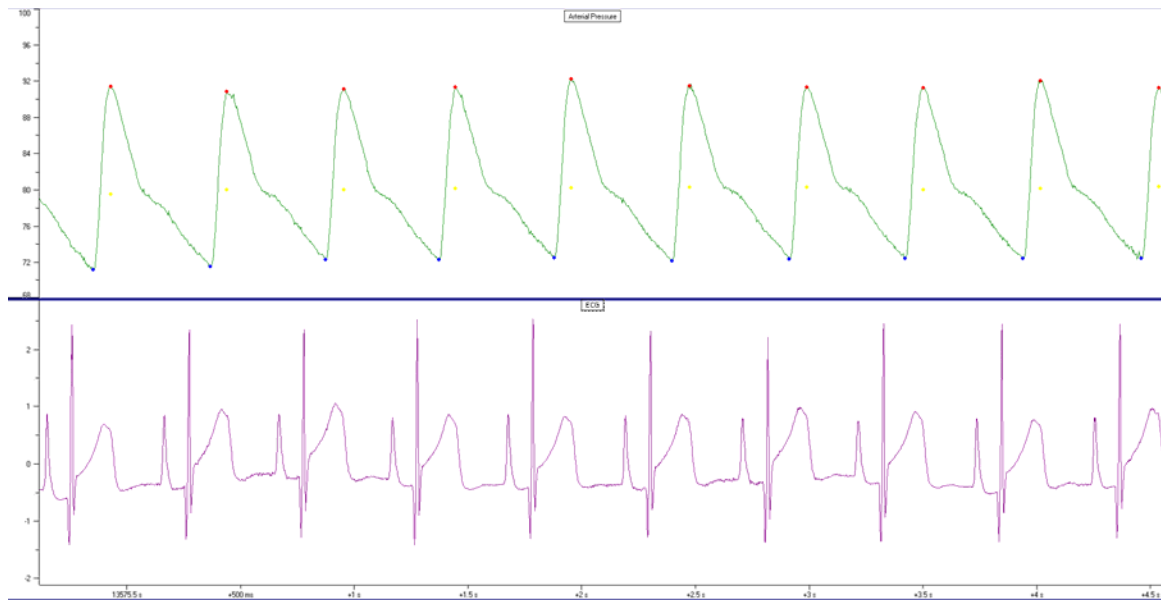


Figure 3: Sample blood pressure and ECG data from primate with PhysioTel Digital L11 implants. The superior quality of digitally-encoded data allowed immediate analysis.

- A greater amount of physiologic data from primates was available for analysis compared to prior experiences with DSI legacy products in dogs. The following graphic shows a 24-hour acquisition with no signal loss, even during active phases for the animals.

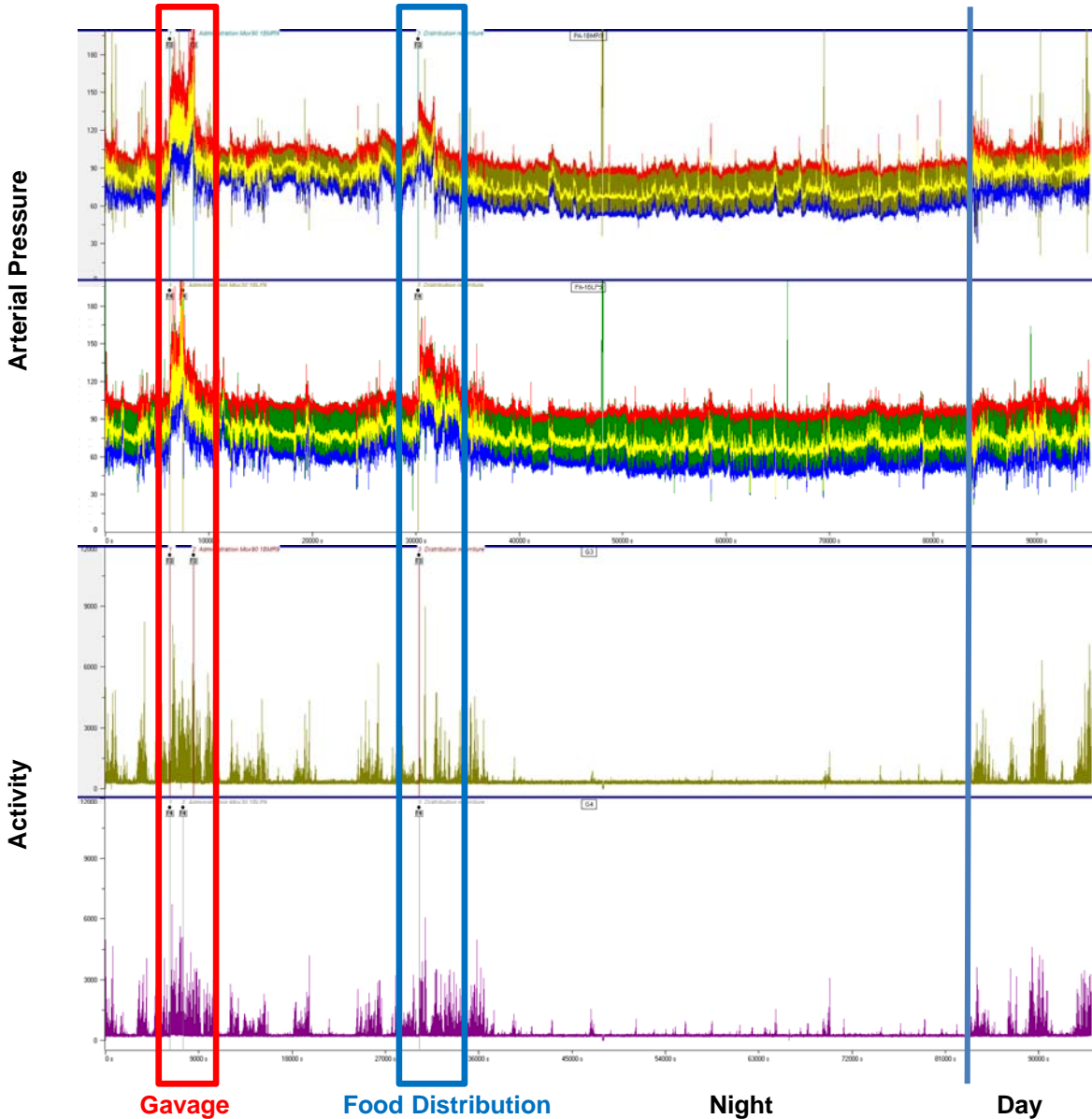


Figure 4: Twenty-four (24) hour recording from two monkeys housed in the same cage showing arterial pressure and activity data in response to gavage, food distribution and during night and day periods

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